DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 4, 2022

Aaron Siri
Siri & Glimstad LLP
200 Park Ave
17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Siri:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 23, 2020, assigned #20-00515-FOIA, for,

Each and every email communication between January 1, 2017, and the present which includes any of the following terms in the subject line or body of the communication: "Informed Consent Action Network" or "ICAN" or "Bigtree" or "Del" and also includes the name or email address of any of the following individuals on the "To", "From", "Cc" or "Bcc" line: Michelle E. Bonds, Robin M. Ikeda, Nancy Messonnier, Rima F. Khabbaz, Amanda Cohn, Frank DeStefano, Sara Clements, Maria V. Cano, Lauri Markowitz, and/or James Sejvar."

We located 435 pages of responsive records (429 pages released in full or part; 6 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) (b)(5) and (b)(6).

EXEMPTION 5

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include email communication.

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process and attorney-client privileges. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions.

Examples of information withheld include email communication from Office of General Counsel.

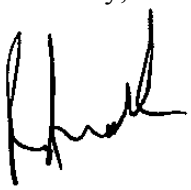
EXEMPTION 6

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as cell phone numbers, names and private email addresses. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by July 3, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

20-00515-FOIA

From: Wharton, Melinda (CDC/OID/NCIRD)
Sent: Fri, 24 Aug 2018 09:36:33 -0400
To: Messonnier, Nancy (CDC/OID/NCIRD)
Subject: confidential attorney/client communication

From: Levine, Emily M. (HHS/OGC)
Sent: Thursday, August 23, 2018 4:18 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Sweis, Roula (HHS/OASH) <Roula.Sweis@hhs.gov>; Aikin, Ann (OS/OASH) <Ann.Aikin@hhs.gov>; Wharton, Melinda (CDC/OID/NCIRD) <mew2@cdc.gov>; Stark, Lucy (OS/OGC) <Lucy.Stark@hhs.gov>
Subject: RE: (b)(5)

(b)(5)

I hope this is helpful. Emily

Emily Marcus Levine
Senior Attorney
Office of the General Counsel, Public Health Division
U.S. Department of Health and Human Services
301-443-6659
Emily.Levine@hhs.gov

dissemination, distribution, or copying of this message is prohibited. If you think you received this message in error, please notify the sender immediately.

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Fri, 20 Jul 2018 02:06:24 +0000
To: Nordlund, Kristen (CDC/OID/NCIRD)
Subject: Fwd: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Attachments: Stipulated Order against HHS.pdf, 7162018 Bigtree & Robert F. Kennedy, Jr Lawsuit Win against HHS.pdf

FYI

From: Amanda Dumenigo <amanda@horsense.net>
Date: July 19, 2018 at 9:39:34 PM EDT
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

ICAN
Informed Consent Action Network

For additional information and interviews please contact
Amanda Dumenigo, Media & Public Relations. ICAN amanda@icandecide.org 305-528-1920
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400

For Immediate Release:

World Renowned Vaccine Safety Expert and producer of the controversial film, Vaxxed, Del Bigtree, was awarded court ordered relief in lawsuit by his non-profit, The Informed Consent Action Network, ICAN, against the U.S. Department of Health and Human Services.
On Monday, June 9th, the United States District Court for the Southern District of New York signed a Stipulation granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN), the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr..

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

In 1986, the Pharmaceutical Industry was under the strain of so many lawsuits for injuries caused by vaccines they were struggling to make a profit. They threatened to stop producing vaccines unless the U.S. government protected them from liability for damages caused by their vaccines. The US Government gave in to the pressure and passed the 1986 Vaccine Injury Compensation Act, which gave unprecedented legal immunity to all vaccine makers, eviscerating the free market incentive to remedy the very safety issues that had landed them in court to begin with. Recognizing that this would leave an unavoidable gap in vaccine safety testing, the US Congress charged the Secretary of Health and Human Services with the explicit responsibility of testing vaccines for safety and working to reduce the adverse events caused by all vaccines.

In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

ICAN was therefore forced to file a lawsuit to inspire HHS to either provide copies of its biannual vaccine safety reports to Congress or admit it never filed these reports. As a result of the lawsuit, HHS has signed a court order admitting that it never, not even once, submitted a single biannual report to Congress detailing the improvements in vaccine safety for 30 years.

Given that HHS is the primary scientific body mandated to protect American citizens from the adverse events caused by vaccines, and given that this lawsuit reveals that they are unable to produce a single report, under court order, to verify *any* work towards safer vaccines, the American people must now be made aware that the vaccines that are mandated upon millions of children, may in fact be dangerous to there health.

For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: Amanda Dumenigo,
Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendant.

STIPULATION

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows:

> (a) General rule
>
> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—
>
> > (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
> >
> > (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
>
> . . .
>
> (c) Report
>
> Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

> actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network ("ICAN") submitted a Freedom of Information Act request (the "FOIA Request") to the Department of Health and Human Services ("HHS" or the "Department"), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

> **Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).**

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary ("IOS") maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

> The [Department]'s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff

By: _____
Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622

Dated: July 6, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By: _____
ANTHONY J. SUN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
(212) 637-2810
anthony.sun@usdoj.gov

SO ORDERED:

_____
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

ICAN

Informed Consent Action Network

For additional information or interviews please contact
Amanda Dumenigo,
Media & Public Relations, ICAN
amanda@icandecide.org 305-528-1920
Catharine Layton, C.O.O., ICAN
cat@icandecide.org 714-360-3400

For Immediate Release: **July 16, 2018**

World Renowned Vaccine Safety Expert and producer of the controversial film, Vaxxed, DEL BIGTREE, awarded court ordered relief in lawsuit by his non-profit, The Informed Consent Action Network, ICAN, against the US Department of Health and Human Services.

On Monday, June 9th, the United States District Court for the Southern District of New York signed an order granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN), the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr..

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

In 1986, the Pharmaceutical Industry was under the strain of so many lawsuits for injuries caused by vaccines they were struggling to make a profit. They threatened to stop producing vaccines unless the U.S. government protected them from liability for damages caused by their vaccines. The US Government gave in to the pressure and passed the 1986 Vaccine Injury Compensation Act, which gave unprecedented legal immunity to all vaccine makers, eviscerating the free market incentive to remedy the very safety issues that had landed them in court to begin with. Recognizing that this would leave an unavoidable gap in vaccine safety testing, the US Congress charged the Secretary of Health and Human Services with the explicit responsibility of testing vaccines for safety and working to reduce the adverse events caused by all vaccines.

In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

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For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: **Amanda Dumenigo,** Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:03:24 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 10: WHO, vision and strategy for immunization

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From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:58 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 10: WHO, vision and strategy for immunization

Dear Secretary Azar,

In 1998 the WHO-report *'The CVI Strategic Plan. Managing opportunity and change: A vision of vaccination for the 21st century'* was written:
https://apps.who.int/iris/bitstream/handle/10665/64635/CVI_GEN_97.04.pdf?sequence=1&isAllowed=y
Currently, the vision and strategy for immunization 2021-2030 is in the co-development phase. This is draft zero:
https://www.who.int/immunization/ia2030_Draft_Zero.pdf
One of the 12 'challenges' in this Draft Zero is addressing vaccine hesitancy and anti-vaccination activism. The response to this challenge is: *"Mobilizing public support through CSO, political leaders and champions to raise the appreciation of vaccination and to seed the value, confidence, and demand for vaccination at the community level."*

On the website of the United Nations is written: *"One of the great achievements of the United Nations is the creation of a comprehensive body of human rights law—a universal and internationally protected code to which all nations can subscribe and all people aspire."* See:
https://www.un.org/en/sections/issues-depth/human-rights/

The World Health Organization is an agency of the United Nations. So, regarding these humans rights, what about the right to informed choice and freedom of choice regarding vaccination in the CVI Strategic Plan and in the Vision and Strategy for immunization 2021-2030?
- What about the right to be informed that many vaccinated persons are not anymore protected against measles due to secundary vaccine failure?
- What about the right to be informed that there exists a subgenotype of the measles virus, which showed a trend toward diminished susceptibility to neutralization?
- What about the right to be informed that people can get measles from the vaccine and excrete the measles virus from the vaccine?
- What about the right to be informed that many vaccinated people contracted serious whooping cough?

- What about the right to be informed that vaccinated people, without any symptoms of whooping cough, may infect unvaccinated persons with whooping cough?
- What about the right to be informed that there was far more fetal DNA in investigated vaccines than the FDA-limit?
- What about the right to be informed that many children had complaints of gastro-intestinal illness and upper respiratory illness after the MMR-vaccine in clinical trials?
- Etcetera.

I look forward to receiving your answers to the abovementioned questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:01:39 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 2: Vaccines, autism and Andrew Wakefield

Fyi.

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 6:40 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 2: Vaccines, autism and Andrew Wakefield

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
Permission granted in full knowledge of the possible consequences.
https://www.lexico.com/en/definition/consent

Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed that autism prevalence increased from about 1 in 10,000 in 1970 to about 1 in 59 these days?

Question 2:
Are people informed, prior to vaccination, that a scientific study showed that the reduction in MMR-vaccine coverage in Norway, Sweden and the UK between 1994 and 2000 was accompanied by lower AD/ASD (Autism Disorder/Autism Spectrum Disorder) rates?

Question 3:
Are people informed, prior to vaccination, that in clinical trials it appeared that many children had complaints of gastro-intestinal illness after the MMR-vaccination?

Question 4:
Are people informed, prior to vaccination, that scientific studies have shown that there is a relationship between autism and gastro-intestinal problems?

Question 5:

Are people informed, prior to vaccination, that Andrew Wakefield and his colleagues wrote in the discussion of the retracted article in the Lancet that they identified a chronic enterocolitis in children that may be related to neuropsychiatric dysfunction and how this is in line with the findings of recent studies?

Question 6:
Are people informed, prior to vaccination, that Del Bigtree interviewed Andrew Wakefield in 2018 about the study published in the Lancet and that in this interview, what happened at the time was analyzed step by step which showed, amongst other things, that the research team did have ethical approval?

Question 7:
Are people informed, prior to vaccination, that de film *'Vaxxed, From Cover Up to Catastrophe'* shows that the CDC had omitted crucial data in their final report that revealed a causal relationship between the MMR-vaccine and autism?

Question 8:
Are people informed, prior to vaccination, that the MMR-vaccine is not only associated with autism because of complaints of gastro-intestinal illness after the MMR-vaccination and the relationship between gastro-intestinal problems and autism, but also because of fetal DNA fragment contaminants in the MMR-vaccine?

Question 9:
Are people informed, prior to vaccination,that not only the MMR-vaccine is associated with autism, but that aluminum in vaccines and immune activation during pregnancy are also associated with autism?

Information for question 1:
Autism prevalence increased from about 1 in 10,000 children in 1970 (Treffert, 1970, PMID 5436867) to about 1 in 59 children in these days (CDC).
Study of Treffert (1970, PMID 5436867):
https://www.ncbi.nlm.nih.gov/pubmed/5436867
CDC about prevalence autism in these days:
https://www.cdc.gov/ncbddd/autism/data.html

Information for question 2:
Dr. Deisher and colleagues found that the reduction in MMR-vaccine coverage in Norway, Sweden and the UK between 1994 and 2000 was accompanied by lower AD/ASD (Autism Disorder/Autism Spectrum Disorder) rates in Norway, Sweden and the UK (PMID 26103708). See figure 1 of this study:
https://soundchoice.s3.amazonaws.com/soundchoice/wp-content/uploads/Deisher-article-2-FINAL1.pdf

Information for question 3:
In clinical trials, it appeared that many children had complaints of gastro-intestinal illness and upper respiratory illness after having received the MMR-vaccine. Del Bigtree shows the results of the clinical trials of the MMR-vaccine in this YouTube-video:
https://www.youtube.com/watch?v=Tw7SnvxZVVQ
The results of the clinical trials of the MMR-vaccine were obtained through the Freedom of Information Act (= FOIA). You can find these results in this document:
https://icandecide.org/government/FDA-Production-FOIA.pdf
In the abovementioned video, Del Bigtree deals with table 10 from study 442, table 10 from study 443 and table 9 from study 459. All three tables can be found in the document.

Information for question 4:
Scientific studies have shown that there is a relationship between autism and gastro-intestinal problems. Rose and colleagues (2018, PMC5953830) concluded that overall, their findings suggest that children with ASD who experience GI symptoms have an imbalance in their immune response, possibly influenced by or influencing metagenomic changes, and may have a propensity to impaired gut barrier function which may contribute to their symptoms and clinical outcome. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5953830/
Professor Paul Ashwood, the senior author of this study, tells on the website of UC Davis (University of California, Davis): *"Children with ASD with increased inflammation are often those who exhibit the most severe behaviors."*

https://health.ucdavis.edu/publish/news/newsroom/12807
Li and colleagues (2017, PMC5408485) summarized the information from multiple studies showing that an abnormal gut microbiota is related to ASD. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5408485/
The observations of Wang and colleagues (2019, PMC6456593) demonstrated the long-term safety and efficacy of Microbiota Transfer Therapy (MTT) as a potential therapy to treat children with ASD who have GI problems. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6456593/
Children with ASD can benefit from a gluten free and casein free diet. These two studies show that:
Knivsberg and colleagues (2002, PMID: 12168688)
https://www.ncbi.nlm.nih.gov/pubmed/12168688
Pennesi and colleague (2012, PMID: 22564339)
https://www.ncbi.nlm.nih.gov/pubmed/22564339

Information for question 5:
For the findings of recent studies, see the information for question 4.
Retracted paper of Andrew Wakefield and colleagues:
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/fulltext
Del Bigtree van The HighWire compared the study of Rose and colleagues from 2018 (PMC5953830) with the study of Wakefield and colleagues from 1998 in the YouTube-video *'Andrew Wakefield was right'*:
https://www.youtube.com/watch?v=cXst2V2RZR0

Information for question 6:
Interview between Del Bigtree and Andrew Wakefield in 2018:
https://www.youtube.com/watch?v=Sh8yjUqzhNs

Information for question 7:
Film *'Vaxxed, From Cover Up to Catastrophe'*:
https://vaxxedthemovie.com/about/

Information for question 8:
Dr. Deisher tells in the YouTube-video *'Dr. Theresa Deisher Guelph, Ontario Canada June 23, 2018'* that it is known from research from many different institutions that about 60% of the children with autism have new mutations that were not inherited from their parents, which are 'de novo' mutations, see:
https://www.youtube.com/watch?v=G1k6xLQnJD8
Here you can find 20 references of studies from 2011 and 2012 regarding autism and (de novo) mutations:
https://www.soundchoice.org/research/mutations-references/
Insertional mutagenesis is mutation caused by insertion of new genetic material into a normal gene, see:
https://medical-dictionary.thefreedictionary.com/insertional+mutagenesis
In the mentioned study of Dr. Deisher and colleagues (PMID 26103708), they write about the possible link between insertional mutagenesis and autism. In her open letter to legislators she writes that human fetal DNA in a vaccinated child can reach up to 5 ng/ml and that from a study appeared that 1.9 ng/ml of DNA fragments resulted in insertion into the genome of stem cells in 100% of mice injected, see:
https://www.soundchoice.org/open-letter-to-legislators/#_edn2

Information for question 9:
Aluminum: See email part 5.
Immune activation during pregnancy: See email part 9.

I look forward to receiving your answers to the abovementioned nine questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:01:55 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 3: Fetal DNA fragments in vaccines

Fyi.

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 6:55 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 3: Fetal DNA fragments in vaccines

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
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https://www.lexico.com/en/definition/consent

Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed, prior to vaccination, that 76 fetuses were used for the development of vaccines in the previous century?

Question 2:
Are people informed, prior to vaccination, that there are fetal DNA fragments in several vaccines, including the MMR-II vaccine (Measles, Mumps and Rubella-vaccine) and the Varivax-vaccine (chickenpox-vaccine)?

Question 3:
Are people informed, prior to vaccination, that a scientific study showed that there was far more human, fetal DNA in two investigated vaccines than the FDA limit of 10 ng/dose?

Question 4:
Are people informed, prior to vaccination, that a scientific study showed that there are HERVK-contaminants (HERVK = human endogenous retrovirus K) in several vaccines, including the MMR-II vaccine?

Question 5:

Are people informed, prior to vaccination, that fetal DNA fragment contaminants and HERVK-contaminants in vaccines are associated with childhood cancer (lymphoma and leukemia)?

Question 6:
Are people informed, prior to vaccination, that fetal DNA in vaccines is associated with autoimmune diseases?

Question 7:
Are people informed, prior to vaccination, that fetal DNA in vaccines is associated with autism?

Information for question 1:
Dr. Stanley Plotkin told in 2018, under oath, that 76 fetuses were aborted in the previous century for the development of vaccines. That can be seen in this video:
https://www.youtube.com/watch?v=_9c7ijoLHCQ

Information for question 2:
The package insert for the MMR-II vaccine shows that the rubella virus has been propagated in WI-38 human diploid lung fibroblasts, see:
https://www.fda.gov/media/75191/download
The package insert for the Varivax-vaccine (chickenpox-vaccine) shows that for the production of this vaccine WI-38 human diploid lung fibroblasts and MRC-5 human diploid cells are used, see:
https://www.fda.gov/media/76000/download
The human, fetal DNA contaminants from the WI-38 and MRC-5 cell line end up in the vaccine, because yield is inversely related to purity, such as Dr. Theresa Deisher, who has a PhD in *'Molecular and Cellular Physiology'*, explains in this YouTube-video:
https://www.youtube.com/watch?v=G1k6xLQnJD8

Information for question 3:
Dr. Deisher and colleagues describe in a scientific article from 2015 (PMID 26103708) that in two investigated vaccines, there was far more human, fetal DNA than the residual DNA limit of 10 ng/dose set by the FDA. See here the study:
https://soundchoice.s3.amazonaws.com/soundchoice/wp-content/uploads/Deisher-article-2-FINAL1.pdf
This limit of 10 ng/dose is mentioned in the FDA Briefing Document *'Vaccines and Related Biological Products Advisory Committee Meeting September 19, 2012: Cell Lines Derived from Human Tumors for Vaccine Manufacture'*, see:
https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB2013100474.xhtml
In this document is written: "*Current recommendations are that the level of residual cell-substrate DNA should be ≤10 ng per dose and a median DNA size of 200 bp or lower.*"

Information for question 4:
The study by Victoria and colleagues (2014, PMC2876658) showed that the MMR-II vaccine is contaminated with the human endogenous retrovirus K (HERVK), see:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2876658/

Information for question 5:
In 2008 Hacein-Bey-Abina and colleagues (PMC2496963) published a study which revealed that while 9 of 10 patients were successfully treated with retrovirus-mediated gene therapy, 4 of the 9 developed T cell leukemia 31–68 months after the gene therapy. In the gene therapy the Moloney Murine Leukemia Retrovirus (MMLV) was used. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2496963/
As mentioned under the additional information for question 4, the MMR-II vaccine contains human endogenous retrovirus K (HERVK) contaminants. For more information about the possible link between DNA and HERVKcontaminants in vaccines and childhood cancer, see:
- Dr. Deisher in an interview about the health risks of fetal DNA in vaccines:
https://www.youtube.com/watch?v=G1k6xLQnJD8
- Dr. Deisher's open letter to legislators regarding fetal cell DNA in vaccines:
https://www.soundchoice.org/open-letter-to-legislators/#_edn2

Quote from Dr. Deisher:
"Not only are the human fetal contaminated vaccines associated with autistic disorder throughout the world, but also with epidemic childhood leukemia and lymphomas. (...) There are a large number of publications about the presence of HERV (human endogenous retrovirus - the only re-activatable endogenous retrovirus) and its association with childhood lymphoma. The MMR II and chickenpox vaccines and indeed all vaccines that were propagated or manufactured using the fetal cell line WI-38 are contaminated with this retrovirus. And both parents and physicians have a right to know this!"
This quote comes from a press-release from the Sound Choice Pharmaceutical Institute, see:
https://mv3462p2bnv2ptxqp33ikj2j-wpengine.netdna-ssl.com/wp-content/uploads/Sound-Choice-Pharmaceutical-Institute-Website1.pdf

Information for question 6:
For more information about the possible link between DNA in vaccines and autoimmune diseases, see Dr. Deisher's open letter to legislators regarding fetal cell DNA in vaccines:
https://www.soundchoice.org/open-letter-to-legislators/#_edn2
Quote from Dr. Deisher in this letter: "*Anyone who says that the fetal DNA contaminating our vaccines is harmless either does not know anything about immunity and Toll- like receptors or they are not telling the truth."*

Information for question 7:
Dr. Deisher tells in the YouTube-video *'Dr. Theresa Deisher Guelph, Ontario Canada June 23, 2018'* that it is known from research from many different institutions that about 60% of the children with autism have new mutations that were not inherited from their parents, which are 'de novo' mutations, see:
https://www.youtube.com/watch?v=G1k6xLQnJD8
Here you can find 20 references of studies from 2011 and 2012 regarding autism and (de novo) mutations:
https://www.soundchoice.org/research/mutations-references/
Dr. Deisher and colleagues found that the reduction in MMR coverage between 1994 and 2000 was accompanied by lower AD/ASD (Autism Disorder/Autism Spectrum Disorder) rates in Norway, Sweden and the UK (PMID 26103708). See figure 1 of this study:
https://soundchoice.s3.amazonaws.com/soundchoice/wp-content/uploads/Deisher-article-2-FINAL1.pdf
Insertional mutagenesis is mutation caused by insertion of new genetic material into a normal gene, see:
https://medical-dictionary.thefreedictionary.com/insertional+mutagenesis
In the mentioned study of Dr. Deisher and colleagues (PMID 26103708), they write about the possible link between insertional mutagenesis and autism. In her open letter to legislators she writes that human fetal DNA in a vaccinated child can reach up to 5 ng/ml and that from a study appeared that 1.9 ng/ml of DNA fragments resulted in insertion into the genome of stem cells in 100% of mice injected, see:
https://www.soundchoice.org/open-letter-to-legislators/#_edn2

I look forward to receiving your answers to the abovementioned seven questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:02:09 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 4: Death after vaccination

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:04 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 4: Death after vaccination

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
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Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed, prior to vaccination, that in a scientific article is written about six cases of sudden infant death after hexavalent vaccination that were autopsied and examined at the Munich Institute of Legal Medicine from 2001 to 2004 and that the authors wrote that autopsy and all further investigations did not reveal other serious abnormalities that could have led to the deaths of the children?

Question 2:
Are people informed, prior to vaccination, that a scientific study showed that 3-5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 compared with not-yet-DTP-vaccinated children?

Question 3:
Are people informed, prior to vaccination, that a scientific study demonstrated that nations that require more vaccine doses tend to have higher infant mortality rates?

Question 4:

Are people informed, prior to vaccination, that a special master of the US Court of Federal Claims wrote that the mother of a girl, who died after vaccination with the HPV-vaccine Gardasil, presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia and that a judicial sentence of a High Court in Spain acknowledged a causal link between the second shot of the HPV-vaccine Gardasil and the death of a Spanish girl?

Question 5:
Are people informed, prior to vaccination, that, as of 30 April 2018, 430 deaths related to HPV-vaccination were reported to the American Vaccine Adverse Event Reporting System (VAERS) according to the MedAlerts search engine?

Question 6:
Are people informed, prior to vaccination, that there are many stories of parents about the death of their child after vaccination?

Information for question 1:
Zinka and colleagues (2006, PMID: 15908063)
https://www.researchgate.net/publication/7833641_Unexplained_cases_of_sudden_infant_death_shortly_after_hexavalent_vaccination

Information for question 2:
Mogensen and colleagues (2017, PMC5360569) found that in an urban community in Guinea-Bissau among 3-5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 compared with not-yet-DTP-vaccinated children. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
Aalby and colleagues (2018, PMC5868131) tested the effect of DTP and OPV on mortality in children aged 6-35 months and concluded: *"Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality."* See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/
Fisker and colleagues (2014, PMID: 24325827) found that the results of their study indicated that pentavalent vaccine (DTP-Hib-HepB) co-administered with MV and YF is associated with increased mortality. See:
https://www.ncbi.nlm.nih.gov/pubmed/24325827

Information for question 3:
Miller and colleague (2011, PMC3170075) found that nations that require more vaccine doses tend to have higher infant mortality rates. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/

Information for question 4:
In America Ms. Emily Tarsell was compensated for the death of her daughter Christina Tarsell according to the National Childhood Vaccine Injury Compensation Program. The special master wrote in the Court document: *"Ultimately, because of the finding that Christina began to experience arrhythmia after her HPV vaccination, Ms. Tarsell has presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia. (...) The Court's Opinion and Order required additional consideration consistent with the legal principles articulated by the Court for analyzing the evidence in this tragic case about a woman, Christina Tarsell, who died much too young. Under the approach dictated by the Court, Ms. Tarsell is entitled to compensation."*. See:
https://www.naturalnews.com/2018-04-05-court-ruling-confirms-gardasil-vaccine-kills-people-scientific-evidence-beyond-any-doubt.html
Court Document: https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2010vv0251-200-0
Regarding the death of Andrea, a Spanish girl, the judicial sentence from the High Court of Asturias, Spain, acknowledges that there is a causal link between the second shot of the HPV-vaccine Gardasil and her death. See:
https://sanevax.org/hpv-vaccine-death-spain/
Court document:

http://www.poderjudicial.es/stfls/TRIBUNALES%20SUPERIORES%20DE%20JUSTICIA/TSJ%20Asturias/DOCUMENTOS%20DE%20INTER%C3%89S/TSJ%20Asturias%20Contencioso%2020%20febrero%202017.pdf

Information for question 5:
https://www.nvic.org/vaccines-and-diseases/hpv/quick-facts.aspx

Information for question 6:
There are several stories of parents about the death of their child after vaccination to be found on the YouTube-channel Vaxxed TV:
https://www.youtube.com/channel/UCwZDSEpPvE398OLazdituKQ/videos

I look forward to receiving your answers to the six abovementioned questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:02:24 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 5: Aluminum in vaccines

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:12 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 5: Aluminum in vaccines

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
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Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed, prior to vaccination, whether the vaccine contains aluminum and if so, how much?

Question 2:
Are people informed, prior to vaccination, that aluminum adjuvants in vaccines are not clinically approved?

Question 3:
Are people informed, prior to vaccination, that several scientific studies have shown negative effects of aluminum in food and of injected aluminum adjuvant?

Question 4:
Are people informed, prior to vaccination, that researchers found extremely high quantities of aluminum in brain tissue from donors with a diagnosis of Autism Spectrum Disorder?

Question 5:
Are people informed, prior to vaccination, that scientific studies in mice have shown that aluminum adjuvant can be captured by immune cells and be transported to several organs, including the brain?

Question 6:
Are people informed, prior to vaccination, that aluminum from vaccines is 100% injected and that aluminum from food is only 0.1% absorbed according to the European Food Safety Agency?

Question 7:
Are people informed, prior to vaccination, that a baby weighing 5 kg only absorbs around 0.04 microgram of aluminum from breast milk per day?

Question 8:
Are people informed, prior to vaccination, what the ratio of absorbed aluminum from breast milk or formula and injected aluminum is on the day of vaccination?

Question 9:
Are people informed, prior to vaccination, with regards to excretion of aluminum, a scientific study showed that injected aluminum was by far not fully excreted within 28 days and that babies have immature kidney function?

Question 10:
Are people informed, prior to vaccination, that in a scientific article from 2013 is written that the aluminum content of infant formulas remains too high and that infant exposure to aluminum is an unnecessary potential health risk to children and may actually contribute towards ill health as adults?

Question 11:
Are people informed, prior to vaccination, that a scientific study from 2017 concluded that 3 available toxico-kinetic studies objectively constitute insu□cient bases to guarantee the absolute safety of aluminum adjuvants administered at very large scale, in particular over the long term?

Information for question 1:
Many vaccines contain aluminum. The package inserts of vaccines show if there is aluminum in the vaccine and how much is in it.

Information for question 2:
Professor Exley told in April 2016 on the 4th International Symposium on Vaccines that he had found out, through conversations with the European Medicines Agency, the FDA in the US and the manufacturers of aluminum adjuvants, that there are no clinically approved adjuvants. See his presentation in which he tells this in the YouTube-video *'The toxicity of aluminium adjuvants'*:
https://www.youtube.com/watch?v=zaExaqCv5vo

Information for question 3:
Negative effects of aluminum in food:
The European Food Safety Authority has established a tolerable weekly dietary intake of aluminum, based on scientific studies:
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2008.754
Martinez and colleagues (2017, PMID 27473855) found that 60-day sub chronic exposure to low doses of aluminum from feed and added to water, which reflect human dietary aluminum intake, reach a threshold sufficient to promote memory impairment and neurotoxicity.
https://www.ncbi.nlm.nih.gov/pubmed/27473855
Martinez and colleagues published another scientific study in 2017 (PMID 28826906) and found in this study that 60-day chronic exposure to aluminum, which reflects common human dietary aluminum intake, appears to pose a risk for the cardiovascular system.
https://www.ncbi.nlm.nih.gov/pubmed/28826906
Negative effects of injected aluminum adjuvant:
Petrik and colleagues (2007, PMID 17114826)
https://www.researchgate.net/publication/6682741_Aluminum_Adjuvant_Linked_to_Gulf_War_Illness_Induces_Motor_Neuron_Death_in_Mice
Shaw and colleagues (2009, PMC2819810)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819810/

Shaw and colleagues (2013, PMID 23932735)
https://www.researchgate.net/publication/259653608_Vaccine_aluminum_injections_associated_with_adverse_behavioural_outcomes_JIB_LTShaw_2013
Crépeaux and colleagues (2017, PMID 27908630)
https://www.ncbi.nlm.nih.gov/pubmed/27908630

Information for question 4:
Mold and colleagues (2018, PMID: 29413113) found extremely high quantities of aluminum in brain tissue from donors with a diagnosis of Autism Spectrum Disorder (ASD). See:
https://www.sciencedirect.com/science/article/pii/S0946672X17308763
Professor Exley, the senior autor of this study, told the following in an interview:
"I did not see a role for aluminum in autism. And I didn't see a role for aluminum in vaccines in autism. I have to change my mind now on both of these. I have to change my mind that aluminum has a role in autism, I believe it now does."
You can see this interview in this YouTube-video:
https://www.youtube.com/watch?v=SmkVv8pcVhc

Information for question 5:
Studies in mice showed that injected aluminum adjuvant was captured at the injection site by immune cells and transported to organs, such as the brain.
Khan and colleagues (2013, PMC3616851)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3616851/
Eidi and colleagues (2015, PMC4482291)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4482291/

Information for question 6:
According to the European Food Safety Authority (EFSA) the bio-availability of aluminum from food is 0.1% (EFSA Journal (2008) 754, 1-34). Bio-availability is defined on page 47 of the EFSA-report as: *"The amount of a substance that is absorbed compared to the amount administered."* Here you can find the EFSA-report:
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2008.754

Information for question 7:
Breast milk contains a maximum of 0.049 mg aluminum per liter. See 1.6 *'How can aluminum affect children?'* on this webpage of the American Agency for Toxic Substances & Disease Registry:
https://www.atsdr.cdc.gov/PHS/PHS.asp?id=1076&tid=34
A baby drinks 150 ml/kg body weight per day, which is 750 ml for a baby weighing 5 kg. So a baby weighing 5 kg takes in a maximum of 0.75 liter*0.049 mg aluminum/liter = 0.04 mg aluminum from breast milk per day. As mentioned under the additional information of question 6, 0.1% is absorbed from food. So a baby weighing 5 kg absorbs a maximum of **0.04 microgram** of aluminum per day.

Information for question 8:
Sometimes a baby gets multiple aluminum-containing vaccines injected in one day. By summing the amounts that are mentioned in the package inserts, you can find out how much aluminum is injected on the day of vaccination. You can compare this with the quantity that is absorbed from breast milk or formula on that day. Milk-based infant formula contains a maximum of 0.15 mg aluminum per liter and soy-based infant formula contains a maximum of 0.93 mg aluminum per liter, see:
https://www.atsdr.cdc.gov/PHS/PHS.asp?id=1076&tid=34
To find out the quantity of absorbed aluminum from formula, you can follow the steps under the information for question 7.

Information for question 9:
Flarend and colleagues (1997, PMID: 9302736) injected aluminum adjuvants in rabbits and found that after 28 days still 94.4% of aluminum from aluminum hydroxide and 78% of aluminum from aluminum phosphate was present in the rabbits. See:
https://www.ncbi.nlm.nih.gov/pubmed/9302736
You can find more information about this study in the study of Masson and colleagues (2017, PMID: 29307441):

https://www.researchgate.net/publication/322106608_Critical_analysis_of_reference_studies_on_the_toxicokinetics_of_aluminum-based_adjuvants
Newborns have an immature kidney function. Glomerular filtration rate (GFR), a measure of the kidney function, is normally 90 or higher, see:
https://www.kidney.org/atoz/content/gfr
See table 1 of the study of Heilbron and colleagues for the GFR-value in infants (1991, PMID: 2025537):
https://link.springer.com/article/10.1007%2FBF00852829

Information for question 10:
Chuchu and colleagues (2013, PMC3851493)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3851493/

Information for question 11:
Masson and colleagues (2017, PMID 29307441) have published a critical analysis of three toxico-kinetic studies, including that of Mitkus and colleagues (2011, PMID 22001122). Study of Masson and colleagues:
https://www.researchgate.net/publication/322106608_Critical_analysis_of_reference_studies_on_the_toxicokinetics_of_aluminum-based_adjuvants
Study of Mitkus and colleagues:
https://www.ncbi.nlm.nih.gov/pubmed/22001122
In their conclusion, Masson and colleagues wrote the following: *"These adjuvants are still intended to be administered to billions of individuals over the next years, because of a massive expansion of vaccine prevention strategies announced worldwide. In this context, given their serious conceptual and methodological weaknesses, the 3 available toxico-kinetic studies objectively constitute insu□cient bases to guarantee the absolute safety of aluminum adjuvants administered at very large scale, in particular over the long term."*

I look forward to receiving your answers to the eleven abovementioned questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:02:30 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 6: HPV-vaccines

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:19 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 6: HPV-vaccines

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
Permission granted in full knowledge of the possible consequences.
https://www.lexico.com/en/definition/consent

Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed, prior to vaccination, what the chance is of getting cervical cancer in developed countries compared to other types of cancer?

Question 2:
Are people informed, prior to vaccination, that pap-tests (pap smears) and HPV-tests exist and what they are for?

Question 3:
Are people informed, prior to vaccination, that in a scientific study from 2013 is written that, based on the findings of the authors, it is expected that the HPV-vaccine will have no effect on the occurrence of cervical carcinomas?

Question 4:
Are people informed, prior to vaccination, that the FDA granted Fast Track approval for the HPV-vaccine Gardasil?

Question 5:
Are people informed, prior to vaccination, that both Gardasil and Cervarix contain aluminum adjuvant and that aluminum adjuvants have not been clinically approved?

Question 6:
Are people informed, prior to vaccination, that in several countries more serious adverse events are reported from the HPV-vaccines than from other vaccines?

Question 7:
Are people informed, prior to vaccination, that a scientific study found that approximately 60% of women who did not receive the HPV vaccine had been pregnant at least once, whereas only 35% of women who were exposed to the vaccine had conceived?

Question 8:
Are people informed, prior to vaccination, that there are several documentaries/films in which the stories of girls appear who developed serious health problems after the HPV-vaccination?

Question 9:
Are people informed, prior to vaccination, that a special master of the US Court of Federal Claims wrote that the mother of a girl, who died after vaccination with the HPV-vaccine Gardasil, presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia and that a judicial sentence of a High Court in Spain acknowledged a causal link between the second shot of the HPV-vaccine Gardasil and the death of a Spanish girl?

Information for question 1:
https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer/incidence#heading-Two

Information for question 2:
https://www.cdc.gov/cancer/cervical/basic_info/screening.htm

Information for question 3:
McCormack and colleagues wrote in their scientific article (2013, PMC3879223): *"In sum, our data indicate that newly formed carcinoma-specific karyotypes generate and maintain carcinomas, independent of latent viral sequences or mutations of tumor suppressor genes. Based on our findings it is expected that a vaccine against human papilloma viruses will have no effect on the occurrence of cervical carcinomas."* See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3879223/

Information for question 4:
Fast Track Approval of Gardasil
https://www.newscientist.com/article/dn9305-first-cervical-cancer-vaccine-is-approved/
See at 23 minutes in the movie 'The greater good'
https://greatergoodmovie.org/
https://www.youtube.com/watch?v=TePZYb3MTp4&list=PL8QtdlPXd3ITY1AD1OJGKdgaZhQnaEHd_

Information for question 5:
Package insert Gardasil 9:
https://www.ema.europa.eu/en/documents/product-information/gardasil-9-epar-product-information_en.pdf
Package insert Cervarix:
https://www.ema.europa.eu/en/documents/product-information/cervarix-epar-product-information_en.pdf
Professor Exley speaks about aluminum in Cervarix and Gardasil in the documentary *'Sacrificial Virgins'*:
https://www.youtube.com/watch?v=KAzcMHaBvLs&list=PLbGGcgXKKaBorcaejsR_YwOoglEhrr9GJ

Information for question 6:
In several countries more serious adverse events are reported from the HPV-vaccines, Gardasil and Cervarix, than from other vaccines.
Japan
See figure 1 of the study of Beppu and colleagues (2017, PMID: 28512072) for both Gardasil and Cervarix.
https://ijme.in/articles/lessons-learnt-in-japan-from-adverse-reactions-to-the-hpv-vaccine-a-medical-ethics-perspective/?galley=html
United Kingdom

See the figure on the website of 'Time for Action', a UK campaign group formed by a group of UK parents whose daughters experienced serious health problems after HPV vaccination:
http://timeforaction.org.uk/campaign-news/high-number-reported-side-effects-hpv-vaccine-ignored-patient-safety-review-open-letter-jeremy-hunt/
The vaccine currently used in the UK is called Gardasil. Cervarix was used in the UK from September 2008, when the programme started, until August 2012. See:
http://vk.ovg.ox.ac.uk/hpv-vaccine

USA

See table 1 in the chapter *'Adverse Reactions to Human Papillomavirus Vaccines'* from the book *'Vaccines and Autoimmunity'*. This chapter is written by Tomljenovic and Shaw. See:
https://www.researchgate.net/publication/300631961_Adverse_Reactions_to_Human_Papillomavirus_Vaccines
Since 2016 Cervarix is no longer marketed in the US:
https://www.nvic.org/vaccines-and-diseases/hpv/vaccine-history.aspx
Fewer than 1% of vaccine adverse events are reported in the American Vaccine Adverse Event Report System (VAERS), see:
https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

Information for question 7:

A scientific study from 2018 (DeLong, PMID: 29889622) showed that approximately 60% of women who did not receive the HPV vaccine had been pregnant at least once, whereas only 35% of women who were exposed to the vaccine had conceived. For married women, 75% who did not receive the shot were found to conceive, while only 50% who received the vaccine had ever been pregnant. See:
https://www.ncbi.nlm.nih.gov/pubmed/29889622
On the website of Children's Health Defense, you can find an article about this study:
https://childrenshealthdefense.org/news/vaccine-safety/vaccine-boom-population-bust-study-queries-the-link-between-hpv-vaccine-and-soaring-infertility/
Little and colleague published in 2014 a scientific article, in which they wrote about three young women who developed premature ovarian insufficiency following quadrivalent human papillomavirus (HPV) vaccination (2014, PMC4528880):
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528880/

Information for question 8:

The documentary *'Sacrificial Virgins'*, which won in 2018 de 'Best of the Festival'-award at the Brisbane Watchdog Film Festival, shows 2 girls who became paralyzed after HPV-vaccination:
https://www.youtube.com/watch?v=KAzcMHaBvLs&list=PLbGGcgXKKaBorcaejsR_YwOoglEhrr9GJ
There are several stories in the documentary *'Manufactured Crisis - HPV, Hype & Horror'*, to be seen of serious adverse events following HPV-vaccination:
https://www.youtube.com/watch?v=o4Lh7i5HOQg
In the film *'The Greater Good'* you can see a girl who developed serious health problems following HPV-vaccination:
https://greatergoodmovie.org/
https://www.youtube.com/watch?v=TePZYb3MTp4&list=PL8QtdlPXd3ITY1AD1OJGKdgaZhQnaEHd_

Information for question 9:

In America Ms. Emily Tarsell was compensated for the death of her daughter Christina Tarsell according to the National Childhood Vaccine Injury Compensation Program. The special master wrote in the Court document: *'Ultimately, because of the finding that Christina began to experience arrhythmia after her HPV vaccination, Ms. Tarsell has presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia. (...) The Court's Opinion and Order required additional consideration consistent with the legal principles articulated by the Court for analyzing the evidence in this tragic case about a woman, Christina Tarsell, who died much too young. Under the approach dictated by the Court, Ms. Tarsell is entitled to compensation.'*. See:
https://www.naturalnews.com/2018-04-05-court-ruling-confirms-gardasil-vaccine-kills-people-scientific-evidence-beyond-any-doubt.html
Court Document: https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2010vv0251-200-0

Regarding the death of Andrea, a Spanish girl, the judicial sentence from the High Court of Asturias, Spain, acknowledges that there is a causal link between the second shot of the HPV-vaccine Gardasil and her death. See:
https://sanevax.org/hpv-vaccine-death-spain/
Court document:
http://www.poderjudicial.es/stfls/TRIBUNALES%20SUPERIORES%20DE%20JUSTICIA/TSJ%20Asturias/DOCUMENTOS%20DE%20INTER%C3%89S/TSJ%20Asturias%20Contencioso%2020%20febrero%202017.pdf

I look forward to receiving your answers to the abovementioned nine questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:02:44 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 7: Whooping cough and vaccination

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From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:39 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 7: Whooping cough and vaccination

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
Permission granted in full knowledge of the possible consequences.
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Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are people informed, prior to vaccination, that several scientific studies have shown that the majority of people who contracted whooping cough were vaccinated?

Question 2:
Are people informed, prior to vaccination, that a scientific study showed that the majority of people who contracted **serious** whooping cough were vaccinated?

Question 3:
Are people informed, prior to vaccination, that Dr. Jason Warfel and colleagues found that vaccinated baboons, which had no symptoms, infected unvaccinated baboons and that scientific studies have indicated that this may also occur in humans?

Question 4:
Are people informed, prior to vaccination, in the light of the study of Dr. Jason Warfel, that unvaccinated children in nurseries, schools and the domestic environment may be infected by vaccinated adults and children?

Question 5:
Are people informed, prior to vaccination, that a scientific study has shown that cocooning (immunization of infant contacts) did not reduce whooping cough in infants younger than 6 months?

Question 6:
Are people informed, prior to vaccination, that scientific studies have shown that immune activation during pregnancy entails risks for the fetus and that women can get a fever after vaccination, which is an immune system response?

Question 7:
Are people informed, prior to vaccination, whether there is aluminum adjuvant in the whooping cough-containing vaccine that is used?

Question 8:
Are people informed, prior to vaccination, that aluminum adjuvants are not clinically approved?

Question 9:
Are people informed, prior to vaccination, that there are many experience stories of health problems after vaccination?

Information for question 1:
Sala-Farré and colleagues (2015, PMID: 24216286)
https://www.ncbi.nlm.nih.gov/pubmed/24216286
Debolt and colleagues (2012, PMID: 22810264)
https://www.researchgate.net/publication/285682866_Pertussis_epidemic_-_Washington_2012
See table 5 of the study of McNamara and colleagues (2017, PMC5755965)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5755965/

Information for question 2:
See table 5 of the study of McNamara and colleagues (2017, PMC5755965)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5755965/

Information for question 3:
The study of Warfel and colleagues (2014, PMC3896208) showed that vaccinated baboons, which had no symptoms, infected unvaccinated baboons:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3896208/
Warfel and colleagues (2012, PMC3318410) demonstrated that the baboon provides an excellent model for clinical pertussis. They found that one hundred percent of baboons infected with a clinical isolate of *Bordetella pertussis* exhibited all of the hallmark manifestations of human pertussis. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3318410/
The study of Storsaeter and colleagues (1990, PMID: 2251872) showed that two acellular pertussis vaccines didn't protect against infection or colonization in humans:
https://www.ncbi.nlm.nih.gov/pubmed/2251872/
Althouse and colleagues (2015, PMC4482312) concluded that asymptomatic transmission is the most parsimonious explanation for many of the observations surrounding the resurgence of *Bordetella pertussis* in the US and UK:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4482312/

Information for question 5:
Healy and colleagues (2015, PMID: 24992123)
https://www.ncbi.nlm.nih.gov/pubmed/24992123

Information for question 6:
See email part 9.

Information for question 8:
Professor Exley told in April 2016 on the 4th International Symposium on Vaccines that he had found out, through conversations with the European Medicines Agency, the FDA in the US and the manufacturers of aluminum adjuvants,

that there are no clinically approved adjuvants. See his presentation in which he tells this in the YouTube-video *'The toxicity of aluminium adjuvants'*:
https://www.youtube.com/watch?v=zaExaqCv5vo

Information for question 9:
There are many experience stories of health problems after vaccination to be found on the YouTube-channel Vaxxed TV:
https://www.youtube.com/channel/UCwZDSEpPvE398OLazdituKQ/videos

I look forward to receiving your answers to the nine abovementioned questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:02:56 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 8: Measles and vaccination

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:47 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 8: Measles and vaccination

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Question 1:
Are people informed, prior to vaccination, that the measles mortality had already fallen enormously before the vaccine was introduced?

Question 2:
Are people informed, prior to vaccination, that scientific articles show that people can get measles from the vaccines, that they can excrete the measles virus from the vaccine and that when excretion happens, they may infect others?

Question 3:
Are people informed, prior to vaccination, that a scientific article showed that people can get measles from the vaccines and excrete the measles virus from the vaccine, while it is misreported as rubella or not recognized?

Question 4:
Are people informed, prior to vaccination, that a scientific study showed that there exists a subgenotype of the measles virus, which showed a trend toward diminished susceptibility to neutralization by human sera pooled from approximately 60 to 80 North American donors?

Question 5:
Are people informed, prior to vaccination, that the concentration of measles antibodies decreased since the introduction of the measles vaccine?

Question 6:
Are people informed, prior to vaccination, that the measles potency specification, defined by the FDA, for intravenous immunoglobulin for persons with primary immunodeficiency disorder has become increasingly difficult to meet and that revaccination-induced titers increases were only 2-fold and short-lived?

Question 7:
Are people informed, prior to vaccination, that in 7% of the people the first MMR-vaccine (Measles, Mumps and Rubella-vaccine) isn't effective against measles due to primary vaccine failure?

Question 8:
Are people informed, prior to vaccination, that scientific studies show that a certain proportion of the vaccinated people are no longer protected against measles after a certain period after the second vaccination due to secondary vaccine failure?

Question 9:
Are people informed, prior to vaccination, that the editor-in-chief of the scientific journal Vaccine wrote in 2012, together with a professor of pediatrics, that sustained elimination, much less eradication, of measles is unlikely?

Question 10:
Are people informed, prior to vaccination, that infants were longer protected by passive immunity prior to the introduction of the measles vaccine and that recovery from the natural measles infection is associated with life-long protective immunity?

Question 11:
Are people informed, prior to vaccination, if people who died from measles were vaccinated, if they became ill from the wild-type virus or the vaccine-type virus, if they had an underlying disease and what were their living conditions?

Question 12:
Are people informed, prior to vaccination, that in clinical trials of the MMR-vaccine many children had complaints of gastro-intestinal illness and upper respiratory illness after the MMR-vaccination?

Question 13:
Are people informed, prior to vaccination, that the MMR-vaccine is associated with autism, childhood cancer and auto-immune diseases?

Question 14:
Are people informed, prior to vaccination, that there are many experience stories of health problems after vaccination?

Information for question 1:
In 1968 the measles vaccine was introduced in Great Britain, see:
http://vk.ovg.ox.ac.uk/measles
On the website of Children's Health Defense, it can be seen that the measles mortality had already fallen enormously in England and Wales before 1968:
https://childrenshealthdefense.org/news/the-impact-of-vaccines-on-mortality-decline-since-1900-according-to-published-science/
For Canada it can be seen on this webpage:
https://vaccinechoicecanada.com/in-the-news/reported-measles-cases-and-deaths-in-canada/

Information for question 2:
Kaic and colleagues (PMID: 20822734) demonstrated excretion of the Schwarz measles vaccine virus in a child with a vaccine-associated febrile rash illness in urine and in pharyngeal excretions. This happened in Croatia in 2010. See:

https://www.eurosurveillance.org/content/10.2807/ese.15.35.19652-en
Murti and colleagues (PMID: 24330942) described a case of vaccine-associated measles in a two-year-old patient from British Columbia, Canada, in October 2013, who received her first dose of measles-containing vaccine 37 days prior to onset of prodromal symptoms. Measles RNA was detected in the nasopharyngeal swab. See:
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES2013.18.49.20649
Roy and colleagues (2017, PMC5328441) wrote in their article that of the 194 measles virus sequences obtained in the United States in 2015, 73 were identified as vaccine sequences. That's 38%. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5328441/
Spreading of measles by someone who is just vaccinated:
Milson (1989, PMID: 2563426) described a brother-to-sister transmission of measles after measles, mumps, and rubella immunization, see:
https://www.ncbi.nlm.nih.gov/pubmed/2563426

Information for question 3:
As mentioned under the information for question 2, Kaic and colleagues (PMID: 20822734) demonstrated excretion of the Schwarz measles vaccine virus in a child with a vaccine-associated febrile rash illness in urine and in pharyngeal excretions. They wrote in their article: *"If measles and rubella were not under enhanced surveillance in Croatia, the case would have been either misreported as rubella or not recognized at all."*

Information for question 4:
Muñoz-Alía and colleagues (2017, PMC5432853) wrote: *"D4.2 subgenotype viruses showed a trend toward diminished susceptibility to neutralization by human sera pooled from approximately 60 to 80 North American donors."* See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5432853/

Information for question 5:
Figure 1 of the study of Modrof and colleagues (2017, PMID: 28968738) shows that measles antibodies decreased from 4 to 4.5 IU/ml prior to the introduction of the measles vaccine to less than 1 IU/ml after the 2-dose vaccine was introduced.
https://academic.oup.com/jid/article/216/8/977/4084678

Information for question 6:
Modrof and colleagues (2017, PMID: 28968738)
https://academic.oup.com/jid/article/216/8/977/4084678

Information for question 7:
On the CDC-website is written: *'One dose of MMR vaccine is 93% effective against measles.'* See:
https://www.cdc.gov/vaccines/vpd/mmr/public/index.html

Information for question 8:
LeBaron and colleagues (2007, PMID: 17339511) found that in their study it was expected that 20 years after the second MMR-II vaccination 33% of vaccinated people are not protected any longer against measles.
https://jamanetwork.com/journals/jamapediatrics/fullarticle/569784
De Serres and colleagues (2013, PMID: 23264672) showed that during an outbreak of measles in a high school in Canada more than 50% of the 110 cases were vaccinated, see table 3 of this study:
https://academic.oup.com/jid/article/207/6/990/898747
Rosen and colleagues published an article about measles transmission from a twice-vaccinated individual with documented secondary vaccine failure (2014, PMID: 24585562). See:
https://academic.oup.com/cid/article/58/9/1205/2895266

Information for question 9:
Dr. Gregory Poland and professor Robert Jacobson wrote in 2012 the following (PMC3905323): *"To date, despite multiple efforts, the reality is that for the practical, socio-cultural, and immunologic reasons outlined above, we have not eradicated measles. (...) our current tool for prevention has limitations that increasingly look to be significant enough that sustained elimination, much less eradication, are unlikely."* See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905323/

Information for question 10:
Passive immunity
Lennon and colleagues (1986, PMID: 3701511) showed that by 8.5 months of age, 95% of the children of the mothers born since 1963 would have become susceptible to measles and responsive to immunization; the same level of susceptibility is not reached by children of mothers born before 1958 until 11.5 months of age. See:
https://www.ncbi.nlm.nih.gov/pubmed/3701511
Waaijenborg and colleagues (2013, PMID: 23661802) found that the duration of protection against measles was 3.3 months in the general population, most of whom were born to vaccinated mothers, 5.3 months for infants born in the orthodox communities, most of whom had unvaccinated mothers. See:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4043230/
Life-long immunity after having experienced natural measles infection
Peter Panum found that, during the 1846 Faroe Island measles epidemic, all those who had measles in the previous epidemic in 1781 were protected despite the lack of apparent re-exposure for 65 years. He wrote: *"In this connection it is quite remarkable, however, that of the many aged people still living on the Faroes who had had measles in 1781, not one, as far as I could find out by careful inquiry, was attacked the second time. I myself saw ninety-eight such old people, who were exempt because they had had the disease iii their youth."* See:
http://www.med.mcgill.ca/epidemiology/courses/EPIB591/Fall%202010/mid-term%20presentations/Paper9.pdf

Information for question 12:
In clinical trials, it appeared that many children had complaints of gastro-intestinal illness and upper respiratory illness after having received the MMR-vaccine. Del Bigtree shows the results of the clinical trials of the MMR-vaccine in this YouTube-video:
https://www.youtube.com/watch?v=Tw7SnvxZVVQ
The results of the clinical trials of the MMR-vaccine were obtained through the Freedom of Information Act (= FOIA). You can find these results in this document:
https://icandecide.org/government/FDA-Production-FOIA.pdf
In the abovementioned video, Del Bigtree deals with table 10 from study 442, table 10 from study 443 and table 9 from study 459. All three tables can be found in the document.

Information for question 13:
Autism and gastro-intestinal problems
See email part 2.
Autism and fetal DNA fragment contaminants
See email part 3.
Cancer and fetal DNA fragment contaminants
See email part 3.
Auto-immune diseases and fetal DNA fragment contaminants
See email part 3.

Information for question 14:
There are many experience stories of health problems after vaccination to be found on the YouTube-channel Vaxxed TV:
https://www.youtube.com/channel/UCwZDSEpPvE398OLazdituKQ/videos

I look forward to receiving your answers to the abovementioned fourteen questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Pope, Kristin (CDC/DDID/NCIRD/OD)
Sent: Mon, 17 Jun 2019 13:03:07 +0000
To: McGowan, Robert (Kyle) (CDC/OD/OCS)
Cc: Berger, Sherri (CDC/OCOO/OD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Barry, Brooke (CDC/DDID/NCIRD/OD); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Khabbaz, Rima (CDC/DDID/NCEZID/OD); Richmond-Crum, Malia (CDC/DDID/NCEZID/OD); Clark, Cynthia K. (CDC/OD/OCS)
Subject: FW: Email to HHS, part 9: Vaccination during pregnancy

---

From: Mathilde ten Voorde <tenvoorde.m@hotmail.com>
Sent: Monday, June 17, 2019 7:50 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Hargan, Eric (OS/IOS) <Eric.Hargan@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Hayes, Kaye (HHS/OASH) <Kaye.Hayes@hhs.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Pope, Kristin (CDC/DDID/NCIRD/OD) <kfp7@cdc.gov>; Norman.sharpless@fda.hhs.gov; Silvis, Lauren (FDA/OC) <Lauren.Silvis@fda.hhs.gov>; comments@whitehouse.gov; info@icandecide.org; del@icandecide.org; rita.shreffler@childrenshealthdefense.org; joyce.ghen@childrenshealthdefense.org; contactnvic@gmail.com; contact@informedchoicewa.org
Subject: Email to HHS, part 9: Vaccination during pregnancy

Dear Secretary Azar,

According to the dictionary of www.lexico.com, ***Informed Consent*** is defined as:
Permission granted in full knowledge of the possible consequences.
https://www.lexico.com/en/definition/consent

Below you will find some questions that I would like you to answer. If the answer to one or more questions is 'no', I would like you to enlighten me as to why people don't receive that (scientific) information and who is responsible for deciding that people don't receive that (scientific) information.

Question 1:
Are pregnant women informed, prior to vaccination, that scientific studies have shown that immune activation during pregnancy entails risks for the fetus and that women can get a fever after vaccination, which is an immune system response?

Question 2:
Are pregnant women informed, prior to vaccination, whether there is aluminum adjuvant in the whooping cough-containing vaccine that is used?

Question 3:
Are pregnant women informed, prior to vaccination, that aluminum adjuvants are not clinically approved?

Question 4:
Are pregnant women informed, prior to vaccination, that in a scientific article is written that aluminum is reported to influence more than 200 biologically important reactions and to cause various adverse effects on the mammalian central nervous system?

Question 5:

Are pregnant women informed, prior to vaccination, that several scientific studies have shown negative effects of aluminum in food and of injected aluminum adjuvant?

Information for question 1:
Risks of immune activation during pregnancy:
Smith and colleagues (2008, PMC2387067)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2387067/
Garay and colleagues (2010, PMC3059681)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3059681/
Malkova and colleagues (2012, PMC3322300)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3322300/
Mandal and colleagues (2013, PMID: 23643646)
https://www.ncbi.nlm.nih.gov/pubmed/23643646
Bauman and colleagues (2014, PMID: 24011823)
https://www.ncbi.nlm.nih.gov/pubmed/24011823
Machado and colleagues (2015, PMID: 25442006)
https://www.ncbi.nlm.nih.gov/pubmed/25442006
Weir and colleagues (2015, PMC5671487)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5671487/
Patient reaction to Tdap vaccination in pregnancy
Perry and colleague (2017, PMID: 28456527)
https://www.ncbi.nlm.nih.gov/pubmed/?term=28456527

Information for question 3:
Professor Exley told in April 2016 on the 4th International Symposium on Vaccines that he had found out, through conversations with the European Medicines Agency, the FDA in the US and the manufacturers of aluminum adjuvants, that there are no clinically approved adjuvants. See his presentation in which he tells this in the YouTube-video *'The toxicity of aluminium adjuvants'*:
https://www.youtube.com/watch?v=zaExaqCv5vo

Information for question 4:
Kawahara en collega's (2011, PMID: 21423554)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056430/
See table 1 of this study for effects of aluminum on the central nervous system with reference to the scientific studies which mention those effects.

Information for question 5:
Negative effects of aluminum in food:
The European Food Safety Authority has established a tolerable weekly dietary intake of aluminum, based on scientific studies:
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2008.754
Martinez and colleagues (2017, PMID 27473855) found that 60-day sub chronic exposure to low doses of aluminum from feed and added to water, which reflect human dietary aluminum intake, reach a threshold sufficient to promote memory impairment and neurotoxicity.
https://www.ncbi.nlm.nih.gov/pubmed/27473855
Martinez and colleagues published another scientific study in 2017 (PMID 28826906) and found in this study that 60-day chronic exposure to aluminum, which reflects common human dietary aluminum intake, appears to pose a risk for the cardiovascular system.
https://www.ncbi.nlm.nih.gov/pubmed/28826906
Negative effects of injected aluminum adjuvant:
Petrik and colleagues (2007, PMID 17114826)
https://www.researchgate.net/publication/6682741_Aluminum_Adjuvant_Linked_to_Gulf_War_Illness_Induces_Motor_Neuron_Death_in_Mice
Shaw and colleagues (2009, PMC2819810)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819810/
Shaw and colleagues (2013, PMID 23932735)

https://www.researchgate.net/publication/259653608_Vaccine_aluminum_injections_associated_with_adverse_behavioural_outcomes_JIB_LTShaw_2013
Crépeaux and colleagues (2017, PMID 27908630)
https://www.ncbi.nlm.nih.gov/pubmed/27908630

I look forward to receiving your answers to the five abovementioned questions.

CC to OIDP, CDC, FDA, White House, Informed Consent Action Network, Children's Health Defense, National Vaccine Information Center, Informed Choice Washington

Yours sincerely,
Mathilde ten Voorde, PhD

From: Markowitz, Lauri (CDC/OID/NCIRD)
Sent: Mon, 17 Jul 2017 16:38:12 +0000
To: Cleveland, Angela Ahlquist (CDC/OID/NCIRD); Gargano, Julia Marie W. (CDC/OID/NCIRD); Lewis, Rayleen (CDC/OID/NCIRD); Meites, Elissa M. (CDC/OID/NCIRD); Singh, Vidisha (CDC/OID/NCIRD)
Subject: FW: Funding announcement from the VoVRN: Concept notes due Aug. 4

Just sending for our awareness

From: Whitney, Cynthia (CDC/OID/NCIRD)
Sent: Saturday, July 15, 2017 5:09 PM
To: Lessa, Fernanda (CDC/OID/NCIRD) <dta3@cdc.gov>; Farrar, Jennifer Loo (CDC/OID/NCIRD) <ihi4@cdc.gov>; Fox, LeAnne M. (CDC/CGH/DPDM) <lff4@cdc.gov>; Mahon, Barbara (CDC/OID/NCIRD) <bdm3@cdc.gov>; Hadler, Stephen (CDC/OID/NCIRD) <sch1@cdc.gov>; Markowitz, Lauri (CDC/OID/NCIRD) <lem2@cdc.gov>; Pallansch, Mark A. (CDC/OID/NCIRD) <map1@cdc.gov>; Parashar, Umesh (CDC/OID/NCIRD) <uap2@cdc.gov>; Jernigan, Daniel B. (CDC/OID/NCIRD) <dbj0@cdc.gov>; Azziz-Baumgartner, Eduardo (CDC/OID/NCIRD) <eha9@cdc.gov>; Novak, Ryan (CDC/OID/NCIRD) <bnk4@cdc.gov>; Van Beneden, Chris A. (CDC/OID/NCIRD) <cav7@cdc.gov>
Subject: FW: Funding announcement from the VoVRN: Concept notes due Aug. 4

FYI See info re call for vaccine economics proposals.

"The Value of Vaccination Research Network (VoVRN) is awarding funding for new research on the broader social and economic impact of vaccination (BSEIV)."

cw

From: Hope Johnson [mailto:hjohnson@gavi.org]
Sent: Saturday, July 15, 2017 2:55 AM
To: Maria Knoll <mknoll2@jhu.edu>; Katherine O'Brien (kobrien2@jhu.edu) <kobrien2@jhu.edu>; Katrin Gorham <kgorham3@jhu.edu>; Olivia Cohen <ocohen3@jhu.edu>; 'Anthony Scott' <ascott@ikilifi.org>; Breiman, Robert F. (rfbreiman@emory.edu) <rfbreiman@emory.edu>; Omer, Saad B <somer@emory.edu>; Kathleen Neuzil <kneuzil@medicine.umaryland.edu>; CHERIAN, Thomas (cheriant@who.int) <cheriant@who.int>; Cohen, Adam (CDC who.int) <cohena@who.int>; Kim Mulholland (kim.mulholland@rch.org.au) <kim.mulholland@rch.org.au>; 'Andrew Pollard' <Andrew.Pollard@paediatrics.ox.ac.uk>; 'ABELA-RIDDER, Bernadette' <abelab@who.int>; 'Dr. Firdausi Qadri' <fqadri@icddrb.org>; 'jakob.zinsstag@unibas.ch' <jakob.zinsstag@unibas.ch>; Macneil, Adam (CDC/CGH/GID) <aho3@cdc.gov>; Parashar, Umesh (CDC/OID/NCIRD) <uap2@cdc.gov>; Whitney, Cynthia (CDC/OID/NCIRD) <cgw3@cdc.gov>; 'Betuel Sigauque' <Betuel.Sigauque@manhica.net>; 'gmackenzie@mrc.gm' <gmackenzie@mrc.gm>; Jennifer Moïsi <jennifermoisi@gmail.com>; Brad Gessner <bgessner@aamp.org>; Sow, Samba <ssow@som.umaryland.edu>; Asad Ali <asad.ali@aku.edu>; Rob Moodie Malawi <rmoodie@medcol.mw>; Richard Duncan <rduncan@unicef.org>; Mamadou Saliou Diallo <mamsdiallo@unicef.org>
Subject: FW: Funding announcement from the VoVRN: Concept notes due Aug. 4

Please find below a call for research concept notes to study the value of vaccines. I would be grateful if you could please circulate to those who may be potentially interested.

Best Regards,

Hope Johnson, PhD, MPH

Director, Monitoring & Evaluation

Tel: + 41 22 909 71 29
Mob: + 41 79 745 23 64

Email: hjohnson@gavi.org

Gavi
The Vaccine Alliance

2, Chemin des Mines, 1202 Geneva, Switzerland
Tel: + 41 22 909 65 00
Web: http://www.gavi.org

From: Sullivan, Jessica J [mailto:jsullivan@hsph.harvard.edu]
Sent: 14 July 2017 23:19
To: HSPH-VovrnInfo <vovrninfo@hsph.harvard.edu>
Subject: Funding announcement from the VoVRN: Concept notes due Aug. 4

Dear Value of Vaccination Research Network (VoVRN) Member,

We are pleased to announce the initiation of a grant-making cycle to fund research on the broader social and economic impacts of vaccination (BSEIV).

Click here to view the instructions and templates for submitting a concept note to the VoVRN. **Concept notes are due by 5 PM EDT on Friday, August 4, 2017.**

We hope you will share this opportunity with your colleagues to ensure a strong and well-rounded pool of submissions.

Please note that other materials for the VoVRN can be found on www.immunizationeconomics.org, along with content from the EPIC and ICAN projects. You can click here to subscribe to our quarterly newsletter.

Sincerely,
Jessica

JESSICA SULLIVAN | Assistant Director of Research
Department of Global Health and Population | Harvard T.H. Chan School of Public Health
665 Huntington Avenue, Room 1202B | Boston, MA 02115
o: 617-432-6739 | f: 617-432-6733
jsullivan@hsph.harvard.edu
Pronouns: She, Her, Hers

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HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH
Department of Global Health and Population

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 16 Jul 2019 14:58:16 +0000
To: Barry, Brooke (CDC/DDID/NCIRD/OD)
Subject: FW: FYI - FW: sps00416114 HHS Vaccine Safety Responsibilities [x-ref 387892; 388672
Attachments: 1-29-2019part3.pdf, Info Copy 00416114_1292019.docx, 1-29-2019part2.pdf, 1-29-2019.Part1.pdf

-----Original Message-----
From: Jarman Miller, Hannah (CDC/DDID/NCIRD/OD) <oqr0@cdc.gov>
Sent: Wednesday, January 30, 2019 12:59 PM
To: DiLiddo, Colleen (CDC/OCOO/OSSAM) <eug4@cdc.gov>; Borrelli, Aaron (CDC/DDID/NCIRD/ISD) <zvt3@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Cc: Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; Barry, Brooke (CDC/DDID/NCIRD/OD) <bmb8@cdc.gov>
Subject: FYI - FW: sps00416114 HHS Vaccine Safety Responsibilities [x-ref 387892; 388672

Hello,

FYI only - This is a letter from ICAN to the Secretary and Director of NVPO.

Thank you,

Hannah Jarman-Miller, MPH
Presidential Management Fellow I Public Health Analyst Office of Policy I National Center for Immunization and Respiratory Diseases (NCIRD) Centers for Disease Control and Prevention (CDC) I Atlanta, GA

Office: 404-718-7151
Email: oqr0@cdc.gov

-----Original Message-----
From: Ryan, Tamara S. (Tammi) (CDC/OD/OCS) <vdv6@cdc.gov>
Sent: Wednesday, January 30, 2019 9:26 AM
To: Jarman Miller, Hannah (CDC/DDID/NCIRD/OD) <oqr0@cdc.gov>; Knights, Paulette (CDC/DDID/NCEZID/OD) <pbf7@cdc.gov>
Cc: Epps, Tanya (CDC/OCOO/OGC) <ate0@cdc.gov>; Turner, Cheryl L. (CDC/OD/OADC) (CTR) <ffd0@cdc.gov>
Subject: FW: sps00416114 HHS Vaccine Safety Responsibilities [x-ref 387892; 388672

INFO ONLY

NCEZID and NCIRD
OGC and OADC

ICAN
Informed Consent Action Networ
10200 West US Highway 290, Suite
Austin, Texas 78736

U.S. Department of Health & Human Services
HHS Office of the Secretary
Alex M. Azar II,
Secretary of Health & Human Services
Tammy R. Beckham,
Acting Director, National Vaccine Program Office
200 Independence Avenue, S.W.
Washington, D.C., 20201

INFORMATION COPY

******INFORMATION ONLY – NO ACTION REQUIRED******

DATE:	01/29/2019

OVERVIEW

SPS#:	00416114
FROM:	Del Bigtree
SUBJECT #:	HHS Vaccine Safety Responsibilities [x-ref 387892; 388672]
POLICY COORDINATOR:	Ciara Johnson, (202) 690-5627

ASSIGNMENT

AUTHORING AGENCY(S):	Office of the Assistant Secretary of Health (OASH)
TASK TYPE:	Info Copy
ROUND #:	1
RECIPIENTS:	OASH
INFO COPY:	CDC, FDA, NIH

You are receiving this assignment as info-only. No action is needed from your office at this time. If you believe that your office should receive this control for clearance, please contact the Exec Sec policy coordinator listed above as soon as possible.

INSTRUCTIONS:

ImmuneSpace database are aimed at establishing the predictors of susceptibility to vaccine injury in the general United States pediatric population.[272]

While HIPC has studiously avoided supporting projects that could identify which children should not receive one or more vaccines due to increased risk of vaccine injury, it has supported projects aimed at identifying biomarkers of inter-subject variability in vaccine immunogenicity (*i.e.*, the ability of recipients to produce a better immune response to a currently licensed vaccine, such as the Hepatitis B vaccine), even though similar tools could be utilized to search for predictors of increased risk of injury from those same vaccines.[273] The ImmuneSpace database even contains studies intended to *expand* the use of vaccines in subgroups where those vaccines are currently contraindicated for use.[274] Thus, HHS's assertion that the HIPC program is conducting studies to identify which children are susceptible to vaccine injury was incorrect.

The second source HHS cites does not fare much better.[275] It provides a list of the five vaccine safety studies HHS has directly funded since 2015, two of which relate to identifying which children would be injured by a vaccine.[276] The first "aims to identify inherited, immunologic, and clinical factors that may predict the occurrence of febrile seizures after measles vaccination" and the second "aims to analyze the genetic determinants of the immune response following yellow fever vaccination among individuals who experience serious adverse events."[277]

Funding only two studies in three years aimed at assessing which children are likely to be vaccine injured is far too slow a pace.[278] There are also serious issues with these studies.

The principal investigator for the measles vaccine febrile seizure study, Dr. Nicole P. Klein, received $1,706,230.28 in funding from the manufacturer of the measles vaccine, Merck, between 2015 and 2017.[279] Selecting someone who receives millions of dollars in funding from Merck to conduct a study about the safety of a Merck vaccine raises serious concern about the study author's objectivity. If Dr. Klein were to produce and publish findings that were adverse to Merck's interests, she may place her future funding from Merck in jeopardy. This conflict should have been obvious to HHS prior to selecting Dr. Klein to conduct this study.

---

[272] https://www.immuneprofiling.org/hipc/page/showPage?pg=projects; https://www.immunespace.org/

[273] https://www.immuneprofiling.org/hipc/page/showPage?pg=projects

[274] For example, a live varicella vaccine, which is currently contraindicated per the CDC's guidelines for immunocompromised children, is being studied in renal transplant recipients. ImmuneSpace project SDY357, *VZV Evaluation of the Safety and Immunogenicity of Varivax (Live-Attenuated Varicella-Zoster Virus Vaccine) in Pediatric Renal Transplant Recipients.*

[275] https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html

[276] https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html

[277] https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html

[278] https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html

[279] https://openpaymentsdata.cms.gov/physician/1081946/payment-information

As for the yellow fever study, that vaccine is *not* a routine childhood vaccine in the U.S. and the resources for this study – especially when only two studies are being funded in three years – would have been far better spent assessing biomarkers for predicting which children are at increased risk of suffering injuries from childhood vaccines routinely used in the United States. For example, HHS could have financed studies seeking to identify biomarkers that would predict which children are likely to experience one or more of the following serious injuries that HHS concedes are caused by one or more routinely administered childhood vaccines: brachial neuritis, encephalopathy, encephalitis, chronic arthritis, thrombocytopenia, and Guillain- Barré syndrome.[280]

Between 2015 and 2017, HHS spent over $14 billion purchasing and promoting the universal use of HHS recommended vaccines.[281] During this same time period, HHS certainly could and should have funded more than two studies seeking to identify which children should be excluded from receiving one or more vaccines in order to prevent a serious vaccine injury.[282] This research should also not be conducted by individuals who receive funding from the pharmaceutical company whose vaccine product is being reviewed.

VI. UNSUPPORTED CLAIM THAT "VACCINES DO NOT CAUSE AUTISM"

HHS declares on its website that "Vaccines Do Not Cause Autism."[283] Our letter therefore asked for the studies that HHS relies upon to make this claim.[284] HHS's response, however, fails to provide a single study to support its claim that *none* of the vaccines given to children by one year of age cause autism.[285] HHS's 2014 "comprehensive review" of vaccine safety even expressly stated it could not identify a single study to support that DTaP or Hepatitis B vaccines do not cause autism.[286] HHS nonetheless continues to contend that "vaccines do not cause autism" when its own "comprehensive review" concedes it cannot scientifically support this claim.

This section will first review the points made in our opening letter regarding vaccines and autism which HHS failed to address and then go through each of the five citations HHS provides to support its claim that "vaccines do not cause autism."

---

[280] https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf
[281] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es
[282] https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html
[283] https://www.cdc.gov/vaccinesafety/concerns/autism.html; https://www.hhs.gov/programs/topic-sites/autism/index.html
[284] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[285] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[286] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

A. Vaccines-Autism Points from Opening Letter Unrebutted by HHS

As explained in our opening letter, HHS paid the IOM to conduct a review regarding whether, among other things, there is a causal relationship between autism and the DTaP vaccine.[287] In 2011, the IOM published its review and stated it could not locate a single study supporting that DTaP vaccine does not cause autism.[288] The IOM therefore concluded:

> The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.[289]

In fact, the only study the IOM could locate regarding whether DTaP vaccine causes autism concluded there *was* an association between DTaP and autism.[290]

Our opening letter further asserted that, like the DTaP vaccine, there are also no published studies showing that autism is not caused by vaccines for Hepatitis B, Rotavirus, Hib, Pneumococcal, Polio, Influenza, Varicella, or Hepatitis A – each of which HHS's vaccine schedule recommends babies receive, typically multiple times, by six months of age.[291] HHS's response fails to provide a single study to rebut the foregoing.

We further asserted that HHS has failed to address the science that does support a link between vaccines and autism.[292] We gave the example that HHS has not addressed a study which found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those that did not.[293] Nor did HHS address two pilot studies recently published out of the School of Public Health at Jackson State University which showed vaccinated children had a 420% increased rate of autism compared to unvaccinated children, and vaccinated preterm babies had an even higher rate.[294] We also pointed out that there is a compelling body of science that supports a clear connection between aluminum adjuvants in vaccines and autism, even citing a complete write-up summarizing the studies supporting same.[295] Yet, HHS failed to directly or substantively address any of the foregoing.

---

[287] https://www.nap.edu/read/13164/chapter/2#2
[288] https://www.nap.edu/read/13164/chapter/12#545
[289] https://www.nap.edu/read/13164/chapter/12#545
[290] https://www.nap.edu/read/13164/chapter/12#545 (Ironically, this study was discarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which is true of much of HHS's "safety science.")
[291] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent. html
[292] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[293] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf
[294] http://www.oatext.com/pdf/JTS-3-186.pdf; http://www.oatext.com/pdf/JTS-3-187.pdf
[295] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf

Moreover, we asserted that HHS's claim that "Vaccines Do Not Cause Autism" improperly relies almost exclusively upon studies examining only one vaccine, MMR (administered no earlier than one year of age), or only one vaccine ingredient, thimerosal.[296] HHS's response, however, did not explain why studies that exclusively evaluated one vaccine or only one vaccine ingredient, while ignoring the balance of HHS's childhood vaccine schedule, support HHS's sweeping declaration that "Vaccines Do Not Cause Autism."

As for the one vaccine HHS claims it has studied with regard to autism, MMR, we pointed out that Senior CDC Scientist, Dr. William Thompson[297], has provided a statement through his attorney that HHS "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by HHS with American children.[298] Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."[299] Dr. Thompson further stated on that call:

> I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did.[300]

Hence, as for MMR, the only vaccine actually studied by HHS with regard to autism, it appears HHS may have concealed an association between that vaccine and autism.[301] HHS's letter completely ignores this serious allegation by one of its own senior scientists.

B. HHS's Citations Do Not Support that Vaccines Do Not Cause Autism

Instead, HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

---

[296] https://www.cdc.gov/vaccinesafety/concerns/autism.html

[297] Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of its vaccine safety claims. https://www.ncbi.nlm.nih.gov/pubmed

[298] http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf

[299] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

[300] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

[301] Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. https://doi.org/10.1093/oxfordjournals.aje.a116479

The *first* link is to a document entitled "Science Summary: CDC Studies on Thimerosal in Vaccines."[302] The studies in this document are plainly insufficient to support the claim that "vaccines do not cause autism" as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled "Immunization Safety Review: Vaccines and Autism."[303] This report also cannot support the CDC's claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. It is nonetheless noteworthy that this report was issued before the admission by Dr. Thompson that the CDC concealed an association between the MMR vaccine and autism, and it is further noteworthy that even this review stated that the IOM "committee's conclusion did not exclude the possibility that MMR could contribute to autism in a small number of children" and that "models for an association between MMR and autism were not ... disproved."[304] But, again, this report is plainly insufficient to support the claim that "vaccines do not cause autism," as it at best only addresses whether the MMR vaccine and thimerosal cause autism.

The *third* link is a study which only looks at one vaccine component – antigens – comparing '*vaccinated* children' with '*vaccinated* children' with different antigen exposure.[305] This study again says nothing about whether any particular vaccine or HHS's childhood vaccine schedule causes autism. This study even concedes: "ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines*."[306]

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.[307] All vaccines on the CDC childhood schedule, including DTaP, have been estimated to have between 1 and 69 antigens per dose while the DTP vaccine, no longer used in the U.S., is estimated to have 3,002 antigens per dose.[308] Hence, to compare antigen exposure, this study simply looks at one group of almost entirely fully vaccinated children who received DTaP with another group of almost entirely fully vaccinated children who received DTP.

---

[302] https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf
[303] http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx
[304] http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx
[305] https://www.ncbi.nlm.nih.gov/pubmed/23545349
[306] https://www.ncbi.nlm.nih.gov/pubmed/23545349 (emphasis added)
[307] https://www.ncbi.nlm.nih.gov/pubmed/23545349
[308] https://www.ncbi.nlm.nih.gov/pubmed/23545349

This study further admits the manner in which it counted "antigens" is not a valid measure of the actual immunogenicity of any given vaccine:

> Admittedly, this approach assumes that all proteins and polysaccharides in a vaccine evoke equivalent immune responses, whereas some proteins actually may be more likely than others to stimulate an immune response. Moreover, the calculations do not take into account the number of epitopes per antigen or the immunologic strength of each epitope.[309]

In addition, HHS's antigen study only included children vaccinated in the late 1990s, despite being published in 2013, by which time the following additional vaccines had already been added to HHS's childhood vaccine schedule: PCV13, Influenza, Hepatitis A, Meningococcal, Tdap, and HPV.[310]

This study further ignores the fact that while "antigens" (as defined in the study) in vaccines have decreased since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased*. Indeed, in 1983 there was one aluminum-adjuvanted vaccine on HHS's vaccine schedule, in 1998 there were three (Hep B, DTaP, Hib[311]), and by 2018 the vaccine schedule included the following aluminum-adjuvanted vaccines: (1) Hep B, (2) DTaP, (3) Hib[312], (4) PCV13, (5) Hep A, (6) Tdap, and (7) HPV (and newer vaccines contain large amounts of aluminum adjuvant).[313] Also, the amount of aluminum adjuvant from Hep B, DTaP and Hib vaccines has increased since the late 1990s.[314] For example, the product with the lowest amount of aluminum for DTaP (DTP) had approximately half the amount of aluminum in 1998 as it did in 2018, and the percent of children receiving these three vaccines has increased markedly since the 1990s.[315] The antigen study HHS cites not only ignores the increasing amount of aluminum adjuvant included in childhood vaccines since 1999, it studiously ignores (as discussed below) the compelling body of science implicating this rising amount of aluminum adjuvant in vaccines with causing neurological dysfunction and autism.[316]

But even putting all these limitations aside, this antigen study says nothing about whether any particular vaccine or group of vaccines cause autism, and, at best, relates to the

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[309] https://www.ncbi.nlm.nih.gov/pubmed/23545349

[310] https://www.cdc.gov/mmwr/preview/mmwrhtml/su6201a2.htm; https://www.ncbi.nlm.nih.gov/pubmed/23545349 (This study also excluded children with fragile X syndrome, and thus cannot address if vaccinating children with fragile X can cause autism.)

[311] In 1998, 1 out of 4 licensed Hib vaccines contained aluminum. Physicians' Desk Reference, 1998, http://www.pdr.net

[312] In 2018, 1 out of 3 licensed Hib vaccines contained aluminum. Physicians' Desk Reference, 2018, http://www.pdr.net

[313] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg; https://www.cdc.gov/mmwr/preview/mmwrhtml/00056261.htm; https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

[314] Compare 1998 and 2018 editions of the Physicians' Desk Reference. http://www.pdr.net

[315] Ibid.; https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/data-reports/index.html

[316] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf

potential connection between antigen exposure and autism (albeit in a study that, in its best light, is unreliable).

The *fourth* link HHS cites is the very IOM review from 2011 cited in our opening letter.[317] However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.[318] Even more astonishing, a different part of HHS's response letter cites the 2014 "comprehensive review" which again could not identify a single study to support the claim that DTaP does not cause autism.[319]

HHS's 2014 review also searched for studies that would support the claim that the Hepatitis B vaccine does not cause autism and also did not find a single study to support this claim.[320] In fact, even after using its strict selection criteria to toss 99% of all studies out of its review, it nevertheless resulted in the inclusion of a vaccine-autism study that was *not* funded by a pharmaceutical company reviewing its own vaccine.[321] This study, from the Stony Brook University Medical Center, found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those who did not get this vaccine at birth.[322] The 2014 review summarizes the results of this study as follows:

> Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.[323]

Having found one study that showed an association, and no studies to disprove this association, HHS's review did not claim that the Hepatitis B vaccine does not cause autism.[324] Rather, it concluded it does not know whether the Hepatitis B vaccine causes autism.[325] In short, the fourth link cited by HHS in fact proves, once again, that HHS cannot claim that vaccines do not cause autism.

The *fifth* (and final) link HHS cites in its letter is the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee, which is part of HHS.[326] Remarkably, this 196 page strategic plan outlines dozens of research

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[317] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[318] http://nationalacademies.org/HMD/Reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx
[319] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[320] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[321] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[322] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf
[323] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[324] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[325] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf
[326] https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.[327]

The strategy plan even explains that "neuroinflammation" may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. For example, encephalitis or encephalopathy are listed as adverse reactions in the package inserts for the following vaccines injected multiple times into babies during their first few months of life: DTaP (Infanrix, Daptacel), Hepatitis B (Recombivax-HB, Engerix -B) and combination vaccines (Pediarix, Pentacel).[328] The strategic plan also recognizes "immune dysregulation" – which again can be caused by vaccines – may cause autism.[329] It also explains that current science suggests "that ASD results from subtle alterations during brain development [including during the first year of life] that affect brain structure, function and connectivity," which have been demonstrated to occur in lab animals following injection of comparable amounts of pediatric vaccines and/or aluminum adjuvants used in pediatric vaccines.[330]

This strategic plan even outlines numerous large scale studies looking at a plethora of environmental exposures, but apparently none of these include looking at the exposure to vaccines.[331] This is despite the fact that numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child's autism.[332] It would be simple to review vaccine exposures along with the hundreds of other exposures already being reviewed in these studies, but for apparently political reasons, HHS has chosen not to address this issue.

C. Vaccine-Autism Concerns Always Broader than MMR and Thimerosal

HHS directs all conversation regarding vaccines and autism toward MMR and thimerosal, despite longstanding concerns regarding the connection between autism and other vaccines and other vaccine ingredients.[333] For example, the concern that pertussis containing vaccines could cause immune and brain dysfunction, including autism, was identified as a research priority in the 1986 Act. Indeed, Congress, when passing the Act,

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[327] https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

[328] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf; https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf

[329] https://onlinelibrary.wiley.com/doi/book/10.1002/9781118663721

[330] https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf; http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf

[331] https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf

[332] https://www.ncbi.nlm.nih.gov/pubmed/16685182; https://www.ncbi.nlm.nih.gov/pubmed/25398603; https://www.ncbi.nlm.nih.gov/pubmed/16547798; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/

[333] https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf

directed HHS to review the scientific evidence for whether pertussis containing vaccines can cause, among other conditions, autism.[334] As expressly provided in the 1986 Act:

> Health and Human Services shall complete a review of all relevant medical and scientific information ... on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis ... and ... Autism[335]

Implementing the foregoing congressional directive, HHS commissioned the IOM in 1989 to identify any and all medical and scientific literature addressing whether pertussis-containing vaccines can cause autism.[336] The IOM conducted this review and issued its report in 1991.[337] While the IOM found at least some evidence bearing on causation for the 20 conditions other than autism it reviewed, the IOM could not find a single shred of evidence to support the claim that pertussis containing vaccines do not cause autism.[338] This is because no studies had been conducted to determine whether pertussis-containing vaccine cause autism. This is part of why the IOM's report in 1991 said:

> In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. ... If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.[339]

Yet when HHS commissioned the IOM twenty-two years later to assess the evidence bearing on whether pertussis containing vaccines cause autism – as this remained (per HHS) one of the most commonly claimed injuries from this vaccine – the IOM again in 2011 had the same conclusion:

> The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.[340]

HHS itself reached this same conclusion again in its 2014 "comprehensive review."[341] These reports show clearly that HHS has known for 27 years that it does not have the scientific

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[334] https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf
[335] https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf
[336] https://www.nap.edu/read/1815/chapter/1#v
[337] https://www.nap.edu/read/1815/chapter/1
[338] https://www.nap.edu/read/1815/chapter/2#7
[339] https://www.nap.edu/read/1815/chapter/9
[340] https://www.nap.edu/read/13164/chapter/12?term=autism#545
[341] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

studies to support its claim that "vaccines do not cause autism," and has willfully chosen to remain ignorant rather than test its *a priori* assumption that vaccines do not cause autism.[342]

D. HHS's Refusal to Study Vaccines-Autism Connection is Troubling

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that HHS's leading autism expert, Dr. Andrew Zimmerman – an expert whom HHS relied upon in the *Cedillo v. HHS* case in Vaccine Court to claim that vaccines never cause autism – has changed his expert opinion.[343]

Dr. Zimmerman is a former Director of Medical Research at the Center for Autism and Related Disorders at the Kennedy Krieger Institute and Johns Hopkins University School of Medicine, and is regarded as the leading national authority on autism and mitochondrial disorder.[344] Dr. Zimmerman testified on November 9, 2016 that vaccines can in fact cause autism and even answered "Yes" when asked under oath: "Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to a regressive autism?"[345] Dr. Zimmerman further testified that once HHS understands and accepts the causal relationship between vaccines and autism, "it will prevent the development of autism in quite a few children."[346]

Dr. Zimmerman's similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony in a deposition under oath:

> *Lawyer: Do you agree with the statement that vaccines do not cause autism?*
>
> Dr. Kelley: No
>
> *Lawyer: Is it generally accepted in the medical community that vaccines do not cause autism?*
>
> Dr. Kelley: It is a common opinion.
>
> *Lawyer: It is generally accepted in the medical field that vaccines do not cause autism?*
>
> Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.
>
> *Lawyer: Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?*

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[342] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

[343] https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/?_ftnref1

[344] https://books.google.com/books?isbn=1603588256

[345] https://books.google.com/books?isbn=1603588256

[346] https://books.google.com/books?isbn=1603588256

Dr. Kelley: Yes. They also say there is no proven association.

Lawyer: Do you agree with the position of the American Academy of Pediatrics?

Dr. Kelley: I agree with their position as a public health measure. I don't agree with it scientifically.

Lawyer: You are actually arguing for a link between vaccines and autism in this case, aren't you?

Dr. Kelley: I am.

Lawyer: And that is contrary to the medical literature, isn't it?

Dr. Kelley: It's not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.

Lawyer: Your opinion is contrary to, say, the opinion of the CDC, correct?

Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.[347]

The view apparently held by HHS that "public health" demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. This view (i) ignores the fact that the real "public health" emergency in the United States is that 1 in 36 children are now diagnosed with autism[348], (ii) stifles research into the association between vaccines on HHS's childhood vaccine schedule and autism, and (iii) forces HHS to ignore any science that does support a vaccine-autism connection.

Indeed, HHS appears frozen when confronted with replicated peer-reviewed studies, many of which were funded by HHS, regarding immune activation and aluminum adjuvants that support a causal relationship between the receipt of vaccines continuing aluminum adjuvants and the development of autism in children.[349] Our opening letter attached letters to HHS from world-renowned experts on the toxicity of aluminum adjuvants, each of whom strongly supported the contention that aluminum adjuvants may have a role in the etiology of autism and cited the body of science that supports their assertion.[350] This science reflects that: injected aluminum adjuvant is taken-up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the

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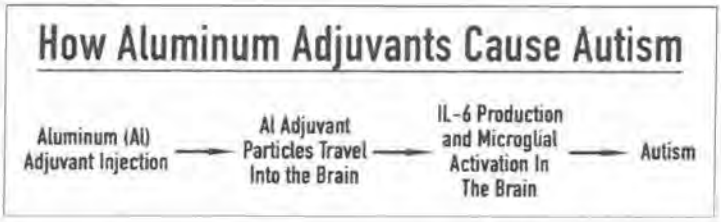
[347] https://books.google.com/books?isbn=1603588256

[348] https://www.cdc.gov/nchs/data/databriefs/db291.pdf

[349] http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf

[350] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf

brain causes a release of interleukin IL-6 and microglial activation, leading to autism.[351] Depicted in simple terms:



Despite years of vaccine safety advocacy demanding that HHS rebut, or at least address, the clear connection between aluminum adjuvant containing vaccines and autism, HHS appears unable to muster anything more than the public relations slogan – "Vaccines Do Not Cause Autism."

On May 24, 2014, Dr. Thompson explained that the CDC is "paralyzed right now by anything related to autism … because they're afraid to look for things that might be associated."[352] The reason for this fear may be that HHS has conceded or has been required by the Vaccine Court to pay financial compensation to at least a few dozen children where receipt of a vaccine on HHS's childhood vaccine schedule resulted in brain, neurological and/or immune dysfunction diagnosed as autism.[353] The damage awards in some of these cases were in the millions of dollars.[354] If a single study conducted by HHS shows that even 1 in 5 cases of autism are caused, directly or indirectly, by vaccines, it would result in approximately $1.3 trillion in liability.[355] Putting such potential liability into perspective, the entire federal budget in 2017 was $3.3 trillion.[356] This and the decimation of HHS's reputation if it were found that certain vaccines cause a significant fraction of autism cases, provide powerful incentives for HHS to *not* fund the basic scientific research needed to determine whether HHS's childhood vaccine schedule is a cause of autism.

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published. The fact that it has not been published is very concerning. For example, HHS recently published a study using the VSD which compared vaccination rates between autistic and non-autistic children, but only looked at vaccination rates *after* an autism diagnosis.[357] It is hard to imagine that HHS also

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[351] http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf
[352] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio
[353] https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pelr
[354] https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pelr
[355] Since approximately 3.5 million American children have autism spectrum disorder and the approximate life time cost per individual is $1.9 million, total cost of care for just 20% of these individual is $1.3 trillion. www.autism-society.org/what-is/facts-and-statistics/
[356] https://www.cbo.gov/publication/53624
[357] https://www.ncbi.nlm.nih.gov/pubmed/29582071; https://www.cnn.com/2018/03/26/health/vaccination-rates-children-autism-study/index.html (lead author even concedes they "did not look at vaccination rates before the children were diagnosed with autism")

did not internally review the vaccination rate *before* the autism diagnoses. Of course, if this comparison showed that fewer vaccines resulted in less autism, publishing such a result would call into serious doubt the competence of HHS in ensuring the safety of vaccines and its childhood vaccine schedule, as well as involve trillions of dollars in financial liability for the harm caused.

HHS's approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child's autism. Numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child's autism.[358] Many of these surveys explain how parents express a clear personal experience with vaccination affirming this conclusion.[359]

The Vaccine Information Statement (**VIS**) produced by HHS for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, www.cdc.gov, which in turn claims that "Vaccines Do Not Cause Autism."[360] Because HHS has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must, under federal law, be "based on available data and information."[361] But, based on available data and information, as discussed above, HHS cannot scientifically claim that "Vaccines Do Not Cause Autism." HHS must therefore remove this claim from the CDC website until it can produce the studies to support the claim that vaccines do not cause autism.

VII. HHS REFUSAL TO CONDUCT VACCINATED V. UNVACCINATED STUDY

In our letter, we asked that HHS advise whether it will "conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of fully/partially vaccinated with completely unvaccinated children?"[362] HHS has failed to actually respond to this question.

A. IOM 2013 Review Highlights Need for Vaccinated v. Unvaccinated Study

HHS's response letter first cites the very same 2013 report by the IOM which we cited in our opening.[363] We cited this report because it clearly supports the need for a properly

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[358] https://www.ncbi.nlm.nih.gov/pubmed/16685182; https://www.ncbi.nlm.nih.gov/pubmed/25398603; https://www.ncbi.nlm.nih.gov/pubmed/16547798; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/

[359] https://www.ncbi.nlm.nih.gov/pubmed/16685182; https://www.ncbi.nlm.nih.gov/pubmed/25398603; https://www.ncbi.nlm.nih.gov/pubmed/16547798; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/

[360] https://www.cdc.gov/vaccines/hcp/vis/current-vis.html; https://www.cdc.gov/vaccinesafety/concerns/autism.html

[361] 42 U.S.C. § 300aa-26

[362] Compare http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf with http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[363] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

powered and controlled prospective study evaluating the health outcomes between vaccinated vs. unvaccinated children.[364] Indeed, HHS commissioned this review to assess the safety of HHS's early childhood vaccine schedule and hence, as explained by the IOM, its "literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule."[365] "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms."[366]

However, instead of answers, the IOM found that no studies had ever been conducted which compared the health outcomes of children receiving HHS's childhood vaccine schedule with children that had not been vaccinated:

> [F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study ... compared the differences in health outcomes ... between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. ...
>
> [Also,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted.[367]

Even when the IOM committee expanded its search for any evidence that could help it assess the safety of HHS's childhood vaccine schedule, it stated that it "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule."[368]

Due to the lack of science regarding the safety of HHS's vaccine schedule, the best the IOM could do was conclude: "There is no evidence that the schedule is not safe."[369] Left unsaid, but equally true: **there is no evidence that the schedule is safe**. That HHS finds the IOM's conclusion acceptable is troubling and another clear dereliction of its vaccine safety

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[364] https://www.nap.edu/read/13563/chapter/1
[365] https://www.nap.edu/read/13563/chapter/2#5
[366] https://www.nap.edu/read/13563/chapter/2#5
[367] https://www.nap.edu/read/13563/chapter/2#5
[368] https://www.nap.edu/read/13563/chapter/6?term=paucity#70
[369] https://www.nap.edu/read/13563/chapter/2#12

duties. Just because HHS refuses to conduct the scientific studies necessary to establish if there is harm does not mean that no harm exists.

Equally troubling is that despite acute adverse events such as persistent crying or extreme lethargy in recently vaccinated babies that can last for days, the IOM acknowledges that science does not yet even know "if there is a relationship between short-term adverse events following vaccination and long-term health issues."[370] Without properly-controlled prospective long-term studies it is not possible to know whether acute vaccine reactions, including the more serious ones like brain inflammation and encephalitis, are causing long-term neurological damage (that takes the form of, for example, increasingly common developmental delays and behavioral disorders).

It is therefore remarkable that HHS cites the IOM report from 2013 as support for *not* conducting a longer-term properly powered and controlled study that would finally compare all health outcomes in vaccinated and unvaccinated children.

B. HHS's Desperation to Avoid Any Valid Vaccinated v. Unvaccinated Study

Hiding behind a claim that it would be unethical to conduct such a study is also without merit. Putting aside that it is unethical for HHS to continue promoting its childhood vaccine schedule as proven safe when HHS lacks the scientific studies necessary to validate the safety of its childhood vaccine schedule, there are ways to "ethically" conduct a vaccinated versus unvaccinated study. As we pointed out in our opening letter, the very IOM report from 2013 asserts it "is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD."[371]

In response, HHS has not published this study. Given the numerous studies HHS publishes each year using the VSD, it is difficult to imagine that if such a study showed no health differences or that vaccinated children were healthier than unvaccinated children, HHS would not have already published that study.

Tellingly, instead of using the VSD to publish the relatively simple study comparing health outcomes between vaccinated and unvaccinated children, HHS instead spent a tremendous amount of resources to publish a 64-page white paper regarding conducting such studies using the VSD.[372]

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[370] https://www.nap.edu/read/13563/chapter/5#45
[371] https://www.nap.edu/read/13563/chapter/2#13
[372] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

This white paper, prominently cited by HHS in its response letter, acknowledges that many chronic disorders children are experiencing today in epidemic numbers are biologically plausible outcomes from exposure to HHS's pediatric vaccination schedule but have not yet been properly studied.[373] While we should be encouraged by such an open admission, the white paper is revealing regarding HHS's approach to vaccine safety.

i. White Paper Guided by Pharmaceutical Company Insiders

First, this white paper was guided by pharmaceutical company insiders. As the white paper authors explain:

> Guided by subject matter expert engagement, we outlined a 4 staged approach for identifying exposure groups of undervaccinated children, developed a list of 20 prioritized outcomes, and described various study designs and statistical methods that could be used to assess the safety of the schedule.[374]

The subject matter experts relied upon to draft the white paper had serious financial and other conflicts of interest. For example, the first subject matter expert listed is Dr. Stanley Plotkin.[375] Dr. Plotkin earned millions of dollars in employment, consulting, and royalties from Merck, GSK, Sanofi and Pfizer (which, combined, manufacture nearly every vaccine on HHS's childhood vaccine schedule) including serving on the boards of the following for-profit pharmaceutical companies involved in vaccine development (while working on the white paper): Dynavax Technologies, VBI Vaccines, Mymetics, Inovio Biomedical Corp, CureVacAG, SynVaccine, GeoVax Labs, GlycoVaxyn AG, Adjuvance Technologies, BioNet Asia, Adcombia Biosciences, and Hookipia Biotech.[376] Three of the four other subject matter experts involved in creating the white paper were similarly conflicted.[377]

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[373] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[374] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[375] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[376] https://openpaymentsdata.cms.gov/physician/510771/summary; http://www.vaxconsult.com/cv-page/; https://patents.google.com/patent/US6290968B1/en; https://www.royaltypharma.com/royalty-pharma-acquires-royalty-interest-in-rotateq-from-the-childrens-hospital-foundation-for-182-million; http://people.equilar.com/bio/stanley-plotkin-dynavax-technologies/salary/91882; https://www.vbivaccines.com/about/scientific-advisory-board/; https://globenewswire.com/news-release/2009/09/09/404297/172906/en/Mymetics-Corporation-Announces-the-Appointment-of-Dr-Stanley-Plotkin-as-Chairman-of-the-Scientific-Advisory-Board-and-Election-of-New-Members.html; https://www.acornmanagementpartners.com/news-events/client-news/post/1713/vaccine-pioneer-joins-inovio-biomedicals-scientific; http://www.curevac.com/company/scientific-advisory-board/; https://www.synvaccine.com/about2; https://finance.yahoo.com/news/geovax-reports-2017-first-quarter-130000205.html; http://www.bionity.com/en/news/107511/glycovaxyn-ag-appoints-dr-stanley-plotkin-to-supervisory-board.html; http://adjuvancetechnologies.com/management-team/; http://www.jkdaily.com/articles/2628/20160322/asian-biotech.htm; http://www.abcombibio.com/advisors; http://hookipabiotech.com

[377] Walter A. Orenstein: https://www.ncbi.nlm.nih.gov/pubmed/18589064; https://www.ncbi.nlm.nih.gov/pubmed/16533116. Edgar K. Marcuse: https://www.ncbi.nlm.nih.gov/pubmed/10432034. M. Alan Brookhart: https://www.ncbi.nlm.nih.gov/pubmed/28370957.

Despite the foregoing, the authors of the white paper state that the "White Paper study team had no conflicts of interest to declare."[378]

The subject matter experts even gathered for a closed-door meeting with HHS to craft the white paper in Atlanta, Georgia in February 2014. Yet, the HHS authors excluded parents and parent organizations concerned about vaccine safety, admitting that the white paper study team "did not engage any parents or parental groups throughout the process."[379]

Bias is evident in the first paragraph of the white paper. Instead of stating its goal is to assess the actual safety of the vaccine schedule, the authors assert that "Maintaining high vaccination coverage within the population is critical" and that the enemy of this goal is "concern about the safety of vaccines," and in particular "the safety of vaccines given to young children."[380]

HHS even falsely asserts, more than once, that the 2013 IOM report concluded that "the current U.S. immunization schedule was safe," when it actually concluded: "There is no evidence that the schedule is not safe."[381] Ironically, it is precisely because of the lack of evidence to support safety that the IOM "highlighted four research questions of highest priority," with the first being "how do child health outcomes compare between fully vaccinated and unvaccinated children."[382]

ii. White Paper Expertly Designed to Support Status Quo

HHS was thus forced into a corner by the very report it commissioned from IOM. It now had to answer "how do child health outcomes compare between fully vaccinated and unvaccinated children."[383] But, the HHS officials and pharmaceutical company representatives who created this white paper are plainly concerned about revealing the health outcome differences between vaccinated and unvaccinated children. The authors dissuade such a comparison and suggest study parameters that would, among other things, result in eliminating the healthiest nonvaccinated subjects from any study.

A vaccinated versus unvaccinated study to assess the safety of HHS's childhood vaccine schedule should be straightforward. Such a study should compare the incidence of all adverse health conditions (ICD-9/10 codes) in vaccinated and unvaccinated children.

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[378] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[379] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[380] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf (The white paper also asserts that "new knowledge generated about adverse events" should be used by "policy makers when weighing all available evidence about the benefits and risks of vaccination," when it should have said that this knowledge should be used to reduce/eliminate the risk of any identified adverse reaction.)
[381] https://www.nap.edu/read/13563/chapter/2#12
[382] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[383] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

Instead, the white paper only puts forth a handful of carefully culled conditions. It does this by first limiting its list to conditions that HHS and the pharmaceutical industry have previously studied.[384] Meaning, their prior bias was already built into the white paper's initial limited list of only 75 conditions.[385]

The authors then discarded those health conditions they deemed lacked "biological and mechanistic plausibility" with vaccination.[386] A lack of available biological and mechanistic studies is one of the major problems the IOM has complained about for decades. Removing outcomes because available science was lacking defeated the purpose of the exercise. Even so, this winnowing process resulted in a list of 43 adverse outcomes admitted by the subject matter experts to be plausibly caused by HHS's childhood vaccine schedule – a surprising admission given HHS's assurance that vaccine safety had already been established.[387] These 43 outcomes included autism spectrum disorder, attention deficit disorder, and numerous other neurological and immunological disorders.[388] Despite finding that all 43 of these outcomes were "plausible to study relative to the childhood immunization schedule," this list was nonetheless winnowed down to 20 conditions.[389] For example, autism was removed based on the demonstrably untrue claim it had "been extensively studied relative to the vaccination schedule."[390]

A comparison of all conditions between vaccinated and fully unvaccinated children, as directed by the IOM, is what should be conducted. Among other reasons, as HHS should be aware, vaccination can cause a spectrum of unexpected adverse effects.

For example, a recent study out of the University of Hong Kong, Queen Mary Hospital, and Centre for Influenza Research compared children receiving the influenza vaccine with those receiving a saline injection in a prospective randomized double-blind study.[391] Both groups had a statistically similar rate of influenza, but the group receiving the influenza vaccine had a statistically significant 440% increase in the rate of non-influenza infections.[392] Thus, the influenza vaccine increased children's susceptibility to other respiratory viral infections.

As another example, Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa and has published over 300 peer-reviewed articles and studies regarding

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[384] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[385] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[386] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[387] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
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[389] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[390] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[391] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[392] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/

vaccination.[393] In 2017, he and co-authors published a study finding that infants were 10 times more likely to die by 6 months of age following their DTP vaccination than those that did not receive any vaccines during the first 6 months of life.[394] Children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[395] This indicated that while DTP's purpose is to reduce the incidence of diphtheria, tetanus, and pertussis, it actually increased mortality from other infections.[396] The study therefore concludes:

> All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.[397]

Perhaps most concerning is that the above study was based on data from the 1980s that had been collecting dust for over 30 years.[398] This begs the question: what other serious vaccine injuries and non-specific adverse effects are being missed by neglecting to conduct desperately needed vaccine safety science comparing vaccinated and unvaccinated children.

Consider that there are over 420 disorders listed on package inserts of vaccines routinely administered to babies and children – a large portion of which are immune and nervous system disorders – which are *only* listed there because its manufacturer has a basis to believe there is a causal relationship between the vaccine and the occurrence of the adverse event.[399] Federal law is clear that this list should include "*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event."[400] Nonetheless, the white paper guides researchers to ignore every adverse health condition that develops following vaccination other than the 20 hand-picked conditions culled by HHS and pharmaceutical company insiders.

iii. White Paper Guides Researchers to Exclude Unvaccinated Children

The white paper then – in contravention to the primary directive of the IOM to compare health outcomes between *vaccinated* with *unvaccinated* children – advocates for comparing *vaccinated* with *vaccinated* children.[401] It begins by arguing that "Comparing fully vaccinated children to totally unvaccinated children would likely be highly confounded"

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393 https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D
394 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
395 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
396 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
397 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
398 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
399 21 C.F.R. 201.57; https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm
400 21 C.F.R. 201.57
401 https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

and, in numerous ways, derides conducting such a comparison.[402] The white paper then guides researchers to compare the health outcomes between fully vaccinated children and partially vaccinated children (which are typically also almost fully vaccinated).[403] But this is precisely the comparison that would be "highly confounded" because children are often only partially vaccinated because parents who stop vaccinating their children (and hence have partially vaccinated children) often do so because of a negative health outcome following a previous vaccination.[404] HHS and authors of the white paper are aware of this bias. As the authors of the white paper admit:

> Parents may alter their intended immunization schedules for a child who experiences a negative health outcome, particularly if the outcome is perceived to be a result of a vaccine.[405]

This means that the partially vaccinated children in the VSD may be sicker than the fully vaccinated children precisely because of their prior vaccinations. It is therefore a comparison of vaccinated with partially vaccinated children that is actually "highly confounded," but yet precisely the type of comparison the white paper strongly recommends. Such a comparison is also nonsensical since it will not answer the outstanding scientific questions that urgently need to be answered regarding the safety of HHS's childhood vaccine schedule.

iv. White Paper Guides Researchers How to Obtain Desired Results

If, despite the above recommendation not to do so, a researcher does conduct a vaccinated versus unvaccinated study, the white paper guides the researcher to use certain "adjustments" to control the study's outcome.

First, the white paper suggests that researchers "exclude unvaccinated children who had fewer than four outpatient visits during the first two years of life."[406] The purported reason for this "adjustment" is to ensure that children in the VSD with no recorded vaccination are actually unvaccinated. But, this "adjustment" is unnecessary because, as the authors of the white paper admit, many VSD sites already link to their state's centralized electronic immunization information system which tracks the vaccination status of every child in the state.[407] (Moreover, the authors of the white paper also admit that a "medical record review" revealed that the vaccination status was accurate for 94% of children when

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[402] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[403] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[404] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[405] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[406] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf (emphasis added)
[407] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

they had at least one V-code for vaccine refusal and that in the VSD, "1,898 (0.6%) [children] had no vaccines and at least one V-code for vaccine refusal."[408])

The transparent reason for excluding unvaccinated children who do not have at least four outpatient visits is to exclude most or all of the very healthy unvaccinated children from the study.

HHS learned the importance of excluding children without outpatient visits from its experience in a prior study in which it found "a positive association between Hib and Hep B vaccination and the incidence of asthma."[409] If this result stood, it could have meant both loss of reputation for HHS and trillions of dollars of financial liability. To eliminate the association between vaccination and asthma, HHS first excluded children without at least one outpatient visit.[410] But when the association remained, HHS then excluded children without "at least two outpatient visits."[411] The result was that the positive finding was no longer statistically significant and a loss of reputation and trillions of dollars in liability was avoided. The white paper therefore advised that researchers restrict "their study populations to children with a minimum amount of health care utilization," such as excluding "unvaccinated children who had fewer than four outpatient visits."[412] Employing this adjustment, a researcher can make almost any safety signal disappear.

In case the above is not sufficient to eliminate a vaccine safety signal, the authors of the white paper created another escape hatch. Vaccine researchers are advised to include another supposed non-vaccine-related condition in each study as a "control" outcome, and if the incidence rate of the control condition is different in vaccinated and unvaccinated children, the study can be considered confounded and discarded.[413] On the surface, this approach seems sensible. However, the control conditions that the authors of the white paper suggest, such as well-child visits, are clearly related to vaccination rates.

Unvaccinated children often do not regularly go to well-child doctor visits because the major reason for these visits is vaccination; in fact, when they do, one-fifth of pediatricians report dismissing these families from their practice for refusing or requesting to delay one or more vaccines.[414] Hence, this control condition will likely yield a different incidence rate between vaccinated and unvaccinated children, providing the researchers

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[408] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[409] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[410] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[411] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[412] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[413] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[414] https://www.ncbi.nlm.nih.gov/pubmed/26527552

with a reason to discard the study.[415] The "controls" suggested by the authors of the white paper are an apparent "insurance" to permit researchers, if the other "adjustments" they suggest do not work, to discard any study that produces concerning results about adverse health outcomes between vaccinated and unvaccinated children.

In summary, the white paper promotes the use of inappropriate study designs that will result in highly compromised studies. The authors appear dedicated to finding a desired result rather than letting the data speak for itself. They do this by narrowing studies to 20 outcome conditions, emphasizing vaccinated vs. vaccinated studies, and claiming vaccinated vs. unvaccinated studies are "highly confounded" and hence, if conducted, require adjustments to exclude healthy unvaccinated children and otherwise a "control" that permits discarding any finding that does not affirm the safety of HHS's childhood schedule.

The results-oriented nature of the white paper makes sense when considering it originates from HHS's Immunization Safety Office, which assists in defeating vaccine injury claims in Vaccine Court. It is plainly conflicted from providing guidance regarding or conducting this or any other vaccine safety study. If HHS really cared about vaccine safety, federal health officials would be requiring and advocating for adherence to the gold standard in scientific research – double-blind long-term placebo-controlled studies during pre-licensure trials, and straightforward vaccinated vs. unvaccinated cohort studies as a follow-up. There is little excuse for not conducting these types of studies when there are already hundreds of thousands of completely unvaccinated children in America, including over 50,000 completely unvaccinated 2-year old children.[416]

Moreover, HHS claims in its letter that the white paper states that the "CDC has started conducting some of the studies mentioned in the white paper."[417] The white paper, however, contains no such claim.[418] Nonetheless, if true, it is troubling that this study is being undertaken by HHS's Immunization Safety Office which assists in defending against vaccine injury claims and is headed by Dr. Frank DeStefano, who is accused by his fellow CDC senior scientist of fraudulently modifying results of prior vaccine studies, including to avoid liability for HHS in Vaccine Court.[419] To be reliable, any vaccinated vs. unvaccinated study must be conducted by individuals completely independent of HHS and otherwise completely impartial. Nobody at HHS can impartially conduct a vaccine safety study because a finding that childhood vaccines cause any serious harm would result in serious

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[415] The white paper also suggests "minor injuries" as a control because "[t]here is no plausible biologic pathway by which vaccines could cause these minor injuries"; but if vaccination causes neurological disorders which render children more prone to injury, vaccinated children would have a higher rate of minor injuries. https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[416] https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm

[417] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[418] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[419] https://soundcloud.com/tomotion/cdc-whistle-blower-full-audio; http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf

reputational harm to HHS, would conflict with its mission to assure high vaccine uptake, and would be used as evidence against HHS in Vaccine Court where HHS is charged to defend against claims of vaccine injury.

This concern is even more acute given that HHS really does not know the actual safety profile of each childhood vaccine nor its childhood vaccine schedule. As HHS acknowledges in its white paper: "the field of vaccine schedule safety is in its infancy."[420]

C. HHS's Bias Leaves It Unable to See Glaring Safety Signals

HHS then states that "should signals arise that there may be a need for investigation," HHS would then conduct an appropriate vaccinated vs unvaccinated study.[421] Let us provide HHS with a few such signals.

A very bright vaccine safety signal is the fact that HHS knows that less than 1% of adverse events occurring after vaccination are reported to VAERS and HHS knows that there were 261,294 adverse vaccine events reported to VAERS in the last five years.[422]

The following finding from the School of Public Health at Jackson State University is another bright flashing vaccine safety signal: 33% of vaccinated preterm babies had a neurodevelopmental disorder while 0% of the unvaccinated preterm babies had a neurodevelopmental disorder; and another pilot study by the same group found that vaccinated children, compared to unvaccinated children (receiving no vaccines), had an increased risk of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.[423]

Another clear vaccine safety signal is the body of replicated peer-reviewed studies evidencing that that aluminum adjuvant in vaccines injected into the muscle tissue of lab animals are phagocytized by macrophages, transported to their brains and cause neurological impairments.[424]

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[420] https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm

[421] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[422] https://wonder.cdc.gov/vaers.html

[423] http://www.oatext.com/pdf/ITS-3-186.pdf; http://www.oatext.com/pdf/ITS-3-187.pdf

[424] http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf. Macrophages phagocytize (ingest) aluminum adjuvant (AA): https://www.ncbi.nlm.nih.gov/pubmed/15297065; https://www.ncbi.nlm.nih.gov/pubmed/18496530. Macrophages transport material into the brain: https://www.ncbi.nlm.nih.gov/pubmed/27213597; https://www.ncbi.nlm.nih.gov/pubmed/21348773; https://www.ncbi.nlm.nih.gov/pubmed/27115998; https://www.ncbi.nlm.nih.gov/pubmed/27213597. AA transport to brain: https://www.ncbi.nlm.nih.gov/pubmed/26384437; https://www.ncbi.nlm.nih.gov/pubmed/27908630; https://www.ncbi.nlm.nih.gov/pubmed/23557144. AA causes neuro impairment: https://www.ncbi.nlm.nih.gov/pubmed/27908630; https://www.ncbi.nlm.nih.gov/pubmed/19740540; https://www.ncbi.nlm.nih.gov/pubmed/23932735. Macrophages infiltrate the brain in autism: https://www.ncbi.nlm.nih.gov/pubmed/16401547; https://www.ncbi.nlm.nih.gov/pubmed/15546155; https://www.ncbi.nlm.nih.gov/pubmed/28167942; https://www.ncbi.nlm.nih.gov/pubmed/24951035.

Another vaccine safety signal is that clinical trials comparing health outcomes in two vaccinated groups typically find that both groups have significant rates of serious adverse events which exceed what would be expected in the general population.[425] The fact that no HHS licensed vaccine, save one, has been safety tested for use in children in a placebo-controlled trial prior to licensure makes each of these safety signals burn even brighter.[426]

The greatest vaccine safety signal may be the ever-growing percentage of Americans refusing to vaccinate their children. According to HHS, between 2001 and 2017 the number of completely unvaccinated two-year-old children in America has increased by 433%.[427] One in 77 two-year old American children are now completely unvaccinated and 1 in 2 children skip one or more vaccines on HHS's childhood vaccine schedule.[428] This growth has occurred despite stricter vaccination laws and access to free vaccinations for lower income populations.

Parents declining one or more HHS recommended vaccinations for their children often have concerns about vaccine safety because they themselves, their children, or someone else close to them, has had a personal experience with a life-altering adverse event following vaccination.[429] Parents who make this informed choice, as HHS admits, are typically well-educated, and do so in the face of social stigma and exclusion; hence, they often never make this decision lightly, but rather after careful research or a personal experience with vaccine injury.[430]

The stated purpose of vaccination is to improve the overall quality of health of Americans and reduce mortality. Yet, the increase in HHS's childhood vaccine schedule over the last 30 years from 8 vaccine injections[431] to 50 vaccine injections[432] (plus 2 injections during pregnancy[433]) has occurred in lockstep with the increase in the rate of autoimmune, developmental and neurological disorders in children from 12.8% to 54%.[434] HHS has no explanation for why U.S. children today are plagued with a chronic disease and disability epidemic.

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[425] For examples see Sections I and IV above.
[426] See Section I above.
[427] https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm
[428] https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm; https://stacks.cdc.gov/view/cdc/59415
[429] https://www.ncbi.nlm.nih.gov/pubmed/25200366
[430] https://www.ncbi.nlm.nih.gov/pubmed/18816357; https://www.ncbi.nlm.nih.gov/pubmed/28578210; https://www.cnn.com/2015/02/03/health/the-unvaccinated/index.html
[431] https://www.cdc.gov/vaccines/schedules/images/schedule1989s.jpg (OPV is given orally)
[432] https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html#schedule (Rotavirus is given orally. Assumes 4-dose Hib series, 3-dose HPV series, and no combination vaccines; but even with combination vaccines still have a total of 40 injections.)
[433] https://www.cdc.gov/vaccines/pregnancy/downloads/immunizations-preg-chart.pdf
[434] Compare https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg with https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

This as yet unexplained explosion in chronic disease and disability among American children, which coincides with the rapid increase in the numbers of vaccinations given to infants and children in the first six years of life, is a neon vaccine safety signal that demands methodologically sound studies to rule out vaccines or the HHS childhood vaccine schedule as a contributing cause. It is accepted science that adverse responses to vaccination can lead to certain chronic disorders, including autoimmune, developmental and neurological disorders – it is only the rate at which this occurs that is either disputed or admittedly unknown.[435] Given that the incidence of chronic diseases and disabilities is at an all-time high among children, especially among babies born healthy who then regress into chronic poor health in early childhood, it is high time to determine if vaccination is a contributing factor for this decline in overall childhood health.

HHS's response fails to provide evidence that these chronic diseases and disabilities are not caused by vaccination. If HHS does not know, then HHS cannot assess whether its childhood vaccine schedule – which produces a financial windfall to pharmaceutical companies[436] and the HHS agencies and employees that receive royalties from childhood vaccine sales[437] – is causing more harm than good. As discussed above, the flawed clinical trials that HHS relies upon to license vaccines are incapable of scientifically determining whether vaccines cause any of the chronic illnesses and developmental disorders that have steadily risen among American children during the past three decades. Despite this gap in safety, and despite the growing chorus of vaccine harm from parents – which is a major reason vaccine rates are declining – HHS defiantly continues to claim there are no vaccine safety signals.

Doctors have long been trained to listen to their patients, and studies have repeatedly shown that parents are the best source of information about their children and provide highly accurate information for detecting symptoms of and addressing developmental and behavioral problems.[438] HHS should take heed of this age-old wisdom and listen to the growing number of parents who, as the vaccine schedule has expanded, have reported that they observed their children regress into poor health after vaccination, including losing

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[435] Among other sources: https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf; https://www.nap.edu/read/1815/chapter/2#7; https://www.nap.edu/read/2138/chapter/2#11; https://www.nap.edu/read/13164/chapter/2#2; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/; children must "prove that the vaccine was the cause" for all off-Table vaccine injuries, https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437, 98% of vaccine injury claims are off-Table, http://www.gao.gov/assets/670/667136.pdf, and partial database of off-Table vaccine injury awards, https://www.uscfc.uscourts.gov/aggregator/sources/7; see studies compiled in this white paper: http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf; conditions listed in Appendix B are reported in one or more pediatric vaccine package inserts, https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm, because, as required by federal law, there is a "basis to believe there is a causal relationship between the drug and the occurrence of the adverse event," 21 C.F.R. 201.57.

[436] https://investors.pfizer.com/financials/annual-reports/default.aspx; https://investors.merck.com/financials/sec-filings/default.aspx; https://www.gsk.com/media/4751/annual-report.pdf; https://www.sanofi.com/en/investors/reports-and-publications/

[437] https://www.ott.nih.gov/royalty/information-nih-inventors; https://www.ott.nih.gov/resources; https://www.ott.nih.gov/reportsstats/top-20-commercially-successful-inventions; https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2017.pdf; https://www.ott.nih.gov/news/nih-technology-licensed-merck-hpv-vaccine; https://www.ott.nih.gov/reportsstats/hhs-licensed-products-approved-fda

[438] https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1440-1754.1999.00342.x

previously met cognitive and physical milestones and suffering changes in personality and behavior. If HHS wants to prove them wrong, it needs to produce real science showing the actual safety of each childhood vaccine and HHS's childhood vaccine schedule. That science demands, at the very least, a properly sized and controlled prospective study comparing health outcomes in vaccinated and completely unvaccinated children.

VIII. HHS REFUSES TO COMMIT TO REDUCING CONFLICTS OF INTEREST

Our opening letter asserted numerous incriminating conflicts of interest at HHS and outright misconduct by HHS officials with regard to fulfilling its critical vaccine safety duties. HHS's response letter does not contest any of these. This may be because almost all of the conflicts of interest and misconduct we referenced in our opening letter were originally identified in congressional and other governmental reports. These reports found, for example, that the "overwhelming majority of members [of HHS's vaccine licensing committee], both voting members and consultants, have substantial ties to the pharmaceutical industry" [439] and that the process of recommending vaccines at HHS reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[440] All of these findings, as noted, remained unchallenged in HHS's response.

Many of these issues arise because HHS, *on the one hand*, is required to promote universal vaccine uptake and to defend vaccines from any claim of harm in Vaccine Court and, *on the other hand*, is responsible for the conflicting duty of assuring vaccine safety. Unfortunately, HHS's vaccine uptake/defense duties have suffocated its vaccine safety duties. We therefore suggested a number of ways in which some balance between these conflicting duties could be created.

Despite not contesting the serious conflicts of interest and misconduct regarding vaccine safety at HHS, your response rejects every single suggestion. Without drastic change, HHS's critical statutory duty to ensure vaccine safety will remain buried by HHS's vaccine uptake/defense duties. Based on HHS's response, the only real solution appears clear: remove vaccine safety into an entirely independent board that has no responsibility for vaccine uptake or defense.

A. HHS's Failure To Perform Its Vaccine Safety Duties

Recent admissions by HHS bring into sharp focus HHS's failure to perform its vaccine safety duties under the 1986 Act. As HHS is aware, when Congress in 1986 granted economic immunity to pharmaceutical companies for vaccine injuries, the financial

[439] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf
[440] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf

incentive for pharmaceutical companies to be accountable for and assure vaccine safety was eliminated.[441] Recognizing the unprecedented elimination of this market force, Congress in 1986 made HHS directly responsible for virtually every aspect of assuring vaccine safety.[442] Congress codified this obligation in 42 U.S.C. § 300aa-27 entitled "Mandate for Safer Childhood Vaccines" (the **Mandate**).

This Mandate underpins all vaccine safety in this country and has three simple parts. The following is a copy of the entire Mandate:

> **(a) General rule.** In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary [of HHS] shall— (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
>
> **(b) Task force.** (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control. (2) The Director of the National Institutes of Health shall serve as chairman of the task force. (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.
>
> **(c) Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.[443]

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[441] 42 U.S.C. § 300aa-10; 42 U.S.C. § 300aa-11
[442] 42 U.S.C. § 300aa-27
[443] 42 U.S.C. § 300aa-27

The first part of the Mandate requires the Secretary of HHS to assure and improve every aspect of vaccine safety.[444] The second part creates the Task Force on Safer Childhood Vaccines (the **Task Force**), comprised of the heads of NIH, FDA and CDC, and requires the Task Force to make recommendations to the Secretary of HHS on how to improve vaccine safety.[445] The third part requires the Secretary of HHS to submit a report to Congress every two years, starting in 1989, detailing the improvements made to vaccine safety in the preceding two years.[446]

Despite these clear requirements, HHS has failed to fulfill any of its duties under the Mandate. After our repeated demands for copies of Task Force recommendations, HHS finally admitted that the Task Force was disbanded in 1998. After we were forced to file a federal lawsuit to obtain copies of biennial vaccine safety reports that HHS was supposed to submit to Congress, HHS finally admitted that it has never once prepared or filed a single report as required by the Mandate.[447]

When HHS fails to accomplish the simple tasks of merely making vaccine safety recommendations (required by part two of the Mandate) and preparing biennial vaccine safety reports to Congress (required by part three of the Mandate), it is unsurprising it has failed to conduct the difficult work required by part one of the Mandate to actually improve vaccine safety. Indeed, the substance of our respective letters make it evident that HHS has failed to perform its basic vaccine safety duties.[448]

B. HHS Must Demand Congress Vest Vaccine Safety in an Independent Board

In creating our system of government, our Founding Fathers recognized that governmental entities in powerful positions inherently have a difficult time regulating themselves. Therefore, a system of checks and balances was instituted in our system of government that has served the nation well for more than two centuries. However, this system of checks and balances has been eliminated when it comes to vaccine safety.

Given that the industry has virtually no financial liability for harms caused by vaccines, and the government department responsible for ensuring vaccine safety is driven by the need to assure vaccine uptake/defense, there is no check and balance to provide any

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[444] 42 U.S.C. § 300aa-27

[445] 42 U.S.C. § 300aa-27

[446] 42 U.S.C. § 300aa-27

[447] https://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf

[448] Not only has HHS abdicated its vaccine safety duties, it is apparently comfortable with its incestuous relationship with the vaccine makers it is supposed to be regulating. For example, the first HHS vaccine committee (ACIP) meeting that ICAN attended began with an honorary ceremony in which ACIP announced it had engraved the name of a decades long pharmaceutical executive, Dr. Stanley Plotkin (whose conflicts are discussed above), on the gavel used at ACIP. https://www.youtube.com/watch?v=AsO5F5hqCQc&t=356s&index=25&list=PLvrp9iOILTQb6D9e1YZWpbUvztptNMKx2 ACIP even announced, to applause, that "all of us have been influenced" by Dr. Plotkin. This event speaks to the true ethos at HHS regarding pharmaceutical company involvement and influence upon HHS's vaccine work and policy, despite the regulations HHS cites purportedly seeking to prevent such conflicts.

level of assurance regarding vaccine safety. There is only an almost militant drive by HHS to promote vaccines, require their use and defend vaccines against any claim they cause harm, including as the defendant in the Vaccine Court.[449]

Product liability attorneys provide a critical check in ensuring unsafe products are either improved or eliminated from the market through civil lawsuits. But when it comes to childhood vaccines, this critical check was eliminated when product liability attorneys were neutralized by the grant of economic immunity to vaccine makers for vaccine injuries.[450] Without economic liability for vaccine injuries, pharmaceutical companies' fiduciary duty to their shareholders to maximize profits dictates licensing and marketing as many vaccines as possible, irrespective of their safety profile.

Congress sought to fill this void in vaccine safety (which it had created) by simultaneously making HHS legally responsible to assure vaccine safety. However, in hindsight, HHS was doomed to fail in assuring vaccine safety because HHS was simultaneously given the obligation to defend against every claim in Vaccine Court and assure high vaccine uptake.[451]

Moreover, HHS has become a "captive agency" co-opted by the very vaccine manufacturers it is supposed to be regulating (termed "agency capture" in academia).[452] There is simply no government agency pushing to ensure vaccine safety. On the other hand, there are billions of dollars spent by HHS and pharmaceutical companies every year to develop and promote vaccines, conduct studies to expand vaccine use, and discredit the scientists and medical professionals who testify on behalf of vaccine injured children in Vaccine Court or raise legitimate safety concerns regarding vaccines.[453]

When a department, such as HHS, is responsible for both promoting an industry and for ensuring the safety of that industry's products/activities, there is well settled precedent for separating these functions. HHS can learn from these precedents. For example, to avoid

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[449] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf (Congressional report describing how the 1986 Act gave HHS the authority to set the rules for the Vaccine Injury Compensation Program (**VICP**) and that HHS used this authority to change the rules of the VICP in its favor so it can more readily defeat vaccine injury claims. Indeed, the 1986 Act created a Vaccine Injury Table (the **Table**) which quickly compensated certain common vaccine injuries. If the petitioner suffered a Table injury, the burden shifted to HHS to prove the vaccine did not cause the injury. After passage of the 1986 Act, almost 90 percent of claims were Table claims and settled quickly. Soon after, in 1995 and 1997, HHS amended the Table such that 98% of new claims are off-Table. This change greatly increased the difficulty of obtaining compensation for vaccine injuries; and while HHS changed the VICP rules in its favor, "DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims.")

[450] https://www.ncbi.nlm.nih.gov/pubmed/12923993; https://media2.mofo.com/documents/101200-ch55.pdf

[451] 42 U.S.C. § 300aa-1; 42 U.S.C. § 300aa-2; 42 U.S.C. § 300aa-10; 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-14; 42 U.S.C. § 300aa-26; 42 U.S.C. § 300aa-27

[452] https://onlinelibrary.wiley.com/doi/abs/10.1111/rego.12209

[453] https://www.hhs.gov/about/budget/index.html; https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf; https://www.uscfc.uscourts.gov/aggregator/sources/7; https://www.ncbi.nlm.nih.gov/pubmed/29564139; https://investors.pfizer.com/financials/annual-reports/default.aspx; https://investors.merck.com/financials/sec-filings/default.aspx; https://www.gsk.com/media/4751/annual-report.pdf; https://www.sanofi.com/en/investors/reports-and-publications/

conflicts of interest inherent in having one department promote transportation as well as assure its safety, the responsibility for transportation safety was transferred from the Department of Transportation to the independent National Transportation Safety Board (**NTSB**).[454] Similarly, to avoid conflicts in having one department promote nuclear energy and assure its safety, the safety function was transferred to the independent Nuclear Regulatory Commission (**NRC**).[455] In the same manner, HHS should support removing vaccine safety from HHS altogether into an entirely independent board, as was done with the NTSB and NRC. In fact, using the NTSB as a model, vaccine researchers from Johns Hopkins University have advocated, as early as 2004, for removing vaccine safety from HHS and placing into an entirely independent National Vaccine Safety Board.[456]

There are, in fact, additional and even more compelling reasons for removing vaccine safety duties from HHS than there were for creating the NTSB and NRC. When transportation or nuclear related injuries occur, the companies causing these injuries are, to varying degrees, economically liable for the injuries. In contrast, when a vaccine injury occurs, the companies causing these injuries are effectively economically immune from liability under the 1986 Act.[457] Hence, unlike the NTSB and NRC, where the companies they regulate still have an economic incentive to assure safety, there is no such economic incentive for vaccine makers.[458] As such, unlike nuclear and transportation safety where the onus of safety still remains with industry, the onus of vaccine safety falls solely on the shoulders of HHS, making its mission to assure safety in many ways far more critical than the safety missions of the NTSB and NRC.

The NTSB and NRC also only assist victims of injury by the transportation and nuclear industries. In contrast, HHS is supposed to play the dual and conflicting roles of identifying and preventing injuries to children from vaccination while simultaneously serving as the defendant in Vaccine Court where, represented by the DOJ, it is statutorily required to defend against any claim that a vaccine injured a child, which HHS does vigorously.[459]

Thus, any study or admission by HHS that would support that a vaccine caused even a potential harm could be used against HHS in the Vaccine Court. Even HHS's Immunization Safety Office, which is responsible for vaccine safety, provides ongoing assistance to HHS's Division of Vaccine Injury Compensation, which is responsible for defending against claims of vaccine injury, in order to defeat claims in Vaccine Court.[460] It

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[454] https://www.ntsb.gov/about/history/pages/default.aspx

[455] https://www.nrc.gov/about-nrc/history.html

[456] https://www.ncbi.nlm.nih.gov/pubmed/15249296

[457] 42 U.S.C. § 300aa-1 et seq.; Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

[458] 42 U.S.C. § 300aa-1 et seq.

[459] 42 U.S.C. § 300aa-12; https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

[460] Advisory Committee on Immunization Practices, Transcript of October 25, 2017 Presentation "Vaccine Injury: Shoulder Injury After Vaccination" available at https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html

is amazing that the Immunization Safety Office is actually involved in fighting against, not for, families claiming their child was seriously injured by a vaccine. It is also unjust to demand that a child, who received vaccines based on HHS's vaccine schedule, prove how one or more of those vaccines caused his or her injury (i.e., prove "causation") in Vaccine Court while fighting against HHS; all while (as discussed above) HHS has not performed the science to understand how and why vaccines cause injury despite being statutorily tasked with that job.[461]

These structural conflicts make removal of vaccine safety from HHS far more compelling than the removal of transportation safety and nuclear safety to the NTSB and NRC.

The above is just a small part of why Congress concluded that the system at HHS for recommending and promoting vaccines reflects "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[462] A December 2009 report by HHS's Office of the Inspector General again found that the "CDC had a systemic lack of oversight of the ethics program for [committee members]," and that, for example, "[m]ost of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."[463] HHS's response letter also does not contest that CDC does accept funding from the pharmaceutical industry, directly and indirectly, despite claiming otherwise on its website, and that key vaccine program personnel are reluctant to take actions that would diminish their chances of securing lucrative private sector jobs with vaccine manufacturers.[464]

Many parents, physicians and scientists, as well as lawmakers, are legitimately concerned about the foregoing, including HHS's long running failure to fulfill its essential vaccine safety duties. Their concern is not rooted in a wild conspiracy or a belief of insidious intent. Rather, it is rooted in the idea that having HHS responsible for promoting vaccines and defending vaccines, including in Vaccine Court, is directly at odds with ensuring vaccine safety, especially where any finding that a childhood vaccine can cause serious harm could result in HHS having to pay damages in Vaccine Court as well as serious reputational

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[461] This was not what Congress intended in passing the 1986 Act. Instead, the 1986 Act created a Vaccine Injury Table (the "**Table**") which was intended to permit the Vaccine Court to quickly compensate certain common vaccine injuries. 42 U.S.C. § 300aa-12. If the child suffered an injury on the Table, the burden shifted to HHS to prove the vaccine did not cause the injury. 42 U.S.C. § 300aa-13. After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled. Stevens v. Secretary of HHS, No. 99-594V (Office of Special Masters 2001). However, in 1995 and 1997, HHS amended the Table such that now 98% of new claims are off-Table. http://www.gao.gov/assets/670/667136.pdf. As a result, injured children must now almost always prove "causation" – the biological mechanism by which the vaccine injured the child. https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437 ("Persons alleging a condition not included in the table ... must prove that the vaccine was the cause.") Requiring an injured child to prove causation adds insult to injury because had HHS conducted the safety science it demands as proof in Vaccine Court, the child's injury may have been avoided altogether.

[462] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf

[463] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf; http://www.nytimes.com/2009/12/18/health/policy/18cdc.html

[464] http://www.bmj.com/content/350/bmj.h2362

harm. HHS has serious conflicts and powerful disincentives which create institutional gridlock that prevent HHS from initiating, admitting or publishing any research that would support a claim that any childhood vaccine or HHS's childhood vaccine schedule causes serious injury or chronic illness in children.

HHS's response letter makes clear that these concerns are not only well founded, but worse than alleged in our opening letter.[465]

IX. VSD AND PRISM

HHS's response asserted that it investigates vaccine safety post-licensure using the Vaccine Safety Datalink (**VSD**) and the Post-licensure Rapid Immunization Safety Monitoring System (**PRISM**). While these could be helpful in assessing vaccine safety, that is not currently the case.

As for the VSD, instead of being used to improve safety, it is used as a tool to silence vaccine critics and expand vaccine recommendations, even for uses not licensed by the FDA. First, the VSD was once maintained at HHS but when scientists began to access the VSD to conduct studies which revealed vaccine harm, HHS purposely moved the VSD to a health industry trade association starting in 2001 to avoid having the VSD data subject to FOIA, and to otherwise assure that only the scientists and studies it approves utilize the VSD.[466]

Second, when a VSD study is conducted by HHS, in violation of basic scientific standards and process, the underlying raw data is almost never available for inspection by the public and other scientists.[467] Refusal to make this data available raises serious concerns regarding reproducibility and transparency. HHS regulations in fact provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but HHS does not apply this same standard to their own VSD studies.[468]

Third, the secret studies that HHS performs using the VSD with secret data are virtually all squarely aimed at increasing vaccine uptake, even for uses and in populations not approved by the FDA. For example, a plurality of the nineteen VSD studies conducted

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[465] Our opening letter also highlighted that HHS is required to assure that any "health care provider who administers a vaccine ... shall record ... in such person's permanent medical record ... the vaccine manufacturer and lot number." (42 U.S.C. §§ 300aa-25(a)) We therefore asked in our opening letter that HHS: "Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?" HHS's response does little more than restate HHS's requirement, and does not show it does anything to enforce this requirement. This is another dereliction of HHS's vaccine safety duties. This statutory obligation could not be any clearer. If HHS will not do anything of substance to assure the simple requirement of recording lot information, so that "hot lots" can be identified, there is little hope that HHS will fulfill its far more complex vaccine safety duties.

[466] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708093/

[467] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/accessing-data.html

[468] https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information

by HHS in 2017 involved the vaccination of pregnant women.[469] This is plainly in response to the HHS recommendation that influenza and Tdap vaccines be administered to every pregnant woman, despite the fact that these vaccines were not licensed by the FDA for use in pregnant women.[470] HHS is essentially engaging in off-label marketing that, if conducted by the vaccine manufacturer, would be illegal, and is seeking to use the VSD as an after-the-fact tool to justify this conduct.[471]

Fourth, the VSD must be retooled to assess the long-term impact of vaccination, which is the real concern the public has about vaccine safety. Indeed, HHS has acknowledged that the public stakeholders "have expressed more concerns about long-term than short-term health outcomes" and that "long-term health outcomes have been less well-studied in the context of vaccine safety," but that VSD is currently geared toward assessing short-term, and not long-term, health outcomes:

> The current safety surveillance systems such as the VSD, and the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system of the Food and Drug Administration (FDA), already have extensive systems in place to assess short-term outcomes ... [despite the fact] the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, [and hence] long-term adverse events may be more biologically plausible than short-term events.[472]

Fifth, it is highly inappropriate that VSD studies are conducted by HHS's Immunization Safety Office which, as discussed above, is headed by an individual accused by a Senior Scientist at HHS of fraudulently modifying results of prior vaccine studies, including for the purpose of avoiding liability for HHS in Vaccine Court.[473]

Sixth, and critically, any VSD study intended to assure the public that vaccines are safe should be designed and performed by an organization for whom a finding that a vaccine causes a serious harm would not have significant financial and/or reputational repercussions, as it would for HHS. In fact, the very HHS office that conducts VSD studies, the Immunization Safety Office, as discussed above, actively assists in defeating vaccine injury claims in Vaccine Court.

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[469] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/publications.html

[470] https://www.cdc.gov/vaccines/pregnancy/hcp/resources.html (advertising materials created by the CDC to promote vaccines to pregnant women); https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm (each vaccine package inserts states, in one form or another, that the safety and effectiveness of the vaccine has not been established in pregnant women)

[471] https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf

[472] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf

[473] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio; http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf

When HHS is ready to be transparent, it should: open the VSD to all researchers; make accessible the underlying data used for all its published studies; subject itself to the same criticism of its VSD studies as other scientists; and, not have these studies conducted by anyone or any organization that participates in defending against vaccine injury claims, is accused of scientific fraud, or has any conflict of interest with finding that a vaccine causes harm. Only then can HHS finally claim the VSD is a valid research tool for improving vaccine safety. Until then, the VSD remains an improperly wielded government tool, like the KGB's Mitrokhin Archive waiting for someone from HHS to defect and share the VSD data with the scientific community.

As for PRISM, putting aside its very limited use, instead of being used to improve vaccine safety, it is also wielded by HHS to silence vaccine critics and expand vaccine recommendations for uses not licensed by the FDA. For example, every single assessment conducted in PRISM in 2018 was conducted to provide after-the-fact support for HHS's vigorous marketing campaign aimed at assuring that every pregnant woman in America receives an influenza vaccine.[474] As discussed above, despite the fact the FDA has not licensed any influenza vaccine for use in pregnant women, HHS has been recommending and promoting this off-label use to pregnant women for a decade.

It is only after HHS could no longer ignore the mounting vaccine injury claims by pregnant women and independent studies finding serious safety signals regarding the risks of vaccinating pregnant women, that HHS used VSD and PRISM to "prove" the safety of its prior pregnancy vaccine use recommendation. But these efforts are plainly not about assuring vaccine safety. If that were the goal, these safety studies would have been conducted before HHS promoted administering influenza vaccine to all pregnant women. Rather, it is a transparent effort to silence recent and growing criticism of its off-label marketing of this vaccine to pregnant women. After vigorously promoting the flu shots to pregnant women for a decade, is HHS really going to publish science that requires it to backtrack and admit: "oops, sorry, actually, it is not safe to inject pregnant women with the flu shot."

Like the VSD, it is unlikely HHS will use PRISM to publish a study that confirms any serious widespread harm from vaccination. If it did, HHS would be developing the very science that would then be used against it in Vaccine Court, potentially resulting in crippling financial liability as well as loss of reputation. This is why HHS's Vaccine Safety Office, instead of working to prevent and obtain compensation for vaccine injuries and deaths, assists HHS's office responsible for fighting against the claims of vaccine injured plaintiffs

[474] https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments

in Vaccine Court. HHS is so blind to this obvious conflict that it openly bragged about this collaboration at a public ACIP meeting held in October 2017.[475]

The VSD and PRISM could be useful tools for assessing vaccine safety (after the baseline safety profile of HHS's childhood vaccine schedule is established in properly sized and controlled trials), but the studies conducted with these systems must be designed and executed by individuals and organizations without conflicts of interest and bias with regard to assessing vaccine safety. Such studies should certainly not be conducted by an organization that could suffer serious financial and reputational harm if it confirms that one or more childhood vaccines can cause serious injury. For example, finding that vaccines cause 1 in 5 cases of either allergic rhinitis, ADHD, learning disabilities or neurodevelopmental delay, all of which preliminary science has shown can be caused by vaccination,[476] would result in trillions of dollars of liability and a loss of public confidence in HHS and its vaccine schedule.

As explained by a renowned professor in the Center for Bioethics, Harvard School of Medicine, member of the Institute of Medicine, and former editor-in-chief of the New England Journal of Medicine:

> It is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*. ...[477]

For these and other reasons discussed above, it is entirely inappropriate to have HHS manage and control VSD and PRISM. These health database platforms are paid for by the American public and should be open to every scientist in this country to conduct studies without any barrier and without requiring any permission from HHS. If HHS truly believes that vaccines are "safe and effective," it should immediately make available to the public and scientific community, as it does with VAERS, the deidentified data in the VSD and let that data speak for itself.

Conclusion

Instead of focusing on defending pharmaceutical companies and their products, including in Vaccine Court, HHS should be focused on protecting and defending children

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[475] Advisory Committee on Immunization Practices, Transcript of October 25, 2017 Presentation "Vaccine Injury: Shoulder Injury After Vaccination" available at https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html

[476] http://www.oatext.com/pdf/JTS-3-186.pdf

[477] https://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/

from vaccine injuries. Pharmaceutical companies are well organized and funded. Parents of current and future vaccine injured children, the citizens the Government is supposed to serve, are not.

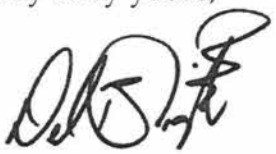
Since vaccine products are injected dozens of times into nearly every baby and child in America and are typically required by law to attend school, they should be tested for safety prior to licensure in extremely well designed clinical trials. Instead the opposite is true. Without impeccable clinical trials—with rigorous methods, large sample sizes, true placebo controls, and extended periods of observation for vaccine injury—yielding results which demonstrate that the benefits of vaccination clearly outweigh the harms, the large-scale vaccination program in this country cannot be ethically justified.

Even absent an ethical imperative, HHS's responsibility for assuring vaccine safety is required by federal law. HHS's response letter seeks to create the impression that there exists a complete understanding of the safety profile of each pediatric vaccine and HHS's childhood vaccine schedule, and that there is almost nothing left for HHS to do to assure vaccine safety. We request that HHS carefully consider all of the information provided above, which is nearly entirely grounded in and anchored by citations to HHS's own publications.

It is our hope that HHS will rise above its internal gridlock and inherent conflicts of interest, and take this opportunity to seriously consider the safety of pediatric vaccines and its childhood vaccine schedule.

We await your response to each of the points raised above and to the questions listed in Appendix A below.

Very truly yours,



Del Bigtree
President

Enclosures: Appendices A and B.[478]

[478] Appendix A of our initial letter, dated October 12, 2017, is amended to add Hope Inc. Academy, Medical Freedom Nevada, Hope from Holly, Educate.Advocate., Autism is Medical, Inc., Oregonians for Medical Freedom, Thinking Moms Revolution, Vaccine Freedom Utah, and Your Health Freedom.

APPENDIX A

QUESTIONS REGARDING VACCINE SAFETY

1. CLINICAL TRIALS

a. Please list each vaccine product that is currently recommended for routine use in children which was licensed for use in children based on a placebo-controlled clinical trial. For each vaccine product listed, please provide the clinical trial report supporting that a "placebo," as defined at www.cdc.gov/vaccines/terms/glossary.html, was used.

b. Please list each vaccine product that is currently recommended for routine use in children which was licensed for use in children based on a clinical trial that used an "active control" previously licensed for use in children based on a placebo-controlled clinical trial. For each vaccine product listed, please provide the clinical trial report supporting that a "placebo," as defined at www.cdc.gov/vaccines/terms/glossary.html, was used.

c. Will HHS henceforth require a placebo-controlled (saline injection) properly-powered (sufficient children) long-term (reviews safety for at least three years or until age eight, whichever is longer) clinical trial prior to licensing any new vaccine product for which no other vaccine exists for the target disease?

2. VACCINES INJECTED DURING THE FIRST 6-MONTHS OF LIFE

a. For each clinical trial relied upon to license any injectable vaccine product HHS currently recommends for routine use in children between birth and six-months of age, please identify (i) the control used and (ii) the trial's safety review period, by completing the following chart and please provide supporting documentation:

Licensed Vaccine Product	Control	Safety Review Period: Solicited Reactions	Safety Review Period: Unsolicited Reactions
Recombivax HB			
Engerix-B			
ActHIB			
PedvaxHIB			
Hiberix			
Infanrix			
Daptacel			
Ipol			
Prevnar 13			
Pediarix			
Pentacel			

b. Please provide the clinical trial report(s) that reflect the cumulative safety profile, by ten years of age, of injecting approximately 22 vaccine doses into babies during the first six months of life, including the rate of any autoimmune, neurological or developmental disorders.

c. Please provide the clinical trial report(s) that reflect the cumulative safety profile, by ten years of age, of injecting approximately 35 vaccine doses into babies and toddlers during the first two-years of life, including the rate of any autoimmune, neurological or developmental disorders.

3. VACCINES INJECTED INTO PREGNANT WOMEN

a. Please provide the clinical trial report(s) relied upon by HHS when licensing influenza and Tdap vaccines for use by pregnant women.

b. Is a pharmaceutical company permitted to advertise or promote the influenza or Tdap vaccines it manufactures to pregnant women? If not, why not?

4. SPECIFIC VACCINES

c. Is it acceptable to inject a healthy baby with a product that contains one or more known or suspected neurotoxic or cytotoxic substances where its licensure is based on a trial that had no control and a short safety review period?

d. Please identify and provide a copy of any placebo-controlled trial with a safety review period longer than one week that HHS relied upon when it recommended that every baby in this country receive either Recombivax HB or Engerix-B on the first day of life.

e. Please advise if HHS disputes that during the Gardasil trials the rate of girls and women 9 through 26 years of age who reported an incident condition potentially indicative of a systemic autoimmune disorder was 2.3% in the group that received Gardasil, 2.3% in the group that received AAHS Control, and 0% for the group that received Saline Placebo.

f. Please explain why it was considered ethical to inject controls during the clinical trials for (i) Gardasil with 225 mcg or 450 mcg of Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) when it has no known therapeutic benefit? (ii) Varivax with 45 mg of neomycin when neomycin is only licensed for topical and oral use?

5. POST-LICENSURE SAFETY

a. After a Harvard Pilgrim Health Care study, conducted pursuant to a grant from an HHS agency, developed a program which automatically identified and generated reports of possible vaccine reactions, please explain why HHS failed to cooperate with Harvard to automate submission of these reports to VAERS.

b. For each vaccine-injury pair for which the IOM, in its 1994 and 2011 reports, could not determine whether or not there is a causal relationship, please list the precise vaccine-injury pairs for which HHS has since determined whether there is a causal relationship. For each vaccine-injury pair identified, please specify HHS's finding regarding causation and provide documentary support.

c. Please list each vaccine on HHS's childhood vaccine schedule that has been evaluated for its (i) carcinogenic potential, (ii) mutagenic potential, or (iii) potential to impair fertility. For each vaccine listed, please identify for which of these three potentials it has been evaluated and provide documentary support.

d. Please identify the specific studies, by title, author and year, which HHS has conducted to determine specific biomarkers or other predictive criteria which can be used to identify whether a given child will suffer a serious vaccine injury.

e. Please provide the deidentified datasets from the following study relating to autism and vaccines in which HHS was involved so that we and the scientific community can analyze the data: https://www.ncbi.nlm.nih.gov/pubmed/?term=29582071

f. Please advise if HHS will forthwith provide public access to the deidentified datasets within the VSD so that all researchers can conduct vaccine safety studies without requiring any permission or approval from HHS or anyone else. Putting aside that taxpayers support the VSD, agreeing to such transparency would accord with CDC's claim that it "embraces intellectual honesty and transparency in its release of information to fully empower public decision."[479]

g. The following white paper provides the peer reviewed scientific support for how aluminum adjuvants injected into the body travel to the brain, can cause IL-6 production and microglial activation in the brain, and that this in turn can cause autism: http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf Please clearly and specifically explain which steps in this chain of causation or any other aspect of this white paper HHS disputes.

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[479] https://www.cdc.gov/about/organization/communication-principles.html

6. CONFLICTS OF INTEREST

a. Please explain why HHS has never once prepared or submitted a biennial report to Congress detailing improvements in vaccine safety as required under federal law, 42 U.S.C. § 300aa-27(c).

b. Please explain why HHS disbanded the Task Force on Safer Childhood Vaccines in 1998 when this task force is mandated to exist pursuant to federal law, 42 U.S.C. § 300aa-27(b), to provide recommendations to assist the Secretary of HHS in his/her ongoing duty to fulfill HHS's vaccine safety obligations pursuant to 42 U.S.C. § 300aa-27(a).

c. Please explain why HHS would place the name of a pharmaceutical executive and consultant on the gavel of its premier vaccine committee, the Advisory Committee on Immunization Practices.

d. Will you support the removal of vaccine safety duties from HHS into an entirely independent government board, similar to the National Transportation Safety Board or the Nuclear Regulatory Commission. If not, please explain why.

APPENDIX B

The following is a *partial* list of post-licensure adverse reactions reported by consumers and physicians, and listed in the package inserts for one or more pediatric vaccines.[480] Pursuant to federal law, these adverse reactions are only listed if the vaccine's manufacturer has a basis to believe there is a causal relationship between the vaccine and the occurrence of the adverse event.[481] Indeed, Federal law is clear that this list should include "*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event."[482]

Immune System Disorders

Alopecia	*autoimmune skin disease causing loss of hair on the scalp and body.*
Anaphylactic Shock	*rapid onset of severe allergic reaction that causes sudden drop in blood pressure and narrowing of airway that can lead to seizures, shock, and death.*
Angioedema	*potentially life-threatening swelling underneath the skin.*
Arthritis	*painful and disabling autoimmune disease that includes joint pain, swelling and progressive stiffness in the fingers, arms, legs and wrists.*
Autoimmune Disease	*disease caused by the immune system mistakenly attacking the body's own tissue.*
Guillain-Barré Syndrome	*autoimmune disease where the immune system attacks the nerves in the legs, upper body, arms and/or face.*
Hemolytic Anemia	*red blood cells are destroyed faster than they can be replaced.*
Henoch-Schonlein Purpura	*abnormal immune response causing inflammation of microscopic blood vessels which can lead to multiple organ damage.*
Lupus Erythematosus	*autoimmune disease in which the immune system attacks multiple organs, including skin, joints, kidney, and brain.*
Multiple Sclerosis	*autoimmune disease in which the immune system attacks nerve fibers, causing them to deteriorate.*

[480] https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm
[481] 21 C.F.R. 201.57
[482] 21 C.F.R. 201.57

Myasthenia	*autoimmune disease causing chronic weakness of the skeletal muscles, including arms and legs, vision problems, and drooping eyelids or head.*
Myositis	*chronic muscle inflammation that damages the muscle fibers causing weakness, and may affect the arteries and blood vessels that pass through muscle.*
Polyarteritis Nodosa	*systemic vasculitis that affect medium-sized and small muscular arteries resulting in ruptures and other damage.*
Stevens-Johnson's Syndrome	*severe autoimmune reaction in which the top layer of skin is burned off and dies.*
Thrombocytopenia	*low blood platelet count which can result in easy bruising and excessive bleeding from wounds or bleeding in mucous membranes.*
Vasculitis	*inflammation of the blood vessels, potentially leading to loss of function of affected tissues and organ damage.*

Nervous System Disorders

Acute Disseminated Encephalomyelitis	*acute, widespread inflammation in the brain and spinal cord that damages myelin.*
Ataxia	*brain damage resulting in loss of full control of bodily movement, impaired speech, eye movement, and swallowing.*
Bell's Palsy	*disfiguring paralysis or weakness on one side of the face.*
Encephalitis	*inflammation of the brain, which can result in permanent injury.*
Encephalomyelitis	*inflammation of the brain and spinal cord.*
Encephalopathy with EEG Disturbances	*damage or malfunction of the brain with severity ranging from altered mental state to dementia, seizures and coma.*
Grand Mal Convulsion	*loss of consciousness and violent muscle contractions.*
Hypotonia	*low muscle tone.*
Hypotonic-Hypo-responsive Episode	*sudden and unexpected loss of tone, unresponsiveness and color change.*
Meningitis	*inflammation of protective membranes covering the brain and spinal cord.*

Migraine	*sudden and severe, pounding headaches, upset stomach, and sometimes disturbed vision.*
Motor Neuron Disease	*neurological disorder that destroys motor neurons that control essential voluntary muscle activity such as speaking, walking, breathing, and swallowing.*
Myelitis	*inflammation of spinal cord that can involve nerve pain, paralysis and incontinence.*
Nerve Deafness	*hearing loss from damage to the nerve that runs from the ear to the brain.*
Neuralgia	*intense painful sensation along a nerve or group of nerves.*
Neuropathy	*nerve problem that causes pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.*
Ocular Palsies	*damage to the nerve of the eye that controls eye movement.*
Optic Neuritis	*inflammation causing eye pain and partial or complete vision loss.*
Paralysis	*inability to move part or all of the body.*
Radial Nerve and Recurrent Nerve Paralysis	*nerve injury to the radial nerve that can cause weakness or difficulty moving the wrist, hand or fingers.*
Radiculopathy	*compressed or pinched nerve.*
Retrobulbar Neuritis	*inflammation and damage to the optic nerve between the back of the eye and the brain.*
Seizures	*sudden, uncontrolled body movements and changes in behavior that occur because of abnormal electrical activity in the brain.*
Stroke	*blood flow blocked to the brain or bleeding in the brain, which can lead to brain damage, long-term disability, or death.*
Subacute Sclerosing Panencephalitis (SSPE)	*progressive neurological disorder affecting the central nervous system leading to mental deterioration, loss of motor function, and ultimately leading to a vegetative state followed by death.*
Syncope	*decrease in blood flow to the brain causing a loss of consciousness and muscle strength.*
Transverse Myelitis	*inflamed spinal cord which may result in paralysis.*

Other Disorders and Chronic Disorders

Aseptic Meningitis	*acute inflammation of the brain and spinal cord.*

Aplastic Anemia	*damage to the bone marrow that slows or shuts down the production of new blood cells.*
Cellulitis	*infection of the deep tissues of the skin and muscles that cause the skin to become warm and tender.*
Cyanosis	*bluish skin discoloration due to low oxygen saturation.*
Death	*permanent end of life.*
Deep Vein Thrombosis	*formation of a blood clot in a deep vein that can break off and block blood flow to organs.*
Diabetes Mellitus	*chronic condition affecting ability to use energy from food.*
Dysphonia	*impairment in the ability to speak.*
Epididymitis	*inflammation of the testicle tube, which can lead to abscess formation, testicular pain, painful urination, tissue death, and decreased functionality of gonads.*
Mental Disorders	*unusual thoughts, perceptions, emotions, behavior, and relationship with others.*
Myalgia	*muscle pain that can become chronic.*
Orchitis	*inflammation of one or more testicles that can cause infertility, testicular atrophy, and severe pain.*
Pancreatitis	*inflammation of the pancreas due to damage by digestive enzymes.*
Pneumonia	*infection in one or both lungs.*
Respiratory Infection	*infection of the respiratory tract.*
Retinitis	*inflammation of the retina which can permanently damage the retina, leading to blindness.*
Rhinitis	*irritation and inflammation of nasal mucous membranes impacting ability to breathe properly.*
Sudden Infant Death Syndrome	*sudden death of infant in good health.*
Tachycardia	*an abnormally rapid heart rate.*
Uveitis	*inflammation of the eye leading to vision loss.*
Vertigo	*problem with the vestibular portion of the inner ear causing dizziness.*

ICAN
Informed Consent Action Network

JAN 2 9 2019

December 31, 2018

U.S. Department of Health & Human Services
HHS Office of the Secretary
Alex M. Azar II, Secretary of Health & Human Services
Tammy R. Beckham, Acting Director, National Vaccine Program Office
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Azar and Acting Director Beckham:

In our letter of October 12, 2017, we notified HHS of a number of serious concerns regarding how the Department of Health & Human Services (**HHS**) fulfills its obligations to ensure vaccine safety under the National Childhood Vaccine Injury Act of 1986 (the **1986 Act**).[1] We voiced these concerns along with 55 other organizations who were copied on our letter and who represent over 5 million Americans.[2]

We thank HHS for the time and resources it dedicated to respond to our concerns in its letter of January 18, 2018, including having its response reviewed and cleared by the following agencies within HHS: the Centers for Disease Control and Prevention (**CDC**), Food & Drug Administration (**FDA**), National Institutes of Health (**NIH**), Office of the General Counsel (**OGC**), Human Resources & Services Administration (**HRSA**), and Agency for Healthcare Research and Quality (**AHRQ**).[3]

We write again because, after careful review, the substance of HHS's responses heightens the serious concerns we previously raised regarding the safety of HHS's childhood vaccine schedule.

As HHS is aware, the 1986 Act gave pharmaceutical companies immunity from liability for injuries caused by most of their vaccines and instead made vaccine safety the responsibility of HHS.[4] As the Secretary of HHS (the **Secretary**), you have the ultimate authority and responsibility to assure implementation of the vaccine safety obligations in

[1] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[2] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[3] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[4] 42 U.S.C. § 300aa-10; 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-22; Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

the 1986 Act.[5] The importance of assuring the safety of the 71 vaccine doses injected into children pre-and-postnatally pursuant to HHS's vaccine schedule cannot be overstated.[6]

Given the gravity of HHS's responsibility, it is deeply troubling that the majority of HHS's letter contains little more than broad unsupported conclusory assertions. Most of these conclusory assertions do not withstand basic scrutiny. HHS's responses even often contradict its own source materials.

HHS's letter begins with the incorrect claim that the safety of many pediatric vaccines was investigated in clinical trials that included a placebo, and falsely implies these trials are typically longer than mere days or weeks. (Section I below). It then fails to support the safety of injecting babies with the Hepatitis B vaccine (Section II) and reaffirms HHS's refusal to: automate VAERS reporting (Section III); research the most commonly claimed vaccine-injury pairs (Section IV); identify which children will suffer a serious vaccine injury (Section V); pause claiming "Vaccines Do Not Cause Autism" until it has the studies to support this claim (Section VI); conduct vaccinated versus unvaccinated studies (Section VII); purge itself of conflicts of interest (Section VIII); or use the Vaccine Safety Datalink and PRISM to actually improve vaccine safety (Section IX).

History is replete with products that caused harm for years or decades longer than necessary because of gridlock at HHS.[7] The gridlock at HHS over vaccines makes that history look trivial.

A large and growing proportion of Americans have concerns regarding vaccines.[8] In order to persuade this population, including the over five million Americans represented by the groups listed on our opening letter, HHS must either substantiate that its vaccine schedule and representations regarding vaccine safety are based on rigorous and robust science, or acknowledge areas of failure to fulfill its vaccine safety duties. Unsupported and incorrect assertions will not suffice and will only deepen concerns regarding vaccine safety.

Only by providing the science to support vaccine safety or acknowledging shortcomings in this science can HHS begin to restore Americans' confidence in its ability to objectively assess and improve vaccine safety. Since parents and children are the most important stakeholders when it comes to vaccine safety, in addition to distributing these letters to the organizations listed in our opening letter, we intend to widely distribute these letters to the news media and the public at large.

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[5] 42 U.S.C. § 300aa-27

[6] https://www.vaccines.gov/

[7] https://prescriptiondrugs.procon.org/view.resource.php?resourceID=005528

[8] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf ("an increasing number of parents have been expressing concerns about vaccine safety over the last two decades" and, in particular, "parents have been voicing concerns about the safety of the recommended immunization schedule as a whole"); https://www.hhs.gov/nvpo/featured-priorities/vaccine-confidence/index.html

I. INVALID PRE-LICENSURE SAFETY REVIEW OF PEDIATRIC VACCINES

In our opening letter, we asked that HHS identify the clinical trial data showing that the safety of pediatric vaccines was carefully studied *prior* to licensing and injecting them into millions of American children.[9] In response, HHS did not cite any such data. Instead, HHS merely made conclusory assertions regarding pediatric vaccine clinical trials that contradict HHS's published documents. We take each point in HHS's letter regarding vaccine clinical trials in turn below.

A. Placebo Controls Were Not Used in Pediatric Clinical Trials

Our opening letter expressed serious concern that the clinical trials relied upon to license pediatric vaccines did not include a control group receiving a placebo. Reflecting its importance, HHS's response letter addresses this concern in its first two sentences:

> I would like to address a comment made in Section II of your letter about pre-licensure safety review of pediatric vaccines. Contrary to statements made on page two of your letter, many pediatric vaccines have been investigated in clinical trials that included a placebo.[10]

Unfortunately, HHS's assertion that prior to licensure for children "many pediatric vaccines have been investigated in clinical trials that included a placebo" is untrue.

(i) HHS's False Claim Regarding Use of Placebos

As defined by the CDC, a "placebo" is: "A substance or treatment that has no effect on human beings."[11] As HHS is aware, common examples of a placebo are a saline injection or sugar pill.[12] The reason that drugs are first evaluated in a clinical trial against a placebo control group, prior to being released to the public, is to assess the drug's safety and effectiveness. As explained by HHS:

> In undertaking a clinical trial, researchers don't want to leave anything to chance. They want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The "gold standard" for testing interventions in people is the "randomized, placebo-controlled" clinical trial. ...

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[9] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[10] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[11] https://www.cdc.gov/vaccines/terms/glossary.html
[12] https://www.ncbi.nlm.nih.gov/pubmed/1330942 ("a placebo is a pharmacologically inactive substance")

> A placebo is an inactive substance that looks like the drug or treatment being tested.[13]

However, for each pediatric vaccine – except one – that HHS promotes for routine injection into children, **the clinical trials relied upon to assess its safety prior to licensing its use in children did *not* use a placebo-control group**.

The following three tables, compiled from HHS's own publications, list each pediatric vaccine that HHS's vaccine schedule provides be routinely injected into American children.[14] Each table addresses a different age range and answers whether the trials relied upon to license each vaccine for use in children included at least one clinical trial that assessed its safety against a placebo control group.

According to HHS's childhood vaccine schedule, babies receive three injections of each of the following vaccines between day one and 6 months of life:

HHS'S CHILDHOOD SCHEDULE: ONE DAY TO 6 MONTHS OF LIFE			
VACCINE TYPE	**TEST GROUP RECEIVED**	**CONTROL GROUP RECEIVED[15]**	**PLACEBO CONTROL?**
DTaP	**Infanrix** (GSK)[16]	DTP	NO
	Daptacel (Sanofi)[17]	DT or DTP	NO
Hib	**ActHIB** (Sanofi)[18]	Hepatitis B Vaccine	NO
	Hiberix (GSK)[19]	ActHIB	NO
	PedvaxHIB (Merck)[20]	Lyophilized PedvaxHIB[21]	NO
Hepatitis B	**Engerix-B** (GSK)[22]	No control group	NO
	Recombivax HB (Merck)[23]	No control group	NO
Pneumococcal	**Prevnar 13** (Pfizer)[24]	Prevnar[25]	NO
Polio	**Ipol** (Sanofi)[26]	No control group	NO

[13] https://www.nia.nih.gov/health/why-are-placebos-important

[14] Pursuant to 21 C.F.R. 201.57 and other relevant regulations, the package insert for each vaccine is required to describe its "clinical trial experience," including identifying the "drug and comparators (e.g., placebo)," as well as accurately describe the clinical trials for each vaccine in its summary basis of approval and clinical trial review, and this letter assumes these documents, available on the FDA website, comply with these regulations. https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

[15] Most vaccines had multiple trials; and where some trials used a control and others did not, only the control is listed.

[16] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf

[17] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf (lists DT vaccine in one of its efficacy trials as a "placebo")

[18] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf

[19] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf

[20] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf

[21] In Lyophilized PedvaxHIB's pre-licensure trials, the test group received Lyphilized PedvaxHIB, OPV and DTP, and the control group received a placebo, OPV and DTP. Ibid. Concomitantly injecting OPV and DTP negate the benefit of having a placebo as it prevents assessing the actual safety profile between Lyophilized PedvaxHIB and a placebo.

[22] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

[23] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf

[24] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM574852.pdf (While a placebo was used in trials for adults over 65 years old, no placebo was used in trials to license this vaccine for children.)

[25] "Prevnar" was also licensed without a placebo-controlled trial. http://labeling.pfizer.com/showlabeling.aspx?id=134

[26] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

HHS'S CHILDHOOD SCHEDULE: ONE DAY TO 6 MONTHS OF LIFE			
VACCINE TYPE	**TEST GROUP RECEIVED**	**CONTROL GROUP RECEIVED**[15]	**PLACEBO CONTROL?**
Combination Vaccines	**Pediarix** (GSK)[27]	ActHIB, Engerix-B, Infanrix, IPV, and OPV	NO
	Pentacel (Sanofi)[28]	HCPDT, PolioVAX, ActHIB, Daptacel, and IPOL	NO

As the above table and HHS's own documentation show, there is not a single vaccine brand routinely injected into American children between day one and 6 months of life that was licensed based on a clinical trial which included a placebo-control group.

According to HHS's childhood vaccine schedule, babies receive a fourth injection of most vaccines in the table above as well as one or two injections of each of the following additional vaccines between 6 months and 18 months of life:

HHS'S CHILDHOOD SCHEDULE: 6 TO 18 MONTHS OF LIFE			
VACCINE TYPE	**TEST GROUP RECEIVED**	**CONTROL GROUP RECEIVED**	**PLACEBO CONTROL?**
Hepatitis A	**Havrix** (GSK)[29]	Engerix-B	NO
	Vaqta (Merck)[30]	AAHS and Thimerosal	NO
MMR	**M-M-R II** (Merck)[31]	No control group	NO
Chicken Pox	**Varicella** (Merck)[32]	Stabilizer and 45mg of Neomycin	NO
Combo Vaccine	**ProQuad** (Merck)[33]	M-M-R II and Varivax	NO
Flu[34]	**Fluarix (IIV4)** (GSK)[35]	Prevnar13, Havrix and/or Varivax or unlicensed vaccine	NO
	FluLaval (IIV4) (ID Bio)[36]	Fluzone (IIV4), Fluarix (IIV3) or Havrix	NO
	Fluzone (IIV4) (Sanofi)[37]	Fluzone (IIV3)	NO

[27] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf

[28] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf (lists DT vaccine in one of its efficacy trials as a "placebo")

[29] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf

[30] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf ("Placebo (Alum Diluent)" contained 300μg AAHS and thimerosal, see https://www.nejm.org/doi/full/10.1056/NEJM199208133270702)

[31] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf (The package insert for M-M-R-II cites a number of pre-licensure trials, typically with small sample sizes and often using children from orphanages, psychiatric institutions, or schools for the handicapped. In total, it cites: one trial for the M-M-R-II comparing it with other vaccines (ref. # 16), one for the measles vaccine in which the test and control group both received the measles vaccine (ref. # 7), three trials for the mumps vaccine in which controls were injected with various experimental vaccines (ref. # 8, 9, 11) and fifteen trials for the rubella vaccine comparing different types of rubella vaccine except for one trial with 23 apparently untreated controls and one trial with 19 controls receiving a saline nasal spray where rubella vaccine was also given intranasally (ref. # 1, 2, 19-26, 28, 29, 31, 56, 57).)

[32] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf (While this insert states 465 children received a "placebo," Merck's peer reviewed publication explains the "placebo consisted of lyophilized stabilizer containing approximately 45 mg of neomycin." https://www.ncbi.nlm.nih.gov/pubmed/6325909. Neomycin is an antibiotic with serious side effects when swallowed, let alone injected: www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview)

[33] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123793.pdf (In one clinical trial, 799 children received ProQuad+Placebo, MMR II+Placebo, or MMR II+Varivax, but none received only a placebo; hence, this was not a placebo-controlled trial nor does it pretend to be in its Clinical Review: http://wayback.archive-it.org/7993/20170723150913/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123800.pdf)

[34] This and the next table include all flu shots the CDC lists for injection into children for the 2018-2019 flu season. https://www.cdc.gov/flu/protect/vaccine/vaccines.htm. One flu vaccine, FluMist (LAIV4), is given via nasal spray, not injection, and hence not discussed.

[35] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619534.pdf (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

[36] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf

[37] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf

As the above table and HHS's own documentation show, there is not a single vaccine brand routinely injected into American babies between 6 months and 18 months of life that was licensed based on a clinical trial which included a placebo-control group.

Finally, according to HHS's childhood vaccine schedule, children receive yet another injection of a majority of the vaccines in the above two tables as well as one to three injections of each of the following additional vaccines, along with an annual influenza vaccine, between 18 months and 18 years of life:

HHS'S CHILDHOOD SCHEDULE: 18 MONTHS TO 18 YEARS OF LIFE			
VACCINE TYPE	**TEST GROUP RECEIVED**	**CONTROL GROUP RECEIVED**	**PLACEBO CONTROL?**
Tdap	**Boostrix** (GSK)[38]	DECAVAC or Adacel	NO
	Adacel (Sanofi)[39]	Td (for adult use)	NO
HPV	**Gardasil** (Merck)[40]	AAHS *or* Gardasil carrier solution (Sodium Chloride, L-histidine, Polysorbate 80, Sodium Chloride, and Yeast Protein) (594 subjects)	NO
	Gardasil-9 (Merck)[41]	Gardasil *or* Placebo (306 subjects that recently received 3 doses of Gardasil)	YES[42]
Mening-ococcal	**Menactra** (Sanofi)[43]	Menomune	NO
	Menveo (GSK)[44]	Menomune, Boostrix, Menactra, or Mencevax	NO
Combination Vaccines	**Kinrix** (GSK)[45]	Infanrix and Ipol	NO
	Quadracel (Sanofi)[46]	Daptacel and Ipol	NO
Flu[47]	**Afluria (IIV3)** (Seqirus)[48]	Fluzone (IIV3)	NO
	Afluria (IIV4) (Seqirus)[49]	Fluarix (IIV4)	NO
	Flucelvax (IIV4) (Seqirus)[50]	Flucelvax (IIV3) or a (Seqirus) investigational vaccine	NO

[38] https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf

[39] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf

[40] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf (While this insert states 594 controls received a "saline placebo," Merck's peer reviewed publication explains the "placebo used in this study contained identical components to those in the vaccine, with the exception of HPV L1 VLPs and aluminum adjuvant," which means this "placebo" contained Sodium Chloride, L-histidine, Polysorbate 80, Sodium Chloride, and Yeast Protein. https://www.ncbi.nlm.nih.gov/pubmed/17484215)

[41] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM429166.pdf

[42] In only one clinical trial, 306 controls received a placebo, and Merck required the 618 subjects in this trial receiving Gardasil-9 to have recently received 3 doses of Gardasil and be in good health. https://clinicaltrials.gov/ct2/show/NCT01047345. Generalized safety conclusions therefore cannot be made from this small trial since it only included subjects with a proven record of receiving Gardasil without health complications. This trial does, however, prove that a saline placebo can be used in vaccine clinical trials.

[43] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf (In one clinical trial, 509 adolescents (between 11 and 18 years of age) received Td for Adult Use plus Menactra and 28 days later received a saline injection, and 512 adolescence received Td for Adult Use plus a saline injection and 28 days later received Menactra. Despite including a saline injection, this is not a placebo-controlled trial nor does it pretend to be in its Clinical Review: http://wayback.archive-it.org/7993/20170722073019/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm176044.htm)

[44] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf

[45] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf

[46] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf

[47] This and the prior table list all injectable flu shots for children for the current flu season: https://www.cdc.gov/flu/protect/vaccine/vaccines.htm

[48] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

[49] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM518295.pdf

[50] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619588.pdf (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

As the above three tables and HHS's own documentation establish, only one out of 30 vaccines brands routinely injected into American children was licensed based on a clinical trial which had a placebo-control group.[51]

The use of placebo control groups is essential to protect society from the harm that could result from widespread use of ineffective or unsafe medical treatments. The fact that HHS does not and apparently will not require pharmaceutical companies to use a placebo control in pediatric vaccine clinical trials evidences HHS's lack of confidence in the safety profile of these products. If HHS had confidence in their safety profiles, it would require that vaccine clinical trials – as is typical for drug clinical trials – include a placebo-control group. For example, drugs such as Botox,[52] Prozac,[53] and Lipitor,[54] typically given to adults rather than children, have placebo controls in their clinical trials. Like almost all drugs, pediatric vaccines should be licensed based on placebo-controlled clinical trials so that HHS can assess their safety profiles prior to approving them for injection into millions of children.

It is troubling that HHS chose to begin its response by misstating that prior to licensure for children "many pediatric vaccines have been investigated in clinical trials that included a placebo."[55] At worst, HHS knowingly perpetuated this inaccurate claim, but at best, HHS was unaware this claim was incorrect. This leaves the public to wonder what other critical assumptions underpinning HHS's confidence in vaccine safety are incorrect.

(ii) HHS Licenses New Vaccines Without Any Placebo-Controlled Trial Even When No Vaccine for the Same Disease Exists

After making the false claim that many vaccines on HHS's childhood schedule were licensed based on a placebo-controlled trial, HHS then states:

> Inert placebo controls are not required to understand the safety profile of a new vaccine, and are thus not required.

This claim is astonishing. For almost all new drugs, especially where no substantially similar product is already licensed, HHS's guidance expects a placebo control group to be part of the clinical trial so that the adverse event rate in the test group receiving the new drug can be assessed against the rate in the placebo group.

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[51] Both Rotavirus vaccines are given via oral drop and hence not discussed. Nonetheless, RotaTeq (Merck)'s "placebo" contained Polysorbate 80, Sucrose, Citrate and Phosphate, and Rotarix (GSK)'s "placebo" contained Sucrose, Dextran, Sorbitol, Amino acids, Dulbecco's Modified Eagle Medium, Calcium Carbonate, and Xanthan. https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133539.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf

[52] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5236lbl.pdf

[53] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/018936s091lbl.pdf

[54] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf

[55] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

HHS's industry guidance explains that using another drug as a so-called "active control" is only appropriate if it is for a similar indication and is a "drug whose effect is well-defined," which means "historical placebo-controlled trials are available to define the active control effect."[56] As the FDA explains:

> The placebo-controlled trial measures the total pharmacologically mediated effect of treatment. In contrast, an active control trial ... measures the effect relative to another treatment. The placebo-controlled trial also allows a distinction between adverse events due to the drug and those due to the underlying disease or background noise.[57]

Hence, the reason researchers do not use a non-inert substance as a control is because, due to its pharmacological effects, it makes it impossible to isolate the effects of just the experimental product being studied. Nevertheless, a placebo control was only used in only one tiny clinical trial for one of the 30 vaccine brands listed in the tables above.

The critical difference between using an inert and non-inert substance as a control can be clearly seen from the trials relied upon to license Gardasil in 2006. The manufacturer's package insert for Gardasil states that it was licensed based on a clinical trial in which: (i) 10,706 women received Gardasil; (ii) 9,092 women received 225 mcg or 450 mcg of Amorphous Aluminum Hydroxyphosphate Sulfate (**AAHS**) – the so-called "AAHS Control" (aluminum adjuvant, such as AAHS, is a known cytotoxic and neurotoxic substance used to induce autoimmunity in lab animals, and which numerous peer-reviewed publications implicate in various autoimmune conditions[58]); and (iii) 320 women received a "Saline Placebo."[59] During the six month study follow-up, 2.3% of the women receiving Gardasil (the "test group") and 2.3% of the women receiving the AAHS Control or Saline Placebo (the "combined control group") reported developing a systemic autoimmune disorder.[60] Since the rate of systemic autoimmune disorders in the "test group" and the "combined control group" were similar, the vaccine was deemed safe and licensed by HHS.

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[56] https://www.fda.gov/downloads/Drugs/Guidances/UCM202140.pdf

[57] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073139.pdf. Also see https://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm ("There are three principal difficulties in interpreting active-control trials. ... One problem is that there are numerous ways of conducting a study that can obscure differences between treatments, such as poor diagnostic criteria, poor methods of measurement, poor compliance, medication errors, or poor training of observers. As a general statement, carelessness of all kinds will tend to obscure differences between treatments. Where the objective of a study is to show a difference, investigators have powerful stimuli toward assuring study excellence. *Active-control studies, however, which are intended to show no significant difference between treatments, do not provide the same incentives toward study excellence, and it is difficult to detect or assess the kinds of poor study quality that can arise.* The other problem is that a finding of no difference between a test article and an effective treatment may not be meaningful.")

[58] https://www.wiley.com/en-us/Vaccines+and+Autoimmunity-p-9781118663431; https://www.ncbi.nlm.nih.gov/pubmed/25923134

[59] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf

[60] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf

What the manufacturer's package insert for Gardasil given to the public failed to disclose is that the Saline Placebo group had *zero* cases of systemic autoimmune disorder (when 7 cases – 2.3% of 320 subjects – would be expected if autoimmune disorders were equally distributed among the Saline Placebo and AAHS Control recipients).[61] This fact was obfuscated by combining the small Saline Placebo group with the large AAHS Control group into a single control group and reporting their combined systemic autoimmune disorder rate, even though all the cases of autoimmunity came from the AAHS Control group.[62] The following is an excerpt from Gardasil's package insert with the combined control group highlighted in yellow:

Table 9: Summary of Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9412)
	n (%)	n (%)
Arthralgia/Arthritis/Arthropathy†	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism	27 (0.3)	21 (0.2)
Hypothyroidism	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease	7 (0.1)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation Disorder	4 (0.0)	3 (0.0)
Psoriasis	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritis	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	1 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
All Conditions	245 (2.3)	218 (2.3)

*AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate

The fact that the Saline Placebo group had no cases of systemic autoimmune disorder is what would be expected.[63] It is not normal for 2.3% of previously healthy girls and women to develop a systemic autoimmune disorder within six months of the commencement of a clinical trial unless there was some environmental exposure that caused the harm, such as an injection of Gardasil or AAHS. This finding is nonetheless ignored because, to license this vaccine, HHS permitted AAHS to serve as the control.

It was also unethical to inject almost 10,000 girls and women with a known neurotoxin like AAHS, which has no therapeutic benefit.[64] The transparent purpose of this unethical study design was to create a "control group" that would yield a similar adverse event rate to the "test group" receiving Gardasil. In this manner the trial masked a serious

[61] https://www.clinicaltrials.gov/ct2/show/results/NCT00092547?term=nct+00092547&rank=1&sect=X430156&view=results
[62] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf
[63] https://www.clinicaltrials.gov/ct2/show/results/NCT00092547?term=nct+00092547&rank=1&sect=X430156&view=results
[64] https://www.wiley.com/en-us/Vaccines+and+Autoimmunity-p-9781118663431

safety issue with Gardasil that should have prevented its licensure.[65] Furthermore, there was no excuse for not requiring a placebo control (saline injection) in clinical trials for Gardasil because, at that time, no other vaccine was yet licensed for the four HPV strains Gardasil was intended to prevent.

As the Gardasil clinical trial shows, HHS does not require a placebo control group for clinical trials of even an entirely new vaccine for an infection for which no other vaccine exists. Another example is the Hepatitis A vaccine.

There are only two Hepatitis A vaccines on the market: Havrix (GSK), licensed in 1995, and Vaqta (Merck), licensed in 1996.[66] Because the clinical trials for both were conducted when there was no Hepatitis A vaccine on the market, these trials should certainly have used a placebo control to assess their safety. Yet, the safety profile for these products was never assessed using a placebo control. Instead, the trial for Havrix had no control group and the trial for Vaqta used AAHS and Thimerosal as a control.[67] The lack of a placebo control in the clinical trials relied upon to license Havrix was such a clear lapse in safety for an entirely new vaccine (for an infection that had no previously licensed vaccine) that its Clinical Review even made a point to disclaim: "There were no placebo controls."[68]

A third example is Varivax (Merck), the very first vaccine licensed for varicella (chicken pox). Varivax was also licensed without any placebo-controlled clinical trial. Recognizing the importance of a placebo control, the package insert for Varivax claims that its safety was reviewed against a "placebo" control.[69] Putting aside that only 465 children received the purported "placebo," Merck's peer reviewed article regarding this trial makes clear this "placebo" was not a placebo, but rather an injection of "lyophilized stabilizer containing approximately 45 mg of neomycin per milliliter."[70] Neomycin is an antibiotic which, in oral form, has a long list of serious adverse reactions, such as hearing loss, kidney problems and nerve problems.[71] An injection which includes neomycin is therefore plainly *not* a placebo. Using a control that can have serious adverse reactions when orally ingested, let alone injected, obfuscated Varivax's actual safety profile.[72]

It is unethical and unacceptable that a placebo control, such as a saline injection, was not used for entirely new vaccines, such as for Hepatitis A and Varicella. Even worse, as

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[65] This defective clinical trial design may have been influenced by the HHS agency and its employees that developed the patent used to develop Gardasil and receive royalties from its sale. https://www.ott.nih.gov/news/nih-technology-licensed-merck-hpv-vaccine

[66] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf

[67] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf (The "Placebo (Alum Diluent)" contained 300µg AAHS and thimerosal, https://www.nejm.org/doi/full/10.1056/NEJM199208133270702)

[68] http://wayback.archive-it.org/7993/20170723025039/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110035.pdf

[69] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf

[70] Ibid.; https://www.ncbi.nlm.nih.gov/pubmed/6325909

[71] www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview

[72] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf

the next section shows, these same vaccines are then used as an "active control" for licensing other vaccines despite having never been safety tested for licensure themselves in a placebo-controlled trial. The use of medications and vaccines in the practice of medicine is ethically justified if the benefits substantially outweigh the harms.[73] When studies to approve vaccines are conducted in which the harms are not accurately assessed because there is no placebo control group, then the use of those vaccines is not justified.[74]

(iii) HHS's "Safety" Pyramid Scheme

After licensing a vaccine without assessing its safety in a placebo-controlled clinical trial, HHS will then often license another vaccine as long as it has a similar adverse event rate to the licensed (but improperly safety tested) vaccine. This is a so-called "active control," which HHS references in its letter. But this form of comparison only provides reliable safety data if the previously licensed "active control" itself had its safety profile previously assessed in a properly designed placebo-controlled trial.

HHS's own industry guidance for drug testing explains that an active control is only appropriate if it is a "drug whose effect is well-defined," which means "historical placebo-controlled trials are available to define the active control effect."[75] Despite its own policy and guidance, HHS does not require this minimal assurance for vaccines. Instead, all vaccines on HHS's pediatric schedule were licensed based on a clinical trial with no control whatsoever, or another vaccine/substance used as a control which itself was never licensed based on a placebo-controlled trial. As noted in our opening letter:

> [Pediatric vaccines] either had no control group or a control group which received other vaccines as a "placebo." This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.[76]

Nonetheless, HHS claims in its letter that when an active control is used "the adverse event profile of that control group is usually known."[77] But this claim is incorrect for all "active

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[73] https://global.oup.com/ushe/product/principles-of-biomedical-ethics-9780199924585?cc=us&lang=en&
[74] https://www.ncbi.nlm.nih.gov/pubmed/4907496
[75] https://www.fda.gov/downloads/Drugs/Guidances/UCM202140.pdf
[76] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[77] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

controls" used to license any vaccine on HHS's childhood vaccine schedule because none of these "active controls" were licensed based on a placebo-controlled trial.

Prevnar 13 provides a good first example of how HHS's claim is incorrect. HHS recommends that every child receive this vaccine at 2, 4, 6, and 12 months of age.[78] HHS licensed this vaccine in 2010 without a clinical trial assessing its safety in children against a placebo control.[79] Instead, it permitted a previously licensed vaccine, Prevnar, to act as the control.[80] However, like Prevnar 13, HHS licensed Prevnar without a clinical trial assessing its safety against a placebo control.[81] Rather, HHS licensed Prevnar based on a clinical trial in which the control was "an investigational meningococcal group C conjugate vaccine [MnCC]."[82] MnCC, in turn, an unlicensed product, was also never licensed based on any placebo-controlled trial.[83]

The clinical trial for Prevnar 13 found that "Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients."[84] Despite this finding, Prevnar 13 was deemed safe and therefore licensed for use in babies because it had a similar serious adverse reaction rate as the control group receiving Prevnar.[85] But a comparison with Prevnar was an invalid measure of safety because Prevnar was safety tested prior to licensure against another experimental vaccine. As a group of FDA and CDC scientists conceded after Prevnar was licensed:

> Prior to licensure, … the control group in [Prevnar's] main study received another experimental vaccine, rather than a placebo. If both vaccines provoked similar adverse effects, little or no difference between the 2 groups might have been evident.[86]

Hence, the trial for Prevnar 13, in which both the Prevnar 13 and Prevnar groups have a 7% to 8% serious adverse event rate, could and should have caused serious concern regarding the safety of both vaccines. Instead, Prevnar 13 was deemed safe because it was as safe as Prevnar. But, as shown, Prevnar itself was only deemed safe because it was tested against an unlicensed experimental vaccine.

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[78] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
[79] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf
[80] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf; http://labeling.pfizer.com/showlabeling.aspx?id=134
[81] http://labeling.pfizer.com/showlabeling.aspx?id=134
[82] http://labeling.pfizer.com/showlabeling.aspx?id=134
[83] See tables above.
[84] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf
[85] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf
[86] https://www.ncbi.nlm.nih.gov/pubmed/15479935

A second example is Heplisav-B, the most recent vaccine approved by HHS.[87] The trials for this new Hepatitis B vaccine, which contains a novel adjuvant, did not use a placebo control.[88] Instead, the control was Engerix-B.[89] The serious adverse event rate in the primary clinical trial for Heplisav-B was 6.2%, which the researchers deemed similar to the serious adverse event rate of 5.3% for Engerix-B.[90] Heplisav-B was therefore deemed safe only because it was as safe as Engerix-B, but Engerix-B was licensed based on a clinical trial without any control, let alone a placebo control.[91] As such, the serious adverse reaction rate for Engerix-B and Heplisav-B should have caused serious concern regarding the safety of both vaccines, not confidence that Heplisav-B is safe.

A third example are influenza vaccines (flu shots). In 1980, HHS licensed Fluzone (IIV3) without assessing its safety against a placebo control.[92] Nonetheless, Fluzone (IIV3) was used as the control in the trials relied upon to license Afluria (IIV3) in 2007 and Fluzone (IIV4) in 2013 for children.[93] Shortly thereafter, Fluzone (IIV4), Fluarix (IIV3) or Havrix were then used as the controls in the clinical trials supporting the licensure of FluLaval (IIV4).[94] This entire pyramid scheme rests on the safety of Fluzone (IIV3) which was licensed for pediatric use based on a trial without any control, let alone a placebo control.[95]

Similarly, Fluarix (IIV4) was licensed for children in 2012 based on a trial using Prevnar 13, Havrix and/or Varivax as controls; Fluarix (IIV4) was then used as the control to license Afluria (IIV4) in 2016.[96] This means Afluria (IIV4) was licensed because it was deemed as safe as Fluarix (IIV4), and that vaccine was licensed because it was deemed as safe as Prevnar 13, Havrix, or Varivax. However, the latter two were licensed without a placebo control; and Prevnar 13 was licensed because it was as safe as Prevnar, but that vaccine was only licensed because it was as safe as "an investigational meningococcal group C conjugate vaccine." Hence, at bottom, none of those vaccines had its safety profile established based on any placebo-controlled clinical trial. On this basis alone the ethics of recommending routine injection of these vaccines into children is questionable.

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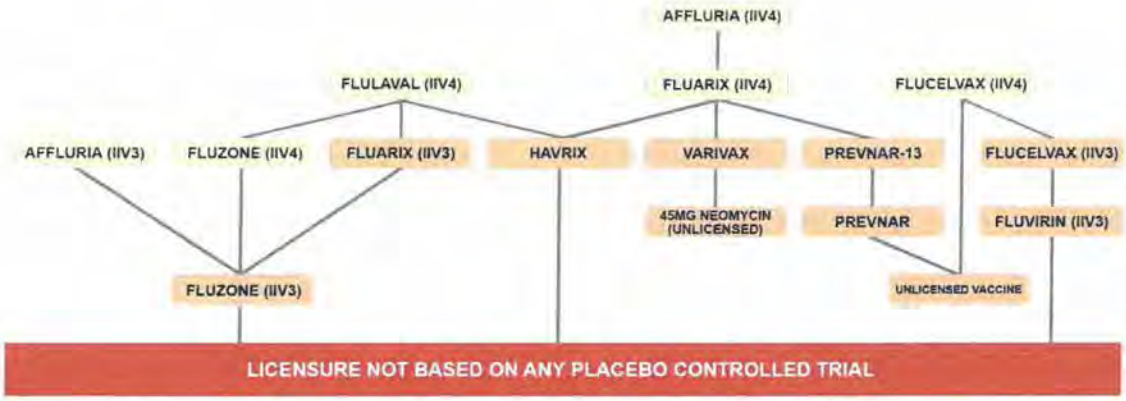
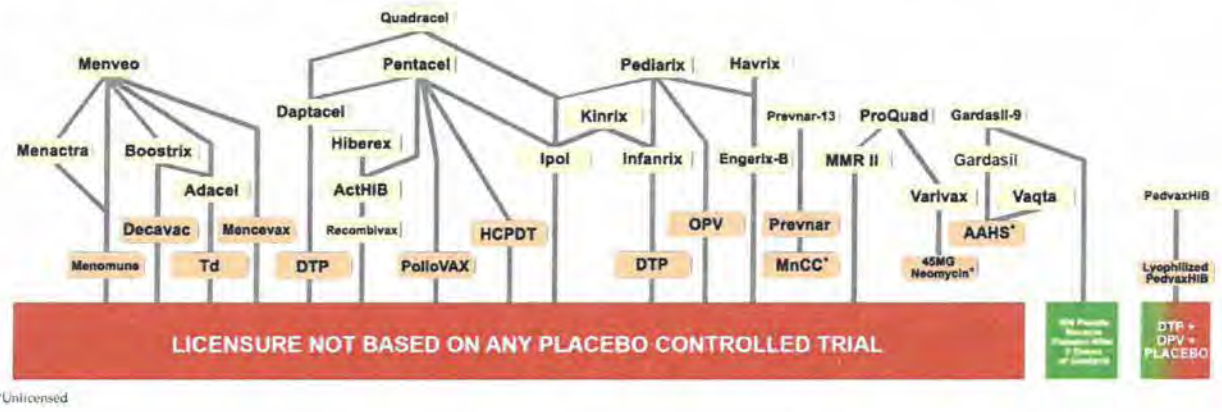
[87] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[88] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[89] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[90] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[91] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[92] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf (Researchers did conduct one efficacy trial for Fluzone (IIV3) long *after* it was licensed which found that "the rate of hospitalization was actually higher in the vaccine group than in the placebo group" with 60% more vaccinated than unvaccinated children being hospitalized for insertion of ear draining tubes. https://www.ncbi.nlm.nih.gov/pubmed/14506120)
[93] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf (placebo control only used in adult trials but never in trials to license this vaccine for children); https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf
[94] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf
[95] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf
[96] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf (44% and 45% of the Fluarix (IIV4) and comparator vaccine group, respectively, reported an unsolicited adverse event within 28 days and 3.6% and 3.3%, respectively, reported a serious adverse reaction)

The following diagram highlights in yellow each flu shot recommended for injection into children during the 2018-2019 flu season; and each descending line shows the control(s) used to license the vaccine above[97]:



As the above diagram makes clear, HHS did not rely on a single placebo-controlled trial to license any flu shot HHS recommends for injection into every child over 6 months of age during the upcoming flu season.

The above examples demonstrate how HHS licenses vaccines by relying on a pyramid of other vaccines that were each licensed without being properly safety tested in a placebo-controlled trial. The diagram below highlights in yellow each vaccine HHS's childhood vaccine schedule lists for routine use (except for influenza vaccines already depicted in the diagram above), and each descending line shows the control(s) used to license the vaccine above:



As is clear, at the bottom of this pyramid there is not a single placebo-controlled trial relied upon to license any vaccine in this pyramid scheme (with the exception of Gardasil-9 in which 306 individuals received a saline injection after three shots of Gardasil).

[97] https://www.cdc.gov/flu/protect/vaccine/vaccines.htm

It is deeply troubling that HHS permits pharmaceutical companies to use "active controls" in clinical trials for new vaccines when none of the "control vaccines" were themselves licensed based on a placebo-controlled trial. This creates layers of assumptions regarding safety that resemble a pyramid scheme. Tracing back the pre-licensure clinical trial for each vaccine used as an active control, one finds that the initial vaccine in the "safety chain" was either licensed without any control group or assessed against another vaccine, including vaccines, such as DTP, which were withdrawn from use due to safety concerns.

(iv) HHS Summarily Dismisses Claims of Vaccine Harm

The lack of a placebo in clinical trials is even more troubling because, when parents assert that a vaccine injured their child, HHS regularly denies these assertions by stating that no cause and effect has been established between vaccination and the alleged injury. But as HHS is well aware, *without* a placebo control trial, cause and effect is very difficult and often impossible to establish.[98] Therefore, no matter how many or what type of vaccine injuries are reported, HHS and manufacturers can and do hide behind the claim that "a cause and effect relationship with the vaccine has not been established."[99]

This avoidance of proper research is reflected in the package insert for each pediatric vaccine. As required by federal law, each package insert lists the serious adverse events reported by doctors and consumers *after* licensure of the vaccine.[100] Federal law is also clear that this list should include "*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event."[101] Appendix B to this letter provides a partial (yet long) list of reported post-licensure reactions listed on pediatric vaccine package inserts, including numerous neurological, brain and immune system disorders.

Instead of these serious adverse event reports resulting in a call to action by HHS to finally conduct long-term studies that could reasonably establish if these adverse events are causally related to vaccination, the response has been the opposite. HHS continues with growing intransigence to hide behind the claim that no causation has been proven. HHS even requires that every vaccine package insert include the following disclaimer before the list of vaccine-related adverse events reported by doctors and consumers post-licensure:

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[98] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html ("establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible," rather, researchers need "to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons"); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505292/ (The entire advantage of a randomized placebo-controlled trial "is the ability to demonstrate causality i.e., cause-effect relationship."); https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html (The Vaccine Adverse Events Reporting System (VAERS) is unable "to determine causation" because "there is a lack of an unvaccinated group for comparison in VAERS.")

[99] Ibid.

[100] 21 C.F.R. 201.57

[101] 21 C.F.R. 201.57

> In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for [vaccine brand] since market introduction of this vaccine are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of [vaccine brand] or other vaccines or drugs. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.[102]

But without carrying out placebo controlled clinical trials, which can determine causation statistically, (and by ignoring existing experimental studies in animal models aimed at establishing the underlying biological mechanisms of potential vaccine injuries,) HHS can, and apparently will, continue to hide behind this disclaimer indefinitely.

As reflected in Appendix B, there is a consistent theme of autoimmunity and neurological disorders running across the serious post-licensure adverse events reported in vaccine package inserts. Yet, HHS refuses to require placebo-controlled clinical trials to determine if any of these events are actually caused by vaccination. HHS claims doing so would be unethical for clinical trials evaluating the safety of an experimental vaccine when there is already a vaccine licensed for the same disease because it would leave a child that could be vaccinated for that disease unvaccinated. This ethical concern however rings hollow, because if ethics were a real concern, HHS would require placebo-controlled trials before licensing each new experimental vaccine where no vaccine yet exists for the infection it is intended to prevent. For example, before licensing the first Hepatitis A or Varicella vaccines as discussed above.

Conducting a placebo-controlled clinical trial will leave a clearly defined group of children unvaccinated only during the duration of the trial in a controlled setting where they can be monitored.[103] In contrast, injecting a vaccine into millions of children in an uncontrolled setting without first having any placebo-controlled trial safety data is, to any objective reasonable observer, grossly unethical conduct.[104] In a comparable situation where the baseline of safety for the "active control" had not been established, researchers from the University of Oxford explained:

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[102] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm075057.pdf

[103] There are already hundreds of thousands of children that are completely unvaccinated in this country. https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm For example, there are many parents that will not vaccinate due to religious beliefs.

[104] https://history.nih.gov/research/downloads/nuremberg.pdf ("voluntary consent ... means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision")

> In some trials placebos were omitted on ethical grounds. This is illogical because studies destined to produce unreliable results should themselves be considered unethical.[105]

As a result, the only "ethical" thing to do at this point is for HHS to comprehensively and impartially fund truly neutral third-parties to conduct placebo-controlled trials for each vaccine and the entire HHS childhood vaccine schedule.

By refusing to conduct any placebo-controlled studies – even for new vaccines for diseases for which no vaccine exists yet – HHS provides itself a convenient way to consistently discount even widespread reported claims of vaccine injury by simply claiming causation has not been proven, knowing full well causation will likely never be proven – one way or another – without a placebo-controlled trial.[106]

The near universal failure to employ a placebo control group in pediatric vaccine clinical trials is scientifically and morally indefensible. The importance of a placebo control group is no doubt why HHS felt compelled to address that point first in its lengthy response letter. And now that HHS knows it was incorrect to claim that prior to licensure "many pediatric vaccines have been investigated in clinical trials that included a placebo," we expect that HHS will address this serious shortcoming by actually conducting appropriate placebo-controlled trials.

B. Duration of Safety Review

In our letter we also questioned the length of time vaccine trials gather and assess adverse reactions, noting as examples that the two Hepatitis B vaccines injected into infants assessed adverse reactions for only four[107] and five[108] days, respectively, and that the only stand-alone polio vaccine reviewed safety for a mere 48 hours.[109] In response, HHS's letter seeks to create the false impression that the safety review period for pediatric vaccine clinical trials occurs over an extended period of time, stating:

> In addition, there appears to be a misunderstanding regarding the term "solicited" adverse events. Typically, in vaccine trials,

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[105] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1113953/

[106] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html ("establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible," rather, researchers need "to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons"); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505292/ (The entire advantage of a randomized placebo-controlled trial "is the ability to demonstrate causality i.e., cause-effect relationship."); https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html (The Vaccine Adverse Events Reporting System (VAERS) is unable "to determine causation" because "there is a lack of an unvaccinated group for comparison in VAERS.")

[107] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

[108] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf

[109] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

> the incidence of certain specific clinical findings that might be expected after vaccination is monitored for a short period of time after vaccination. Because these events are pre-specified, they are considered to be "solicited" events. In addition, other unexpected or severe adverse events, which may occur over a longer period of time following vaccination, are also analyzed and evaluated by FDA, but because these events are not predicted prior to initiation of the study, these are not called "solicited" adverse events.[110]

There was no misunderstanding regarding "solicited" versus "unsolicited" adverse events in our initial letter. The duration that solicited *or* unsolicited adverse events are tracked in pediatric vaccine clinical trials is typically far too short to detect adverse effects beyond a few days or weeks of vaccination. This is no doubt why HHS vaguely refers to "short period" versus "longer period" without actually specifying the duration of the so-called "longer period." As HHS knows, the "longer period" is still often only days or weeks, or at most a few months, instead of the several years needed to assess the actual safety profile after injecting a baby.

Whether reviewing solicited or unsolicited events, vaccine clinical trials are almost always far too short to capture developmental delays, autoimmune issues, and other chronic conditions that are likely to be diagnosed only years after vaccination.

(i) Safety Review Periods in Clinical Trials for Pediatric Vaccines are Too Short to Detect Most Chronic Health Conditions

HHS's own publications leave no doubt as to the incredibly short safety review period for almost all vaccines on HHS's childhood vaccine schedule.

On the *first day of life*, HHS's schedule instructs that all newborns receive a Hepatitis B vaccine.[111] The two Hepatitis B vaccines licensed in the United States for newborns are Recombivax HB (Merck) and Engerix-B (GSK).[112] Both were licensed based on clinical trials which reviewed so-called solicited and unsolicited reactions for no longer than *five days after vaccination*.[113] As required by HHS's own regulations[114], the clinical trial experience upon

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[110] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[111] HHS purposely shifted the burden of this vaccine from those at risk, such as intravenous drug users, to all newborns. https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm

[112] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/us-vaccines.pdf

[113] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

[114] 21 CFR 201.57(c)(7)

which the licensure of each vaccine is based must be summarized in its package insert, and the inserts for these two vaccines explain as follows:

> "In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) *who were monitored for 5 days after each dose.*"[115]
>
> "In 36 clinical studies, a total of 13,495 doses of ENGERIX-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. *All subjects were monitored for 4 days post-administration.*"[116]

Putting aside that the number of babies in these trials is unclear, five days is not long enough to assess the safety profile of these products. Moreover, without a placebo control, these trials do not even provide an actual safety profile for the five days in which safety was purportedly reviewed.

At *two months of life*, HHS's schedule instructs that babies be injected with the Hepatitis B, Hib, DTaP, IPV, and PCV 13 vaccines.[117] The safety review period of so-called solicited and unsolicited adverse reactions in the trials relied upon to license these vaccines were also too short to capture any resulting chronic health conditions. This is confirmed by HHS's own documentation for each:

Target Disease	Product Name (Manufacturer)	Duration of Safety Review After Injection	
		Solicited Reactions	Unsolicited Reactions
Hepatitis B	Recombivax HB (Merck)[118]	5 days	5 days
	Engerix-B (GSK)[119]	4 days	4 days
Hib	ActHIB (Sanofi)[120]	3 days	30 days
	PedvaxHIB (Merck)[121]	3 days	3 days
	Hiberix (GSK)[122]	4 days	31 days
DTaP	Infanrix (GSK)[123]	8 days	28 days
	Daptacel (Sanofi)[124]	14 days	6 months
Poliovirus	Ipol (Sanofi)[125]	3 days	3 days

[115] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf (emphasis added)
[116] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf (emphasis added)
[117] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[118] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm110114.pdf
[119] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf
[120] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf
[121] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm253652.pdf
[122] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm179530.pdf
[123] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf
[124] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf
[125] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf

Pneumococcal	Prevnar 13 (Wyeth)[126]	7 days	6 months
Combination Vaccines	Pediarix (GSK)[127]	8 days	30 days + phone call at 6 months
	Pentacel (Sanofi)[128]	7 days	60 days + phone call at 6 months

Again, without a placebo controlled clinical trial, which none of the above had, the actual safety profile of each vaccine cannot be assessed even for the limited duration that its safety was reviewed. Moreover, even assuming placebo controls were used, tracking safety for (at most) a mere 6 months after injecting a 2-month old baby will not reveal if the vaccine caused autoimmune, neurological or developmental disorders that are likely to only be apparent or diagnosed after the child is a few years of age.

At *four months of life*, HHS's vaccine schedule instructs that babies again be injected with the Hib, DTaP, IPV, and PCV 13 vaccines.[129] The above table shows the issues with these vaccines' testing durations.

At *six months of life*, HHS's vaccine schedule instructs that babies again be injected with the Hepatitis B, Hib, DTaP, IPV, and PCV 13 vaccines.[130] In addition, HHS's schedule also lists the influenza vaccine already discussed above.[131]

As early as *twelve months of life*, HHS's vaccine schedule provides that babies again be injected with Hib and PCV13 vaccines, as well as receive the MMR, Varicella and Hepatitis A vaccines.[132] As for MMR, its package insert does not describe, as would be required by federal law, a single clinical trial of the MMR vaccine upon which its licensure is based.[133]

As for Varicella, its clinical trial, which used an injection of 45 mg of neomycin as a control (as discussed above), only assessed safety for a period of weeks.[134] As for the two Hepatitis A vaccines, solicited reactions for both were gathered for approximately two weeks and unsolicited reactions for approximately a month and Havrix conducted a six month non-obligatory follow-up telephone call.[135] Even this limited vaccine safety monitoring reveals nothing about the actual safety profile of these products since there was

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[126] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm201669.pdf
[127] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf
[128] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf
[129] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[130] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[131] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[132] https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf
[133] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf. See footnote 31.
[134] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf (Greater than 1 percent of children had one or more of these reactions: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, contact rash, headache, malaise, abdominal pain, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions, stiff neck, heat rash/prickly heat, arthralgia, dermatitis, constipation, itching.)
[135] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf
https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf

no placebo control used in their clinical trials. And even if a placebo was used, a single six month follow-up phone call will not reveal the developmental, neurological or autoimmune issues that will only become apparent after a baby is at least a few years old.

In sharp contrast to the short safety testing periods for vaccines, most drugs have pre-licensure safety review periods which last years. For example, the drugs Enbrel[136], Lipitor[137], and Botox[138] had safety review periods of 6.6 years, 4.8 years and 51 weeks, respectively, and each had an actual placebo control group. And these drugs are typically for adults, not infants and children.

Moreover, even though safety review periods for vaccines typically lasted only days or weeks, the efficacy review period for vaccines often lasted years.[139] The "efficacy review" typically tracks antibody levels to assess how well the new vaccine will likely prevent the target infection. This review often lasts years because the biological changes in the body a vaccine seeks to achieve, typically production of vaccine strain antibodies, often require multiple injections over a period of months or years followed by monitoring efficacy for at least a few years.[140] Vaccine safety should be tracked at least as long as vaccine efficacy because it can take years for chronic conditions causally linked to or suspected to be caused by vaccines to become apparent. As HHS has explained: "because the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events."[141]

Indeed, scientific findings, including by HHS, clearly refute the assumption that any adverse outcome of vaccination, especially when vaccinating babies during the first six months of life, will be apparent fairly immediately.[142] Yet this assumption underlies the design for assessing safety in the clinical trials relied upon to license pediatric vaccines. At the very least, since efficacy is already being tracked for years, safety should also be tracked for the same duration.

It is common sense that if HHS licenses vaccines without safety data extending beyond a few days, weeks or months, it is scientifically impossible to ascertain if babies will develop immunological, developmental or neurological disorders beyond these short safety review periods. There is no justifiable reason why HHS refuses to examine whether giving 29 vaccine doses by one year of age can lead to health issues at 5 years of age. As the Institute

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[136] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf
[137] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf
[138] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
[139] https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm
[140] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html; https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
For example, pursuant to HHS's vaccine schedules, every person is to receive a diphtheria containing vaccine at the following ages: 2-months, 4-months, 6-months, 15-months, 4-years, 11-years, and then every ten years until death.
[141] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf
[142] Ibid.; https://www.ncbi.nlm.nih.gov/pubmed/22235051

of Medicine admitted: science still does not know "if there is a relationship between [the numerous known] short-term adverse events following vaccination and long-term health issues."[143]

(ii) HHS's "Solicited" v. "Unsolicited" Scheme Further Conceals Actual Safety Profile

Moreover, unlike almost all drugs, HHS permits pharmaceutical companies to use preset lists of adverse reactions they ask their researchers to monitor and evaluate in vaccine clinical trials – so called "solicited" adverse reactions.[144] Asking about certain "solicited" adverse reactions undoubtedly creates a bias in favor of parents reporting those adverse reactions, rather than reporting "unsolicited," but more serious, adverse reactions. The reason for this approach appears to be that HHS and pharmaceutical companies are trying to institutionalize a few adverse events, such as injection site soreness, as the only adverse events that are caused by vaccination. This "don't ask, and hope they don't tell" policy is troubling.

Having a pre-set list of adverse reactions that are "solicited" by researchers institutionalizes and legitimizes HHS and the pharmaceutical industry's customary practice of accepting a very small number of minor reactions as being "caused" by vaccines. This allows the "unsolicited" reports made by subjects and their parents, many of which would likely fall outside the short review period, to be easily relegated to a broad wastebasket category, such as "new medical condition." This practice leaves the pharmaceutical industry entirely free and indeed highly likely to reject these "unsolicited" reactions as unrelated to vaccination or consider them idiosyncratic medical events based on a preexisting genetic predisposition or other latent tendency, and therefore "coincidental" and unrelated to the vaccine.

The problems created by the solicited vs. unsolicited categories are not merely abstract concerns. To the contrary, the trials conducted for the HPV vaccine, Gardasil, provide a ready example of how this dual category structure biases researchers against finding that unsolicited adverse reactions are caused by the vaccine. When Gardasil was tested for safety in clinical trials in Denmark, many participants repeatedly advised clinicians conducting the trials that after vaccination they could no longer engage in various basic life functions due to numerous brain and immune dysfunction symptoms.[145] These "unsolicited" Gardasil vaccine reactions, however, were discarded by the clinical trial researchers, who were paid by the pharmaceutical company seeking a license for Gardasil.[146]

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[143] https://www.nap.edu/read/13563/chapter/5#45

[144] https://www.ncbi.nlm.nih.gov/pubmed/16231957 ("Spontaneous (unsolicited) collection of adverse event data is used in most pharmaceutical trials.")

[145] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html

[146] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html

The researchers could discard this data because, despite being an entirely new vaccine for a new disease, no placebo control was used.[147] As a result, the pharmaceutical company paid researchers used their "judgment," not the scientific method, to decide if any complications were related to the vaccine.[148]

Even more troubling, these researchers actually told women reporting serious life altering reactions that, "This is not the kind of side effects we see with this vaccine" – an inexplicable and unscientific response for researchers conducting clinical trials of a new vaccine.[149] The only reason this fact came to light was because of a thorough eight-month long investigation by Slate (a strongly pro-vaccine news outlet) which sought out and found the clinical trial patients and matched them with their clinical trial records.[150]

(iii) HHS Gives False Impression it Determines Whether Each Reported Adverse Reaction is Related to the Vaccine on Trial

As this incident with Gardasil shows, even if pediatric vaccine clinical trials did gather sufficient medical data to assess safety, the determination of whether an adverse event reported during the clinical trial is associated with the vaccine under review is left to the pharmaceutical company paid researchers conducting the clinical trial.[151] Nevertheless, HHS's letter seeks to mislead the reader by stating:

> Serious adverse events are always evaluated by FDA to determine potential association with vaccination regardless of their rate of incidence in the control group.[152]

However, because pharmaceutical companies and their paid researchers determine if each reported adverse event in a trial is related to the vaccine, HHS's assertion that "[s]erious adverse events are always evaluated by the FDA to determine potential association with vaccination" is disingenuous.

Ironically, if placebo control groups were used, then there would be no need for a case-by-case determination regarding whether each reported "unsolicited" adverse reaction is related to the vaccine under review. It is only because of the scientifically and morally

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[147] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html
[148] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html
[149] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html
[150] https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html
[151] For example, in the clinical trial for ActHIB there was no control group and 3.4% of the babies receiving this vaccine had a serious adverse event within 30 days of vaccination; HHS nonetheless licensed this vaccine because the trial investigators working for ActHIB's manufacturer decided none of them were related to the vaccine. https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109841.pdf ("within 30 days ... (3.4%) participants [babies] experienced a serious adverse event" but "[n]one was assessed by the investigators as related to the study of vaccines")
[152] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

defunct refusal to require placebo-controlled trials that there is a need to rely on the "judgment" of pharmaceutical company paid researchers to decide if the "unsolicited" adverse event is related to the vaccine.[153]

This adds a very dangerous bias into what is already unreliable (no placebo control) and limited (duration too short) safety data from vaccine clinical trials. Pharmaceutical companies have a powerful financial incentive to minimize any safety concerns to ensure licensure since they have almost no liability for vaccine injuries but yet stand to typically earn billions of dollars from each newly licensed pediatric vaccine. As explained by Dr. Marcia Angell[154], currently a professor in the Center for Bioethics, Harvard School of Medicine, and member of the Institute of Medicine, and former editor-in-chief of the New England Journal of Medicine:

> Clinical trials are also biased through designs for research that are chosen to yield favorable results for sponsors. ... In short, it is often possible to make clinical trials come out pretty much any way you want, which is why it's so important that investigators be truly disinterested in the outcome of their work. ...
>
> It is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*. ...[155]

Dr. Angell also points out that, "Most of the big drug companies have settled charges of fraud," including GSK and Merck, explaining that the legal "costs, while enormous in some cases, are still dwarfed by the profits generated by these illegal activities, and are therefore not much of a deterrent."[156]

C. Conclusion to HHS's Claims Regarding Vaccine Clinical Trials

Best scientific research practices should not be bent or broken to allow HHS to approve pediatric vaccines. With all drugs, the pharmaceutical industry remains accountable for safety and liable in civil court for injuries caused by the drugs they put on the market. Hence, during pre-licensure clinical trials testing experimental drugs,

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[153] The false and misleading claims regarding clinical trials undercut any basis for relying on the following conclusory assertion in HHS's letter: "*Please be assured that vaccine safety is carefully examined regardless of whether there is a placebo included in the clinicals trials.*"

[154] http://bioethics.hms.harvard.edu/person/faculty-members/marcia-angell

[155] https://www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/

[156] https://www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/

pharmaceutical companies at least have a financial incentive to their shareholders to ascertain each drug's safety profile – to determine if its liability exposure exceeds its likely revenue stream – otherwise after licensure they could face losses that exceed the drug's expected sales. This is likely why pharmaceutical companies conduct long-term placebo-controlled trials before seeking licensure for even short-acting, minor or cosmetic prescription or over-the-counter drugs.[157]

In contrast, pharmaceutical companies do not have liability for injuries caused by most of their vaccine products. Therefore, in line with their fiduciary duty to their shareholders, they have a financial incentive to get a new vaccine licensed by HHS as fast as possible with as little review of the vaccine's safety profile as possible. Newly licensed or even longstanding vaccines recommended by HHS for routine use by all children, such as Gardasil, Prevnar 13, or MMR, generate billions of dollars in revenue annually.[158] If it turns out that the vaccine causes serious harm, and a parent can prove it in Vaccine Court (over the defense mounted by the DOJ representing HHS), the claim is paid by the Federal Government using funds obtained from an excise tax collected from vaccine consumers – not paid by pharmaceutical companies.[159] Thus, pharmaceutical companies have a financial disincentive to identify safety issues that would prevent licensure and literally no incentive to identify safety issues after licensure.

This is precisely why the 1986 Act, simultaneous with granting vaccine makers financial immunity, made HHS responsible for vaccine safety.[160] Yet, HHS has abandoned this duty by not requiring long-term placebo-controlled clinical trials. Without such trials, the actual safety profile of each pediatric vaccine, or any combination thereof, cannot be determined before they are – pursuant to HHS's childhood vaccine schedule – injected into millions of American children. Once that happens, HHS becomes utterly conflicted from funding or conducting research that may find that a vaccine HHS previously licensed and recommended does, in fact, cause significant harm to more than a few children.

Indeed, admitting after licensure that a vaccine causes a certain serious harm would eliminate HHS's ability to defend itself against claims alleging such harm in Vaccine Court, which could amount to billions or even trillions of dollars in financial liability. It would also tarnish HHS's reputation and reduce the public's trust in HHS because, unlike drugs, HHS spends billions of dollars annually purchasing, distributing and vigorously promoting childhood vaccines.[161] This creates a serious conflict of interest within HHS that prevents it

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[157] For example, the weight loss drug, Belviq (only indicated for adult use), was safety tested in a placebo-controlled trial for two years before being licensed. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf

[158] https://investors.pfizer.com/financials/annual-reports/default.aspx; https://investors.merck.com/financials/sec-filings/default.aspx; https://www.gsk.com/media/4751/annual-report.pdf; https://www.sanofi.com/en/investors/reports-and-publications/

[159] 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-15

[160] 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-27

[161] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es

from rationally evaluating post-licensure reports of adverse events. It is therefore critical for HHS to have a clear and robust picture of the actual safety profile of each vaccine and the vaccination schedule *before* it is recommended and promoted by HHS to the public.

For example, Engerix B, manufactured by GSK, was originally licensed for children in the late 1980s based on an uncontrolled trial that only reviewed safety for five days (as discussed above).[162] Engerix B had to be reapproved by HHS almost twenty years later after the preservative used in the vaccine was changed.[163] The vaccine otherwise remained identical to what had been approved twenty years prior.[164] In the reapproval clinical trial report submitted by GSK to HHS in 2005, more than half of the babies reported an adverse event within 3 days of receiving this vaccine and 55 of the 587 babies in the study reported a serious adverse event.[165] That means 9.4% of the babies experienced a serious adverse event. Absent a placebo control group, however, it was left to GSK's paid researchers to decide whether these adverse events were caused by the vaccine.[166] Unsurprisingly, the GSK researchers declared the adverse events were not caused by its vaccine, and the vaccine was reapproved.[167] If HHS had overruled that finding, it could serve as an admission it previously licensed, recommended and widely promoted a vaccine that caused numerous serious adverse events in American babies, thereby creating buckling financial liability as well as serious reputational damage to HHS. This conflict makes it unlikely HHS will ever admit after licensure, due to at least willful blindness, that a vaccine causes any serious widespread harm.

This structural conflict at HHS is dangerous. There should be no compromise when it comes to the health of children, especially babies and newborns. The American public deserves nothing short of long-term placebo-controlled trials to know the true adverse event rate, without any bias.[168]

The bottom line is that when vaccines are licensed and recommended to be injected into every American child, apart from certain reactions, such as a sore arm, occurring within days of the vaccination, HHS does not know the safety profile of these products. As even HHS's own paid experts, the IOM, explain: "Because [vaccine] trials are primarily … for determination of efficacy, conclusions about vaccine safety derived from these trials are

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[162] https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf

[163] https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf

[164] https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf

[165] Ibid.

[166] Ibid.

[167] Ibid.

[168] This is in fact what the *Nuremberg Code* demands. https://history.nih.gov/research/downloads/nuremberg.pdf ("The voluntary consent of the human subject is absolutely essential. This means that the person … should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.")

limited."[169] HHS apparently proceeds nonetheless to license, recommend and promote these products based on its *a priori* assumption of and belief in their safety. This should be concerning because if HHS's "belief" is incorrect, it could have negative consequences for the health of current and future generations of American children.

Please respond to all points above and answer the questions in Appendix A.

II. SAFETY OF INJECTING BABIES WITH HEPATITIS B VACCINE

In our opening letter, we asked that HHS "Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life."[170]

A. Safety Data for Hepatitis B Licensure is Plainly Deficient

HHS begins its response by stating: "Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert."[171] It is troubling that HHS responds to the above request by citing the package inserts when our opening letter explained that these precise package inserts provide that their safety was not monitored for longer than five days after injection.[172] As a result, HHS's response merely affirms the concerns we expressed in our original letter that the Hepatitis B vaccine was inadequately tested for safety prior to licensure.

Recombivax HB's package insert asserts it was deemed safe for children based on a clinical trial in which 147 infants and children (up to 10 years of age) were monitored for five days after vaccination.[173] This trial is useless for assessing the safety of this vaccine for pediatric use (let alone for babies on the first day of life) because the sample size is too small, the safety review period is too short, and there is no placebo control. The safety information in the package insert for Engerix-B is just as inadequate since the clinical trial for this vaccine also had no placebo control and only monitored safety for four days after vaccination.[174]

These package inserts plainly do not support the safety of administering these products to babies. Hence, HHS's assertion that the "Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert" is very troubling.

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[169] https://www.nap.edu/read/13563/chapter/4
[170] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[171] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[172] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[173] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf
[174] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf

B. Safety of Hepatitis B Recommendation for Babies Plainly Deficient

Aside from the package inserts, HHS's response points to only one other identifiable document to support its claim that the Hepatitis B vaccine is safe for babies – a report from the Advisory Committee on Immunization Practices (**ACIP**) that HHS asserts it relied upon for its "recommendation for all children to receive these vaccines."[175] Sadly, as with the package inserts, this ACIP report does not support the safety of these vaccines for babies or children. A copy of the report is cited in a footnote to this sentence.[176]

The ACIP report cites seven studies to support its recommendation that every baby in this country receive Hepatitis B vaccine injections at 1-day, 1-month, and 6-months of life.[177] Two of the cited studies only included adult homosexual males and therefore provide no useful data to evaluate the safety of injecting newborns.[178] The third was a retrospective study that did not use either of the Hepatitis B vaccines licensed for infants in the United States, excluded children that did not complete the vaccine series and lacked a placebo control.[179] The fourth was a retrospective study of potential neurological events from the Hepatitis B vaccine based on reports submitted to a passive surveillance system.[180] This study is also useless for assessing the safety of administering the Hepatitis B vaccine to infants because the study involved "virtually all" adults and did not provide any separate results for infants or children.[181] Moreover, its conclusions regarding safety are pure speculation because, as study authors explained, "underreporting is a well-recognized problem of such surveillance systems" and the "magnitude of underreporting of neurological events after hepatitis B vaccination is unknown."[182] This once again drives home the need for a placebo-controlled trial for each pediatric vaccine prior to licensure.

The three remaining studies relied upon to support the safety of the Hepatitis B vaccine cited in the ACIP report were clinical trials. But none of these clinical trials are useful for understanding the safety of injecting Hepatitis B vaccine into babies.[183] First, none of them had a placebo control.[184] Second, none of these trials assessed safety for longer than seven days after vaccination.[185]

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[175] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[176] https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm

[177] https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm

[178] https://www.ncbi.nlm.nih.gov/pubmed/6810736; https://www.ncbi.nlm.nih.gov/pubmed/6997738

[179] Chen D-S. Control of hepatitis B in Asia: mass immunization program in Taiwan. In: Hollinger FB, Lemon SM, Margolis HS, eds. Viral hepatitis and liver disease. Baltimore: Williams & Wilkins, 1991:716-9.

[180] https://www.ncbi.nlm.nih.gov/pubmed/2962488

[181] https://www.ncbi.nlm.nih.gov/pubmed/2962488

[182] https://www.ncbi.nlm.nih.gov/pubmed/2962488

[183] https://www.ncbi.nlm.nih.gov/pubmed/2952812; https://www.ncbi.nlm.nih.gov/pubmed/2943814; https://www.ncbi.nlm.nih.gov/pubmed/2528292

[184] https://www.ncbi.nlm.nih.gov/pubmed/2952812; https://www.ncbi.nlm.nih.gov/pubmed/2943814; https://www.ncbi.nlm.nih.gov/pubmed/2528292

[185] https://www.ncbi.nlm.nih.gov/pubmed/2952812; https://www.ncbi.nlm.nih.gov/pubmed/2943814; https://www.ncbi.nlm.nih.gov/pubmed/2528292

Indeed, one study had 122 infants and monitored safety for only 7 days.[186] Another study had 79 children monitored for 5 days.[187] Remarkably, in this study 18 percent of the children experienced a systemic or serious adverse reaction (fatigue/weakness, diarrhea, etc.), but, absent a placebo control, the pharmaceutical company paid researchers were left to decide whether or not these reactions were related to the vaccine.[188] The final study had 3,000 infants and children but *only* monitored safety on the day of and the third day after vaccination.[189] As HHS is well aware, autoimmune, neurological and developmental disorders will often not be diagnosed until after babies are a few years old.[190] The ACIP report even acknowledges that "systematic surveillance for adverse events [in infants] has been limited."[191]

As this shows, even though we asked for the science to support the safety of injecting every newborn with the Hepatitis B vaccine starting on the first day of life, the studies HHS has provided do not support such safety and would not be sufficient to license these products for veterinary use in farm animals. For example, prior to licensure of a vaccine for use in chickens, "Daily observation records are required for at least 21 days after vaccination."[192]

C. Urgent Need for Placebo-Controlled Trial of Hepatitis B Vaccine

The need to assess the safety of each Hepatitis B vaccine in robust clinical trials is manifest. The following is a list of the reported post-marketing adverse reactions added to the package insert for Engerix-B because Merck had a "basis to believe there is a causal relationship between the drug and the occurrence of the adverse event"[193]:

> Abnormal Liver Function Tests; Allergic Reaction; Alopecia; Anaphylactoid Reaction; Anaphylaxis; Angioedema; Apnea; Arthralgia; Arthritis; Asthma-Like Symptoms; Bell's Palsy; Bronchospasm; Conjunctivitis; Dermatologic Reactions; Dyspepsia; Earache; Eczema; Ecchymoses; Encephalitis;

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[186] https://www.ncbi.nlm.nih.gov/pubmed/2952812
[187] https://www.ncbi.nlm.nih.gov/pubmed/2943814
[188] https://www.ncbi.nlm.nih.gov/pubmed/2943814
[189] https://www.ncbi.nlm.nih.gov/pubmed/2528292
[190] For example, according to the CDC, even for a common neurological disorder such as ADHD, "5 years of age was the average age of diagnosis for children reported as having severe ADHD." https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html As another example, learning disabilities, a group of common developmental issues, are often "identified once a child is in school." https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed Even asthma, a very common autoimmune condition, whose symptoms are obvious, for children under 5 years of age "diagnosis can be difficult because lung function tests aren't accurate before 5 years of age" and "[s]ometimes a diagnosis can't be made until later, after months or even years of observing symptoms." https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513
[191] https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm
[192] https://www.aphis.usda.gov/animal_health/vet_biologics/publications/memo_800_204.pdf
[193] 21 C.F.R. 201.57

> Encephalopathy; Erythema Multiforme; Erythema Nodosum; Guillain-Barré Syndrome; Hypersensitivity Syndrome (serum sickness-like with onset days to weeks after vaccination); Hypoesthesia; Keratitis; Lichen Planus; Meningitis; Migraine; Multiple Sclerosis; Myelitis; Neuritis; Neuropathy; Optic Neuritis; Palpitations; Paralysis; Paresis; Paresthesia; Purpura; Seizures; Stevens-Johnson Syndrome; Syncope; Tachycardia; Tinnitus; Transverse Muscular Weakness; Thrombocytopenia; Urticaria; Vasculitis; Vertigo; Visual Disturbances.[194]

And these are the reported post-marketing adverse reactions for Recombivax HB added to its package insert because GSK had a basis to conclude each has a causal relationship with that vaccine:

> Agitation; Alopecia; Anaphylactic/Anaphylactoid Reactions; Arthralgia; Arthritis; Arthritis Pain In Extremity; Autoimmune Diseases; Bell's Palsy; Bronchospasm; Constipation; Conjunctivitis; Dermatologic Reactions; Ecchymoses; Eczema; Elevation Of Liver Enzymes; Encephalitis; Erythema Multiforme; Erythema Nodosum; Exacerbation Of Multiple Sclerosis; Febrile Seizure; Guillain-Barré Syndrome; Herpes Zoster; Hypersensitivity Reactions; Hypersensitivity Syndrome (serum sickness-like with onset days to weeks after vaccination); Hypesthesia; Increased Erythrocyte Sedimentation Rate; Irritability; Lupus-Like Syndrome; Migraine; Multiple Sclerosis; Muscle Weakness; Myelitis Including Transverse Myelitis; Optic Neuritis; Peripheral Neuropathy; Petechiae; Polyarteritis Nodosa; Radiculopathy; Seizure; Stevens-Johnson Syndrome; Somnolence; Syncope; Systemic Lupus Erythematosus (SLE); Tachycardia; Thrombocytopenia; Tinnitus; Urticaria; Urticaria; Uveitis; Vasculitis; Visual Disturbances.[195]

These post-marketing reactions reveal a consistent pattern of autoimmune, neurological and other chronic disorders that would appear or only be diagnosed years after vaccinating a baby. Nevertheless, instead of investigating these adverse events in methodologically sound clinical trials, HHS responds to these post-marketing reports of chronic life-long injuries by saying that "causation has not been proven," knowing full well that causation is highly unlikely to be proven, one way or another, until a placebo-controlled trial of sufficient duration is conducted.

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[194] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf
[195] https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm110114.pdf

By approving, recommending and aggressively promoting use of the Hepatitis B vaccine for all infants, HHS created a liability-free captive market for Merck and GSK by ensuring millions of babies every year will be injected with their Hepatitis B products. Since HHS's recommendation in 1991 for the universal pediatric use of these products, these companies have generated over $10 billion in sales from this vaccine.[196] Yet, HHS's response makes clear that it lacked the clinical trial safety data necessary to support its licensure and aggressive marketing of this product for use in all babies.

It is deeply troubling that, despite repeated assurances by HHS that the safety science for this vaccine is robust and complete, when we demanded to actually see this science, HHS was unable to produce it because it apparently does not exist.

Please respond to the above and the specific questions listed in Appendix A.

III. THE VACCINE ADVERSE EVENT REPORTING SYSTEM

Between 2013 and 2018, the Vaccine Adverse Event Reports System (**VAERS**), operated by HHS, has received 261,294 reports of adverse vaccine events, including 2,081 deaths, 5,477 permanent disabilities, and 20,778 hospitalizations.[197] As HHS is aware, "fewer than 1% of vaccine adverse events are reported" because reporting to VAERS is voluntary.[198] We therefore asked in our opening letter why, after Harvard developed a system for spontaneously creating vaccine adverse event reports, "HHS failed to cooperate with Harvard to automate VAERS reporting?"[199] HHS's response does not answer this question.

In 2006, an HHS agency, the Agency for Healthcare Research and Quality, provided a $1 million grant to create a spontaneous reporting system to VAERS at Harvard Pilgrim Health Care.[200] The result was the successful creation of a system at Harvard Pilgrim which automatically created adverse vaccine event reports:

> Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions … were identified.[201]

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[196] https://www.thomsonone.com/
[197] https://wonder.cdc.gov/vaers.html
[198] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[199] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[200] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[201] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

After automating the spontaneous creation of adverse event reports at Harvard Pilgrim, its developers asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS.[202] One would expect the CDC to rush to take this final step given that the preliminary data from this project showed that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.[203] Instead, the CDC refused to cooperate. As the Harvard researchers explained:

> Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.[204]

Given HHS's statutory mandate to assure safer vaccines, it should have moved forward quickly with implementing the spontaneous VAERS reporting system developed by Harvard -- not refused to even communicate with the Harvard Medical School researchers being funded by HHS.

We therefore asked why HHS did not cooperate in implementing the spontaneous VAERS reporting system, and HHS's response incongruously states that doctors may "submit reports directly online" or "download and complete the writable and savable VAERS 2.0 form and submit it using an electronic document upload feature."[205] This does not answer our question. Nor does it address the basic issue that VAERS is a voluntary passive reporting system and history has shown that clinicians do not fill out VAERS reports with any regularity, resulting in only a minuscule number of adverse vaccine events being reported.[206] It also does not correct the problem that VAERS is a passive reporting system, thus limiting its usefulness in making determinations about vaccine safety.[207] The fact that HHS has refused to automate this process leads to the question of whether the decision to keep VAERS as a passive reporting system is intentional in order to hamper its ability to provide reliable information regarding the rate at which a given injury occurs after a given vaccine.

These issues with VAERS have been highlighted for over 30 years and could be easily addressed by implementing automated reporting systems at hospitals and health clinics so

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[202] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[203] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[204] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[205] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[206] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf "Reasons for clinical under-reporting might include failure to associate an acute health event to recent vaccines, lack of awareness of VAERS, the misperception that only serious events should be reported, and lack of time to report." https://www.ncbi.nlm.nih.gov/pubmed/26060294 (cited by HHS)
[207] https://vaers.hhs.gov/about.html; https://vaers.hhs.gov/data/dataguide.html

that reports are electronically generated based on patients' medical records and submitted to VAERS automatically. This would also assure reporting from a known sample size and thus convert VAERS from a passive to an active reporting system, thereby permitting more reliable conclusions to be drawn from the analysis of the VAERS database. But, as discussed above, the CDC refused to cooperate with Harvard to implement such a system in 2007.

The 2015 study cited in HHS's letter shows that HHS continues to refuse to cooperate to implement an automated system.[208] HHS claims that this three-year-old study shows that the "CDC is developing the next generation of spontaneous reporting mechanisms for the VAERS."[209] This claim is at best disingenuous.

The program described in this 2015 study, which the CDC created to generate "spontaneous reporting," makes clear the CDC is desperate to avoid any actual spontaneous reporting.[210] Despite the fact that this program does spontaneously generate vaccine adverse events reports from patients' medical records, the CDC does not permit this program to automatically submit these reports to VAERS.[211] Instead, it emails each report to the patient's doctor and asks the doctor to review and decide whether to submit the report to VAERS.[212] This requirement is backwards.

The purpose of VAERS is to identify previously unknown associations between a vaccine and a condition (ICD-9/10 code). A doctor will, of course, be unlikely to affirm that a reaction is related to a vaccine without a known clinical precedent, the very evidence VAERS is intended to compile. Unsurprisingly, in the eight-month period it tested this new program, the system generated 1,385 vaccine adverse event reports but doctors who received these reports only clicked to submit a grand total of 16 of them to VAERS.[213]

Moreover, the CDC designed this program to even prevent it from generating reports for any conditions (ICD-9/10 code) the CDC predetermined are not associated with a vaccine.[214] The CDC also prevents the program from generating any reports for an adverse event or health condition that the patient had experienced prior to vaccination, thereby eliminating reports of any instance where the vaccine worsened or caused a relapse of a preexisting condition.[215] Hence, the *only* reports the program can generate are for adverse events the CDC deems permissible to associate with a vaccine.[216]

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[208] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[209] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[210] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[211] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[212] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[213] Doctors failed to transmit reports reflecting harms that even HHS accepts are caused by vaccines; doctors affirmatively selected to not transmit 209 reports, which reflects the institutionalized belief about what injuries are caused by vaccines; and for the remaining 1,176 reports, nearly 85% of all reports, there was no clinical response. https://www.ncbi.nlm.nih.gov/pubmed/26060294
[214] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[215] https://www.ncbi.nlm.nih.gov/pubmed/26060294
[216] https://www.ncbi.nlm.nih.gov/pubmed/26060294

In short, the CDC has assured that its vaccine reaction reporting program will only generate reports for injuries the CDC deems acceptable to associate with a vaccine, and then creates the hurdle of requiring busy clinicians to review and click to affirmatively submit a report, which they are highly unlikely to do for the reasons discussed above.

When one considers that the CDC long-ago developed and championed the use of electronic systems that track the movement of each vaccine from its manufacture to its administration, as well as the vaccination status of every child in each state, there is little excuse for not similarly championing the use of long ago developed programs for automatically generating and transmitting adverse reactions reports to VAERS.[217]

We therefore ask – again – for HHS to explain "why HHS failed to cooperate with Harvard to automate VAERS reporting?" as well as address the issues raised above and provide responses to the specific questions in Appendix A.

IV. VACCINE-INJURY PAIRS IN 1994 AND 2011 IOM REPORTS

In our opening letter, we asked HHS to provide the studies it has conducted to determine if there is a causal relationship between vaccination and what HHS claims are the 173 most commonly claimed injuries following vaccination.[218]

HHS's answer points to a recent 740-page review it conducted in 2014, entitled *Safety of Vaccines Used for Routine Immunization in the United States*, which HHS claims is "the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States."[219] However, this report simply reaffirms that HHS has still not conducted studies to determine whether almost any of the 173 most commonly claimed injuries from vaccines (as determined by HHS) are caused by vaccines.

Worse, as discussed below, this 2014 "comprehensive review" of vaccine safety by HHS reveals that HHS does not understand the actual safety profile of its childhood vaccine schedule.

A. HHS's Paid Expert, the IOM, Finds Vaccine Safety Has Been Neglected

In 1991 and 1994, at HHS's request and in compliance with a congressional mandate in the 1986 Act, the Institute of Medicine (**IOM**) of the National Academy of Sciences appointed committees to examine the scientific literature and other evidence that could

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[217] https://www.cdc.gov/vaccines/programs/vtrcks/about.html; https://www.cdc.gov/vaccines/programs/iis/index.html
[218] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[219] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

either prove or disprove a causal link between commonly reported serious health problems following administration of vaccines recommended by HHS for children. The first report, *Adverse Effects of Pertussis and Rubella Vaccines*, was published in 1991, and the second report, *Adverse Effects Associated with Childhood Vaccines*, was published in 1994.

The 1994 report evaluated 54 commonly reported serious injuries and vaccination for Diphtheria, Tetanus, Measles, Mumps, Polio, Hepatitis B, and Hib.[220] The IOM located sufficient science to support a causal connection between these vaccines and 12 serious injuries, including death, thrombocytopenia, and GBS.[221] The IOM, however, found that the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> Arthritis, Aseptic Meningitis, Demyelinating diseases of the central nervous system, Insulin-Dependent Diabetes Mellitus, Myelitis, Neuropathy, Residual Seizure Disorder, Sensorineural Deafness, Sudden Infant Death Syndrome, Sterility, Transverse Optic Neuritis[222]

The IOM lamented that: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[223]

Fifteen years later, in 2011, HHS paid the IOM to review the available science regarding whether there is a causal relationship between vaccination and what HHS asserted are the 158 most common injuries claimed to occur from vaccines for Varicella, Hepatitis B, Tetanus, Measles, Mumps, and Rubella.[224] The IOM located science to support a causal relationship with 18 of these injuries, including pneumonia, meningitis, MIBE, and febrile seizures.[225] The IOM, however, found the scientific literature insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

> Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Poly-neuropathy, Chronic Urticaria, Encephalitis, Encephalopathy,

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[220] https://www.nap.edu/read/2138/chapter/2#12
[221] https://www.nap.edu/read/2138/chapter/2#12
[222] https://www.nap.edu/read/2138/chapter/2#12
[223] https://www.nap.edu/read/2138/chapter/12
[224] https://www.nap.edu/read/2138/chapter/12
[225] https://www.nap.edu/read/13164/chapter/2#3

> Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, Transverse Myelitis[226]

Thus, out of the 158 most common serious injuries claimed to have been caused by one or more of these vaccines, the IOM found that for over 86% of those the science simply had not been performed to determine if there is a causal relationship between the vaccine and the injury.[227]

We therefore asked in our opening letter for HHS to identify the studies it has undertaken to determine whether there is a causal relationship between the 173 vaccine-injury pairs for which this question remained unanswered in the 1994 and 2011 IOM Reports.

B. HHS's "Comprehensive Review" of Vaccine Safety is Deeply Troubling

To support it has studied these vaccine-injury pairs, HHS, as noted above, points to its 2014 review entitled *Safety of Vaccines Used for Routine Immunization in the United States*.[228] But, the 2014 HHS review reached the same conclusion that there is insufficient evidence to conclude whether – save for four – there is a causal relationship between the 173 vaccine-injury pairs from the 1994 and 2011 IOM Reports.[229] It is therefore incredible that HHS would cite this report as proof it has conducted the scientific studies necessary to rule out or confirm a causal relationship for these vaccine injury pairs.

Far more troubling, if the 2014 HHS review is "the most comprehensive review" of the published literature on vaccine safety, as HHS claims, then this review should cause grave concern within HHS and the public regarding vaccine safety.

First, this so-called "comprehensive" review only looked at certain narrow vaccine-injury pairs pre-selected by HHS.[230] This narrow approach reveals nothing about the actual safety profile of these pediatric vaccines on HHS's childhood vaccine schedule. The only

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[226] https://www.nap.edu/read/13164/chapter/2#3
[227] https://www.nap.edu/read/13164/chapter/2#3
[228] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[229] https://www.ncbi.nlm.nih.gov/books/NBK230053/ (HHS's 2014 review also added the following vaccine-injury pairs to the list of what it asserts are the most commonly claimed vaccine injuries: spontaneous abortion from HPV vaccine and meningitis from MMR vaccine.)
[230] https://www.ncbi.nlm.nih.gov/books/NBK230053/

way to actually know the true safety profile of HHS's childhood vaccine schedule or any individual vaccine on that schedule is a placebo-controlled trial of sufficient size and duration. This could provide an actual safety profile of each pediatric vaccine and HHS's childhood vaccine schedule. Instead of this basic trial design used for all drugs to understand their safety profile, HHS's approach is to work backwards by putting forth a self-selected smattering of vaccine-injury pairs, and if HHS cannot find a study proving the vaccine causes the injury (because no study was performed or adequately designed to find a causal relationship), it deems the vaccine safe.[231] This approach entirely ignores the scientific method and is transparently unsound because it begins with the *a priori* assumption that vaccines are safe and then relies upon a "comprehensive review" of self-selected, scarce and incomplete post-licensure vaccine literature to validate this assumption if it cannot find proof of harm.[232]

Second, after HHS assumed safety and narrowed the review to certain vaccine-injury pairs, the review then eliminated almost all studies showing that vaccines cause harm by excluding 20,312 of the 20,478 studies it identified as related or potentially related to vaccine safety.[233] The handful of studies that HHS did include for review were overwhelmingly studies in which a pharmaceutical company funded and/or authored (usually both) a review of its own vaccine.[234]

For example, it excluded all individual case reports despite the fact that practitioners can typically only afford to publish (typically instances of immediate and obvious vaccine injuries) in this form.[235] HHS excluded all experimental studies which could actually explain the biological mechanisms of how vaccines can cause injury or death.[236] HHS even excluded animal studies which – because experimentation with animals does not have ethical restrictions applicable to human research – often provide the best available scientific evidence of how vaccines can harm immune function, the brain and other tissue.[237]

The result is that this review included only 97 studies that are applicable to children[238], 77 of which were directly funded and/or authored (typically both) by the very vaccine manufacturer whose vaccine(s) the study reviews.[239] As for the remaining 20 studies, almost all were funded and/or authored by agencies and/or individuals that directly or indirectly receive funding from the manufacturer whose vaccine(s) the study reviews.[240]

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[231] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[232] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[233] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[234] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[235] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[236] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[237] https://www.ncbi.nlm.nih.gov/books/NBK230053/ (HHS also excluded all studies using VAERS, one of the few resources available to study vaccine safety without pharmaceutical type funding.)
[238] The 2014 HHS review lists the study, Zaman K. et al. (2012), twice in Table 22 and the study, Khatun S. et al. (2012), twice in Table 25.
[239] https://www.ncbi.nlm.nih.gov/books/NBK230053/
[240] https://www.ncbi.nlm.nih.gov/books/NBK230053/

For example, HHS *excluded* an actual randomized, double-blind, placebo-controlled study which compared the rate of respiratory infections between controls receiving a placebo (saline injection) and subjects receiving inactivated influenza vaccine (**TIV**).[241] This non-pharma-funded nine-month study carefully tracked influenza-like illness symptoms through "symptom diaries and telephone calls," and "illness reports in any household member triggered home visits, during which nasal and throat swab specimens were collected."[242] The result:

> There was no statistically significant difference in the risk of confirmed seasonal influenza infection between recipients of TIV or placebo. ... However, participants who received TIV had higher risk of ARI [acute respiratory illness] associated with confirmed noninfluenza respiratory virus infection (RR, 4.40; 95% CI, 1.31–14.8).[243]

This meant both groups had a similar rate of influenza, but the vaccinated group had 440% more cases of noninfluenza acute respiratory illness.[244] It appears that getting the flu shot may have significantly "reduced immunity to noninfluenza respiratory viruses."[245]

While this well designed and executed study reflecting serious negative impact of vaccination on health was *excluded* from HHS's comprehensive vaccine safety review, this review *included* a study funded by GSK and conducted by GSK employees which nonsensically compared 199 infants receiving PHiD-CV, DTPa, HBV, IPV and Hib (test group) with 101 infants receiving DTPa, HBV, IPV and Hib (control group).[246] Ironically, this study found that 4.5% of test infants and 5.9% of control infants had one or more serious adverse reactions following vaccination, but HHS accepted GSK's unsubstantiated and self-serving conclusion that none were "considered to be causally related to [GSK's] vaccination."[247]

Third, having limited the review of vaccine safety for children to 97 studies, HHS then claims that 59 of these studies compared "vaccinated versus unvaccinated children or adolescents"[248] The following is a break-down of these 59 studies by vaccine type: Rotavirus (34 studies), HPV (13 studies), Influenza (6 studies), Hib (3 studies), Meningococcal (2

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[241] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[242] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[243] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[244] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[245] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[246] https://www.ncbi.nlm.nih.gov/pubmed/23432812
[247] https://www.ncbi.nlm.nih.gov/pubmed/23432812
[248] https://www.ncbi.nlm.nih.gov/books/NBK230053/

studies), and Varicella (1 study).[249] We commend HHS for making clear it understands there is a critical importance of comparing vaccinated and unvaccinated children to scientifically evaluate and understand vaccine safety. It is, however, unfortunate that HHS mislabels these studies as comparing "vaccinated versus unvaccinated children or adolescents" when the unvaccinated cohort is not really unvaccinated.[250]

For example, HHS lists two studies involving the meningococcal vaccine as comparing "vaccinated versus unvaccinated children."[251] However, in one study the test group and control group both received a meningococcal vaccine, and in the other study the test group received seven vaccines and the control group received six vaccines.[252] Claiming these two studies compared "vaccinated versus unvaccinated children" is misleading. The following table details these two studies and highlights the rate of serious adverse events (**SAE**s) that are ignored because the control group, wrongly labeled "unvaccinated," is used as the baseline for what is deemed "safe":

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Meningococcal MCV4 (**Sanofi**)	Funded by **Sanofi** & authors include **Sanofi** employees	Khalil, M. et al. 2012 (Saudi Arabia)	MCV4 (151 children who received MPSV4 as babies)	MCV4 (85 children who did not receive MPSV4 as babies)	1.3% and 2.4% of the children in the subject and control group, respectively, had a serious adverse reaction (**SAE**)
Meningococcal MenACWY (**Novartis**)	Funded by **Novartis** & authors include **Novartis** employees	Klein, N.P. et al. 2012 (Three countries)	MenACWY, DTaP, IPV, Hib, HBV, IPV, PCV7, RV, V & MMRII (≈1000 babies)	DTaP, IPV, Hib, HBV, IPV, PCV7, RV, V & MMRII (≈500 babies)	75% of subject and 76% of control babies had an AE and "SAEs were reported with similar frequency among groups"

Similarly, the following table summarizes every purported "vaccinated versus unvaccinated" study that HHS could identify regarding the Hib vaccine (injected per HHS at 2, 4, 6 and 12 months of age) and again highlights the rate of serious adverse events that are ignored because the control group, wrongly labeled "unvaccinated," is used as the baseline for what is deemed "safe":

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Hib - OPMC (**Merck**)	Funded by **Merck** & authors include **Merck** employees	Santosham M. et al., 1991 (U.S.)	OPMC, DTP, and OPV (2,588 infants)	DTP and OPV (2,602 infants)	4% of infants in each group were hospitalized within 30 days of vaccination
Hib - PHiD-CV (**GSK**)	Funded by **GSK** & authors include **GSK** employees	Huu, T.N. et al. 2013 (Vietnam)	PHiD-CV, DTPa, HBV, IPV & Hib (199 infants)	DTPa, HBV, IPV & Hib (101 infants)	4.5% and 5.9% of infants in the subject and control groups, respectively, reported a SAE

[249] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[250] The rotavirus vaccine is given orally, not injection, and hence not considered. Nonetheless, the 35 rotavirus studies HHS states compare "vaccinated with unvaccinated children" actually compare children receiving oral drops of rotavirus with children receiving oral drops of the following vaccine ingredients: Polysorbate 80, Sucrose, Citrate, Phosphate, Dextran, Sorbitol, Amino acids, Dulbecco's Modified Eagle Medium, Calcium Carbonate, and/or Xanthan. https://www.ncbi.nlm.nih.gov/books/NBK230057/table/results.t19/?report=objectonly

[251] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[252] https://www.ncbi.nlm.nih.gov/books/NBK230053/

Hib - PRP-OMP, POP-T, and HbOC (various)	No conflicts declared	Capeding M. R. Z. et al.,1996 (Philippines)	Hib, BCG, OPV, DTP and HBV (130 infants)	BCG, OPV, DTP and HBV (44 infants)	Admits that because "vaccines were administered simultaneously with other … vaccines … it is not possible to attribute the systemic reactions to any individual vaccine used in the study."

Similarly, for the six influenza vaccine studies listed by HHS as comparing "vaccinated with unvaccinated children," only four involved an injection of influenza vaccine,[253] and only one of these can be properly labeled as comparing "vaccinated with unvaccinated children." This one placebo-controlled study involved HIV-infected children and, while it provided almost no useful safety data because it only monitored safety for three days, it demonstrates that it is ethically permissible to use a saline placebo in a vaccine trial.

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Flu - TIV (**Sanofi**)	Funded by **Sanofi** and authors include **Sanofi** employees	Englund J. A. et al., 2010 (U.S.)	TIV, DTaP, Hib, PNC, IPV, & HepB (915 babies)	Placebo, DTaP, Hib, PNC, IPV & HepB (460 babies)	Only collected "SAEs using previously defined criteria," yet within 28 days 1.9% of subject and 1.5% of control babies had a SAE
Flu – TIV (unknown)	None disclosed	Gotoh K. et al., 2011 (Japan)	TIV or no TIV (38 liver transplant recipients)	TIV (63 healthy children)	Safety not compared between subject and control groups
Flu - TIV (**Sanofi**)	None disclosed	Greenhawt, M.J. et al. 2012 (U.S.)	TIV (14 children)	TIV thirty minutes after saline injection (17 children)	Both groups had comparable adverse event rates
Flu - Vaxigrip (**Sanofi**)	Sponsored by Bristol- Myers Squibb	Madhi, S.A. et al. 2013 (South Africa)	TIV (203 HIV infected children)	Placebo - Saline (200 HIV-infected children)	Adverse events only collected for 3 days post-vaccination

As for the 13 studies regarding HPV vaccine labeled by HHS as "vaccinated versus unvaccinated," all – except for one study with a control group of 17 HIV-positive girls – use other vaccines or an injection of the aluminum adjuvant contained in the HPV vaccine as a control.[254] The table below reveals high rates of serious injuries and chronic illness reported by the HPV vaccine recipients, which were dismissed as not being a vaccine safety issue because the rates were similar to those reported in the "spiked" control group. It is noteworthy that unlike most of the vaccines in the tables above, the HPV vaccines were studied in adolescent and older women who, unlike children or babies, are able to clearly express if they are experiencing a serious adverse reaction, such as neurological issues.

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[253] Two studies involved LAIV administered via nasal spray. In both, a pharmaceutical company reviewed its own product. One involved 20 immunocompromised children with cancer in which 10 received LAIV and 10 received a placebo with .5 mL of sucrose-phosphate buffer and no SAEs were reported since the pharmaceutical company's funded researchers did not consider them related to LAIV. (Halasa N. et al., 2011 (U.S.).) The other compared 261 children receiving LAIV with 65 children receiving placebo of .5 mL sucrose-phosphate buffer and being offered LAIV after 28 days which negated reaching safety conclusions. (Mallory R. M. et al.,2010 (U.S.).)

[254] https://www.ncbi.nlm.nih.gov/books/NBK230053/

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
HPV - Gardasil (**Merck**)	Funded by **Merck** and authors include **Merck** employees	Moreira Jr E. D. et al.,2011 (18 countries)	Gardasil (2,020 boys and men)	225 ug of AAHS (2,029 boys and men)	"systemic AE was generally comparable between the vaccine and placebo group (31.7% vs. 31.4%, respectively)"
HPV - Cervarix (**GSK**)	Funded by **GSK** and authors include **GSK** employees	Roteli-Martins C. M. et al., 2012 (Brazil)	Cervarix (223 girls and women)	500 ug Aluminum Hydroxide (213 girls and women)	24.6% of subjects and 15.5% of controls had a SAE, new onset of chronic disease or medically significant condition
HPV - Cervarix (**GSK**)	Funded by **GSK** and authors include **GSK** employees	Schwarz, T.F. et al. 2012 (5 countries)	Cervarix (1,035 girls)	Havrix and, after delay, Cervarix (1,032 girls)	38.8% of subjects and 32.4% of controls had a SAE, new onset of chronic disease or medically significant condition
HPV – Cervarix (**GSK**)	Funded by **GSK** and authors include **GSK** employees	Sow, P. S. et al. 20131 (Africa)	Cervarix (450 girls and women)	500 ug Aluminum Hydroxide (226 girls and women)	75.2% of subjects and 69.3% of controls reported a "Medically significant condition"
HPV - Gardasil (**Merck**)	Funded by **Merck** and authors include **Merck** employees	Block S. L. et al., 2010 (global)	Gardasil (11,792 people aged 9-23)	AAHS (9,092 aged 16-23) Gardasil minus AAHS and antigens (596 aged 9-15)	Between 9% and 14% of subjects and controls each had vaginal candidiasis, bacterial vaginosis, urinary tract infection and vaginal discharge
HPV - Cervarix (**GSK**)	Funded by **GSK** and authors include **GSK** employees	De Carvalho N. et al., 2010 (Brazil)	Cervarix (222 women)	500 ug Alumi-num Hydroxide (211 women)	9.9% of subjects and 8.6% of controls had a SAE or medically significant AE
HPV - Gardasil (**Merck**)	Funded by **Merck** and authors include **Merck** employees	Giuliano A. R. et al., 2011 (18 countries)	Gardasil (2,020 males)	225 or 450 ug of AAHS (2,029 males)	14.1% of subjects and 14.6% of controls had a systemic adverse event within 15 days
HPV – Cervarix (**GSK**)	None declared	Khatun S. et al., 2012 (Bangladesh)	Cervarix (50 girls)	Nothing given (17 girls)	Vomiting occurred in 8% of subjects after 1st dose, 10% after 2nd dose, and 32% after 3rd dose
HPV - Cervarix (**GSK**)	Funded by **GSK** and authors include **GSK** employees	Kim S. C. et al., 2011 (Korea)	Cervarix (149 women)	500 ug Aluminum Hydroxide (76 women)	"fatigue, myalgia and headache was frequent in both groups" and 22.8% of subjects and 13.2% of controls reported a medically significant adverse condition(s)
HPV - Gardasil (**Merck**)	Authors include **Merck** employees	Levin M. J. et al., 2010 (U.S.)	Gardasil (96 HIV positive children)	"identical placebo" (30 HIV positive children)	7% of subjects and controls had grade 3 or 4 event w/n 14 days, and 15 AEs were not graded
HPV - Gardasil (**Merck**)	Funded by **Merck** and authors include **Merck** employees	Li R. et al., 2012 (China)	Gardasil (302 people)	225 or 450 ug of AAHS (298 people)	42.7% of subjects and 39.9% of controls had systemic adverse event
HPV - Gardasil (**Merck**)	Funded by **Merck**	Kang, S. et al. 2008 (Korea)	Gardasil (117 females)	225 ug of AAHS (59 females)	31.6% of subjects and 44.1% of controls had systemic adverse reaction within 14 days
HPV - Gardasil (**Merck**)	Funded by **Merck** and authors include **Merck** employees	Clark, L.R. et al. 2013 (global)	Gardasil (373 women)	225 ug of AAHS (393 women)	49% of subjects and 41% of controls had systemic reactions, both had similar rate of SAEs

The above tables make clear that HHS is misleading the public when it labels these studies as "vaccinated versus unvaccinated" because the control group in each study almost always received another vaccine and/or an active ingredient found in the vaccine.[255]

Little comfort should be derived from the fact that the rate of serious adverse events is the same in an experimental vaccine test group and a control group receiving another vaccine or toxic substance, especially when that rate is higher than what would be expected in the general population. For example, it is troubling that a serious adverse event rate of over 30% (or even 2% of babies) is dismissed just because it occurred in both the subject and control groups, especially where the control group received another vaccine or toxic substance.

These outcomes of these purported "vaccinated versus unvaccinated" studies should be cause for concern regarding vaccine safety, not used as proof of safety.

Finally, it is evident that the real goal of HHS's "comprehensive review" was *not* about providing good scientific evidence to reassure the public that the vaccines on HHS's childhood vaccine schedule are safe. As the introduction to the review makes clear, it was about assuring high vaccine uptake, even at the expense of throwing away objectivity and basic scientific principles to produce a report that provides only the superficial appearance of vaccine safety for the public.[256] Indeed, the review begins by focusing upon and bemoaning that "vaccination rates remain well below established Healthy People 2020 targets for many vaccines" and that "Increasing vaccination rates remains critically important."[257] HHS even laments in its review that "public concerns about vaccine safety continue to persist" despite "the rigorous processes new vaccines must undergo before receiving approval" and that they meet "stringent criteria for safety."[258] HHS's predetermined objective and conclusion is thus made clear from the outset of its review.

Despite its predetermined conclusion regarding vaccine safety and the limitations placed on the inclusion of studies as discussed above, the 2014 review still found that vaccines can cause babies and children to develop numerous serious adverse reactions, such as febrile seizures, arthralgia (pain in the joints), thrombocytopenic purpura (the immune system attacking the body's own platelets), meningitis (inflammation of the membranes surrounding the brain and spinal cord), and encephalitis (inflammation of the brain).[259]

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[255] As for the one purported "vaccinated versus unvaccinated" varicella (chicken pox) vaccine study, it compared a test group of 54 children with systemic lupus erythematosus that either received or did not receive varicella with a control group of 28 healthy children that received varicella. (Weinberg, A. et al. 2010 (U.S.).)

[256] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[257] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[258] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[259] https://www.ncbi.nlm.nih.gov/books/NBK230053/

Given all of the foregoing issues with the 2014 review, it is not surprising that HHS's response letter only cites an executive summary of this review.[260] The full text of this review, which HHS understandably wanted to avoid publicizing as part of its response, is available at the URL in the footnote to this sentence.[261]

C. Studies Published After HHS's 2014 Review Reaffirm the Above Concerns

Apart from the 2014 review, HHS's response provides a link to the CDC website which HHS states contains a "list of CDC vaccine safety publications" which "address several of the vaccine-injury pairs that have been identified in the reports mentioned above."[262] These studies, however, add little to closing the gap regarding whether a causal relationship exists for the 173 vaccine-injury pairs from the 1994 and 2011 IOM Reports.

The studies published prior to August 2013 should have been swept up by HHS's 2014 "comprehensive review" (discussed above), which HHS asserts encompassed all vaccine safety studies prior to August 2013.[263] As for studies published after August 2013, those based on VAERS data cannot be used to determine causation for any vaccine-injury pair because according to HHS: "A major limitation of VAERS data is that VAERS cannot determine if the adverse health event reported was caused by the vaccination."[264] What remains are only 6 non-VAERS studies published after August 2013 on the CDC webpage cited by HHS which analyze any of the relevant vaccine-injury pairs from the 1994 and 2011 IOM reports.[265]

HHS's response to our letter sought to mislead the public into believing it has conducted studies to fill the vaccine safety science gaps identified by the IOM between 1991 and 2013, when this is clearly not the case. HHS's response and its 2014 "comprehensive

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[260] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[261] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

[262] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf

[263] https://www.ncbi.nlm.nih.gov/books/NBK230053/

[264] https://wonder.cdc.gov/vaers.html. HHS also explains that VAERS cannot be used "to determine causation" because "there is lack of an unvaccinated group for comparison in VAERS. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html. Also, since VAERS is a passive reporting system, the absence of adverse event reports in VAERS cannot establish safety. https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[265] Five of these six studies were conducted using the VSD and the issues with the VSD are discussed below in Section IX; and the authors in half of these studies received funding from the pharmaceutical companies whose vaccines were being reviewed. The six studies are: (1) Hambridge (2014) - Reviewed risk of seizures, but expressly excluded all unvaccinated children and instead compared the rate of seizures within 2 days or between 7 to 10 days of vaccination (depending on vaccine) with the rate of seizures during the next 14 days plus the 14 days starting four weeks before vaccination. It found an increased risk of seizures from some vaccines. (2) Rowhani-Rahbar (2013) - Compared risk of seizures 7 to 10 days after vaccination with the risk in days 1 to 6 plus 11 to 42 after vaccination between MMRV alone or MMR and V concurrently but separately. (3) Klein (2015) - Also compared MMRV alone with MMR and V concurrently but separately. (4) McCarthy (2013) - Evaluated influenza vaccine, but excluded reactions on the day of vaccination for most conditions, had no unvaccinated control, and comingled data for children and adults with the exception of seizures. As for seizures, only included seizures occurring within one day of vaccination and excluded complex febrile seizures. (5) Kawai (2014) - Also reviewed influenza vaccine, had same issues as McCarthy, plus excluded all reactions occurring during outpatient visits when vaccines are administered. (6) Daley (2014) - Compared receipt of DTaP-IPV as single injection with receipt of DTaP and IPV at same time in separate injections and excluded most reactions during outpatient visits.

review" provide further evidence that it has failed to fulfill and cannot be trusted to fulfill its critical statutory vaccine safety duties.

Please respond to the above points with relevant studies, and please provide answers to the specific questions raised in Appendix A.

V. FAILURE TO IDENTIFY CHILDREN SUSCEPTIBLE TO VACCINE INJURY

In our opening letter we noted that the IOM in 1994 asserted that it "was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not" and hence urged that "research should be encouraged to elucidate the factors that put certain people at risk."[266] We also pointed out that in 2013, the IOM acknowledged this research still had not been conducted, stating that it

> found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited.[267]

We thereafter asked that HHS "advise when [it] intends to begin conducting research to identify which children are susceptible to serious vaccine injury" and "[i]f HHS believes it has commenced this research, please detail its activities regarding same."[268]

We appreciate that HHS's response appears to acknowledge that this is an important area of study by asserting that "HHS is currently supporting several initiatives that focus on advancing research" that would identify which children are susceptible to serious vaccine injury.[269] Unfortunately, the two sources HHS cites do not support that it is actually conducting this research.

HHS first cites the "About Us" page for the Human Immunology Project Consortium (**HIPC**).[270] To be sure, this webpage asserts that "the HIPC program will ... establish predictors of vaccine safety in different populations."[271] But, none of the projects listed on the "HIPC Projects" webpage nor the 64 HIPC-funded studies within the associated

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[266] https://www.nap.edu/read/2138/chapter/12#307. See also https://www.nap.edu/read/1815/chapter/9
[267] https://www.nap.edu/read/13563/chapter/9#130. See also https://www.nap.edu/read/13164/chapter/5#82
[268] http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf
[269] http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf
[270] https://www.immuneprofiling.org/hipc/page/showPage?pg=sci-about
[271] https://www.immuneprofiling.org/hipc/page/showPage?pg=sci-about

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 5 Jun 2019 20:46:38 +0000
To: Vaughn, William (CDC/DDID/NCEZID/DHQP) (CTR)
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Subject: FW: FYI only - U.S. measles epidemic tops 1,000 cases

In case you have not seen.
https://www.washingtonpost.com/health/2019/06/05/brooklyn-anti-vaccine-event-attracts-pro-vaccine-protests-amid-measles-outbreak/?utm_term=.968bd44d6651

-Lyn

Lyn Thi Nguyen, MPH
Public Health Analyst (Policy)
Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329
(b)(6)
(Tel)
(BB)
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

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From: POLITICO Pro <politicoemail@politicopro.com>
Sent: Wednesday, June 5, 2019 4:42 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Subject: U.S. measles epidemic tops 1,000 cases

By Arthur Allen

06/05/2019 04:40 PM EDT

The worst measles epidemic since 1992 topped 1,000 cases, the government said today, and HHS Secretary Alex Azar promised to redouble efforts to help public health officials fighting the virus and the spread of misinformation about vaccines.

CDC has reinforced its monitoring and education efforts with special outreach to ultra-Orthodox Jewish communities in New York state, where the disease has been circulating for nearly eight months, an HHS release said. The agency added that CDC was trying "to figure out how to develop culturally appropriate communications resources" for those areas.

"The measles vaccine is among the most-studied medical products we have and is given safely to millions of children and adults each year," Azar said in the release.

Anti-vaccine activists held a rally Tuesday night in Brooklyn featuring an anti-vaccine rabbi and Del Bigtree, who produced a film accusing the government of suppressing evidence that links vaccination and autism.

"They should be allowed to have the measles if they want the measles," Bigtree told reporters outside the meeting. He called measles, which kills hundreds of thousands of children worldwide each year and has hospitalized one in 10 patients in the current U.S. outbreak, "a trivial childhood illness."

POLITICOPRO

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Mon, 13 Feb 2017 03:33:55 +0000
To: Barry, Brooke (CDC/OID/NCIRD)
Cc: Pope, Kristin (CDC/OID/NCIRD)
Subject: FW: fyi

FYI.

From: Smith, Jean Clare (CDC/OID/NCIRD)
Sent: Friday, February 10, 2017 11:47 PM
To: Reingold, Arthur MD (CDC berkeley.edu) <reingold@berkeley.edu>
Cc: Walter Orenstein <WORENST@emory.edu>; Philippe Duclos <duclosp@who.int>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: RE: fyi

Art

Thanks for bringing this to our attention. I did not know about it, but Amanda (copied) may have. I am in (b)(6)

Jean

Jean Clare Smith, MD, MPH
CAPT USPHS
Medical Officer, Advisory Committee on Immunization Practices| National Center for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention | 1600 Clifton Rd, NE - Mailstop A-27, Atlanta, GA 30329-4027 USA |office 1-404-639-6227 cell 1-404-317-5585 Fax 1-404-471-8081| ACIP web site: http://www.cdc.gov/vaccines/recs/acip/

From: Reingold, Arthur MD (CDC berkeley.edu)
Sent: Saturday, February 11, 2017 6:41 AM
To: Smith, Jean Clare (CDC/OID/NCIRD) <jis6@cdc.gov>
Cc: Walter Orenstein <WORENST@emory.edu>; Philippe Duclos <duclosp@who.int>
Subject: Fwd: fyi

You know about this?

Sent from my iPhone

Begin forwarded message:

From: Ruth Karron <rkarron@jhu.edu>
Date: February 10, 2017 at 1:59:45 PM PST

To: Art Reingold <reingold@berkeley.edu>, "Belongia, Edward A" <belongia.edward@marshfieldclinic.org>, Emmanuel Walter <chip.walter@duke.edu>, Nana Bennett <nancy_bennett@urmc.rochester.edu>
Subject: FW: fyi

From: Sarah Despres <sdespres@pewtrusts.org>
Date: Thursday, February 9, 2017 at 1:28 PM
To: Ruth Karron <rkarron@jhu.edu>, Josh Sharfstein <joshua.sharfstein@jhu.edu>
Subject: fyi

Something to put on your calendars….

The anti-vaccine cohort is promoting a march on Washington, DC on Friday, March 31 called the "Revolution for Truth."

There is a full day's worth of events scheduled, including a march from the National Press Club to the U.S. Capitol, where there will be a rally featuring RFK Jr., Brian Hooker, Barbara Loe Fisher, and Del Bigtree – among others.

On the event website, it's suggested that participants meet with their legislators on the Hill the day prior (March 30), though no specific timing or talking points are supplied.

Thus far, the event has only been promoted by March Against Monsanto and Age of Autism.

From: Nguyen, Lyn (CDC/OID/NCEZID)
Sent: Thu, 16 Nov 2017 11:32:24 -0500
To: Shimabukuro, Tom (CDC/OID/NCEZID); Destefano, Frank (CDC/OID/NCEZID)
Subject: FW: fyi

Tom and Frank,

Wanted to give you a heads up on the letter CDC-W shared with the Center (see link below). It was sent to HHS in October and has not been sent out to the OPDivs yet. I spoke with the Center this morning on the sections that apply to ISO and can update you tomorrow when I am over at Century Center on where things are.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH
Public Health Analyst (Policy)
Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329
(b)(6)
(Tel) [redacted]
(BB) [redacted]
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

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From: McMillen, Amy (CDC/OID/NCEZID)
Sent: Thursday, November 16, 2017 10:14 AM
To: Nguyen, Lyn (CDC/OID/NCEZID) <ivx1@cdc.gov>
Subject: FW: fyi

FYI too.

From: Miner, James B. (CDC/OID/NCEZID)
Sent: Thursday, November 16, 2017 10:07 AM
To: Knights, Paulette (CDC/OID/NCEZID) <pbf7@cdc.gov>; McMillen, Amy (CDC/OID/NCEZID) <auh1@cdc.gov>; Holmes, Carissa B. (CDC/OID/NCEZID) <ipz3@cdc.gov>
Subject: FW: fyi

Oct. letter to HHS.

From: Katsoyannis, Miranda (CDC/OD/CDCWO)
Sent: Thursday, November 16, 2017 10:03 AM
To: Wiley, Sarah D. (CDC/OID/OD) <sed5@cdc.gov>; Miller, Rebecca (CDC/OID/NCEZID) <ckq0@cdc.gov>; Beauvais, Denise (CDC/OID/NCIRD) <cry2@cdc.gov>; Miner, James B.

(CDC/OID/NCEZID) <fmz5@cdc.gov>
Cc: Jamieson, Sara R. (CDC/OD/CDCWO) <hvh0@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Subject: fyi

Good morning,

A partner brought this notice http://icandecide.com/white-papers/ICAN-HHS-Notice.pdf to our attention. Have you seen it? Not sure if the Department has done anything but I have shared it with Melinda (NVPO) for her awareness.

Thanks,
Randy

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 16 Jul 2019 14:58:26 +0000
To: Barry, Brooke (CDC/DDID/NCIRD/OD)
Subject: FW: IMPORTANT: Fwd: ICAN Letter to HHS re VICP
Attachments: ICAN Letter to HHS re VICP Oct2017.pdf, ATT00001.htm

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From: Pope, Kristin (CDC/OID/NCIRD) <kfp7@cdc.gov>
Sent: Thursday, November 16, 2017 2:03 PM
To: Messonnier, Nancy (CDC/OID/NCIRD) <nar5@cdc.gov>; Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Cc: Wiley, Sarah D. (CDC/OID/OD) <sed5@cdc.gov>
Subject: FW: IMPORTANT: Fwd: ICAN Letter to HHS re VICP

Phyllis shared the attached letter – I believe its posted on a website (Brooke sent me a link this morning, but I couldn't open it). CDC has not received this formally from HHS for any response at this point.

From: Phyllis Arthur [mailto:parthur@bio.org]
Sent: Thursday, November 16, 2017 1:43 PM
To: Pope, Kristin (CDC/OID/NCIRD) <kfp7@cdc.gov>; Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>
Subject: IMPORTANT: Fwd: ICAN Letter to HHS re VICP

Hi. I wanted to make sure you both saw this letter from a collection of anti vaccine orgs to the Acting HHS Secretary. Happy to chat anytime. Phyllis

Sent from my iPhone

Begin forwarded message:

From: "Amy Walker" <awalker@bio.org>
To: "Phyllis Arthur" <parthur@bio.org>
Subject: ICAN Letter to HHS re VICP

See attached.

ICAN
Informed Consent Action Network

VIA FEDEX

October 12, 2017

U.S. Department of Health & Human Services
HHS Office of the Secretary
Eric D. Hargan
Acting Secretary of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Hargan:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b).

Americans, including the over 55 organizations listed below, whose members exceed 5 million Americans, are concerned about vaccine safety. The National Childhood Vaccine Injury Act of 1986 (the **1986 Act**) made nearly every aspect of vaccine safety the exclusive responsibility of the Department of Health & Human Services (**HHS**). As the Secretary of HHS (the **Secretary**), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. These specific requests are numbered sequentially in this notice. We would welcome the opportunity to meet and discuss reasonable means for complying with these requests. If that is not possible, the 1986 Act authorizes "a civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty" under the 1986 Act.

I. Background

The 1986 Act granted economic immunity to pharmaceutical companies for injuries caused by their vaccines. (42 U.S.C. § 300aa-11.) The 1986 Act thereby eliminated the market force which drives safety for all other products – actual and potential product liability. Recognizing the unprecedented elimination of this market force, the 1986 Act makes HHS directly responsible for virtually every aspect of vaccine safety. (42 U.S.C. §§ 300aa-2, 300aa-27.)

When the CDC recommends a pediatric vaccine for universal use, it creates for that vaccine's maker a liability free market of 78 million children typically required by law to receive the vaccine. The number of required vaccines has grown rapidly since 1986. In 1983, the CDC recommended that babies under one receive two vaccines: DTP and Polio.[1] As of 2017, the CDC recommends that babies under one receive multiple doses of ten vaccines: DTaP, Polio, Hep B, Rotavirus, Hib, Pneumococcal, Influenza, MMR, Varicella, and Hep A.[2] In total, the current CDC childhood vaccine schedule includes 56 injections of 73 doses of 30 different vaccines.

II. Deficiencies in the Pre-Licensure Safety Review of Pediatric Vaccines

All drugs licensed by the FDA undergo long-term double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. For example: Enbrel's pre-licensure trials followed subjects up to 80 months and controls received a saline injection.[3] Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.[4] Botox's pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.[5] And even with these long-term studies, drugs are still often recalled.

In contrast, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, of the two Hepatitis B vaccines licensed by the FDA for injection into one-day-old babies, Merck's was licensed after trials that solicited adverse reactions for *only five days* after vaccination and GlaxoSmithKline's was licensed after trials that solicited adverse reactions for *only four days* after vaccination.[6] Similarly, the HiB vaccines sold by these same companies were licensed based on trials which solicited adverse reactions for three and four days, respectively, after vaccination.[7] The only stand-alone polio vaccine was licensed after a mere 48-hour follow-up period.[8]

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[1] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
[2] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf
[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
[6] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[7] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf
[8] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

Moreover, these trials either had no control group or a control group which received other vaccines as a "placebo."[9] This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.

The 1986 Act expressly requires that you, as the Secretary, "shall make or assure improvements in … the licensing … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(1) Please explain how HHS justifies licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an inert placebo?

(2) Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?

III. Post-Licensure Surveillance of Vaccine Adverse Events

The lack of pre-licensure safety data leaves the assessment of vaccine safety to the post-licensing period when they are being administered to children in the "real world." To capture vaccine adverse events in the real world, the 1986 Act established the Vaccine Adverse Events Reporting System (**VAERS**) operated by HHS. (42 U.S.C. § 300aa-25.)

In 2016, VAERS received 59,117 reports of adverse vaccine events, including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.[10]

However, only a tiny fraction of adverse vaccine events are reported to VAERS. An HHS-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 715,000 patients and found that "fewer than 1% of vaccine adverse events are reported."[11] A U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."[12]

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[9] Ibid.
[10] https://wonder.cdc.gov/vaers.html
[11] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[12] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

Assuming VAERS captures a full 1 percent of adverse events – which is more than is estimated – the VAERS data above from 2016 may reflect that in that year alone there were 5,911,700 adverse vaccine events, including 43,200 deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency room visits.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially avoiding these injuries and deaths.

The idea of automating adverse reaction reporting to VAERS is not new or even difficult to achieve.[13] An agency within HHS, the Agency for Healthcare Research and Quality, sought to do exactly that in 2007 when it provided an approximately $1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.[14] The result was the successful automation of adverse event reports at Harvard Pilgrim:

> *Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions … were identified.*[15]

These results should have been concerning to HHS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.

After automating adverse events reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

> *Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*[16]

After three years and spending $1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting -- not ignored the requests by the HHS's Harvard grant recipients.

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[13] https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system
[14] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[15] Ibid.
[16] Ibid.

While HHS strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.[17] Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.[18] Capturing "fewer than 1% of vaccine adverse events" thirty years after the passage of the 1986 Act is unacceptable -- and potentially deadly.

The 1986 Act expressly provides that you, as the Secretary, "shall make or assure improvements in … adverse reaction reporting … in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(3) Please explain why HHS failed to cooperate with Harvard to automate VAERS reporting? And detail any steps that HHS has taken since toward automating VAERS reporting?

(4) Please explain any specific steps taken by HHS to improve adverse reaction reporting to VAERS?

IV. Identifying What Injuries Are Caused by Vaccines

The first step in assuring safer vaccines is to identify what harms they cause. This would normally be accomplished pre-licensure by long-term, inert-placebo controlled trials – but these are never performed for vaccines. As for post-licensure monitoring, HHS has refused to improve VAERS as discussed above. Hence, assessing which vaccines cause which injuries is mainly left to post-licensure studies. HHS, unfortunately, has neglected to perform these studies.

In 1991, the Institute of Medicine (**IOM**) examined 22 commonly reported serious injuries following the DTP vaccine.[19] The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.[20] The IOM, however, found the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries:

> *Aseptic meningitis; Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome; Erythema multiforme; Autism; Peripheral mononeuropathy; Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*[21]

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[17] http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf; https://www.ncbi.nlm.nih.gov/pubmed/26209838; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/

[18] Ibid.

[19] https://www.nap.edu/read/1815/chapter/2#7

[20] Ibid.

[21] Ibid.

The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines" and on the poor design of the few existing studies.[22] It therefore cautioned that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."[23]

In 1994, the IOM issued another report which examined the scientific literature for evidence that could either prove or disprove a causal link between 54 commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.[24] The IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.[25] The IOM, however, found the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> *Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*[26]

As in 1991, this IOM Report again stated, "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[27]

In 2011, more than fifteen years after the IOM Reports in 1991 and 1994, HHS paid the IOM to conduct another assessment regarding vaccine safety.[28] This third IOM Report reviewed the available science with regard to the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and rubella.[29] The IOM located science which "convincingly supports a causal relationship" with 14 of these injuries, including pneumonia, meningitis, hepatitis, MIBE, febrile seizures, and anaphylaxis.[30] The review found sufficient evidence to support "acceptance of a causal relationship" with 4 additional serious injuries.[31]

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

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[22] https://www.nap.edu/read/1815/chapter/2#8
[23] https://www.nap.edu/read/1815/chapter/9
[24] https://www.nap.edu/read/2138/chapter/2#12
[25] https://www.nap.edu/read/2138/chapter/2#12
[26] Ibid.
[27] https://www.nap.edu/read/2138/chapter/12
[28] https://www.nap.edu/read/13164/chapter/2#2
[29] Ibid.
[30] https://www.nap.edu/read/13164/chapter/2#3
[31] Ibid.

Encephalitis, Encephalopathy, Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia, Acute Disseminated Encephalomyelitis, Transverse Myelitis, Optic Neuritis, Neuromyelitis Optica, Multiple Sclerosis, Guillain-Barre Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, Brachial Neuritis, Amyotrophic Lateral Sclerosis, Small Fiber Neuropathy, Chronic Urticaria, Erythema Nodosum, Systemic Lupus Erythematosus, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia, Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura[32]

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence supported a causal relationship for 18 of them, rejected a causal relationship for 5 of them, but for the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found that the science simply had not been performed.[33]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) The first step in reducing adverse reactions is identifying what adverse reactions are caused by vaccine. Given this statutory obligation:

(5) For each of the 38 vaccine-injury pairs reviewed in the 1994 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

(6) For each of the 135 vaccine-injury pairs reviewed in the 2011 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

Further to your duties to identify what injuries are caused by vaccines, the 1986 Act also expressly requires you to "make or assure improvements in … the … recall of reactogenic lots or batches, of vaccines … in order to reduce the risks of adverse reactions to vaccines" and thus each "health care provider who administers a vaccine … shall record … in such person's permanent

[32] Ibid.

[33] Ibid.

medical record … the vaccine manufacturer and lot number." (42 U.S.C. §§ 300aa-25(a), 300aa-27(a)(2).) Since health care providers often fail to record this information:

> **(7) Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?**

V. Identifying Which Children are Susceptible to Vaccine Injury

The IOM has consistently acknowledged there is individual susceptibility to serious vaccine injuries. The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure. HHS, unfortunately, has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 report, stated: "The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."[34] The IOM urged that "research should be encouraged to elucidate the factors that put certain people at risk."[35]

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

> *Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact…*
>
> *Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine… much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.* [36]

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.[37] The IOM again explained that while "most children who experience an adverse reaction to immunization have preexisting susceptibility," the IOM:

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[34] https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9

[35] Ibid.

[36] https://www.nap.edu/read/13164/chapter/5#82

[37] https://www.nap.edu/read/13563/chapter/1

> *found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes.*[38]

HHS had failed to even define the terminology for the study of susceptible subpopulations and hence IOM admonished HHS to "develop a framework that clarifies and standardizes definitions of … populations that are potentially susceptible to adverse events."[39]

The IOM correctly points out in 2011 that given the "widespread use of vaccines" and "state mandates requiring vaccination of children … it is essential that safety concerns receive assiduous attention."[40] This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has never been conducted.

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

> **(8) Please advise when HHS intends to begin conducting research to identify which children are susceptible to serious vaccine injury? If HHS believes it has commenced this research, please detail its activities regarding same?**

VI. Removing Claim "Vaccines Do Not Cause Autism" from the CDC Website

HHS, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that "Vaccines Do Not Cause Autism" even though this broad claim is plainly not supported by the scientific literature.[41]

Indeed, as part of the IOM's 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.[42] The IOM could not locate a single study supporting

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[38] https://www.nap.edu/read/13563/chapter/9#130
[39] Ibid.
[40] https://www.nap.edu/read/13164/chapter/3#28
[41] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[42] https://www.nap.edu/read/13164/chapter/2#2

that DTaP does not cause autism.[43] The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[44] The IOM's full explanation in its 2011 Report for this finding is attached as Appendix B. In fact, the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.[45] No research has been published since 2011 that could change the IOM's conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that there is no causal relationship between vaccines and autism. The CDC nonetheless claims on its website that "Vaccines Do Not Cause Autism."

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive, typically multiple times, by one year of age.[46]

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.[47] Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC's pediatric vaccine schedule cannot support the CDC's overarching declaration that "Vaccines Do Not Cause Autism."

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson[48], recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.[49] Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."[50] Dr. Thompson further stated on that call:

> *I have great shame now when I meet families with kids with autism because I have been part of the problem … the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway*

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[43] https://www.nap.edu/read/13164/chapter/12#545
[44] Ibid.
[45] Ibid. Ironically, this study was disregarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which would be true of any study using VAERS data.
[46] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent. html
[47] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[48] Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC's vaccine safety claims. https://www.ncbi.nlm.nih.gov/pubmed
[49] http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf
[50] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

> *there's still a lot of shame with that. … I am completely ashamed of what I did.*[51]

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.[52]

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."[53] When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"[54]

Former NIH Director Dr. Healy goes on to explain:

> *This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. …*
>
> *The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*[55]

The CDC has also failed to address the science supporting a link between vaccines and autism.[56] For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.[57] Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated

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[51] Ibid.
[52] Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. https://doi.org/10.1093/oxfordjournals.aje.a116479
[53] http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/
[54] Ibid.
[55] Ibid.
[56] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[57] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf

children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.[58] There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.[59] Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. Without proper long-term trials comparing those receiving the vaccine to an inert-placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated with unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done. The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP vaccine, let alone the entire vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, are to "develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table." (42 U.S.C. § 300aa-26(a).) This section further provides that:

> The information in such materials shall be based on available data and information … and shall include … (1) a concise description of the benefits of the vaccine, (2) a concise description of the risks associated with the vaccine, (3) a statement of the availability of the National Vaccine Injury Compensation Program, and (4) such other relevant information as may be determined by the Secretary.

(42 U.S.C. § 300aa-26(c).) The VIS produced for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, www.cdc.gov.[60] The CDC website in turn claims that "Vaccines Do Not Cause Autism."[61] Since HHS has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must be "based on available data and information." *Id.* But, based on available data and information, as highlighted by the IOM, HHS cannot validly claim that "Vaccines Do Not Cause Autism." Hence:

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[58] http://www.oatext.com/pdf/JTS-3-186.pdf; http://www.oatext.com/pdf/JTS-3-187.pdf
[59] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf
[60] https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
[61] https://www.cdc.gov/vaccinesafety/concerns/autism.html

(9) Please confirm that HHS shall forthwith remove the claim that "Vaccines Do Not Cause Autism" from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?

VII. Refusal to Conduct Vaccinated Versus Unvaccinated Study

The only scientifically valid way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered and controlled study comparing the rate of all adverse events between vaccinated children and completely unvaccinated children. This is the same type of study required by HHS for every drug pre-licensure. HHS has nonetheless refused to conduct any such study, even retrospectively.

The need for this study is highlighted by the results of a few recent limited vaccinated vs. unvaccinated studies.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.[62] In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.[63] Dr. Aaby's study therefore concluded that: "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[64] More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[65] This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[66]

It is equally troubling that Dr. Abby's study was based on data that had been collecting dust for over 30 years[67] This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science.

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.[68] The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk

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[62] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D

[63] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ Dr. Aaby's study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby's study was one of the few specifically designed to avoid this error.

[64] Ibid.

[65] Ibid.

[66] Ibid.

[67] Ibid.

[68] http://www.oatext.com/pdf/JTS-3-186.pdf

of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.[69] Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.[70]

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.[71] Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.[72] Like the DTP study, the flu vaccine increased susceptibility to other infections.

A properly sized vaccinated versus unvaccinated study is necessary and possible. As stated by the IOM in 2013: "It is possible to make this comparison through analyses of patient information contained in large databases such as VSD."[73] Senior CDC Scientist, Dr. Thompson similarly stated this type of study can and "needs to be done" but that the CDC is "not doing what they should be doing because they're afraid to look for things that might be associated."[74] When vaccine makers are generating over $33 billion in vaccine revenue annually and the CDC is spending over $5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.[75]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Since comparing children receiving the vaccines recommended by the CDC with those that have not received any vaccines is the only scientifically valid way to assess the safety of the CDC's vaccine schedule:

> **(10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of**

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[69] Ibid.

[70] http://www.oatext.com/pdf/JTS-3-187.pdf

[71] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/

[72] Ibid. *See also* http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf (The CDC in 2001 apparently conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not. The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays. Note that while the abstract discusses comparing thimerosal exposure, since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study appears to have primarily compared children receiving Hepatitis B with children that did not receive this vaccine.)

[73] https://www.nap.edu/read/13563/chapter/2#13

[74] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

[75] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf; https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html

fully/partially vaccinated children with completely unvaccinated children?

VIII. Reducing Conflicts of Interest at HHS

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS. The 1986 Act's scheme thus places HHS in charge of two competing duties. On one hand, HHS is responsible for vaccine safety. On the other hand, HHS is required to promote vaccine uptake and defend against any claim they cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense function to such a degree that it has essentially abandoned its vaccine safety function. To restore balance, HHS must take serious steps to create an "ethics firewall" between these competing functions. HHS also must take action with regard to its vaccine committee members and employees that have conflicts with vaccine makers.

HHS Licenses & Recommends Vaccines. With regard to the FDA's Vaccines and Related Biological Products Advisory Committee (**VRBPAC**), which effectively decides whether to license a vaccine, in 2000 the U.S. House Committee on Government Reform (the **Committee**) "determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."[76] The Committee concluded of the VRBPAC: "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."[77]

With regard to the CDC's Advisory Committee on Immunization Practices (**ACIP**), which effectively decides whether to universally recommend a pediatric vaccine, the Committee found that ACIP members routinely fail to disclose conflicts with vaccine makers and when conflicts are disclosed "[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts."[78] The Committee drew focus on the vaccine most recently approved by the ACIP and found extensive and troubling conflicts of interest for most the ACIP members voting to recommend its universal use for children.[79] The Committee was further concerned that "ACIP liaison representatives have numerous ties to

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[76] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf (For instance, "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had significant financial ties to pharmaceutical companies that were developing different versions of the vaccine.")

[77] Ibid.

[78] Ibid.

[79] Ibid. (The Committee's findings were that: (1) The chairman served on Merck's Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a $350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division, a principal investigator for SmithKline and received funds from various vaccine makers; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.)

vaccine manufacturers" but act like voting members of ACIP.[80] The Committee further took issue with the extensive conflicts of interests of members of ACIP's working groups which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.[81] The Committee concluded that ACIP reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[82]

Despite the concerns the Committee expressed in its 2000 report, not much changed. A December 2009 report by the HHS Office of Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for SGEs [a.k.a. **committee members**]".[83] For example, "Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."[84]

In fact, the Inspector General found that the "CDC certified [conflict disclosure forms] with at least one omission in 2007 for 97 percent … of SGEs," "58 percent … of SGEs had at least one potential conflict of interest that CDC did not identify," and when the CDC identified a conflict, it improperly granted broad waivers despite being castigated for this improper practice in 2000.[85] Even worse, "32 percent … of SGEs … had at least one potential conflict of interest that CDC identified but did not resolve" and 13 percent of SGEs were allowed to participate in committee meetings without even having a conflict disclosure form on file.[86]

As the system is set up, an ACIP vote to recommend a vaccine, grants a vaccine manufacturer a liability-free market of 78 million American children, who are legally compelled to receive the vaccine, and billions of taxpayer dollars guaranteeing payment. In such a system, an ACIP vote must be completely insulated from any influence by the vaccine manufacturer. Instead, the opposite appears to be the norm.

HHS Promotes Vaccines. Moreover, while the CDC states on its website -- not less than 130 times -- that "CDC does not accept commercial support," this is simply not true.[87] For example, the British Medical Journal reported in 2015 that: "Despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."[88] As another example, pharmaceutical companies and other private entities, through the "CDC Foundation," can create and fund programs at the CDC (over half a billion dollars' worth to-date), endow positions at the

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[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[84] http://www.nytimes.com/2009/12/18/health/policy/18cdc.html
[85] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf (Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.)
[86] Ibid.
[87] https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main
[88] http://www.bmj.com/content/350/bmj.h2362

CDC, and even place individuals to work at the CDC, paid through "private funding." (42 U.S.C.A. § 280e-11(h)(1), (2).)

Worse, the promotion track for CDC management extends into vaccine makers. The most prominent example is former CDC Director Dr. Julie Gerberding, who headed the agency from 2002 through 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported $2.5 million annual salary and lucrative stock options.[89]

HHS Defends Vaccines. After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with very limited safety data, this very same government agency is mandated to defend against any claim that the vaccine caused harm.

There is no other for-profit product where the very department responsible for regulating that product is statutorily required to promote its uptake and simultaneously defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury. (42 U.S.C. § 300aa-10 *et seq.*)[90] The injured must litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury. (§ 300aa-12.) DOJ and HHS have the government's vast resources, while the injured child must secure a private attorney. (§ 300aa-15.) Moreover, the injured child's damages are limited to $250,000 for death and pain and suffering. (*Id.*)

Worst of all, the injured child must almost always prove "causation" – the biological mechanism by which the vaccine injured the child.[91] Requiring an injured child to prove causation adds insult to injury because had HHS conducted the vaccine safety science it demands as proof in the VICP before licensing a vaccine, the child's injury may have been avoided altogether.

This truly is the epitome of injustice: requiring a child receiving a compulsory pharmaceutical product to medically prove to HHS how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government department, HHS, tasked with this job.[92] As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.[93] It has failed to conduct even one properly sized study comparing vaccinated to

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[89] https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884

[90] *See also* Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

[91] http://www.gao.gov/assets/670/667136.pdf

[92] See Sections II, III, IV, V, VI, and VII above.

[93] See Section IV above.

unvaccinated children, despite all the resources at its disposal.[94] It is no wonder a single injured child's claim faces a high likelihood of failure in the VICP.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief an insidious intent. Rather, this system eliminates the incentive, and in fact creates a disincentive for HHS and vaccine makers, to conduct research to uncover long term chronic conditions, including the immune and neurological system disorders, which can result from the current vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, have at least equal and arguably greater responsibility for vaccine safety than for vaccine promotion. (42 U.S.C. §§ 300aa-2, 300aa-27.) In accordance with this statutory responsibility:

(11) Please advise if you will:

a. prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?
b. prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?
c. require that vaccine safety advocates comprise half of HHS's vaccine committees?
d. allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?
e. support the creation of a vaccine safety department independent of HHS?
f. support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?

IX. Conclusion

HHS can do better. With hundreds of vaccines in the pipeline it must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will in fact strengthen the vaccine program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to HHS's vaccine program due to safety concerns.

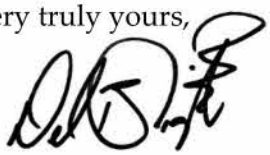
[94] See Section VII above.

Unless HHS performs its vital statutory obligations regarding vaccine safety, and until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injuries. Nor will children injured by vaccines be able to access the services they need. We can do far better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination. The first step in avoiding these harms and helping children already harmed is admitting there are deficiencies and working diligently to improve vaccine safety.

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. These, in fact, reflect nothing more than what Congress already explicitly recognized when passing the 1986 Act: vaccines can and do cause serious injury and HHS needs to work diligently to identify and reduce these harms. If you would like to meet and discuss the foregoing, we would welcome that opportunity and hope to work cooperatively to address these issues.

If that is not possible, Congress, as a final resort to assure vaccine safety, authorized a "civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under" the 1986 Act. (42 U.S.C. § 300aa-31(a).) We are prepared to authorize such an action and this letter constitutes the notice required by 42 U.S.C. § 300aa-31(b). It is, however, our hope that the vaccine safety issues identified herein can be resolved cooperatively, with all interested parties working together toward the common goal of vaccine safety entrusted to HHS under the 1986 Act.

Very truly yours,



Del Bigtree

cc: See Appendix A.
Enclosures: Appendices A to C.

Appendix A

A Voice For Choice
A Voice For Choice Advocacy
Christina Hildebrand, President
530 Showers Drive, Suite 7404
Mountain View, CA 94040

Alliance For Natural Health
Gretchen DuBeau, President
3525 Piedmont Road NE B6-310
Atlanta, GA 30305

Arizona Coalition Against Mandated Vaccines
Kelsey Davis, President
Gilbert, AZ 85212

Autism Action Network
John Gilmore, President
550 East Chester Street
Long Beach, NY 11561

Autism Giving Tree
Christina Stafford, M.Ed., BCBA, LBS, President
660 'W' Street
King of Prussia, PA 19406

AutismOne
Ed Arranga, President
1816 West Houston Avenue
Fullerton, CA 92833

The Canary Party
Jennifer Larson, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Colorado Coalition for Vaccine Choice
Fran Sincere, President
125 S. Zephyr
Lakewood, CO 80226

DAIR Foundation
Dawn Loughborough, President
10200 US HWY 290 West
Austin, TX 78736

Elizabeth Birt Center for Autism Law and Advocacy
Kim Mack Rosenberg, President
200 Cabrini Boulevard, Suite 66
New York, NY 10033

Enriched Parenting
Rebecca Fleischman, President
1208 Avenue M, Suite 2323
Brooklyn, NY 11230

Focus for Health Foundation
Shannon Mulvihill, R.N., Executive Director
776 Mountain Boulevard, Suite 202
Watchung, NJ 07069

Georgia Coalition for Vaccine Choice
Sandi Marcus, Founder/CEO
P.O. Box 45
Silver Creek, GA 30173

Health Choice
Mark Blaxil, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Health Choice Massachusetts
Candice Edwards, President
P.O. Box 175
Manchaug, MA 01526

Health Choice Maryland
Emily Tarsell, President
1501 Sulgrave Avenue, Suite 208
Baltimore, MD 21209

Health Choice Connecticut
Dr. Elissa Diamond Fields, President
P.O. Box 29
Roxbury, CT 06783

Health Freedom Florida
Dr. Ryan Fenn & MacKenzie Fraser, Co-Presidents
153 Ivernia Loop
Tallahassee, FL 32312

Health Freedom Idaho
Miste Gardner Karlfeldt, President
1045 S Ancona Ave Ste 140
Eagle, ID 83616

Healthcare Freedom Hawaii
Jessica McCormick &
Natasha Sky, Co-Directors
Mililani, HI 96789

Illinois Coalition for Informed Consent
Jen Suter &
Danielle Olson, Co-Directors
Jacksonville, IL 62650

Indiana for Medical Freedom
Melissa Sura, President
5424 Grapevine Drive
Indianapolis, IN 46235

Informed Choice Washington
Jena Dalpez, President
14106 93rd Avenue NE
Kirkland, WA 98034

Kentucky Vaccine Rights Coalition
Jennifer Benge & Ashley Kennedy, Co-Presidents
899 Corinth Road
Corbin, KY 40701

Know The Vax
Angela Gallagher, President
4553 Aldrich Avenue North
Minneapolis, MN 55412

Learn the Risk
Brandy Vaughan, President
3463 State Street, Suite 182
Santa Barbara, CA 93105

Louisiana Parents for Vaccine Rights
Melisha Dooley &
Sunny Dixon, Co-Directors
413 Toby Lane
Metairie, LA 70003

Maine Coalition for Vaccine Choice
Ginger Taylor, Director
11 High Street
Brunswick, ME 04011

March Against Monsanto
Tami Canal, President
7878 South 1960 East
South Weber, UT 84405

Michigan for Vaccine Choice
Suzanne M. Waltman, President
22615 Francis Street
St. Clair Shores, MI 48082

Minnesota Natural Health Coalition
Lee Beaty, President
1043 Grand Ave, Suite 317
St. Paul MN 55105

Minnesota Natural Health Legal Reform Project
Leo Cashman, President
1043 Grand Ave, Suite 317
St. Paul, MN 55105

Minnesota Vaccine Freedom Coalition
Angela Gallagher, President
4553 Aldrich Avenue North
Minneapolis, MN 55412

Mississippi Parents for Vaccine Rights
MaryJo Perry, President
P.O. Box 141
Pelahatchie, MS 39145

Missouri Parents Against Vaccines
Janessa Baake & Kendal Bourne, Co-Presidents
323 N. Fox Ridge Drive, Suite 204
Raymore, MO 64083

Moms Across America
Zen Honeycutt, President
24000 Alicia Parkway, Suite 17-236
Mission Viejo, CA 92691

Montanans For Medical Freedom
Edna Kent, Director
PO Box 1443
Florence, MT 59833

My Kids, My Choice
Rita Palma, President
2 Purdy Avenue
Baypoint, NY 11705

National Health Freedom Action
Jerri Johnson, President
PMB 218, 2136 Ford Parkway
St. Paul, MN 55116

National Health Freedom Coalition
Roseanne Lindsay, President
PMB 218, 2136 Ford Parkway
St. Paul, MN 55116

New York Alliance for Vaccine Rights
Aimee Villella McBride & Maria Gavriel, Co-Presidents
550 East Chester Street
Long Beach, NY 11561

Ohio Advocates for Medical Freedom
Robert M. Wise, President
P.O. Box 1236
Hartville, OH 44632

Oklahomans for Vaccine and Health Choice
Liza Greve, President
P.O. Box 721356
Norman, OK 73070

Organic Consumers Association
Ronnie Cummins, CEO
6771 South Silver Hill Dr.
Finland, MN 55603

Parents United 4 Kids
Stefanie Fetzer & Shawna Lambert, Co-Presidents
2925 Bonanza
San Clemente, CA 92673

People Advocating Vaccine Education, Inc.
Lisa Jillani, CEO
P.O. Box 690712
Charlotte, NC 28227

Physicians for Informed Consent
Dr. Shira Miller, Executive Director
13749 Riverside Drive
Sherman Oaks, CA 91423

Rogue Recovery
Tyler Dahm, President
3221 West 96th Avenue
Westminster, CO 80031

South Carolina Health Coalition
Jennifer Black & Rebekah Watson, Co-Presidents
1754 Woodruff Road, Suite 112
Greenville, SC 29607

Spectrum Revolution
Catharine Layton, President
357 S. Earlham Street
Orange, CA 92869

Tennessee Coalition for Vaccine Choice
Kristen Odom-Holland, President
P.O. Box 4508
Chattanooga, TN 37405

Vaccine Injury Awareness League
Michelle Ford, President
10866 Washington Blvd, Suite 65
Culver City, CA 90232

Vaccine Safety Council Minnesota
Patti Carroll, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Vermont Coalition for Vaccine Choice
Jennifer Stella, President
P.O. Box 74
Waitsfield, VT 05673

Virginians for Health Freedom
Deborah Hommer, President
P.O. Box 2015
Spotsylvania, VA 22553

West Virginians for Health Freedom
Dr. Chanda Adkins, Director
108 Yorktown Court
Beckley, WV 25801

Weston A. Price Foundation
Sally Fallon Morell, President
PMB 106-380, 4200 Wisconsin Avenue NW
Washington, D.C., 20016

World Mercury Project
Robert F. Kennedy, Jr., Chairman
1227 North Peachtree Parkway, Suite 202
Peachtree City, GA 3026

Appendix B

Adverse Effects of Vaccines

Evidence and Causality

Committee to Review Adverse Effects of Vaccines
Board on Population Health and Public Health Practice
Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,
Editors

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

Mechanistic Evidence

The committee identified one publication reporting the development of ataxia after the administration of DTaP vaccine. Kubota and Takahashi (2008) did not provide evidence of causality beyond a temporal relationship of 2 days between vaccine administration and development of cerebellar symptoms leading to a diagnosis of acute cerebellar ataxia. The publication did not contribute to the weight of mechanistic evidence.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia as lacking.

Causality Conclusion

Conclusion 10.5: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

ACUTE DISSEMINATED ENCEPHALOMYELITIS

Epidemiologic Evidence

No studies were identified in the literature for the committee to evaluate the risk of acute disseminated encephalomyelitis (ADEM) after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, or acellular pertussis antigens alone or in combination.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and ADEM.

Mechanistic Evidence

The committee identified five publications of ADEM developing after the administration of vaccines containing diphtheria toxoid and tetanus toxoid antigens alone or in combination. Four publications did not provide evidence beyond temporality, one of which was deemed too short based on the possible mechanisms involved (Abdul-Ghaffar and Achar, 1994; Bolukbasi and Ozmenoglu, 1999; Hamidon and Raymond, 2003; Rogalewski et al., 2007). In addition, Rogalewski et al. (2007) reported the administration of vaccines against hepatitis B, hepatitis A, and poliovirus in

Appendix C

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Faculty of Medicine
Department of Ophthalmology
& Visual Sciences
Shaw Laboratory
828 West 10th Avenue, Room 386
Vancouver, BC Canada V5Z 1L8

Phone 604 875 4111 Local 68375
Fax 604 875 4376
www.neuraldynamicsubc.ca

June 24, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am writing to you in regard to aluminum adjuvants in vaccines. This subject is one my laboratory works on intensively and therefore one where I feel that I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder (ASD). Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

These studies and the broader existing literature regarding aluminum toxicity, lead almost invariably to the conclusion that aluminum in any chemical form is always neurotoxic when administered to humans. Further, I am convinced that aluminum adjuvants in vaccines may contribute to neurological disorders across the lifespan. In adults, such adjuvant may induce macrophagic myofasciitis, a disease with neuropathological aspects. In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans even though, pursuant to the recommended vaccine schedule published by the Centers for Disease Control (CDC), a baby may be injected with up to 3,675 micrograms of aluminum adjuvant by six months of age.

In regard to the above, it is my belief that the CDC's claim on its website that "Vaccines Do Not Cause Autism" is wholly unsupported. Given this, I remain convinced that much more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is warranted and should be a research priority for the NIH and other funding bodies.

Yours sincerely,

Christopher A. Shaw, Ph.D
Professor
Dept. of Ophthalmology and Visual Sciences
University of British Columbia
828 W. 10th Ave.
Vancouver, British Columbia
Canada, V5Z1M9
Tel: 604-875-4111 (ext. 68373)
Email: cashawlab@gmail.com

Relevant Publications (Shaw Laboratory)

1. Crepeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, giros B, authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective dose neurotoxicity. *Toxicology*. 375:48-57. (2016).

2. Crepeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *J. Inorg. Biochem*. 152:199-205. (2015).

3. Shaw CA, Li D, Tomljenovic L. Are there negative CNS impacts of aluminum adjuvants in vaccines and immunotherapy? *Immunotherapy*. 6 (10):1055-1071. (2014).

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5. Shaw CA, Kette SD, Davidson RM, Seneff S. Aluminum's role in CNS-immune system interactions leading to neurological disorders. *Immunome Res*. 9:1.

6. Shaw CA, Marler TE. Aluminum and the human diet revisited. In: Communicative & Integrative Biology; *Landes Bioscience*. 6:e26369. (2013).

7. Shaw CA, Tomljenovic L. Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity. *Immunol Res*. (2013).

8. Shaw CA, Li Y, Tomljenovic L. Administration of aluminum to neonatal mice in vaccine in vaccine-relevant amounts is associated with adverse long term neurological outcomes. *J Inorg Chem*. (2013).

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13. Shaw CA and Petrik MS. Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration. *J Inorganic Biochem*. 103 (11): 1555-62. (2009).

14. Petrik MS, Wong MC, Tabata RC, Garry RF, and Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *J Neuromolecular Medicine*. 9: 83-100. (2007).

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de recherche biomédicale

UNIVERSITÉ
PARIS-EST

June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants toxicity in humans and animal models. I have been working in this field since the initial description of the AI vaccine-induced macrophagic myofasciitis in 1998. Since that time I have written 40 peer-reviewed scientific publications and one book on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours very sincerely

Romain K. Gherardi
Professor, Neuromuscular Pathology Expert Centre
University Paris-Est, INSERM U955-E10,
Henri Mondor hospital, Créteil France
Contact at the hospital
Tel 00 (33) 1 49812746
romain.gherardi@hmn.aphp.fr

UMR U955 INSERM / UPEC

Team 10
« Biology of the neuromuscular system»

Fred Relaix, director
FrançoisJérome Authier, co-director

Romain Gherardi, former director
Tél. +33 (0)1 49 81 27 42
Fax. +33 (0)1 49 81 27 33
romain .gherardi@inserm.fr

Inserm U955 - Faculté de Médecine
8, rue du Général Sarrail 94010 Créteil Cedex
institutmondor@inserm.fr

Selection of significant publications from our group in the field

Gherardi R. Toxic Story: deux ou trois vérités embarrassantes sur les adjuvants des vaccins. **Actes Sud** (publisher), Paris, 2016, 250 pages

Crépeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, Giros B, Authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. **Toxicology**. 2017 Jan 15;375:48-57.

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Tel: 01782 734080
Fax: 01782 712378
e-mail: c.exley@keele.ac.uk
http://www.keele.ac.uk/aluminium

June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
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Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
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Re: *Aluminum Adjuvants*

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I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours faithfully

Christopher Exley PhD
Professor in Bioinorganic Chemistry

Honorary Professor, University of the Highlands and Islands

List of Recent, Relevant and Significant Publications From Our Group

Exley C, Siesjö P & Eriksson H (2010) The immunobiology of aluminium adjuvants: how do they really work? Trends in Immunology 31, 103-109.

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Mirza A, King A, Troakes C and Exley C (2016) The identification of aluminium in human brain tissue using lumogallion and fluorescence microscopy. Journal of Alzheimer's Disease 54, 1333-1338.

Mold M, Shardlow E and Exley C (2016) Insight into the cellular fate and toxicity of aluminium adjuvants used in clinically-approved human vaccinations. Scientific Reports 6:31578.

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Shardlow E, Mold M and Exley C (2017) From stock bottle to vaccine: Elucidating the particle size distributions of aluminium adjuvants using dynamic light scattering. Frontiers in Chemistry 4, 48.

Exley C (2017) Aluminium should now be considered a primary aetiological factor in Alzheimer's disease. Journal of Alzheimer's Disease Reports 1, 23-25.

Telephone number +44 (01782) 584211
Fax +44 (01782) 712378

Keele University, Staffordshire, ST5 5BG United Kingdom
Telephone number +44 (01782) 621111 http://www.keele.ac.uk

From: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 19 Jul 2019 16:04:46 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Vaughn, William (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: FW: kennedy

You might be interested in this little debate on if or how to respond to various vaccine safety allegations.

Frank DeStefano, MD, MPH

From: Heidi Larson <Heidi.Larson@LSHTM.ac.uk>
Sent: Thursday, July 18, 2019 9:29 AM
To: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; 'Offit, Paul' <OFFIT@email.chop.edu>
Subject: RE: kennedy

I would agree with Stan that we should make the accurate information available (as Kennedy and Bigtree's followings will undoubtedly be provoked to search for these answers/other evidence on line …) BUT, I would not necessarily frame the information as a direct responses to Kennedy, but make sure there are accessible, accurate answers for those who start searching for them online..
Best, Heidi

From: Stanley Plotkin [mailto:stanley.plotkin@vaxconsult.com]
Sent: 16 July 2019 20:01
To: 'Stanley Plotkin' <stanley.plotkin@vaxconsult.com>
Cc: 'Destefano, Frank (CDC/DDID/NCEZID/DHQP)' <fxd1@cdc.gov>; 'Offit, Paul' <OFFIT@email.chop.edu>; Heidi Larson <Heidi.Larson@LSHTM.ac.uk>
Subject: RE: kennedy

On reflection, I think this issue is a key one. Should responsible authorities address critics like Kennedy or not? I contend that silence by responsible authorities is surrender and admission of guilt. What do you all think? This is not a theoretical issue.
Stan

From: Stanley Plotkin [mailto:stanley.plotkin@vaxconsult.com]
Sent: Tuesday, July 16, 2019 9:20 AM
To: 'Markowitz, Lauri (CDC/DDID/NCIRD/DVD)'
Cc: 'Destefano, Frank (CDC/DDID/NCEZID/DHQP)'; 'Offit, Paul'
Subject: RE: kennedy

That may work, on the condition that each of the 25 accusations are countered. My opinion, for what it's worth, is that CDC can no longer ignore people like Kennedy and Wakefield with the hope that they will not be listened to.
Stanley

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) [mailto:lem2@cdc.gov]
Sent: Monday, July 15, 2019 3:00 PM
To: Stanley Plotkin
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Subject: RE: kennedy

Dear Stanley,

We are working with ISO and the CDC communications teams to update the HPV vaccine safety page for clinicians. CDC prefers to highlight credible information and resources rather than directly addressing each source of misinformation, because that can draw more attention to the misinformation, website or media. We can send you the link to the updated CDC pages when they are done.

Lauri

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Monday, July 15, 2019 12:34 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
Subject: kennedy

Dear Laurie:

On the Kennedy website he has an article giving 25 reasons for not taking Gardasil. Have you thought of preparing a response to that article?

Regards,

Stanley

From: Messonnier, Nancy (CDC/OID/NCIRD)
Sent: Wed, 15 Feb 2017 20:32:02 +0000
To: Cohn, Amanda (CDC/OID/NCIRD)
Subject: FW: MEDIA MONITORING - February 15, 2017

How about this one?
http://www.healio.com/pediatrics/vaccine-preventable-diseases/news/online/%7Bd42df4cf-1764-427c-baab-978eb5a63901%7D/concomitant-administration-of-menveo-other-vaccines-linked-to-bells-palsy

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From: NCIRD Media Monitoring (CDC)
Sent: Wednesday, February 15, 2017 2:14 PM
To: NCIRD Media Monitoring (CDC) <ncirdmediamonitoring@cdc.gov>
Subject: MEDIA MONITORING - February 15, 2017

INTERNAL MEDIA MONITORING BULLETIN Wednesday, February 15, 2017

Contents

Other. 4

Vaccines & Immunizations

AAFP Joins Other Groups in Touting **Vaccines**' Safety, Efficacy AAFP News

7 letter(28 page PDF) to President Donald Trump that emphasized the safety and efficacy of **vaccines**, and called for greater effort to educate the ...

2017 update to the immunization schedule for kids Harvard Health (blog)

... dose of **Hepatitis B** vaccine within the first 24 hours of life, if possible, to give the best protection in case of an undiscovered infection in the mother.

What Vaccinations Do Women Need Before Getting Pregnant? The CDC Has Tips For A Healthy ... Romper

Additionally, if you didn't have **chickenpox** as a child you may need the varicella vaccine if you are not immune to the extremely contagious disease.

Americans Still Skipping Out on Helpful **Vaccines** Healthline

CDC officials released new guidelines for **vaccinations** while they note a significant percentage of U.S. adults are not getting recommended ...

Are There Certain **Vaccines** Adults Can Skip? New Guidelines Eliminate Some Options - Romper

Oregon Students Have Until Feb. 15 To Be Vaccinated KUOW News and Information

Parents are allowed to seek **immunization** waivers if their children have health concerns, or if they have personal or religious objections to vaccines.

The Ector County Health Department looks to social media to get West Texans their **immunizations** CBS7 News (press release)

Gino Solla, the director of the Ector County Health Department, says this is their way to educate the public about the facts of **immunizations**. Solla also ...

Parent consent warning as high school students miss **vaccines** The Mercury

TOO many high school children are missing out on vital **vaccines** due to an outdated and unreliable process for obtaining parental consent, ...

Gaps in world-class school **vaccination** program need to be closed, Immunisation Coalition says - Bellingen Courier Sun

Wed 9 AM | The Work It Takes To Create A Vaccine Jefferson Public Radio

Scientists worked for decades to find a vaccine for **rubella**, finally succeeding in the late 60s. This is the story told in Meredith Wadman's book The ...

Lakeland Health First Michigan Hospital to Query **Immunization** Records Directly through EMR Healthcare Informatics

In 1996, the Michigan Legislature established a “childhood **immunization** registry” to be used as a comprehensive central repository for all children's ...

Bill and Melinda Gates make the case for **vaccines** — and US engagement in global health
STAT
The letter stresses the importance of **vaccines**, calling them one of the best deals in global health spending. It also emphasizes how critical it is that ...

Gates Foundation, India Cut Ties On **Immunization** iTech Post
The **Immunization** Technical Support Unit (ITSU) has long been funded by the Gates Foundation. This organization provides **immunization** programs ...

ICA Goes on the **Vaccine** Offensive Dynamic Chiropractic
Have you watched the **vaccination** documentary, "Vaxxed: From Cover-Up to Catastrophe," by Andrew Wakefield MD, director, and Del Bigtree, ...

"Complacency is the enemy of **vaccination**" Salon
Although most medical institutions around the world agree on the safety and efficacy of approved **vaccines**, concerns regarding them remain.

The looming battle against anti-vaxxers The Week Magazine
They're signing petitions, contacting lawmakers, and sharing personal stories about the importance of **vaccines** to counter their opponents' emotional ...

Religious **vaccine** exemptions on the rise in NJ Vineland Daily Journal
ATLANTIC CITY - More parents in New Jersey are choosing religious exemptions for child **vaccinations**, resulting in a steady increase in unvaccinated ...

Italy's Vaccination Rates Raise Government's Concern Wall Street Journal
The country's 2015 **immunization** rates were the lowest in Western Europe, WHO figures show, roughly on par with those in Serbia and Romania.

Future of Global Travel **Vaccines** Market : 2015 – 2021 Medgadget (blog)
Health related complications are greater in developing countries and rural areas because of dissimilarities in sanitary conditions, available food and ...

Global Travel Vaccines Market to Reach US$2224 mn by 2019 owing to Increasing Uptake of ...
openPR (press release)
"The Report Travel Vaccines Market to 2019 - Hepatitis A, Japanese Encephalitis and **Meningococcal** Vaccine Segments to Drive Growth provides ...

STRIVE Ebola Vaccine Trial

Ebola 'super-spreaders' cause most cases BBC News
The study looked at cases in and around the capital of **Sierra Leone**, ... The study may also feed into plans to prepare a stockpile of **Ebola vaccine**.

Flu

Deadly **flu** strain sweeps the US killing five children with a little girl, 6, the latest to die The Sun
The virus began as one of the most common **flu** strains but morphed into a rare autoimmune disease that caused her own body to attack her brain.

Girl's flu death spurs questions about **vaccines** Tribune-Review
The flu-related death of a Washington County girl last week has put the spotlight on flu **vaccines** as this season's outbreak is peaking. It remains ...
Pa. girl, 10, dies of the **flu**, raising questions - PennLive.com
First Flu-Related Death In Sussex County Senior; Cases Among Children And Youth Surging - news.delaware.gov

Flu claims fourth child in Ohio MyDaytonDailyNews
Four children have died in Ohio in the past two weeks from **flu**-like symptoms and **flu**-related hospitalizations continue to rise throughout the Miami ...

Child flu-related deaths reported in Ohio Marion Star
The best way to prevent getting sick with the flu, is to be vaccinated and only injectable flu **vaccines** are recommended this year per Centers for ...

Pediatric flu deaths reported Portsmouth Daily Times
According to the Ohio Department of Health (ODH), there is an increase in flu activity across Ohio, including four confirmed pediatric **influenza** ...

Influenza widespread in 43 states, 5 more fatal cases in children Pharmacy Today, American Pharmacists Association, pharmacist.com
CDC reported Friday a significant increase in U.S. **influenza** activity in the previous week. According to CDC's **influenza** map, **influenza** is now ...
CDC Flu Update: **Influenza** A Viruses Continue to Predominate - Infection Control Today

CDC: Flu cases spiking across the United States kttn
"It would have been better to get **vaccinated** in October, and you may want to think about that next year, but you can still get **vaccinated** and see benefit ...

Flu Is Widespread in at Least 43 States LifeZette
It's not too late to get your **flu** shot. And you may want it this year — for real. The **flu** is now widespread in at least 43 states and several U.S. territories, ...

Flu widespread in Central Texas KWTX
WACO, Texas (KWTX) - The CDC reports **flu** season is on the rise all across ... Newman said it's important to get a **flu** shot and not try to wait out the ...

At least 9 Texas schools have closed due to flu outbreaks this month mySanAntonio.com
The release said, "the percentage of specimens testing positive for **influenza** reported by hospital, public health laboratories and patient visits due to ...

Flu Grips Central Illinois CIproud.com
NORMAL - **Flu** season is in full swing and local hospitals are seeing more patients showing **flu**-like symptoms. There's been a spike in **flu** cases in the ...

Pennsylvania **flu** cases keep climbing Reading Eagle

Pennsylvania saw an increase in positive **flu** reports last week, according to the latest report from the state Department of Health. There were nearly ...

Increase in **Flu** Cases Around SA 550 KTSA

"It takes about two weeks for the vaccine to take effect in your body… but, **flu** season runs from October to May… so we're just in the middle of it" ...

Metro Health: **Flu** cases increasing in SA - KSAT San Antonio

DHEC: South Carolina reports widespread flu activity WMBF

According to the most recent information from the S.C. Department of Health and Environmental Control, a total of 5,199 **influenza** cases were reported ...

Flu cases high, widespread in SC - WBTW - Myrtle Beach and Florence SC

"Widespread" **flu** season affects hundreds of Alaskans KTUU.com

ANCHORAGE (KTUU) - With 440 confirmed influenza cases in January, the Alaska Division of Public Health is monitoring the annual **flu** epidemic ...

North Iowans continue to be hammered by the **flu** KCHA News

Mercy Medical Center Public Relations Director Jenny Monteith says the worst strain is not the stomach **flu** but upper respiratory infection. However ...

Franklin County school shuts down for days due to the **flu** ABC6OnYourSide.com

Madison Christian School is closed through at least Thursdaybecause so many students and teachers have come down with the **flu**. (WSYX/WTTE).

Flu outbreak closes Groveport school for three days - NBC4i.com

Flu season's not over yet: Doctors say vaccine is your best defense WKBN.com

YOUNGSTOWN, Ohio (WKBN) – As the annual **flu** season is just now starting to peak, local doctors said it's not too late to get a **flu** shot to protect ...

Reduced Immune Response After Intradermal Flu Shot in Eczema Doctors Lounge

The researchers found that seroprotection rates for **influenza** B, H1N1, and H3N2 did not differ between participants with AD and non-atopic ...

Eczema May Deter Effectiveness Of Flu **Vaccines** SFGate

To be specific if you suffer from Eczema it is suggested that you request the **vaccine** be given into the muscle, rather than just under the skin.

Eczema may leave some flu shots less effective, study finds - UPI.com

Eczema May Leave Some Flu Shots Less Effective, Study Finds - WebMD

Fist bump, not handshake, during **flu** season wwlp.com

DAYTON, Ohio (WDTN) – A nurse and infectious disease expert from Greene County Public Health, said to help prevent the spread of germs during **flu** ...

Flu **Vaccines** and Egg Allergies NBC2 News

Dr. Pierre Loredo, a pediatrician with Lee Health, says the flu **vaccine** is the safest way to protect your child from getting the flu. "The flu virus is ...

New website Communidy tracks real-time **flu** trends near you ABC15 Arizona
Realizing that people are turning to technology more to keep tabs on their health, a new website is launching in Phoenix to help track **flu** trends.

H1N1 **vaccine** out of stock in CMCH as flu spreads The New Indian Express
COIMBATORE, TIRUCHY, PUDUCHERRY : The Coimbatore Medical College Hospital (CMCH) currently does not have any swine flu **vaccines** ...

China death toll from bird **flu** surges to 79 people in January Reuters
A quarantine researcher checks on a chicken at a poultry farm in Xiangyang, Hubei province, China, February 3, 2017. Picture taken February 3, 2017.
China death toll from bird **flu** soars to 79 in January - South China Morning Post

Wales introduces new avian **influenza** Prevention Zone in place until 30 April FarmingUK
The Cabinet Secretary said: "My decision to put in place a new Avian **Influenza** Prevention Zone until 30 April is based on sound expert and industry ...

Influenza Diagnostics Market By Test Type, By End Use and Segment Forecasts to 2024
Satellite PR News (press release)
LONDON, Feb. 13, 2017 — The **influenza** diagnostics market is expected to reach USD 3.3 billion by 2024, according to a new report by Grand View ...

Avian **Influenza** Vaccines Sales Market 2016: Challenges and Frontiers of Growth Satellite PR News (press release)
The Avian **Influenza** Vaccines Sales Market Research Report is a comprehensive analysis of the market with a chapter wise explanation of each ...

Global H5N1 Infection (Avian **Influenza**) Clinical Trials Review by Country and Sponsor Type 2016 openPR (press release)
"The Report H5N1 Infection (Avian **Influenza**) Global Clinical Trials Review, H1, 2016 provides information on pricing, market analysis, shares, ...

Global Influenza **Vaccines** Market is Expected to Reach Nearly US$ 5 Billion by 2021 Satellite PR News (press release)
The global influenza **vaccines** market is anticipated to reach nearly US$ 5 Billion by 2021. Influenza is a highly communicable disease and typically ...

MERS-CoV (novel coronavirus)

South Korea Seals Off 2 Hospitals Due to Outbreak of Middle East Respiratory Syndrome Santa monica Observed
Middle East Respiratory Syndrome (**Mers**) has infected 126 people in South Korea and killed 11 since it was first diagnosed just over three weeks ago ...

Saudi Arabia reports more **MERS** cases; WHO announces Buraydah outbreak over CIDRAP
The Saudi Arabian Ministry of Health (MOH) reported three new **MERS**-CoV cases over the weekend and two deaths, while the World Health ...

Researchers Study Effective Inhibition of **MERS**-CoV Infection by Resveratrol Infection Control Today

Middle East Respiratory Syndrome coronavirus (**MERS**-CoV) is an emerging viral pathogen that causes severe morbidity and mortality. Up to date ...

Buraidah **MERS** outbreak over: WHO Saudi Gazette

Riyadh — The Ministry of Health (MOH) reported three new Middle East Respiratory Syndrome coronavirus (**MERS**-CoV) cases over the weekend and ...

Hepatitis B

EMA Committee Rules Favorably on VBI **Vaccine** for Hepatitis B Hepatitis News Today

A committee of the European Union's drug regulatory agency has given its blessing to Sci-B-Vac, a **vaccine** for hepatitis B developed by ...

More women, babies given ineffective **hepatitis** B and Boostrix vaccines at Bankstown Hospital dailytelegraph.com.au

An internal investigation was launched this month after it was discovered more than 280 infants received **hepatitis** B vaccines from **a** fridge found to be ...

Short-Course Tocilizumab May Up **Hep B** Reactivation in RA Doctors Lounge

For patients with rheumatoid arthritis, one to three doses of tocilizumab may increase the risk of **hepatitis B** virus reactivation, according to a study ...

Tocilizumab-Related HBV Reactivation Examined in RA Monthly Prescribing Reference (registration)

(HealthDay News) — For patients with rheumatoid arthritis (RA), one to three doses of tocilizumab may increase the risk of **hepatitis B** virus (HBV) ...

VBI Vaccines, Inc. (NASDAQ:VBIV) Gets European Support For Pivotal Phase III Sci-**B**-Vac Trial Market Exclusive

... III trial on its flagship third generation **hepatitis B** vaccine Sci-B-Vac, and that this trial can be used as the basis for a market authorization application.

United States Human **Hepatitis B** Immunoglobulin Market Overview, Growth, Demand and Trends ... Satellite PR News (press release)

United States Human **Hepatitis B** Immunoglobulin Market report focuses on the major drivers and restraints for the key players. It also provides ...

Rotavirus

Rotavirus Group A Forecast for Selected Asian Markets 2017-2027 Yahoo Finance

Rotavirus is a contagious virus that can cause gastroenteritis (inflammation of the stomach and intestines). Symptoms include severe watery diarrhoea ...

Global **Rotavirus** Vaccine Market Research Report 2017 Analysis and Forecast to 2022
NewsMaker (press release)
WiseGuyReports.com adds "**Rotavirus** Vaccine Market 2017 Global Analysis,Growth,Trends and Opportunities Research Report Forecasting to ...

Pertussis

Whooping Cough on the Rise in Michigan GroundReport
Eric McGrath, M.D., infectious diseases specialist at DMC Children's Hospital of Michigan explains that whooping cough, also known as **pertussis**, is a ...

Pertussis persists, despite **vaccinations** Pueblo Chieftain
When the pertussis **vaccine** was introduced, the number of cases dramatically dropped. Despite this, cases and outbreaks of pertussis still happen in ...

Whooping cough cases reported Taipei Times
The Centers for Disease Control (CDC) yesterday reported the first cases of **pertussis** — also known as whooping cough, a highly contagious ...
Son-mother year's first whooping cough cluster infection case: CDC - Focus Taiwan News Channel

That Whooping cough Jamaica Observer
"The US Centers for Disease Control (CDC) now recommends that pregnant women receive the **pertussis** vaccine in the early part of their third ...

Public Health Wales updates pregnancy vaccination advice on **pertussis** and flu Nursing Times
Women should be offered the **pertussis** vaccine "as soon as possible" after 16 weeks gestation, according to the updated guidance that reflects expert ...

Diphtheria, Tetanus

Quadracel™ **DTaP**-IPV Vaccine Now Available in US MedicalResearch.com (blog)
Quadracel vaccine and the other FDA-approved **DTaP**-IPV vaccine differs with respect to the amounts and types of active ingredients they contain.

County urges residents to make preteen vaccinations a priority Eureka Times Standard
California state law requires students entering seventh grade to provide proof of a **Tdap** booster shot before starting school. The **Tdap** shot protects ...

Can You Get Vaccinated For Tetanus When You're Pregnant? Here's How To Best Protect You ... Romper
The **Tdap**, or Tetanus toxoid, reduces diphtheria toxoid, and the acellular pertussis vaccine prevents tetanus, whooping cough, and diptheria, all three ...

Cleveland's most famous canine, Balto, to visit Alaska (vintage photos) cleveland.com
... dog on the brutal final leg of a sled expedition through a winter blizzard to deliver lifesaving serum to the **diphtheria**-stricken town of Nome, Alaska.

Haemophilus influenzae type b

Growing Prevalence of **Haemophilus Influenzae Type B** Infections to Drive Number of Clinical Trials openPR (press release)

"The Report **Haemophilus influenzae Type B** Infections Global Clinical Trials Review, H1, 2016 provides information on pricing, market analysis, ...

Bacterial MENINGITIS and your baby Jamaica Observer

In fact, sometimes in the early stages, they may mimic flu-like symptoms. ... caused by a type of bacteria called **haemophilus influenzae type b**.

Pneumococcal

23-valent **pneumococcal** vaccine shows low, moderate effectiveness in older adults Healio

A 23-valent vaccine showed only low to moderate effectiveness in protecting older adults from **pneumococcal** pneumonia, researchers in Japan ...

Pfizer whistleblower's claims: NHRC asks govt to respond The Indian Express

... and not testing its popular **pneumococcal** vaccine Prevenar as per norms — these are the key allegations of a whistleblower against pharmaceutical ...

Measles, Mumps, & Rubella

Three cases of **measles** confirmed in Halifax, investigation ongoing CTV News

HALIFAX -- Health officials in Nova Scotia have confirmed three cases of **measles** in the Halifax area -- the first time in nine years the highly ...

All 3 **measles** cases in Halifax linked but source not yet known, says health official - CBC.ca

Three cases of **measles** confirmed in Halifax for first time in 9 years - Toronto Star

Nova Scotia Health Authority investigating 3 **measles** cases in Halifax - Globalnews.ca

Measles outbreak hits Orang Rimba tribe Jakarta Post

Measles outbreak hits Orang Rimba tribe A family of the Orang Rimba tribe lives in a flimsy hut deep in the jungle of Jambi. The Indigenous People's ...

University of Missouri Offering Free Mumps **Vaccines** KBIA

Boone County Health Department community relations specialist Eric Stann says that the **vaccines** will help strengthen students' immunity against the ...

Number of mumps cases in Manitoba doubles; outbreak expected to continue for months CBC.ca

They're also trying to get the word out about **vaccines**. ... In Manitoba, about 70 per cent of people are vaccinated, and the **vaccine** is only about 85 per ...

Mumps cases rising in Greene County KY3
The latest round -- hitting a teacher in Willard. She is symptom-free now, and back to the classroom. Health officials say we're up to 11 confirmed ...

Mumps spreads in Grant County The Spokesman-Review
MOSES LAKE – There are currently nine confirmed cases of **mumps** in Grant County, with another 11 under investigation, according to the Grant ...

Marquette University student contracts the **mumps** WTMJ-TV (press release) (registration) (blog)
Mumps is spread through the air, and can be transmitted through coughing or sneezing. Symptoms include headache, fever, body aches and swelling ...

DCHHS Confirms Seventh **Mumps** Case in Dallas County D Healthcare Daily
The Dallas County Health and Human Services confirmed the seventh **mumps** case in Dallas County for 2017. According to a statement, the exposure ...

Alton School District confirms elementary student diagnosed with mumps RiverBender.com
Students typically receive their **MMR** vaccine prior to attending school, but a small percentage of people can still contract the mumps even after being ...

After state review, SUNY Geneseo **mumps** cases back to zero The Livingston County News
The number of **mumps** cases at SUNY Geneseo since the beginning of the semester has been reset at zero. The state Department of Health ruled ...

Worldwide **Measles** Testing Market Key Trends & Industry Forecast 2016 - 2023 Digital Journal
Worldwide **Measles** Testing Market Key Trends & Industry Forecast 2016 - 2023 ... Hence, in developed countries to control the prevalence of **measles** ...

Varicella

HCMC copes with chickenpox SGGP
Head of the Department of Preventive Medicine Tran Dac Phu said that chickenpox is an acute disease caused by **Varicella** Zoter virus which causes ...

Chicken pox, measles outbreak in Hyderabad NYOOOZ
Summary: Hyderabad : As the season is taking a turn there has been a spurt in cases of measles and **chicken pox** in the city. Children are more prone ...

Your child's risk for **chicken pox** Jamaica Observer
AS children we can all recall the domino effect of the **chicken pox** — once all the young ones in the household and even in the classroom came down ...

Shingles

Dr. Marla Shapiro talks shingles **vaccine** in Brockville www.insidebrockville.com/

The Leeds & Grenville Community Family Health Team (LGCFHT) welcomed celebrity Dr. Marla Shapiro to its Brockville site for a lunchtime ...

Hepatitis A

90000 **Hepatitis A** follow-up injections coming due in Hawaii Food Safety News
illustration syringes vaccination More than 90,000 people received the first shot of a two-injection **Hepatitis A** vaccination in the second half of 2016, ...

Meningococcal

South Gate teacher dies after contracting meningitis, causing parental concern Los Angeles Times
"We realize that our teacher's death from a **meningococcal** bacteria-related illness may be causing concern. However, we want to assure our students, ...
LAUSD urging antibiotics at school where teacher died of meningitis - LA Daily News
Health Officials Provide Antibiotics After Teacher's Meningitis Death - NBC Southern California

Two-Year-Old South Australian Boy Diagnosed With **Meningococcal** Disease Huffington Post Australia
A toddler from regional South Australia has been hospitalised with an invasive case of **Meningococcal** Disease, the fourth case in the state in the past ...

Father whose daughter's death prompted petition for more meningitis **vaccines** accuses ... Telegraph.co.uk
Ministers are also yet to release calculations on how **vaccines** are deemed to be affordable and have not yet launched a meningitis awareness ...
Family devastated by meningitis B accuse government of complacency over **vaccines** - Yorkshire Post

Father of girl who died of meningitis condemns inaction on **vaccine** The Guardian
A man whose daughter's death from meningitis sparked a nationwide petition for more children to be **vaccinated** against it has accused the ...
Meningitis B: Call to extend **vaccine** to all children aged under five - Sky News

Concomitant administration of Menveo, other vaccines linked to Bell's palsy Healio
"The [CDC]'s Advisory Committee on Immunization Practices recommends routine vaccination with **meningococcal** vaccines for persons 11 through 18 ...

School joins **meningococcal** study - 15-Feb-2017 The Monitor Roxby Downs
Roxby Downs Area School (RDAS)will join more than 200 schools taking part in the 'B Part of It' study which gives year ten, 11 and 12 students access ...

HPV

HPV **vaccine**: the underused cancer-prevention **vaccine** Dallas News (blog)

Nearly five thousand women will die this year from a cancer that could be prevented with a **vaccine**. The American Cancer Society estimates that ...

Schoolgirls offered second chance to get cervical cancer **vaccine** - Irish Times

Teen girls will be offered catch-up HPV **vaccine** after 'untrue stories' spread about jab - Irish Independent

10 Truths (and Lies) You've Been Told About the HPV **Vaccine** - The Cheat Sheet

HPV vaccine vital for cervical health Pueblo Chieftain

MIAMI, FL - SEPTEMBER 21: A bottle of the **Human Papillomavirus** vaccination is seen at the University of Miami Miller School of Medicine on ...

Women still ignorant about cause of cervical cancer, study finds - Daily Nation

HPV series completion lags among boys ModernMedicine

Researchers emphasize that early **vaccination** against human papillomavirus (HPV) is important for protecting boys as well as girls, and encourage ...

Survey finds 50 percent of males have **HPV** News 10NBC

The findings are stunning when you consider **HPV** infections cause no symptoms and most disappear without treatment, but a new study shows a ...

Inovio and ApolloBio to Collaborate on Development and Commercialization of **HPV** Pre-cancer ... PipelineReview.com (press release)

PLYMOUTH MEETING, PA, USA I February 13, 2017 I Inovio Pharmaceuticals, Inc. (NASDAQ: INO) today announced that it has entered into a ...

ApolloBio Licenses Inovio's Late-Stage **HPV** DNA Immunotherapeutic for China Genetic Engineering & Biotechnology News

Chinese biomed ApolloBio negotiated exclusive rights to develop Inovio's lead DNA immunotherapeutic for **human papillomavirus** (**HPV**), VGX-3100, ...

Suit opens in Tokyo court over cervical cancer **vaccine** side effects The Japan Times

Twenty-eight girls and women suffering what they say are side effects from a cervical cancer **vaccine** that was recommended by the government ...

Polio

War against **polio** Pakistan Observer

KP Government deserves appreciation for the good steps it has taken in health sector and its recent decision to take strict action against parents not ...

Rotary bringing the world to Atlanta in June Yahoo News

The global eradication of **polio** has been Rotary's top priority since 1985. Through the Global **Polio** Eradication Initiative – a public-private partnership ...

Polio then and now: story of crippling disease on verge of worldwide eradication The Independent

A passage in Philip Roth's novel Nemesis describes the horror of catching **polio** in the US town of Newark in 1944, when outbreaks of the disease ...

Anti-**polio** drive continues in all provinces Pakistan Observer

The anti-polio campaign is in progress in all four provinces to protect the ... **Inactivated polio vaccine** (IPV) and 707,138 children with Oral poliovirus ...

WHO welcomes and orientates 16 members of the Stop Transmission of **Polio** (STOP) 49 to South ... Reliefweb

09 February 2017, Juba, South Sudan – In South Sudan, **polio** eradication continues to be a national priority with renewed commitment at all levels to ...

India **polio**-free for six years: meet the people fighting to keep it that way The Independent

There were just 37 cases of **polio** worldwide in 2016, in Pakistan, Afghanistan and Nigeria. **Polio** campaigners say the world is 'on the brink of a ...

UAE Exchange India Supported the Pulse **Polio** Health Programme NewsNow.IN

The strong motive to eradicate **polio** from the nation leads the community health centres in Hyderabad to join the government's Pulse **polio** programme ...

Parents refusing vaccination to face action DAWN.com

PESHAWAR: The parents of 8,781 children in Peshawar district have refused IPV (Inactivated **Polio** Vaccine) to their children during the ongoing ...

Norovirus

How to clean up after **norovirus** outbreak Minnesota Public Radio News

The **norovirus** hit Minnehaha Accademy last week, sickening dozens of people and forcing the Minneapolis school to close temporarily. Some 20 ...

Avoiding the **norovirus** WJHG-TV

CLEVELAND CLINIC - **Norovirus**, which is commonly called the stomach flu, ... Dr. Seth Podolsky of Cleveland Clinic says **norovirus** can cause some ...

Vaxart Announces Positive Phase 1 Study of Oral **Norovirus** Vaccine Business Wire (press release)

"The **norovirus** Phase 1 results are an important milestone for our oral vaccine platform as well as for the entire vaccine space," said Dave Liebowitz, ...

New study re-evaluates the total burden of **norovirus** on the UK The FINANCIAL

The FINANCIAL -- Researchers from the University of Liverpool have found that the annual number of estimated number of **norovirus** cases annually ...

Legionnaires' disease

Fresno nursing home patient dies of **Legionnaires' disease** Fresno Bee

Fresno County health officials said Monday a nursing home resident has died of **Legionnaires' disease**. The patient's identity, age and date of death ...

Legionella Discovered at a Hospital in Pennsylvania WebWire (press release)

Legionnaires' disease is a severe form of pneumonia that is caused by **Legionella bacteria** and is fatal in 10% of cases. **Legionnaires' disease** is not ...

Michigan orders Flint hospital to address **Legionella** risks Detroit Free Press

Elevated levels of lead, a neurotoxin, were detected in children, and 12 people died in the **Legionnaires' disease** outbreak — 10 of them associated ...

NEW: McLaren Flint responds to states orders to take action regarding **Legionella** - ABC 12 News (press release)

State orders crackdown on McLaren Flint hospital's water over **Legionnaires'** concerns Crain's Detroit Business

A spike in cases of **Legionnaires' disease** in Genesee County in 2014 and 2015 corresponded with Flint's switch to the Flint River for its primary ...

The Latest: State orders Flint hospital to fix health risks - Yahoo News

Worldwide **Legionella** Testing Market by Analysis of Major Industry Segments 2023 Satellite PR News (press release)

Albany, NY — — 02/14/2017 — According to the Centers for **Disease** Control and Prevention, it has been reported that around 8,000 to 18,000 people ...

Worldwide **Legionella** Testing Market by Analysis of Major Industry Segments 2023 - Digital Journal

Other

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Mon, 23 Jul 2018 20:09:35 +0000
To: Helfand, Rita (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: FW: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Attachments: ICAN-LetterheadLogo-Simple.png

FYI....

From: Amanda Dumenigo <amanda@horsense.net>
Sent: Thursday, July 19, 2018 9:39 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

<ICAN-LetterheadLogo-Simple.png>

For additional information and interviews please contact
Amanda Dumenigo, Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400

For Immediate Release:

World Renowned Vaccine Safety Expert and producer of the controversial film, Vaxxed, Del Bigtree, was awarded court ordered relief in lawsuit by his non-profit, The Informed Consent Action Network, ICAN, against the U.S. Department of Health and Human Services.

On Monday, June 9th, the United States District Court for the Southern District of New York signed a Stipulation granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN), the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr..

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

In 1986, the Pharmaceutical Industry was under the strain of so many lawsuits for injuries caused by vaccines they were struggling to make a profit. They threatened to stop

producing vaccines unless the U.S. government protected them from liability for damages caused by their vaccines. The US Government gave in to the pressure and passed the 1986 Vaccine Injury Compensation Act, which gave unprecedented legal immunity to all vaccine makers, eviscerating the free market incentive to remedy the very safety issues that had landed them in court to begin with. Recognizing that this would leave an unavoidable gap in vaccine safety testing, the US Congress charged the Secretary of Health and Human Services with the explicit responsibility of testing vaccines for safety and working to reduce the adverse events caused by all vaccines.

In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

ICAN was therefore forced to file a lawsuit to inspire HHS to either provide copies of its biannual vaccine safety reports to Congress or admit it never filed these reports. As a result of the lawsuit, HHS has signed a court order admitting that it never, not even once, submitted a single biannual report to Congress detailing the improvements in vaccine safety for 30 years.

Given that HHS is the primary scientific body mandated to protect American citizens from the adverse events caused by vaccines, and given that this lawsuit reveals that they are unable to produce a single report, under court order, to verify *any* work towards safer vaccines, the American people must now be made aware that the vaccines that are mandated upon millions of children, may in fact be dangerous to there health.

For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: **Amanda Dumenigo,**
Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

<Stipulated Order against HHS.pdf>
<7162018 Bigtree & Robert F. Kennedy, Jr Lawsuit Win against HHS.pdf>

ICAN
Informed Consent Action Network

Informed Consent Action Network

From: Vaughn, William (CDC/OID/NCEZID) (CTR)
Sent: Fri, 20 Jul 2018 15:46:09 -0400
To: Destefano, Frank (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Nguyen, Lyn (CDC/OID/NCEZID)
Subject: FW: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Attachments: Stipulated Order against HHS.pdf, 7162018 Bigtree & Robert F. Kennedy, Jr Lawsuit Win against HHS.pdf

Hi there – FYSA…not sure what the implications of this ruling are yet…just getting this info

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From: Nordlund, Kristen (CDC/OID/NCIRD)
Sent: Friday, July 20, 2018 3:26 PM
To: Vaughn, William (CDC/OID/NCEZID) (CTR) <hbv2@cdc.gov>
Subject: FW: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

From: Amanda Dumenigo <amanda@horsense.net>
Date: July 19, 2018 at 9:39:34 PM EDT
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

ICAN
Informed Consent Action Network

For additional information and interviews please contact
Amanda Dumenigo, Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920
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In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

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Given that HHS is the primary scientific body mandated to protect American citizens from the adverse events caused by vaccines, and given that this lawsuit reveals that they are unable to produce a single report, under court order, to verify *any* work towards safer vaccines, the American people must now be made aware that the vaccines that are mandated upon millions of children, may in fact be dangerous to there health.

For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: Amanda Dumenigo,
Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendant.

STIPULATION

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows:

> (a) General rule
>
> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—
>
> > (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
> >
> > (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
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> Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

> actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network ("ICAN") submitted a Freedom of Information Act request (the "FOIA Request") to the Department of Health and Human Services ("HHS" or the "Department"), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

> **Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).**

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary ("IOS") maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

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WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff

By: _____
Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622

Dated: July 6, 2018
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GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By: _____
ANTHONY J. SUN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
(212) 637-2810
anthony.sun@usdoj.gov

SO ORDERED:

_____
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

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From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Fri, 20 Jul 2018 07:57:08 -0400
To: Pope, Kristin (CDC/OID/NCIRD); Barry, Brooke (CDC/OID/NCIRD); Messonnier, Nancy (CDC/OID/NCIRD)
Subject: FW: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Attachments: Stipulated Order against HHS.pdf, 7162018 Bigtree & Robert F. Kennedy, Jr Lawsuit Win against HHS.pdf

FYI. I also sent to Kristen Nordlund in case we get questions.

From: Amanda Dumenigo <amanda@horsense.net>
Sent: Thursday, July 19, 2018 9:39 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

ICAN
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Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff

By: _____
Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622

Dated: July 6, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By: _____
ANTHONY J. SUN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
(212) 637-2810
anthony.sun@usdoj.gov

SO ORDERED:

_____
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

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From: Khabbaz, Rima (CDC/OID/NCEZID)
Sent: Fri, 20 Jul 2018 14:12:20 +0000
To: Helfand, Rita (CDC/OID/NCEZID)
Subject: FW: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Attachments: ICAN-LetterheadLogo-Simple.png, ATT00001.htm, Stipulated Order against HHS.pdf, ATT00002.htm, 7162018 Bigtree & Robert F. Kennedy, Jr Lawsuit Win against HHS.pdf, ATT00003.htm

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From: Messonnier, Nancy (CDC/OID/NCIRD)
Sent: Friday, July 20, 2018 8:44 AM
To: Khabbaz, Rima (CDC/OID/NCEZID) <rfk1@cdc.gov>
Subject: Fwd: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

Fysa. We're connecting with rita and ISO and Kevin Malone.

From: Amanda Dumenigo <amanda@horsense.net>
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ICAN
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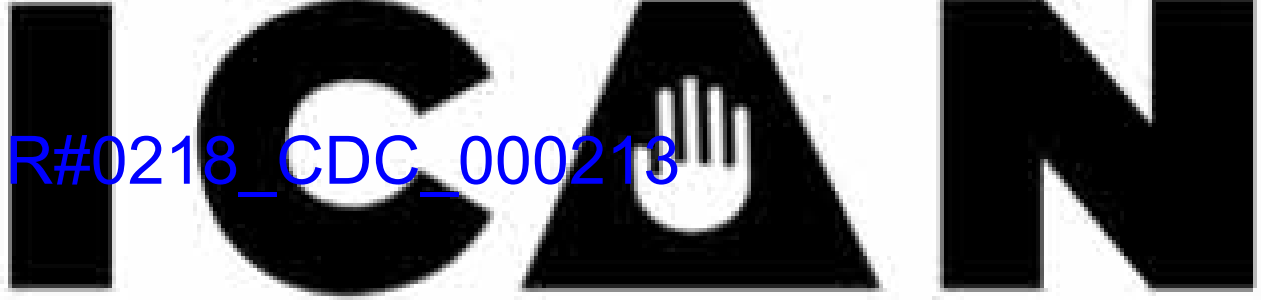

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WHEREAS, the HHS Immediate Office of the Secretary ("IOS") maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

> The [Department]'s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff

By: _____
Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622

Dated: July 6, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By: _____
ANTHONY J. SUN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
(212) 637-2810
anthony.sun@usdoj.gov

SO ORDERED:

_____
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

Informed Consent Action Network

For additional information or interviews please contact
Amanda Dumenigo,
Media & Public Relations, ICAN
amanda@icandecide.org 305-528-1920
Catharine Layton, C.O.O., ICAN
cat@icandecide.org 714-360-3400

For Immediate Release: **July 16, 2018**

World Renowned Vaccine Safety Expert and producer of the controversial film, Vaxxed, DEL BIGTREE, awarded court ordered relief in lawsuit by his non-profit, The Informed Consent Action Network, ICAN, against the US Department of Health and Human Services.

On Monday, June 9th, the United States District Court for the Southern District of New York signed an order granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN), the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr..

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

In 1986, the Pharmaceutical Industry was under the strain of so many lawsuits for injuries caused by vaccines they were struggling to make a profit. They threatened to stop producing vaccines unless the U.S. government protected them from liability for damages caused by their vaccines. The US Government gave in to the pressure and passed the 1986 Vaccine Injury Compensation Act, which gave unprecedented legal immunity to all vaccine makers, eviscerating the free market incentive to remedy the very safety issues that had landed them in court to begin with. Recognizing that this would leave an unavoidable gap in vaccine safety testing, the US Congress charged the Secretary of Health and Human Services with the explicit responsibility of testing vaccines for safety and working to reduce the adverse events caused by all vaccines.

In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

ICAN was therefore forced to file a lawsuit to inspire HHS to either provide copies of its biannual vaccine safety reports to Congress or admit it never filed these reports. As a result of the lawsuit, HHS has signed a court order admitting that it never, not even once, submitted a single biannual report to Congress detailing the improvements in vaccine safety for 30 years.

Given that HHS is the primary scientific body mandated to protect American citizens from the adverse events caused by vaccines, and given that this lawsuit reveals that they are unable to produce a single report, under court order, to verify *any* work towards safer vaccines, the American people must now be made aware that the vaccines that are mandated upon millions of children, may in fact be dangerous to there health.

For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: **Amanda Dumenigo,** Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

From: Schluter, W. William (CDC/CGH/GID)
Sent: Fri, 2 Mar 2018 17:19:31 -0500
To: Craig, Allen (CDC/OID/NCIRD); Cohn, Amanda (CDC/OID/NCIRD)
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE
Attachments: UNICEF response to ICAN DTP concern 20180212.pdf

Dear Allen/Amanda:
Last week when we met with John and Alejandro, I mentioned this vaccine safety letter that was received by UNICEF and to which UNICEF responded. Just FYI.
Kind regards,
Will

From: Robin Nandy [mailto:rnandy@unicef.org]
Sent: Tuesday, February 13, 2018 11:02 AM
To: Ana Maria Henao-Restrepo <henaorestrepoa@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dki4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Colleagues

Please find attached letter that went out today. There were substantial delays from our side and multiple reviewers. But happy to let you know that no further changes were made compared to the version we settled on. The only change is that it went out from our Chief of Health rather than our Deputy Executive Director. Given that the content of the letter is technical, there was a feeling among management that it was best for it to go out from the Head of our Health Section.

I will keep you informed if we get a response from Mr Bigtree. I do not think that this is the end of the story. More episodes to come, I'm sure.

Thanks again to you all for your collaboration.

Regards

Robin

Dr. Robin Nandy

(b)(6)

Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel:
Mob:
Email: rnandy@unicef.org

United Nations Children's Fund
Three United Nations Plaza
New York, New York 10017

Telephone 212 326 7000
Facsimile 212 888 7465
212 888 7454
www.unicef.org

Date 6 February 2018

Dear Mr Bigtree

Many thanks for your message expressing interest in learning more regarding the safety and effectiveness of the DTP vaccine. I was asked by our outgoing Executive Director, Anthony Lake to prioritize the response to your letter, as he was preparing to leave office, and he asked me to convey his apologies for not responding himself.

I would like to assure you that we take the issue of vaccine safety very seriously. Vaccine safety, along with the safety of all health interventions, are closely followed and monitored by ourselves, in close association with technical agencies like the World Health Organization (WHO). The wellbeing of children, as you are aware, is central to the mandate of UNICEF and we do not compromise in any way in fulfilling this mandate.

There are various independent and multidisciplinary expert bodies at global and national level, which regularly review the evidence on the impact of vaccines and on its safety profile and provide advice to WHO and UNICEF. Notably, the Strategic Advisory Group of Experts (SAGE) is the principal advisory group to WHO for vaccines and immunization (established in 1999). It is charged with advising on overall global policies and strategies, ranging from vaccines (impact and safety) and technology, research and development, to delivery of immunization and its linkages with other health interventions. The Global Advisory Committee on Vaccine Safety (GACVS) responds to vaccine safety issues of potential global importance (established in 1999). The GACVS provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short or long term national immunization programmes. The Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC) provides independent advice on matters related to implementation research and their relevance to immunization policies and practices, and reviews best practices relating to methods for conducting and reporting on quantitative immunization and vaccines-related research (including vaccine impact and safety evaluations).

Some authors have suggested that some of the vaccines routinely administered to infants and children also affect the risk of illness and death from conditions other than the specific infectious diseases they are designed to prevent. The hypotheses concerning these "non-specific effects" of vaccines include that, under some circumstances, some vaccines (for example, measles and Bacillus Calmette-Guérin (BCG)) lower subsequent risk, whereas others (such as DTP) increase subsequent risk of illness and death from other causes. It is further postulated that the magnitude of these effects depends on other factors, including gender and vitamin A supplementation status. The potential for non-specific vaccine effects has led some authors to question whether the vaccination schedules currently recommended by WHO should be adjusted.

WHO with the support of several independent experts has been reviewing and discussing evidence around the non-specific effects of vaccines and immunization programmes since 2001. In 2012, SAGE requested that WHO review the evidence concerning the possible non-specific effects of routine infant vaccines on mortality. A working group was established in March 2013 to review data on non-specific mortality effects and assess whether current evidence is sufficient to inform adjustments in policy recommendations, or if further scientific

United Nations Children's Fund
Three United Nations Plaza
New York, New York 10017

Telephone 212 326 7000
Facsimile 212 888 7465
212 888 7454
www.unicef.org

investigation is required. A systematic review was conducted to evaluate the non-specific effects on all-cause mortality, in children under 5, of Bacillus Calmette-Guérin (BCG), diphtheria-tetanus-pertussis (DTP), and standard titre measles containing vaccines (MCV); to examine internal validity of the studies; and to examine any modifying effects of gender, age, vaccine sequence, and co-administration of vitamin A.

In 2014 SAGE reviewed the outcomes of this review and concluded that, regarding the possible non-specific effect of DTP on all-cause mortality, the available data neither exclude nor confirm the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality. Randomized controlled trials did not contribute any evidence on non-specific effects of DTP. Evidence was largely from observational studies considered at a high risk of bias. Further, SAGE stated that further observational studies are unlikely to contribute to policy decisions. SAGE considered that the non-specific effects on all-cause mortality warranted further research. SAGE recommended that the IVIR- AC be tasked with providing advice on which priority research questions need to be addressed to inform policy decisions, and what kinds of studies and study designs would provide answers to these questions. SAGE concluded that the evidence does not support a change in policy for DTP, and emphasized the benefit of DTP in preventing disease and the importance of the current recommendation.

In conclusion, I would like to reiterate that UNICEF (and WHO) takes the issue of vaccine safety very seriously and for several decades has reviewed the evidence to guide policy decisions. While available evidence does not support a change in DTP vaccination policy, there is substantial evidence on the benefits of DTP (and pentavalent) vaccines in preventing disease and on the substantial risk for unvaccinated population DTP vaccines as evidenced by diphtheria, pertussis and tetanus cases and deaths that we are seeing today. In a number of locations globally, we are experiencing diphtheria outbreaks with high case fatality, which is a direct result of these children not receiving the recommended doses of vaccines in their childhood. Diphtheria, Tetanus and Pertussis were among the leading causes of childhood death in the pre-vaccine era causing several hundred thousand cases each year.

I hope my message provides you with the information that you were seeking. I am copying representatives of our member states who are included in your original message.

Please do not hesitate to contact us if you have further queries or require clarifications. The appropriate point of contact in our office is Dr. Robin Nandy, Principal Advisor and Chief of Immunizations and he can be contacted at **rnandy@unicef.org**

Sincerely,

Dr. Stefan Peterson
Associate Director, Health
UNICEF Headquarters

unite for children

unicef

From: Schluter, W. William (CDC/CGH/GID)
Sent: Sat, 9 Dec 2017 18:30:34 -0500
To: Cochi, Steve (CDC/CGH/GID); Shefer, Abigail (CDC/CGH/GID); Gidudu, Jane (CDC/CGH/GID); Shimabukuro, Tom (CDC/OID/NCEZID); Destefano, Frank (CDC/OID/NCEZID)
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Attachments: Letter from Informed Consent Action Network (ICAN)- RE Deaths caused by DTP.PDF, Research Paper -Introduction of DTP and Oral Polio Vaccine.pdf
Importance: High

Here's the original.

-----Original Message-----
From: Robin Nandy [mailto:rnandy@unicef.org]
Sent: Friday, December 8, 2017 9:56 AM
To: Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Importance: High

Gents

FYI. Will need your assistance in framing an appropriate response.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

-----Original Message-----
From: Robin Nandy
Sent: Thursday, December 7, 2017 5:38 PM
To: FRIEDE, Martin Howell <friedem@who.int>; 'Chang Blanc, Diana (changblancd@who.int)' <changblancd@who.int>
Cc: Benjamin Schreiber (bschreiber@unicef.org) <bschreiber@unicef.org>
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Importance: High

Dear Martin, Diana

Please see message attached which was received by our ED. I was wondering if your DG has received something similar.

In my view, I feel we need to be completely aligned in the way we respond to this. Peter Aaby's work is familiar to

all of us but (b)(6)

I am at WHO for the Polio PPG meeting tomorrow (Friday, Dec 8) and wonder if you would have a moment for a quick coffee to discuss this further and chart a course of action. Please let me know. My mobile number is in the signature if we are unable to connect in person and have to speak on the phone.

Regards

Robin

(b)(6)
Dr. Robin Nandy
Principal Advisor & Chief of Immunizations UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel:
Mob: (b)(6)
Email: rnandy@unicef.org

Date Received: 12/07/2017 Record Number **CF/RAI/NYHQ/OED/2017-01818**

unicef

Office of the EXECUTIVE DIRECTOR (OED)

Logging and Routing Slip

CF/RAI/NYHQ/OED/2017-01818

TO: S. Peterson

Subject: Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP

ACTION: OED: ADVISE OED ON RECOMMENDED ACTION AND RESPONSE

DUE DATE: 12/13/2017

- ☐ Advise OED on Recommended Action and Response
- ☐ Take Action and Inform OED
- ☐ For Your Attention/Information

*Response to be accompanied by OED Clearance Fc

Notes CC: T. Chaiban, O. Abdi, S. Wijesekera, O. Abdi

Dear Stephan,

Grateful if in consultation with relevant colleagues a draft response can be prepared for ED's review.

Thank you

Please return this form to OED with the completed action including the clearance form

ICAN
Informed Consent Action Network

VIA FEDEX

December 5, 2017

UNICEF House
Dr. Anthony Lake
Executive Director
3 United Nations Plaza
New York, NY 10017
Telephone: +1(212) 32 67 490
Facsimile: +1(212) 32 67 477

Re: Deaths caused by DTP

Dear Dr. Lake,

UNICEF has been instrumental in vaccination campaigns in many countries, including their prior and ongoing DTP vaccination campaign. We write to bring to your attention an alarming study, published this year, which found that children vaccinated with DTP were 10 times more likely to die in the first six months of life than those children that were unvaccinated.[1] A copy of this study is enclosed.

Dr. Peter Aaby, the lead author of this study, is renowned for studying and promoting vaccines in Africa with over 300 published studies.[2] Dr. Aaby, after concluding that children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated, states:

> "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[3]

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[1] A copy of this study can also be found here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
[2] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/

This study also found that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[4] This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[5]

Unlike most vaccine safety studies in which subjects are not well matched, Dr. Aaby's study is reliable because the subjects were accurately matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. (This issue is explained in detail in a publication by vaccine safety scientists at the U.S. Centers for Disease Control.[6]) Dr. Aaby's study is the only study looking at death from DTP specifically designed to avoid this error.

When an extremely well-designed study from accomplished vaccine proponents at the Research Centre for Vitamins and Vaccines and Institute of Clinical Research at the University of Southern Denmark/Odense University Hospital finds that children receiving a certain product are dying at 10 times the rate of children not receiving that product, prudence dictates pausing the distribution of that product. Please confirm that UNICEF has ceased distributing DTP and kindly advise what research UNICEF is undertaking regarding deaths from DTP vaccine, including identifying the families killed by this vaccine in order to provide them with reparations.

We also note that continued vaccination with DTP without disclosing the findings in Dr. Aaby's study would violate the Nuremberg Code which provides that:

> "The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."[7]

The Nuremberg Code thus draws a sharp line when stating that no human being should receive a medical procedure and/or product without informed consent. Failing to advise

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[4] Ibid.

[5] Ibid.

[6] https://www.ncbi.nlm.nih.gov/pubmed/1415136

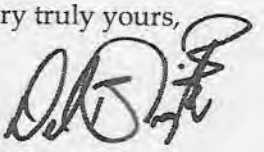
[7] https://history.nih.gov/research/downloads/nuremberg.pdf

the findings of Dr. Aaby's study to parents prior to administering the DTP vaccine would violate this basic human right.

While medical interventions have saved countless lives, the graveyard of history is also replete with once lauded but later abandoned medical inventions and practices. When an issue with a medical procedure is identified, especially when it is killing children, immediate action is necessary. We hope that political and economic considerations will not cloud the clear moral and ethical duty to protect children from death from DTP vaccine.

If UNICEF does not intend to cease distribution of DTP vaccine or at least confirm that parents of children receiving this vaccine are advised of Dr. Aaby's findings, we intend to take appropriate legal action. We look forward to receiving a timely response to this letter so that we can follow-up with all member states cc'd on this communication with regard to what actions UNICEF intends to take in response to Dr. Aaby's extremely concerning finding that children receiving DTP vaccine had a death rate 10 times that of children that were not vaccinated.

Very truly yours,



Del Bigtree

cc: See Appendix A (*Countires Using DTP Vaccine*)

Enclosure: Mogensen S.W., Andersen A., Rodrigues A., Benn C.S., Aaby P., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, EBioMedicine. 2017;17:192–198.

APPENDIX A

Permanent Mission of Afghanistan to the United Nations
H.E. Mr. Mahmoud Saikal
Permanent Representative
633 Third Avenue, 27th Floor
New York, N.Y. 10017
Phone: (212) 972-1212
Email: info@afghanistan-un.org

Permanent Mission of the Republic of Albania to the United Nations
H.E. Ms. Besiana Kadare
Permanent Representative
320 East 79th Street
New York, N.Y. 10075
Phone: (212) 249-2059
Email: mission.newyork@mfa.gov.al
albania.un@albania-un.org

Permanent Mission of Algeria to the United Nations
H.E. Mr. Sabri Boukadoum
Permanent Representative
326 East 48th Street
New York, N.Y. 10017
Phone: (212) 750-1960
Email: algeria@un.int

Permanent Mission of the Republic of Angola to the United Nations
H.E. Mr. Ismael Abraão Gaspar Martins
Permanent Representative
820 Second Avenue, 12th Floor
New York, N.Y. 10017
Phone: (212) 861-5656
Email: themission@angolaun.org

Permanent Mission of Antigua and Barbuda to the United Nations
H.E. Mr. Walton Alfonso Webson
Permanent Representative
305 East 47th Street, 6th Floor
New York, N.Y. 10017
Phone: (212) 541-4117
Email: unmission@abgov.org

Permanent Mission of Argentina to the United Nations
H.E. Mr. Martín García Moritán
Permanent Representative
One United Nations Plaza, 25th Floor
New York, N.Y. 10017
Phone: (212) 688-6300
Email: enaun@mrecic.gov.ar

Permanent Mission of the Republic of Armenia to the United Nations
H.E. Mr. Zohrab Mnatsakanyan
Permanent Representative
119 East 36th Street
New York, N.Y. 10016
Phone: (212) 686-9079
Email: armenia@un.int

Permanent Mission of the Republic of Azerbaijan to the United Nations
H.E. Mr. Yashar T. Aliyev
Permanent Representative
866 United Nations Plaza, Suite 560 New York, N.Y. 10017
Phone: (212) 371-2559
Email: azerbaijan@un.int

Permanent Mission of the Commonwealth of the Bahamas to the United Nations
H.E. Mr. Elliston Rahming
Permanent Representative
231 East 46th Street
New York, N.Y. 10017
Phone: (212) 421-6925
Email: mission@bahamasny.com

Permanent Mission of the Kingdom of Bahrain to the United Nations
H.E. Mr. Jamal Fares Alrowaiei
Permanent Representative
866 Second Avenue, 14th and 15th Floors
New York, N.Y. 10017
Phone: (212) 223-6200
Email: bahrain1@un.int

Permanent Mission of the People's Republic of Bangladesh to the United Nations
H.E. Mr. Masud Bin Momen
Permanent Representative
820 Second Avenue, 4th Floor
New York, N.Y. 10017
Phone: (212) 867-3434
Email: bangladesh@un.int;
bdpmny@gmail.com;
fsnypmbd@mofa.gov.bd;
z.aynuzzaman@gmail.com

Permanent Mission of Barbados to the United Nations
H.E. Mr. Keith Hamilton Llewellyn Marshall
Permanent Representative
820 Second Avenue, 9th Floor
New York, N.Y. 10017
Phone: (212) 551-4300
Email: prun@foreign.gov.bb;
barbados@un.int

Permanent Mission of the Republic of Belarus to the United Nations
H.E. Mr. Andrei Dapkiunas
Permanent Representative
136 East 67th Street, 4th Floor
New York, N.Y. 10065
Phone: (212) 535-3420
Email: usaun@mfa.gov.by

Permanent Mission of Belize to the United Nations
H.E. Ms. Lois Michele Young
Permanent Representative
675 Third Avenue, Suite 1911
New York, N.Y. 10017
Phone: (212) 986-1240
Email: blzun@belizemission.com
blzun@aol.com

Permanent Mission of the Republic of Benin to the United Nations
H.E. Mr. Jean-Francis Régis Zinsou
Permanent Representative
125 East 38th Street
New York, N.Y. 10016
Phone: (212) 684-1339
Email: beninewyork@gmail.com

Permanent Mission of the Kingdom of Bhutan to the United Nations
H.E. Mrs. Kunzang C. Namgyel
Permanent Representative
343 East 43rd Street
New York, N.Y. 10017
Phone: (212) 682-2268
Email: bhutanmission@pmbny.bt

Permanent Mission of the Plurinational State of Bolivia to the United Nations
H.E. Mr. Sacha Sergio Llorentty Solíz
Permanent Representative
801 Second Avenue, 4th Floor, Suite 402
New York, N.Y. 10017
Phone: (212) 682-8132
Email: missionboliviaun@gmail.com

Permanent Mission of Bosnia and Herzegovina to the United Nations
H.E. Mr. Miloš Vukašinović
Permanent Representative
420 Lexington Avenue, Suites 607 & 608
New York, N.Y. 10170
Phone: (212) 751-9015
Email: bihun@mfa.gov.ba

Permanent Mission of Botswana to the United Nations
H.E. Mr. Charles Thembani Ntwaagae
Permanent Representative
154 East 46th Street
New York, N.Y. 10017
Phone: (212) 889-2277
Email: botswana@un.int

Permanent Mission of Brazil to the United Nations
H.E. Mr. Antonio de Aguiar Patriota
Permanent Representative
747 Third Avenue, 9th Floor
New York, N.Y. 10017-2803
Phone: (212) 372-2600
Email:
Distri.delbrasonu@itamaraty.gov.br
www.un.int/brazil

Permanent Mission of Burkina Faso to the United Nations
H.E. Mr. Yemdaogo Eric Tiare
Permanent Representative
633 Third Avenue, Suite 31A, 31st Floor
New York, N.Y. 10017
Phone: (212) 308-4720
Email: bfapm@un.int

Permanent Mission of the Republic of Burundi to the United Nations
H.E. Mr. Albert Shingiro
Permanent Representative
336 East 45th Street, 12th Floor
New York, N.Y. 10017
Phone: (212) 499-0001
Email: ambabunewyork@yahoo.fr

Permanent Mission of the Republic of Cabo Verde to the United Nations
H.E. Mr. Fernando Jorge Wahnon Ferreira
Permanent Representative
27 East 69th Street
New York, N.Y. 10021
Phone: (212) 472-0333
Email: capeverde@un.int

Permanent Mission of the Kingdom of Cambodia to the United Nations
H.E. Mr. Ry Tuy
Permanent Representative
327 East 58th Street
New York, N.Y. 10022
Phone: (212) 336-0777
Email: cambodia@un.int English

Permanent Mission of the Republic of Cameroon to the United Nations
H.E. Mr. Michel Tommo Monthe
Permanent Representative
22 East 73rd Street
New York, N.Y. 10021
Phone: (212) 794-2295
Email: cameroon.mission@yahoo.com

Permanent Mission of the Central African Republic to the United Nations
H.E. Ms. Ambroisine Kpongo
Permanent Representative
866 United Nations Plaza, Suite 444
New York, N.Y. 10017
Phone: (646) 415-9122
Email: repercaf.ny@gmail.com

Permanent Mission of the Republic of Chad to the United Nations
H.E. Mr. Mahamat Zene Cherif
Permanent Representative
129 East 36th Street
New York, NY 10016
(212) 986-0980
Email: chadmission@gmail.com

Permanent Mission of Chile to the United Nations
H.E. Mr. Cristián Barros Melet
Permanent Representative
One Dag Hammarskjöld Plaza 885
Second Avenue, 40th Floor
New York, N.Y. 10017
Phone: (917) 322-6800
Email: chile.un@minrel.gob.cl

Permanent Mission of Colombia to the United Nations
H.E. Ms. María Emma Mejía Vélez
Permanent Representative
140 East 57th Street, 5th Floor
New York, N.Y. 10022
Phone: (212) 355-7776
Email: colombia@colombiaun.org

Permanent Mission of the Union of the Comoros to the United Nations
H.E. Mr. Mohamed Soilihi Soilih
Permanent Representative
866 United Nations Plaza, Suite 418
New York, N.Y. 10017
Phone: (212) 750-1637
Email: comoros@un.int

Permanent Mission of the Republic of the Congo to the United Nations
H.E. Mr. Raymond Serge Balé
Permanent Representative
14 East 65th Street
New York, N.Y. 10065
Phone: (212) 744-7840
Email: congo@un.int;
mpcongo_onu@hotmail.com

Permanent Mission of Côte d'Ivoire to the United Nations
H.E. Mr. Claude Stanislas Bouah-Kamon
Permanent Representative
800 2nd Avenue, 5th Floor
New York, N.Y. 10017
Phone: (646) 649-5061
Email: cotedivoiremission@yahoo.com

Permanent Mission of Cuba to the United Nations
H.E. Mr. Rodolfo Reyes Rodríguez
Permanent Representative 315 Lexington Avenue
New York, N.Y. 10016
Phone: (212) 689-7215
Email: cuba_onu@cubanmission.com

Permanent Mission of the Democratic People's Republic of Korea to the United Nations
H.E. Mr. Ja Song Nam
Permanent Representative
820 Second Avenue, 13th Floor
New York, N.Y. 10017
Phone: (212) 972-3105
Email: Dprk.un@verizon.net English

Permanent Mission of the Democratic Republic of the Congo to the United Nations
H.E. Mr. Ignace Gata Mavita wa Lufuta
Permanent Representative
866 United Nations Plaza, Suite 511
New York, N.Y. 10017
Phone: (212) 319-8061
Email: missiondrc@gmail.com

Permanent Mission of the Republic of Djibouti to the United Nations
H.E. Mr. Mohamed Siad Doualeh
Permanent Representative
866 United Nations Plaza, Suite 4011
New York, N.Y. 10017
Phone: (212) 753-3163
Email: djibouti@nyct.net

Permanent Mission of the Commonwealth of Dominica to the United Nations
H.E. Mrs. Loreen Ruth Bannis-Roberts
Permanent Representative
800 Second Avenue, Suite 400H
New York, N.Y. 10017
Phone: (212) 949-0853
Email: domun@onecommonwealth.org; dominicaun@gmail.com

Permanent Mission of the Dominican Republic to the United Nations
H.E. Mr. Francisco Antonio Cortorreal
Permanent Representative
144 East 44th Street, 4th Floor
New York, N.Y. 10017
Phone: (212) 867-0833
Email: drun@un.int

Permanent Mission of Ecuador to the United Nations
H.E. Mr. Horacio Sevilla Borja
Permanent Representative
866 United Nations Plaza, Room 516
New York, N.Y. 10017
Phone: (212) 935-1680
Email: ecuador@un.int

Permanent Mission of the Arab Republic of Egypt to the United Nations
H.E. Mr. Amr Abdellatif Aboulatta
Permanent Representative
304 East 44th Street
New York, N.Y. 10017
Phone: (212) 503-0300
Email: egypt@un.int; pr.egypt@un.int

Permanent Mission of El Salvador to the United Nations
H.E. Mr. Rubén Ignacio Zamora Rivas
Permanent Representative
46 Park Avenue
New York, N.Y. 10016
Phone: (212) 679-1616
Email: elsalvador@un.int

Permanent Mission of Equatorial Guinea to the United Nations
H.E. Mr. Anatolio Ndong Mba
Permanent Representative
800 Second Avenue, Suite 305
New York, N.Y. 10017
Phone: (212) 223-2324
Email: equatorialguineamission@yahoo.com

Permanent Mission of Eritrea to the United Nations
H.E. Mr. Girma Asmerom Tesfay
Permanent Representative
800 Second Avenue, 18th Floor
New York, N.Y. 10017
Phone: (212) 687-3390
Email: general@eritrea-unmission.org

Permanent Mission of the Federal Democratic Republic of Ethiopia to the United Nations
H.E. Mr. Tekeda Alemu
Permanent Representative
866 Second Avenue, 3rd Floor
New York, N.Y. 10017
Phone: (212) 421-1830
Email: ethiopia@un.int

Permanent Mission of the Republic of Fiji to the United Nations
H.E. Mr. Peter Thomson
Permanent Representative
801 Second Avenue, 10th Floor
New York, N.Y. 10017
Phone: (212) 687-4130
Email: mission@fijiprun.org

Permanent Mission of the Gabonese Republic to the United Nations
H.E. Mr. Baudelaire Ndong Ella
Permanent Representative
18 East 41st Street, 9th Floor
New York, N.Y. 10017
Phone: (212) 686-9720
Email: info@gabonunmission.com

Permanent Mission of the Islamic Republic of the Gambia to the United Nations
H.E. Mr. Mamadou Tangara
Permanent Representative
336 East 45th Street, 7th Floor
New York, N.Y. 10017
Phone: (212) 949-6640
Email: gambia_un@hotmail.com

Permanent Mission of Georgia to the United Nations
H.E. Mr. Kaha Imnadze
Permanent Representative
One United Nations Plaza, 26th Floor
New York, N.Y. 10017
Phone: (212) 759-1949
Email: geomission.un@mfa.gov.ge

Permanent Mission of Ghana to the United Nations
H.E. Mrs. Martha Ama Akyaa Pobee
Permanent Representative
19 East 47th Street
New York, N.Y. 10017
Phone: (212) 832-1300
Email: ghanaperm@aol.com

Permanent Mission of Grenada to the United Nations
H.E. Ms. Keisha A. McGuire
Permanent Representative
800 Second Avenue, Suite 400K
New York, N.Y. 10017
Phone: (212) 599-0301
Email: grenada@un.int

Permanent Mission of Guatemala to the United Nations
H.E. Mr. Jorge Skinner-Klée
Permanent Representative
57 Park Avenue
New York, N.Y. 10016
Phone: (212) 679-4760
Email: guatemala@un.int; onupnud@minex.gob.gt

Permanent Mission of the Republic of Guinea to the United Nations
H.E. Mr. Mamadi Touré
Permanent Representative
140 East 39th Street
New York, N.Y. 10016
Phone: (212) 687-8115
Email: missionofguinea@aol.com

Permanent Mission of the Republic of Guinea-Bissau to the United Nations
H.E. Mr. João Soares Da Gama
Permanent Representative
336 East 45th Street, 13th Floor
New York, N.Y. 10017
Phone: (212) 896-8311
Email: guinea-bissau@un.int;
guinebissauonu@gmail.com

Permanent Mission of the Republic of Guyana to the United Nations
H.E. Mr. Rudolph Michael Ten-Pow
Permanent Representative 801 Second Avenue, 5th Floor
New York, N.Y. 10017
Phone: (212) 573-5828,
Email: guyana@un.int

Permanent Mission of Haiti to the United Nations
H.E. Mr. Denis Régis
Permanent Representative
815 Second Avenue, 6th Floor
New York, N.Y. 10017
Phone: (212) 370-4840
Email: mphonu.newyork@diplomatie.ht

Permanent Mission of Honduras to the United Nations
H.E. Ms. Mary Elizabeth Flores
Permanent Representative
866 United Nations Plaza, Suite 417
New York, N.Y. 10017
Phone: (212) 752-3370
Email: Ny.honduras@hnun.org

Permanent Mission of India to the United Nations
H.E. Mr. Syed Akbaruddin
Permanent Representative
235 East 43rd Street
New York, N.Y. 10017
Phone: (212) 490-9660
Email: india@un.int
ind_general@indiaun.net

Permanent Mission of the Republic of Indonesia to the United Nations
H.E. Mr. Dian Triansyah Djani
Permanent Representative
325 East 38th Street
New York, N.Y. 10016
Phone: (212) 972-8333
Email: ptri@indonesiamission-ny.org

Permanent Mission of the Islamic Republic of Iran to the United Nations
H.E. Mr. Gholamali Khoshroo
Permanent Representative
622 Third Avenue, 34th Floor
New York, N.Y. 10017
Phone: (212) 687-2020
Email: iran@un.int

Permanent Mission of the Republic of Iraq to the United Nations
H.E. Mr. Mohamed Ali Alhakim
Permanent Representative
14 East 79th Street
New York, N.Y. 10075
Phone: (212) 737-4433
Email: iraqny@un.int

Permanent Mission of Israel to the United Nations
H.E. Mr. Danny Danon
Permanent Representative
800 Second Avenue
New York, N.Y. 10017
Phone: (212) 499-5510
Email: UNInfo@newyork.mfa.gov.il

Permanent Mission of Jamaica to the United Nations
H.E. Mr. E. Courtenay Rattray, Permanent Representative
767 Third Avenue, 9th Floor
New York, N.Y. 10017
Phone: (212) 935-7509
Email: jamaica@un.int

Permanent Mission of the Hashemite Kingdom of Jordan to the United Nations
H.E Ms. Sima Sami Bahous
Permanent Representative
866 Second Avenue, 4th Floor
New York, N.Y. 10017
Phone: (212) 832-9553
Email:
missionun@jordanmissionun.com

Permanent Mission of the Republic of Kenya to the United Nations
H.E. Mr. Macharia Kamau Permanent Representative
866 United Nations Plaza, Room 304
New York, N.Y. 10017
Phone: (212) 421-4740
Email: info@kenyaun.org

Permanent Mission of the Republic of Kiribati to the United Nations
H.E. Mrs. Makurita Baaro
Permanent Representative
800 Second Avenue, Suite 400B
New York, N.Y. 10017
Phone: (212) 867-3310
Email: Kimission.newyork@mfa.gov.ki

Permanent Mission of the State of Kuwait to the United Nations
H.E. Mr. Mansour Ayyad SH A Alotaibi
Permanent Representative
321 East 44th Street
New York, N.Y. 10017
Phone: (212) 973-4300
Email: kuwait@kuwaitmissionun.org

Permanent Mission of the Kyrgyz Republic to the United Nations
H.E. Ms. Mirgul Moldoisaeva
Permanent Representative
866 United Nations Plaza, Suite 477
New York, N.Y. 10017
Phone: (212) 486-4214
Email: kyrgyzstan@un.int

Permanent Mission of the Lao People's Democratic Republic to the United Nations
H.E. Mr. Khiane Phansourivong
Permanent Representative
317 East 51st Street
New York, N.Y. 10022
Phone: (212) 832-2734
Email: lao.pr.ny@gmail.com

Permanent Mission of Lebanon to the United Nations
H.E. Mr. Nawaf Salam
Permanent Representative
866 United Nations Plaza, Room 531-533
New York, N.Y. 10017
Phone: (212) 355-5460
Email: contact@lebanonun.org

Permanent Mission of the Kingdom of Lesotho to the United Nations
H.E. Mr. Kelebone Maope
Permanent Representative
815 Second Avenue, 8th Floor
New York, N.Y. 10017
Phone: (212) 661-1690
Email: lesothonewyork@gmail.com

Permanent Mission of the Republic of Liberia to the United Nations
H.E. Mr. Lewis G. Brown
Permanent Representative
866 United Nations Plaza, Suite 480
New York, N.Y. 10017
Phone: (212) 687-1033
Email: 1035 Liberia@un.int

Permanent Mission of the Republic of Madagascar to the United Nations
H.E. Mr. Zina Andrianarivelo-Razafy
Permanent Representative
820 Second Avenue, Suite 800
New York, N.Y. 10017
Phone: (212) 986-9491
Email: repermad@verizon.net

Permanent Mission of the Republic of Malawi to the United Nations
H.E. Mr. Necton D. Mhura
Permanent Representative
866 United Nations Plaza, Suite 486
New York, N.Y. 10017
Phone: (212) 317-8738
Email: MalawiNewyork@aol.com; MalawiU@aol.com

Permanent Mission of the Republic of Maldives to the United Nations
H.E. Mr. Ahmed Sareer
Permanent Representative
801 Second Avenue, Suite 202
New York, N.Y. 10017
Phone: (212) 599-6194
Email: info@maldivesmission.com

Permanent Mission of the Republic of Mali to the United Nations
H.E. Mr. Issa Konfourou
Permanent Representative
111 East 69th Street
New York, N.Y. 10021
Phone: (212) 737-4150
Email: malionu@aol.com

Permanent Mission of the Islamic Republic of Mauritania to the United Nations
H.E. Mr. Mohamed Lemine El Haycen
Permanent Representative
116 East 38th Street
New York, N.Y. 10016
Phone: (212) 252-0113
Email: mauritaniamission@gmail.com

Permanent Mission of the Republic of Mauritius to the United Nations
H.E. Mr. Jagdish Dharamchand Koonjul
Permanent Representative
211 East 43rd St., 22nd Floor
New York, N.Y. 10017
Phone: (212) 949-0190
Email: mauritius@un.int

Permanent Mission of Mexico to the United Nations
H.E. Mr. Juan José Gómez Camacho
Permanent Representative
Two United Nations Plaza, 28th Floor
New York, N.Y. 10017
Phone: (212) 752-0220
Email: onuusr1@sre.gob.mx

Permanent Mission of Mongolia to the United Nations
H.E. Mr. Sukhbold Sukhee
Permanent Representative
6 East 77th Street
New York, N.Y. 10075
Phone: (212) 861-9460
Email: mongolianmission@twcmetrobiz.com

Permanent Mission of the Kingdom of Morocco to the United Nations
H.E. Mr. Omar Hilale
Permanent Representative
866 Second Avenue, 6th and 7th Floors
New York, N.Y. 10017
Phone: (212) 421-1580
Email: morocco.un@maec.gov.ma

Permanent Mission of the Republic of the Union of Myanmar to the United Nations
H.E. Mr. Hau Do Suan
Permanent Representative
10 East 77th Street
New York, N.Y. 10075
Phone: (212) 744-1271
Email: myanmarmission@verizon.net

Permanent Mission of the Republic of Namibia to the United Nations
H.E. Mr. Wilfried I. Emvula
Permanent Representative
135 East 36th Street
New York, N.Y. 10016
Phone: (646) 627-8670
Email: namibia@un.int

Permanent Mission of the Republic of Nauru to the United Nations
H.E. Ms. Marlene Moses
Permanent Representative
801 Second Avenue, Third Floor
New York, N.Y. 10017
Phone: (212) 937-0074
Email: nauru@un.int
nauru@onecommonwealth.org

Permanent Mission of the Federal Democratic Republic of Nepal to the United Nations
H.E. Mr. Durga Prasad Bhattarai
Permanent Representative
820 Second Avenue, Suite 17B (17th Floor)
New York, N.Y. 10017
Phone: (212) 370-3988
Email: nepal@un.int;
nepalmissionusa@gmail.com

Permanent Mission of Nicaragua to the United Nations
H.E. Mrs. María Rubiales de Chamorro
Permanent Representative
820 Second Avenue, 8th Floor
New York, N.Y. 10017
Phone: (212) 490-7997
Email: nicaragua@un.int

Permanent Mission of the Republic of Niger to the United Nations
H.E. Mr. Abdallah Wafy
Permanent Representative
417 East 50th Street
New York, N.Y. 10022
Phone: (212) 421-3260
Email: nigermission@ymail.com

Permanent Mission of Nigeria to the United Nations
828 Second Avenue
New York, N.Y. 10017
Email: permny@nigeriaunmission.org

Permanent Mission of the Sultanate of Oman to the United Nations
H.E. Mr. Khalifa Ali Issa Al Harthy
Permanent Representative
3 Dag Hammarskjöld Plaza
305 East 47th Street, 12th Floor
New York, N.Y. 10017
Phone: (212) 355-3505
Email: oman@un.int

Permanent Mission of Pakistan to the United Nations Pakistan House
H.E. Ms. Maleeha Lodhi
Permanent Representative
8 East 65th Street
New York, N.Y. 10065
Phone: (212) 879-8600
Email: pakistan@un.int

Permanent Mission of Panama to the United Nations
H.E. Ms. Laura Elena Flores Herrera
Permanent Representative
866 United Nations Plaza, Suite 4030
New York, N.Y. 10017
Phone: (212) 421-5420
Email: emb@panama-un.org

Permanent Mission of the Independent State of Papua New Guinea to the United Nations
H.E. Mr. Max Hufanen Rai
Permanent Representative
201 East 42nd Street, Suite 2411
New York, N.Y. 10017
Phone: (212) 557-5001
Email: pngun@pngmission.org

Permanent Mission of Paraguay to the United Nations
801 Second Avenue, 15th Floor, Suite 1501
New York, N.Y. 10017
Phone: (212) 687-3490
Email: paraguay@un.int

Permanent Mission of Peru to the United Nations
H.E. Mr. Gustavo Meza-Cuadra
Permanent Representative
820 Second Avenue, Suite 1600
New York, N.Y. 10017
Phone: (212) 687-3336
Email: onuper@unperu.org

Permanent Mission of the Republic of the Philippines to the United Nations
H.E. Ms. Lourdes Ortiz Yparraguirre
Permanent Representative
556 Fifth Avenue, 5th Floor
New York, N.Y. 10036
Phone: (212) 764-1300
Email: newyorkpm@gmail.com

Permanent Mission of the Republic of Poland to the United Nations
H.E. Mr. Bogusław Winid
Permanent Representative
750 Third Avenue, 30th Floor
New York, N.Y. 10017
Phone: (212) 744-2506
Email: poland.un@msz.gov.pl

Permanent Mission of the State of Qatar to the United Nations
H.E. Ms. Alya Ahmed Saif Al-Thani
Permanent Representative
809 United Nations Plaza, 4th Floor
New York, N.Y. 10017
Phone: (212) 486-9335
Email: pmun@mofa.gov.qa

Permanent Mission of the Republic of Moldova to the United Nations
H.E. Mr. Vlad Lupan
Permanent Representative
35 East 29th Street
New York, N.Y. 10016
Phone: (212) 447-1867
Email: unmoldova@aol.com

Permanent Mission of the Russian Federation to the United Nations
H.E. Mr. Vitaly I. Churkin
Permanent Representative
136 East 67th Street
New York, N.Y. 10065
Phone: (212) 861-4900,
Email: press@russiaun.ru

Permanent Mission of the Republic of Rwanda to the United Nations
124 East 39th Street
New York, N.Y. 10016
Phone: (212) 679-9010
Email: ambanewyork@minaffet.gov.rw
ambanewyork@gmail.com

Permanent Mission of Saint Kitts and Nevis to the United Nations
H.E. Mr. Sam Terence Condor
Permanent Representative
414 East 75th Street, 5th Floor
New York, N.Y. 10021
Phone: (212) 535-1234
Email: sknmission@aol.com

Permanent Mission of Saint Lucia to the United Nations
H.E. Ms. Menissa Rambally
Permanent Representative
800 Second Avenue, 5th Floor
New York, N.Y. 10017
Phone: (212) 697-9360
Email: info@stluciamission.org

Permanent Mission of Saint Vincent and the Grenadines to the United Nations
H.E. Ms. Inga Rhonda King
Permanent Representative
800 Second Avenue, Suite 400F
New York, N.Y. 10017
Phone: (212) 599-0950
Email: mission@svg-un.org;
svgmission@gmail.com

Permanent Mission of the Independent State of Samoa to the United Nations
H.E. Mr. Ali'ioaiga Feturi Elisaia
Permanent Representative
800 Second Avenue, Suite 400J
New York, N.Y. 10017
Phone: (212) 599-6196
Email: office@samoanymission.ws

Permanent Mission of Sao Tome and Principe to the United Nations
H.E. Mr. Carlos Filomeno Agostinho das Neves
Permanent Representative
675 Third Avenue, Suite 1807
New York, NY 10017
Phone: (212) 651-8116
Email: rdstppmun@gmail.com

Permanent Mission of the Republic of Senegal to the United Nations
H.E. Mr. Fodé Seck
Permanent Representative
229 East 44th Street
New York, N.Y. 10017
Phone: (212) 517-9030
Email: senegal.mission@yahoo.fr

Permanent Mission of the Republic of Seychelles to the United Nations
H.E. Ms. Marie-Louise Potter
Permanent Representative
800 Second Avenue, Suite 400G
New York, N.Y. 10017
Phone: (212) 972-1785
Email: seychelles@un.in,
seychellesmissionun@gmail.com

Permanent Mission of the Republic of Sierra Leone to the United Nations
H.E. Mr. Vandi Chidi Minah
Permanent Representative
245 East 49th Street
New York, N.Y. 10017
Phone: (212) 688-1656
Email: sierraleone@un.int

Permanent Mission of Solomon Islands to the United Nations
800 Second Avenue, Suite 400L
New York, N.Y. 10017-4709
Phone: (212) 599-6192
Email: simun@solomons.com

Permanent Mission of the Federal Republic of Somalia to the United Nations
425 East 61st Street, Suite 702
New York, N.Y. 10065
Phone: (212) 688-9410
Email: somalia@un.int

Permanent Mission of the Republic of South Sudan to the United Nations
H.E. Mr. Akuei Bona Malwal
Permanent Representative
336 East 45th Street, 5th Floor
New York, N.Y. 10017
Phone: (212) 937-7977
Email: info@rssun-nyc.org

Permanent Mission of the Democratic Socialist Republic of Sri Lanka to the United Nations
H.E. Mr. Amrith Rohan Perera
Permanent Representative
820 Second Avenue, 2nd Floor
New York, N.Y. 10017
Phone: (212) 986-7040
Email: mail@slmission.com

Permanent Mission of the Republic of the Sudan to the United Nations
H.E. Mr. Omer Dahab Fadl Mohamed
Permanent Representative
305 East 47th Street 3
Dag Hammarskjöld Plaza, 4th Floor New York, N.Y. 10017
Phone: (212) 573-6033
Email: sudan@sudanmission.org

Permanent Mission of the Republic of Suriname to the United Nations
866 United Nations Plaza, Suite 320
New York, N.Y. 10017-1822
Phone: (212) 826-0660
Email: uriname@un.int

Permanent Mission of the Kingdom of Swaziland to the United Nations
H.E. Mr. Zwelethu Mnisi
Permanent Representative
408 East 50th Street
New York, N.Y. 10022
Phone: (212) 371-8910
Email: swaziland@un.int;
swazinymission@yahoo.com

Permanent Mission of the Syrian Arab Republic to the United Nations
H.E. Mr. Bashar Ja'afari
Permanent Representative
820 Second Avenue, 15th Floor
New York, N.Y. 10017
Phone: (212) 661-1313
Email: exesec.syria@gmail.com

Permanent Mission of the Republic of Tajikistan to the United Nations
H.E. Mr. Mahmadamin Mahmadaminov
Permanent Representative
216 East 49th Street, 5th Floor
New York, N.Y. 10017
Phone: (212) 207-3315
Email: tajikistan@un.int;
tajikistanun@aol.com

Permanent Mission of Thailand to the United Nations
H.E. Mr. Virachai Plasai
Permanent Representative
351 East 52nd Street
New York, N.Y. 10022
Phone: (212) 754-2230
Email: thailand@un.int

Permanent Mission of the former Yugoslav Republic of Macedonia to the United Nations
H.E. Mr. Vasile Andonoski
Permanent Representative
866 United Nations Plaza, Suite 570
New York, N.Y. 10017
Phone: (212) 308-8504
Email: newyork@mfa.gov.mk

Permanent Mission of the Democratic Republic of Timor-Leste to the United Nations
H.E. Ms. Maria Helena Lopes de Jesus Pires
Permanent Representative
866 United Nations Plaza, Suite 441
New York, N.Y. 10017
Phone: (212) 759-3675
Email: timor-leste@un.int

Permanent Mission of Togo to the United Nations
H.E. Mr. Kokou Kpayedo
Permanent Representative
336 East 45th Street
New York, N.Y. 10017
Phone: (212) 490-3455
Email: togo@un.int;
togo.mission@yahoo.fr

Permanent Mission of the Kingdom of Tonga to the United Nations
H.E. Mr. Mahe'uli'uli Sandhurst Tupouniua
Permanent Representative 250 East 51st Street
New York, N.Y. 10022
Phone: (917) 369-1025
Email: tongaunmission@gmail.com

Permanent Mission of the Republic of Trinidad and Tobago to the United Nations
H.E. Ms. Pennelope Althea Beckles
Permanent Representative
633 Third Avenue, 12th Floor
New York, N.Y. 10017
Phone: (212) 697-7620
Email: tto@un.int

Permanent Mission of Tunisia to the United Nations
H.E. Mr. Mohamed Khaled Khiari
Permanent Representative
31 Beekman Place
New York, N.Y. 10022
Phone: (212) 751-7503
Email: tunisnyc@nyc.rr.com

Permanent Mission of Turkmenistan to the United Nations
H.E. Mrs. Aksoltan Ataeva
Permanent Representative
866 United Nations Plaza, Suite 540
New York, N.Y. 10017
Phone: (212) 486-8908
Email: turkmenistan@un.int

Permanent Mission of Tuvalu to the United Nations
H.E. Mr. Aunese Makoi Simati
Permanent Representative
800 Second Avenue, Suite 400D
New York, N.Y. 10017
Phone: (212) 490-0534
Email: tuvalu.un@gmail.com

Permanent Mission of the Republic of Uganda to the United Nations
H.E. Mr. Richard Nduhuura
Permanent Representative
336 East 45th Street
New York, N.Y. 10017
Phone: (212) 949-0110
Email: ugandaunny@un.int

Permanent Mission of Ukraine to the United Nations
H.E. Mr. Volodymyr Yelchenko
Permanent Representative
220 East 51st Street
New York, N.Y. 10022
Phone: (212) 759-7003
Email: uno_us@mfa.gov.ua

Permanent Mission of the United Republic of Tanzania to the United Nations
H.E. Mr. Tuvako Nathaniel Manongi
Permanent Representative
307 East 53rd Street, 5th Floor
New York, N.Y. 10022
Phone: (212) 697-3612
Email: tanzania@un.int, tzrepny@aol.com

Permanent Mission of Uruguay to the United Nations
H.E. Mr. Elbio Rosselli
Permanent Representative
866 United Nations Plaza, Suite 322
New York, N.Y. 10017
Phone: (212) 752-8240
Email: urudeleg@mrree.gub.uy

Permanent Mission of the Republic of Uzbekistan to the United Nations
H.E. Mr. Muzaffarbek Madrakhimov
Permanent Representative
801 Second Avenue, 20th Floor
New York, N.Y. 10017
Phone: (212) 486-4242
Email: uzbekistan.un@gmail.com

Permanent Mission of the Republic of Vanuatu to the United Nations
H.E. Mr. Odo Tevi
Permanent Representative
800 Second Avenue, Suite 400C
New York, N.Y. 10017
Phone: (212) 661-4303
Email: vanunmis@aol.com

Permanent Mission of the Bolivarian Republic of Venezuela to the United Nations
H.E. Mr. Rafael Darío Ramírez Carreño
Permanent Representative
335 East 46th Street
New York, N.Y. 10017
Phone: (212) 557-2055
Email: misionvenezuelaonu@gmail.com

Permanent Mission of the Socialist Republic of Viet Nam to the United Nations
H.E. Mrs. Nguyen Phuong Nga
Permanent Representative
866 United Nations Plaza, Suite 435
New York, N.Y. 10017
Phone: (212) 644-0594
Email: info@vietnam-un.org

Permanent Mission of the Republic of Yemen to the United Nations
H.E. Mr. Khaled Hussein Mohamed Alyemany
Permanent Representative
413 East 51st Street
New York, N.Y. 10022
Phone: (212) 355-1730
Email: ymiss-newyork@mofa.gov.ye

Permanent Mission of the Republic of Zambia to the United Nations
H.E. Dr. Mwaba Patricia Kasese-Bota
Permanent Representative
237 East 52nd Street
New York, N.Y. 10022
Phone: (212) 888-5770
Email: zambia@un.int

Permanent Mission of the Republic of Zimbabwe to the United Nations
H.E. Mr. Frederick Musiiwa Makamure Shava
Permanent Representative
128 East 56th Street
New York, N.Y. 10022
Phone: (212) 980-9511
Email: zimnewyork@gmail.com

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Research Paper

The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment

Søren Wengel Mogensen [a,1], Andreas Andersen [b,1], Amabelia Rodrigues [a], Christine S Benn [b,c], Peter Aaby [a,b,*]

[a] Bandim Health Project, Indepth Network, Apartado 861, Bissau, Guinea-Bissau
[b] Research Centre for Vitamins and Vaccines (CVIVA), Bandim Health Project, Statens Serum Institute, Artillerivej 5, 2300 Copenhagen S, Denmark
[c] OPEN, Institute of Clinical Research, University of Southern Denmark/Odense University Hospital, 5000 Odense C, Denmark

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ABSTRACT

Background: We examined the introduction of diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau in the early 1980s.
Methods: The child population had been followed with 3-monthly nutritional weighing sessions since 1978. From June 1981 DTP and OPV were offered from 3 months of age at these sessions. Due to the 3-monthly intervals between sessions, the children were allocated by birthday in a 'natural experiment' to receive vaccinations early or late between 3 and 5 months of age. We included children who were <6 months of age when vaccinations started and children born until the end of December 1983. We compared mortality between 3 and 5 months of age of DTP-vaccinated and not-yet-DTP-vaccinated children in Cox proportional hazard models.
Results: Among 3–5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 (95% CI 1.53–16.3) compared with not-yet-DTP-vaccinated children. Differences in background factors did not explain the effect. The negative effect was particularly strong for children who had received DTP-only and no OPV (HR = 10.0 (2.61–38.6)). All-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19)).
Conclusion: DTP was associated with increased mortality; OPV may modify the effect of DTP.

1. Introduction

Individually randomized studies to measure impact on child survival of different vaccines were not conducted when the Expanded Program on Immunization (EPI) was introduced in low-income countries in the 1970s. The disease-protective effects were well documented, so the main issue was at which age to introduce the vaccine most effectively (The Expanded Programme on Immunization, 1982). Except for measles vaccine (MV), surprisingly few studies examined the introduction of vaccines and their impact on child survival (Aaby et al., 1983, 2003a; Holt et al., 1990; The Kasongo Project Team, 1981). One trial of measles-vaccinated and measles-unvaccinated communities in Congo showed a larger than expected reduction in child mortality (Aaby et al., 1981); this observation was subsequently corroborated by community "trials" and before-after studies in several countries (Aaby et al. 1984, 1993, 2003a; Holt et al., 1990; Kapoor and Reddaiah, 1991). Hence, a vaccine may have non-specific effects (NSEs) on susceptibility to other infections (Aaby et al., 1995). WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recently reviewed the potential NSEs of BCG, diphtheria-tetanus-pertussis (DTP) and MV and recommended further research (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014).

Though protective against the target diseases, DTP may increase susceptibility to unrelated infections (Aaby et al., 2003b, 2004a, 2012) (Appendix A). The SAGE review noticed that the majority of studies found a detrimental effect of DTP (Higgins et al., 2014). However, SAGE considered the evidence inconsistent because two studies reported beneficial effects (Higgins et al., 2014) and that most studies underestimated the benefit of DTP because studies were conducted in situations with herd immunity. Furthermore, all studies gave DTP and OPV together, making it impossible to separate effects of DTP and OPV (SAGE non-specific effects of vaccines Working Group, 2014).

On the other hand, the "unvaccinated" children in these studies have usually been frail children too sick or malnourish to get vaccinated, and the studies may therefore have underestimated the negative effect of DTP. We therefore examined what happened when DTP and OPV were first introduced, but not always given together, in 1981–1983 in

* Corresponding author at: Bandim Health Project, Statens Serum Institute, Artillerivej 5, 2300 Copenhagen S, Denmark.
E-mail address: p.aaby@bandim.org (P. Aaby).
[1] Joint first-authorship.

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the capital of Guinea-Bissau. In this situation the children were allocated by birthday to receive vaccines early or late and the "unvaccinated" were therefore not frail children.

2. Methods

2.1. Background

Bandim Health Project (BHP) has followed an urban community with a demographic surveillance system since December 1978, and took part in the introduction of vaccines well before a full-fledged national program was implemented with UNICEF support in 1986 (Aaby et al., 1984, 2004a).

2.2. Demographic Surveillance

In 1978–1979, under-five mortality was nearly 500/1000. Since malnutrition was assumed to be the main cause, a study was initiated to determine why children were malnourished (Aaby et al., 1983). However, severe malnutrition was not evident, and to understand the high mortality we started a health and demographic surveillance system (HDSS). The area was mapped and a census conducted. Four health workers were employed to identify pregnant women, encourage women to attend ante-natal clinics, and to follow children with anthropometric measurements to assess growth patterns and detect malnourished children. Each health worker followed a population of 1500–2000 individuals. The health workers were supervised by an expatriate nurse.

For each sub-district in Bandim, the responsible health worker kept a list of children under three years of age. BHP had no computerized surveillance system until 1990 but kept an A5 card ("BHP card") for each child, where weights and vaccination dates were noted. The child's growth card was kept by the mother.

The Bandim population was very mobile. It was important to maintain contact with the natal village for ceremonial purposes and to secure rice. Furthermore, mothers were not supposed to have sexual relations during breastfeeding (Jakobsen et al., 2004). Breastfeeding was prolonged in Guinea-Bissau. Thus, many women stayed in the rural areas with their natal family while breastfeeding. These cultural traditions introduced variability in the participation in weighing and vaccination sessions.

2.3. Anthropometry

We arranged quarterly weighing sessions in each sub-district. The responsible health worker advised mothers the day before a community weighing. The following morning, the weight was measured and noted on the child's growth card and the BHP card. When the World Food Program provided supplementary feeding this was given to families with malnourished children.

2.4. Vaccinations

There was no community vaccination program in 1981 except that we had organized a few measles vaccination campaigns (Aaby et al., 1984). Mothers could take their children to the Mother and Child Health Program in town. However, this clinic was mainly attended by the urban elite. Few children were vaccinated before BHP organized vaccination sessions (Table 1).

In June 1981, BHP started to provide vaccinations at the quarterly weighing sessions. A health center nurse accompanied the weighing team and vaccinated eligible children. DTP and OPV were provided from 3 months and MV from 9 months of age. OPV-at-birth was not given then. The three DTP and OPV doses could be given with an interval of one month but since we only arranged weighing every three months, most children had longer intervals between doses. DTP was administered intramuscularly and OPV as an oral drop. When both vaccines were administered at the same session OPV was usually given first and then DTP; the children would usually start crying after DTP due to the pain of the injection and it would therefore have complicated the administration of OPV to give DTP first. There were several periods where either OPV or DTP was missing (Fig. 1). BCG was rarely provided at the weighing sessions since most nurses were not trained to administer intra-dermal vaccination. A total of 269 children may have been BCG vaccinated as they had a vaccination date on their card (N = 192) or were noted to have received BCG but no date given (N = 77).

The expatriate nurse sometimes organized additional vaccination sessions in which the children were not weighed. During these sessions,

Table 1
Median age of vaccination and coverage for BCG, DTP and OPV of study cohort.

	1980	1981	1982	1983	1981–1983
Median age in days (N vaccines)					
BCG	9 (4)	48.5 (50)	34 (46)	25 (68)	33 (164)
DTP1	97 (12)	127 (147)	121 (164)	117 (278)	121 (589)
OPV1	98 (12)	118 (185)	121.5 (170)	117 (225)	118 (580)
MV	181 (5)	141 (53)	157 (2)	110 (1)	141.5 (56)
Coverage at 6 months of age					
BCG	1.7% (5/289)	3.5% (12/342)	23.7% (72/304)	17.4% (57/327)	14.5% (141/973)
DTP1	4.2% (12/289)	31.3% (107/342)	61.2% (186/304)	73.1% (239/327)	54.7% (532/973)
DTP3	2.4% (7/289)	0.9% (3/342)	4.3% (13/304)	4.0% (13/327)	3.0% (29/973)
OPV1	4.2% (12/289)	43.0% (147/342)	62.5% (190/304)	69.7% (228/327)	58.1% (565/973)
OPV3	2.4% (7/289)	2.0% (7/342)	4.3% (13/304)	4.0% (13/327)	3.4% (33/973)
MV	2.8% (8/289)	15.2% (52/342)	0.7% (2/304)	0% (0/327)	5.5% (54/973)
Coverage at one year of age					
BCG	2.6% (3/116)	2.4% (7/294)	15.4% (51/332)	17.4% (46/264)	11.7% (104/890)
DTP1	2.6% (3/116)	32.7% (96/294)	71.1% (236/332)	83.0% (219/264)	61.9% (551/890)
DTP3	2.6% (3/116)	4.4% (13/294)	18.4% (61/332)	43.2% (114/264)	21.1% (188/890)
OPV1	2.6% (3/116)	37.4% (110/294)	77.4% (257/332)	84.8% (224/264)	66.4% (591/890)
OPV3	2.6% (3/116)	12.2% (36/294)	32.5% (108/332)	44.3% (117/264)	29.3% (261/890)
MV	15.5% (18/116)	68.0% (200/294)	34.0% (113/332)	51.1% (135/264)	50.3% (448/890)

Notes: The inclusion criteria for the cohort in Table 1 are the same as for our study cohort: weight examination after 15 days of age and contribute time between 91 and 183 days of age.
Median age: 'year' means the year the vaccination was given, and median age is the median age at time of vaccination with a given vaccine among children vaccinated before turning 6 months. E.g. the 4 BCG vaccines in the 1980 column were given in 1980 to children with a median age of 9 days.
Coverage: 'year' means the year when the child turned exactly 1 year (or 6 months) old and coverage was assessed. Only children surviving to 1 year (or 6 months) of age were assessed for coverage. Children turning 1 year in 1984 were thus not presented in the table.

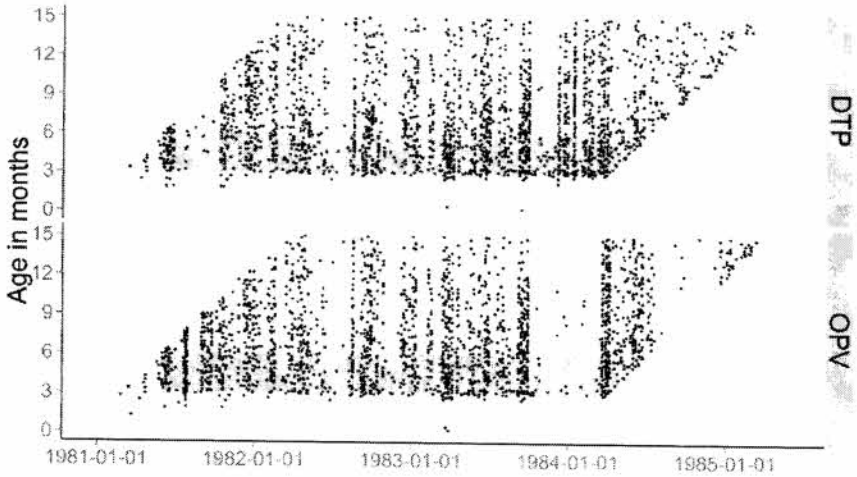

Fig. 1. Each vaccination of the specified type is plotted according age of the recipient and date of vaccination.

vaccinations were noted on the BHP cards. Both nurses and mothers thought that sick children should not be vaccinated; the BHP card often indicated that the child was 'sick', 'malnourished' or 'orphan' as an explanation of why an age-eligible child had not been vaccinated.

2.5. Data Control

When a computerized system became available in 1990–1991, weights and vaccinations from the BHP cards were entered. For the present analysis, all information on dates of visit, weights and vaccination dates was checked against the original cards. A few cards were not available or could no longer be found (Fig. 2).

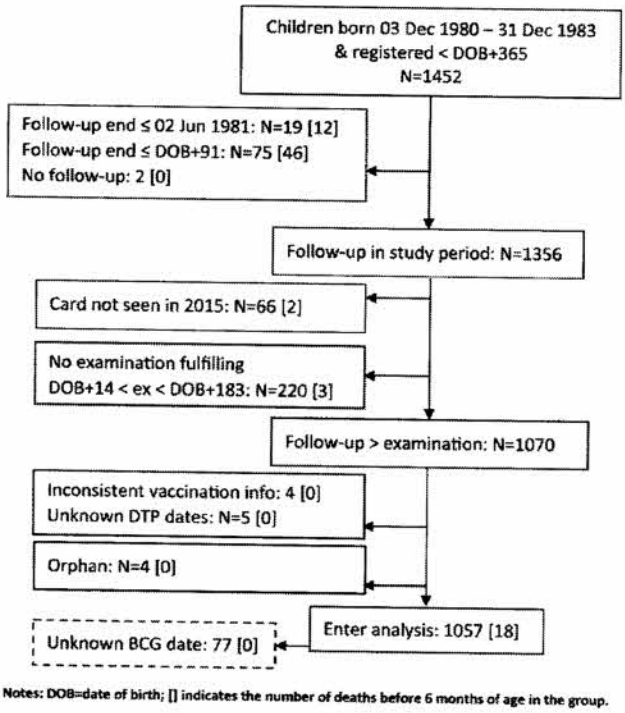

Fig. 2. Flowchart of study population and children included in the analyses. Notes: DOB = date of birth; [] indicates the number of deaths before 6 months of age in the group.

2.6. The Study Cohort

We included children born from December 3, 1980 as they would become eligible for vaccination before 6 months of age (Fig. 2). Few children were vaccinated with BCG (Table 1). Children who travelled and never attended any session were not included in the 'unvaccinated' group. Children weighed within a fortnight of their birth to obtain a birth weight were only included if they took part in a subsequent community weighing session. Furthermore, we excluded orphans since they were not breastfed and were likely to have different care. The cohort is depicted in Supplementary Fig. 1.

2.7. Natural Experiment for 3–5-month-old Children

Though not individually randomized, the present study is a natural experiment with limited bias in group allocation: With 3-monthly intervals between weighing sessions, children were allocated by their birthday to receive their first vaccinations early or late between 3 and 5 months of age (Fig. 3). We therefore compared 3–5-month-old children who had received DTP (±OPV) vaccinations early with children who had not yet received these vaccinations. Since there were no healthy "unvaccinated" children after 6 months of age unless they had travelled, we censored follow-up of all children at 6 months of age (Fig. 3).

Sick children were not vaccinated, in the main analysis we therefore censored 'unvaccinated' children who attended a weighing session but did not receive a vaccination (Fig. 3). Since the censoring of sick children could have introduced a bias, we also conducted an intention-to-treat analysis in which the censored children were transferred to the DTP group. Hence, in this analysis we compared the mortality of the intended-DTP-vaccinated group and the not yet DTP-vaccinated group.

Children were included from 91 days of age if they had been examined in a weighing session before 91 days; if they were only seen in a weighing session after 3 months of age they were only included from the day seen. DTP was not administered elsewhere and the follow-up time of children was therefore counted as DTP-unvaccinated time in the survival analysis until BHP provided the vaccine. Time as DTP-unvaccinated also came from children who did not turn up at the weighing sessions between 3 and 5 months of age but had been seen before 3 months of age and therefore were part of the community cohort (Fig. 3). Hence, the DTP-vaccinated and DTP-unvaccinated children were all children from the same cohort of children born in Bandim and their allocation depended on the timing of their birth date, the timing of the weighing sessions and their travelling pattern. We

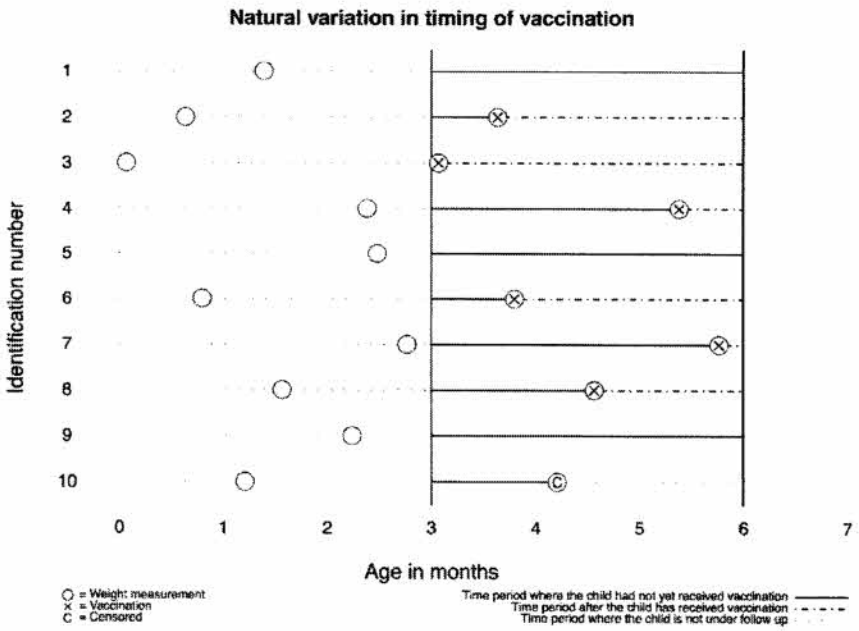

Fig. 3. Natural experiment study design. Note: Children were weighed every third month. After 3 months of age they received DTP and OPV on weighing days if they were healthy. Children who attended but were not vaccinated at a weighing session after 3 months of age were censored in the survival analysis comparing DTP-vaccinated and unvaccinated children.

compared the background factors for the children who were DTP vaccinated, attended a weighing session between 3 and 5 months but were not vaccinated and those who did not attend a weighing session (Table 2).

We also examined the mortality of children who due to logistic reasons had received DTP-only. Absences and travelling patterns are unlikely to differ between children who at their first vaccination had received DTP1 + OPV versus DTP1-only; these two groups were equally likely to receive subsequent vaccinations both with respect to timing of subsequent vaccinations and coverage (data available on request).

2.8. Statistical Methods

First possible enrolment date was June 2, 1981, when DTP and OPV vaccinations were introduced. Different vaccination groups were compared using a Cox proportional hazard model with age as underlying time.

Children were classified according to their most recent vaccination (Supplementary Table 1). We ignored BCG vaccinations in the main analysis because we gave few BCG vaccinations (Table 1) and some children had received BCG at the maternity ward without proper documentation as some children had a BCG scar but no vaccination card. To avoid survival bias, we used a landmark approach (Jensen et al., 2007); hence, a child's vaccination status was only updated from the day the information was collected. Due to the additional vaccination sessions organized by the expatriate nurse some "unvaccinated" children received a vaccine before the weighing session where they changed status to "vaccinated"; it is noted in the footnote to Table 3 how many had received such vaccinations. As a sensitivity analysis we also did an analysis including the additional vaccination sessions as landmarks. For the remainder of this paper, we will refer to these landmarks as vaccination-days-without-weighing.

The WHO z-score for weight-for-age was used to assess nutritional status. Control for sub-district, ethnic group and twinning did not change the results (data not shown). There was no obvious clustering

Table 2
Background factors children in the main analysis of vaccination and mortality between 3 and 5 months of age.

		DTP-vaccinated at 3–5 months	Attended weighing session at 3–5 months, not vaccinated	Did not attend weighing session at 3–5 months
Number		662	186	209
Male sex		52.1%	53.2%	54.1%
Twin		2.7%	2.2%	2.9%
Birth weight (SD)		3.23 (0.025)	3.28 (0.061)	3.22 (0.051)
Ethnic group				
• Pepel		46.8%	54.8%	45.0%
• Balanta		11.8%	13.4%	16.3%
• Other ethnic groups		41.4%	31.7%	38.8%
Mean weight-for-age z-score (SD) at examination before 3 months of age		−0.30 (0.037)	−0.34 (0.084)	−0.43 (0.066)
Follow-up time (person-years) between 3 and 5 months; [Median number of days of follow]	All time	135.5 [92]	36.8 [86]	47.4 [92]
	As DTP vaccinated	73.3	1.8	2.0
	As unvaccinated	62.2	35.1	45.4
Mean number (SD) of weighing sessions per year between 6 and 11 months of age		2.7 (0.03)	2.2 (0.07)	1.6 (0.08)

Table 3
Mortality rate and hazard rate (HR) for children from 3 months of age until first examination without vaccination or 6 months of age. Natural experiment.

Age group 3–5 months	Mortality rate (deaths/person-years)			HR (95% CI) for DTP vs unvaccinated
All				
Unvaccinated (N = 651)	4.5 (5/111.4)	DTP (±OPV) (N = 462)	17.4 (11/63.1)	5.00 (1.53–16.3)
		DTP only (N = 101)	35.2 (5/14.2)	10.0 (2.61–38.6)
		DTP + OPV (N = 361)	12.3 (6/48.9)	3.52 (0.96–12.9)
Girls				
Unvaccinated (N = 313)	1.9 (1/51.9)	DTP (±OPV) (N = 222)	13.3 (4/30.1)	9.98 (0.81–123.0)
		DTP only (N = 44)	16.2 (1/6.2)	12.0 (0.56–257.2)
		DTP + OPV (N = 178)	12.5 (3/23.9)	9.50 (0.73–124.0)
Boys				
Unvaccinated (N = 338)	6.7 (4/59.5)	DTP (±OPV) (N = 240)	21.2 (7/33.0)	3.93 (1.01–15.3)
		DTP only (N = 57)	49.8 (4/8.0)	8.93 (2.01–39.7)
		DTP + OPV (N = 183)	12.0 (3/24.9)	2.21 (0.44–11.0)

Notes: There were no deaths due accidents in this age group. BCG is disregarded in the analysis. Hence, the unvaccinated children have not received DTP, OPV or MV but may have received BCG. Of the 651 unvaccinated children, 219 received DTP and/or OPV before their first weighing examination. These children counted as 'unvaccinated' until their first weighing examination. Of the 462 children who received DTP (±OPV), 177 received an additional DTP or OPV before 6 months of age. The OPV-only is not presented in the table because there were no deaths and very little follow-up time in this age group.

of deaths and control for season and calendar time did not change estimates (data not shown).

There were 18 deaths between 3 and 5 months of age: 3 had cough and respiratory infections as the main symptom, 3 had fever (presumed malaria), 2 were due to diarrhea, 5 had diarrhea and vomiting, 1 was a sudden death, and 4 had no information on cause.

2.9. Ethics

The study of nutritional status was planned by SAREC (Swedish Agency for Research Collaboration with Developing Countries) and the Ministry of Health in Guinea-Bissau.

3. Results

Of 1356 children registered in Bandim and followed to 3 months of age (Fig. 2), 286 were never weighed, had no card or their card was lost. An additional 13 children had inconsistent information, vaccinations marked with a cross but without dates or were orphans. Hence, 1057 children were included in the study cohort. The median ages for DTP1 and OPV1 were 121 and 118 days, respectively (Table 1). The vaccination coverage at 6 months of age was 55% for DTP1; 3% got DTP3 (Table 1). Coverage for MV was only 6%. Of the DTP1, OPV1 and MV vaccinations noted on the BHP card 90–95% had been administered by the BHP.

For children examined after 91 days, a one-unit increase in w/a z-score was associated with an odds ratio of 1.07 (0.93–1.24) for receiving a vaccination at that weighing session.

3.1. Natural Experiment with 3–5-month-old Children

There were no marked differences in background factors for the three groups of children who were DTP vaccinated at 3–5 months of age, those who attended a weighing session but were not vaccinated, and those who did not attend a weighing session at 3–5 months of age (Table 2). Birth weight was similar in the three groups. Weight-for-age z-score before 3 months of age did not differ for the three groups (Table 2). Those who did not attend a weighing session at 3–5 months of age were significantly less likely to attend later weighing sessions during infancy, the mean number of visits being lower for those not attending than for those being DTP-vaccinated ($p < 0.001$) (Table 2); hence, they are likely to have travelled more than those who were DTP-vaccinated.

In the main experiment depicted in Fig. 3, DTP vaccination (±OPV) compared with 'DTP-unvaccinated' was associated with a HR of 5.00 (1.53–16.3) (Table 3); the HR was 9.98 (0.81–123) for girls and 3.93 (1.01–15.3) for boys. If we also included vaccinations given on vaccinations-days-without-weighing in the landmark analysis, DTP (±OPV) compared with unvaccinated was associated with a HR of 3.90 (1.20–12.3). When DTP had been given alone without OPV the HR was 10.0 (2.61–38.6) (Table 3). The difference between DTP-only children and DTP-plus-OPV does not reflect differences in follow-up and other vaccinations since the time to DTP2 and prevalence of DTP2 was the same for DTP-only and DTP-plus-OPV vaccinated children (data not shown). If we excluded the 269 children who may have been BCG vaccinated results were similar (Supplementary Table 2).

If the analysis was conducted as an intention-to-treat analysis in which the children weighed but not vaccinated were not censored but transferred to the DTP group, the intended-DTP-vaccinated group had a HR of 3.92 (1.20–12.8) compared with the not-yet vaccinated group (Supplementary Table 3).

3.2. Secondary Analyses

Since the introduction of DTP and OPV apparently was associated with increased mortality, we examined what happened to infant mortality from 3 to 12 months of age after the introduction of these vaccines. The mortality rate for all 3–11 months old children increased 2-fold (HR = 2.12 (1.07–4.19)) from 1980, before vaccinations, to 1982–1983, after the introduction of DTP and OPV (Table 4).

4. Discussion

4.1. Main Observations

DTP vaccinations were associated with increased infant mortality even though there was no vaccine-induced herd immunity. When unvaccinated controls were normal children who had not yet been eligible for vaccination, mortality was 5 times higher for DTP-vaccinated children. Co-administration of OPV with DTP may have reduced the negative effects of DTP.

4.2. Strength and Weaknesses

The present analysis assessed DTP and child survival in a "natural experiment" in which the children were allocated by the timing of their birth and community weighing sessions and the group allocation was therefore not influenced by the usual selection biases to the same extent as most other studies of DTP (Aaby et al., 2016). To assure that the censoring from the main analysis of children who were not vaccinated had not produced the unexpected strong result we made an intention-to-treat analysis but this did not change the result. If anything the unvaccinated children had slightly worse nutritional status before 3 months of age than the children who were subsequently DTP vaccinated ($p = 0.09$) (Table 2); the unvaccinated children travelled more than the DTP vaccinated children. These biases would tend to favor rather than increase mortality in the DTP group and the

Table 4
Mortality rates (deaths/100 person-years) between 3 and 11 months of age by study year.

Mortality rate	1980	1981	1982	1983	HR (95% CI) for 1982–1983 versus 1980
Children aged 3–11 months	4.7 (10/211.8) (N = 547)	7.2 (18/250.8) (N = 678)	8.0 (19/237.1) (N = 632)	12.1 (30/247.5) (N = 638)	2.12 (1.07–4.19)

Notes: Event recorded as accidents were not removed from this analysis.

estimates from the natural experiment may therefore still be conservative.

The estimated effects of DTP and OPV are unlikely to have been influenced by other vaccinations since very few had received other vaccines; if the children who may have received BCG were censored in the analysis the result was essentially the same (Supplementary Table 2).

The 3-monthly community examinations assured that we had follow-up information for all children and relatively accurate information on the time of death. Some children were excluded because a BHP card could not be found and we did not know whether they had been vaccinated or were travelling. Most likely, BHP cards may never have been made because the child was not coming for examination, or the card may have disappeared at community examinations, at the later handling of BHP cards by field workers or data entry clerks, or due to mice. However, the few missing cards are unlikely to have affected the main analysis as the mortality rate in this group was similar to the general mortality rate (Fig. 2).

To assure comparability of vaccinated and unvaccinated groups, also with respect to travelling, we included only children who had been weighed in Bandim in connection with the 3-monthly community examinations. This meant that children who mostly stayed outside the area were not included in the analysis; these children had no access to community vaccinations and they lived elsewhere where the mortality risk might have been quite different, e.g. due to a higher risk of malaria infection.

The present study was not a planned trial. The study would have been a cleaner natural experiment if vaccinations had only been administered at the weighing sessions. However, the expatriate nurse did organize additional vaccinations and some 'unvaccinated' children had therefore already received a vaccination before coming for a weighing session. These 'misclassifications' do not explain the increased mortality in the DTP group. The estimate for DTP-vaccinated (±OPV) compared with DTP-unvaccinated children was 4-fold higher mortality when we included these additional landmarks in the analysis.

4.3. Comparison with Previous Studies of DTP and OPV

There is only one other study of the introduction of DTP. In rural Guinea-Bissau, DTP (±OPV) was associated with 2-fold higher mortality (Aaby et al., 2004a). All studies that documented vaccination status and followed children prospectively indicate that DTP has negative effects; a meta-analysis of the eight studies found 2-fold higher mortality for DTP-vaccinated compared with DTP-unvaccinated, mostly BCG-vaccinated controls (Aaby et al., 2016) (Appendix A).

The negative effect of DTP was much worse in this natural experiment than has been reported in previous studies of DTP. This is presumably due to the "unvaccinated" control children in previous studies having been a frail subgroup too frail to get vaccinated. Previous studies have not been able to compare DTP-vaccinated children with "normal" controls. Hence, most previous studies have probably underestimated the negative effect of DTP.

The potentially differential effects of DTP and OPV have only been examined in few studies. However, we have recently been able to document marked beneficial NSEs of OPV. In an RCT, OPV at birth (OPV0) reduced infant mortality by 32% (0–57%) before the children received campaign-OPV (Lund et al., 2015). In Bissau campaign-OPV reduced the mortality rate by 19% (5–32%) (submitted). When DTP was missing for several months in Bissau, we showed that the all-cause case-fatality at the pediatric ward was 3-fold lower if the children had OPV-only as their most recent vaccination rather than the recommended combination of DTP and OPV (Aaby et al., 2004b). Thus, OPV may have modified the negative effect of DTP.

This pattern was also seen when DTP was first introduced in the rural areas of Guinea-Bissau in 1984 (Aaby et al., 2004a). OPV was not used the first year and the HR for DTP versus unvaccinated was 5.00 (0.63–39.7). In the period from 1985 to 1987, when DTP and OPV were nearly always administered together, the MRR was 1.90 (0.91–3.97). In the present study, the hazard ratio was 10.0 (2.61–38.6) for DTP-only but 3.52 (0.96–12.9) for children who received DTP and OPV simultaneously (Table 3). Based on these two studies of the introduction of DTP, the HR compared with DTP-unvaccinated children was significantly different for children who had received DTP-only (HR = 8.14 (2.63–15.2)) and for children who received both DTP and OPV (HR = 2.21 (1.16–4.19)) (test of interaction, p = 0.049). Hence, simultaneous administration of DTP and OPV may have alleviated the negative non-specific effect of DTP.

5. Conclusions

DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the performance of national vaccination programs.

It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections.

The recently published SAGE review called for randomized trials of DTP (Higgins et al., 2014). However, at the same time the IVIR-AC committee to which SAGE delegated the follow-up studies of the NSEs of vaccines has indicated that it will not be possible to examine the effect of DTP in an unbiased way. If that decision by IVIR-AC remains unchallenged, the present study may remain the closest we will ever come to a RCT of the NSEs of DTP.

Funding

The present study and cleaning of the original data was supported by a common grant from DANIDA and the Novo Nordisk Foundation (FU-11-551). The work on non-specific effects of vaccines has been supported by the Danish Council for Development Research, Ministry of Foreign Affairs, Denmark [grant number 104.Dan.8.f.], Novo Nordisk Foundation and European Union FP7 support for OPTIMUNISE (grant: Health-F3-2011-261375). CSB held a starting grant from the ERC (ERC-2009-StG-243149). CVIVA is supported by a grant from the Danish National Research Foundation (DNRF108). PA held a research professorship grant from the Novo Nordisk Foundation.

Conflict of Interest

Nothing to declare

Contributions

CSB and PA proposed the study. PA collected the original data. AR is responsible for the demographic surveillance system. SWM and PA cleaned the data. SWM and AA conducted the statistical analyses. The first draft was written by PA; all authors contributed to the final version of the paper. PA and SWM will act as guarantors of the study.

Independence

The funding agencies had no role in the study design, data collection, data analysis, data interpretation, or the writing of the report.

Data Sharing

Through request to the authors

Appendix A. The DTP Controversy

The issue of DTP vaccination and child mortality in high mortality areas was raised 15 years ago when a study from rural Guinea-Bissau showed 1.84-fold higher mortality for children who had received DTP1 vaccination (Aaby et al., 2016; Kristensen et al., 2000). All subsequent prospective studies have supported a negative effect (Aaby et al., 2016). Furthermore, DTP may have a negative effect when given simultaneously with or after MV (Aaby at el., 2003b, 2012). For example, the negative effect of high-titer measles vaccination (HTMV) in girls, which led to the global withdrawal of HTMV, was due to DTP being administered after MV because HTMV had been given early at 4–5 months of age (Aaby et al., 2003b).

DTP has not been shown to have beneficial effects in RCTs or natural experiments. The current policy for DTP has only been examined by reanalyses of existing data sets collected for other purposes. All such studies have had methodological problems related to different forms of frailty and survival bias (Aaby et al., 2012). These studies have updated follow-up time for DTP-vaccinated children who survived but children who died without their vaccination status being documented were classified as "unvaccinated". Such procedures give a misleading high mortality rate in the unvaccinated group, and the comparison of DTP-vaccinated survivors and "unvaccinated" children will therefore give a beneficial estimate for DTP (Aaby et al., 2016). If the mortality rate of unvaccinated children is unnaturally increased, the HR of unvaccinated children versus children who have received at least one vaccine may indicate how much bias there might be in the study, and we have called this HR the "bias-index". All studies with prospective follow-up have had a bias index below 2.0 (Aaby et al., 2016); in the present study the bias index was 0.41 (0.15–1.15) in the 3–5 months age group (Supplementary Table 2). In studies with survival bias and unnaturally high mortality in the unvaccinated group, the bias index has been 3–8 times higher (Aaby et al., 2016).

SAGE recently reviewed the potential NSEs of BCG, MV and DTP (Higgins et al., 2014; Strategic Advisory Group of experts on Immunization, 2014). The reviewers indicated that the majority of studies showed a deleterious effect of DTP but they concluded that the results were inconsistent because two studies showed a beneficial effect. The beneficial effect in these studies was not surprising because the mortality rate in the unvaccinated group was unnaturally high, and the bias index was 3.40 (2.93–3.95) and 7.52 (5.15–10.97), respectively (Aaby et al., 2016).

SAGE's working group on non-specific effects of vaccines further emphasized that the overall effect remains unclear because DTP has been given in combination with other vaccines and under circumstances where the burden of the target diseases has been reduced to a very low level. However, several previous studies have shown that the negative effect of DTP-plus-OPV was not due to OPV (Aaby et al., 2004a,b, 2012). OPV has probably reduced the overall negative effect of DTP. Previous studies have indicated that DTP (±OPV) was associated with a 2-fold higher mortality than DTP-unvaccinated children (Aaby et al., 2016). Since pertussis did not account for >5–6% of infant deaths in the only existing African study of the impact of pertussis on child mortality (Mahieu et al., 1978), it is not surprising that DTP is also associated with a strong negative effect prior to vaccine-induced herd immunity (Aaby et al., 2012).

Appendix B. Supplementary Data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ebiom.2017.01.041.

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From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Thu, 2 Aug 2018 12:52:24 +0000
To: Malone, Kevin M. (CDC/OCOO/OGC)
Cc: MacNeil, Jessica R. (CDC/OID/NCIRD); Pope, Kristin (CDC/OID/NCIRD)
Subject: FW: Pics
Attachments: IMG_1499.jpg, ATT00001.txt, IMG_1500.jpg, ATT00002.txt, IMG_1501.jpg, ATT00003.txt, IMG_1502.jpg, ATT00004.txt, IMG_1503.jpg, ATT00005.txt

Kevin,

(b)(5)

Thanks!
Amanda

-----Original Message-----
From: Lee, Grace <GMLee@stanfordchildrens.org>
Sent: Wednesday, August 1, 2018 6:18 PM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/OID/NCIRD) <aji8@cdc.gov>; Jose Romero <RomeroJose@UAMS.edu>
Subject: Pics

ICAN
Informed Consent Action Network

July 31, 2018

VIA FEDERAL EXPRESS
Grace M. Lee, MD, MPH
Professor of Pediatrics
Stanford University School of Medicine
300 Pasteur Drive, G-306b
Stanford, CA 94305

Re: *Efficacy of the mumps vaccine*

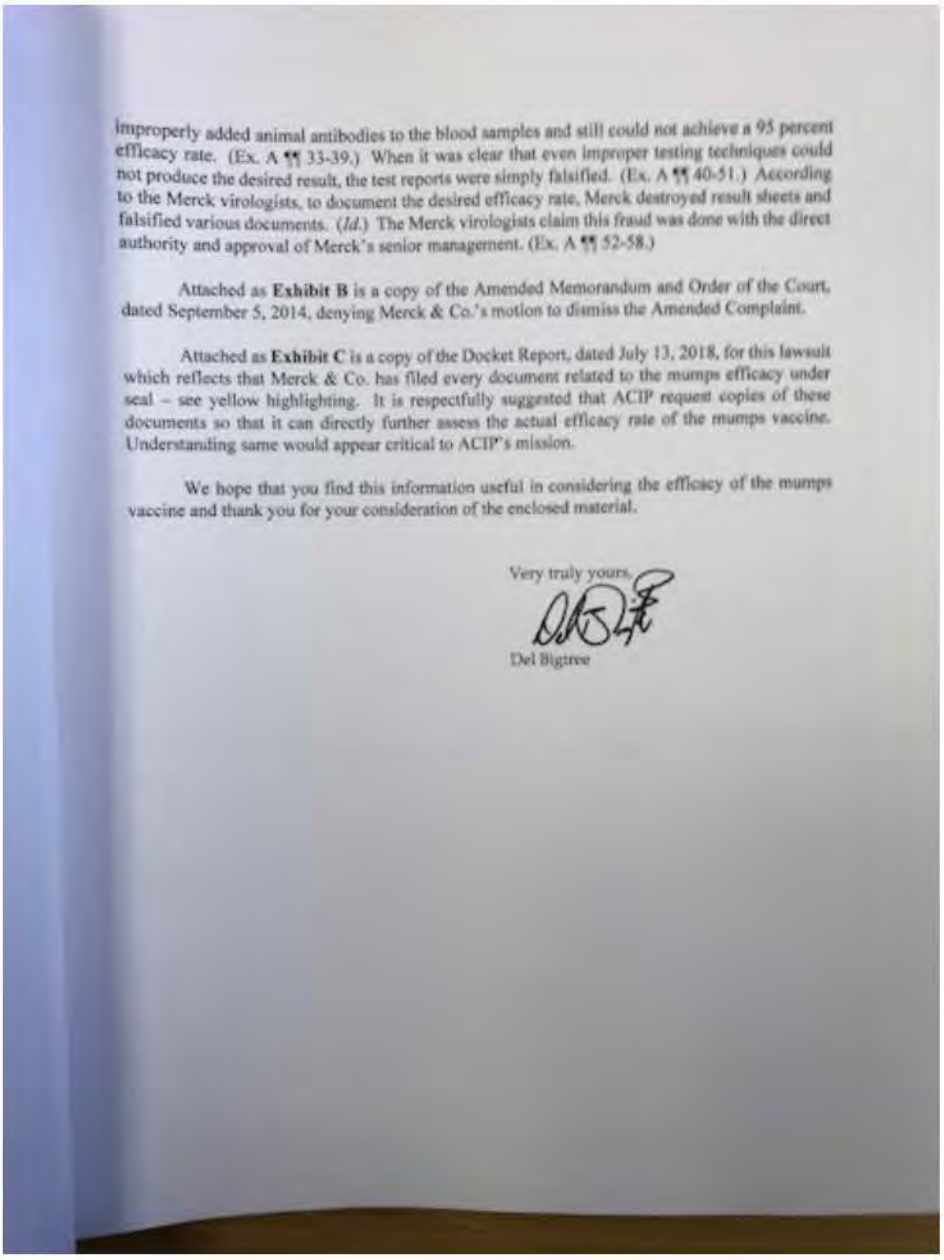
Dear Dr. Lee,

Thank you for the opportunity to speak regarding the efficacy of the mumps vaccine at the Advisory Committee on Immunization Practices ("ACIP") meeting held on June 20, 2018. As a follow-up to that comment, attached is information concerning a civil lawsuit filed against Merck & Co. ("Merck") that every member of ACIP should be aware of when considering the efficacy of the mumps vaccine.

Attached as **Exhibit A** is a copy of the Amended Complaint in *United States of America et al. v. Merck & Co., Inc.*, Case No. 10-4373, dated April 27, 2012, filed in Federal Court. In that document, the plaintiffs, the United States of America and two former Merck virologists, describe "Merck's efforts for more than a decade to defraud the United States through Merck's ongoing scheme to sell the government a mumps vaccine that is ... falsely certified as having an efficacy rate that is significantly higher than it actually is." (Ex. A ¶ 1.)

As detailed in the Amended Complaint, Merck obtained a license for its mumps vaccine in 1967 and is the only company to ever obtain a license for a mumps vaccine in the United States. (Ex. A ¶ 16.) In the late 1990s, in order to obtain approval for ProQuad in the U.S. and Europe, Merck needed to reconfirm its claims of efficacy for its mumps vaccine made thirty years prior. (Ex. A. ¶ 22.) Merck's virologists working on testing the efficacy of the mumps vaccine revealed that after Merck could not demonstrate a 95 percent efficacy for its mumps vaccine, the results were simply fraudulently falsified to achieve this result. (Ex. A ¶¶ 15-131.)

As explained by Merck's virologists, Merck took blood samples pre-vaccinated with the mumps vaccine and then exposed them to the mumps virus. (Ex. A ¶¶ 25-28.) When a test against a live strain of mumps would not yield a 95 percent efficacy, Merck tried to improperly obtain this rate using an attenuated strain of the mumps virus. (Ex. A ¶¶ 29-30.) When this *still* would not achieve 95 percent efficacy, Merck tried different virus dilutions, different straining procedure, and even more liberal antibody counting techniques. (Ex. A ¶¶ 31-32.) The Merck lab even



improperly added animal antibodies to the blood samples and still could not achieve a 95 percent efficacy rate. (Ex. A ¶¶ 33-39.) When it was clear that even improper testing techniques could not produce the desired result, the test reports were simply falsified. (Ex. A ¶¶ 40-51.) According to the Merck virologists, to document the desired efficacy rate, Merck destroyed result sheets and falsified various documents. (*Id.*) The Merck virologists claim this fraud was done with the direct authority and approval of Merck's senior management. (Ex. A ¶¶ 52-58.)

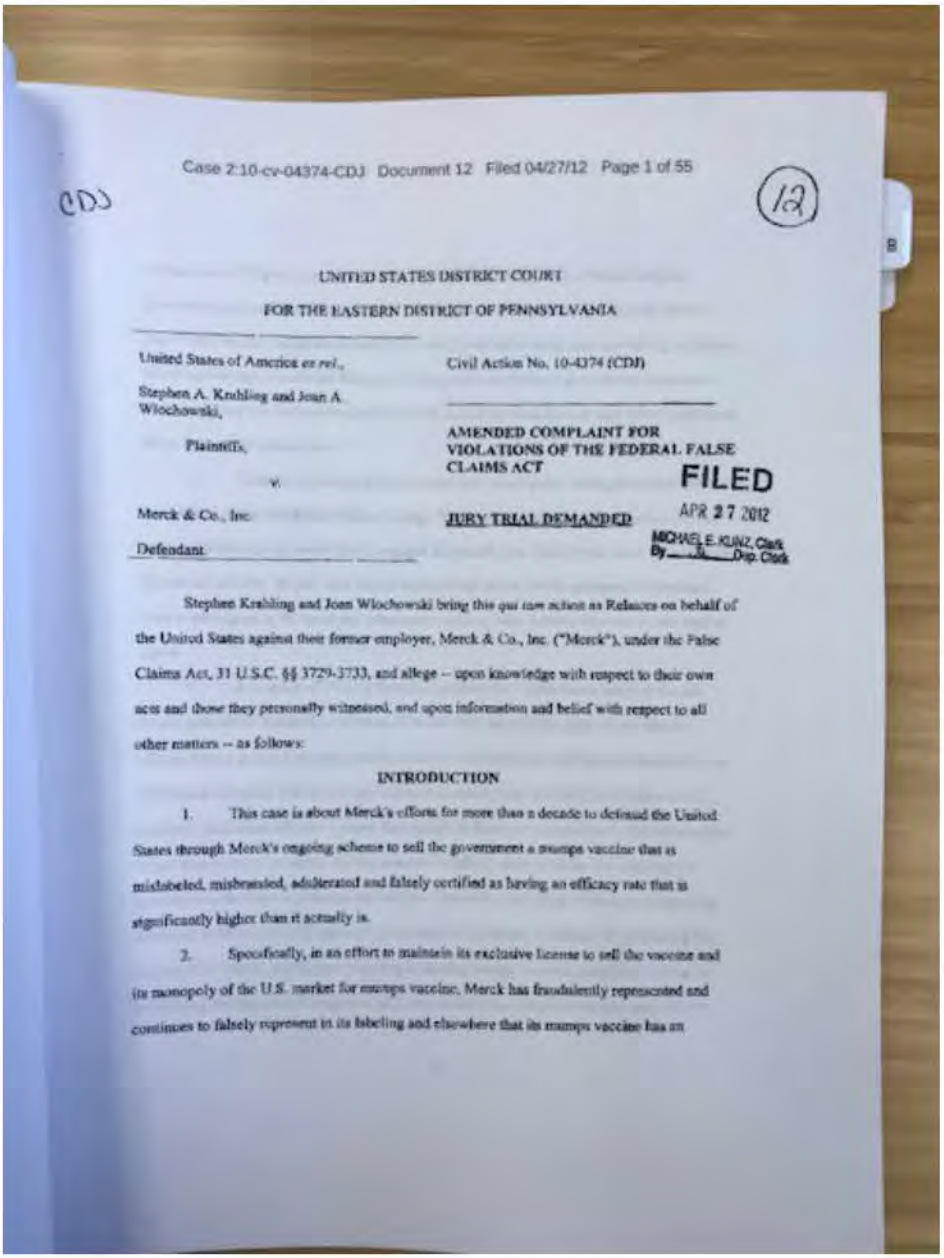
Attached as **Exhibit B** is a copy of the Amended Memorandum and Order of the Court, dated September 5, 2014, denying Merck & Co.'s motion to dismiss the Amended Complaint.

Attached as **Exhibit C** is a copy of the Docket Report, dated July 13, 2018, for this lawsuit which reflects that Merck & Co. has filed every document related to the mumps efficacy under seal – see yellow highlighting. It is respectfully suggested that ACIP request copies of these documents so that it can directly further assess the actual efficacy rate of the mumps vaccine. Understanding same would appear critical to ACIP's mission.

We hope that you find this information useful in considering the efficacy of the mumps vaccine and thank you for your consideration of the enclosed material.

Very truly yours,

Del Bigtree



CDJ

(12)

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America *ex rel.*, Stephen A. Krahling and Joan A. Wlochowski, Plaintiffs, v. Merck & Co., Inc. Defendant	Civil Action No. 10-4374 (CDJ) **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT** **JURY TRIAL DEMANDED**

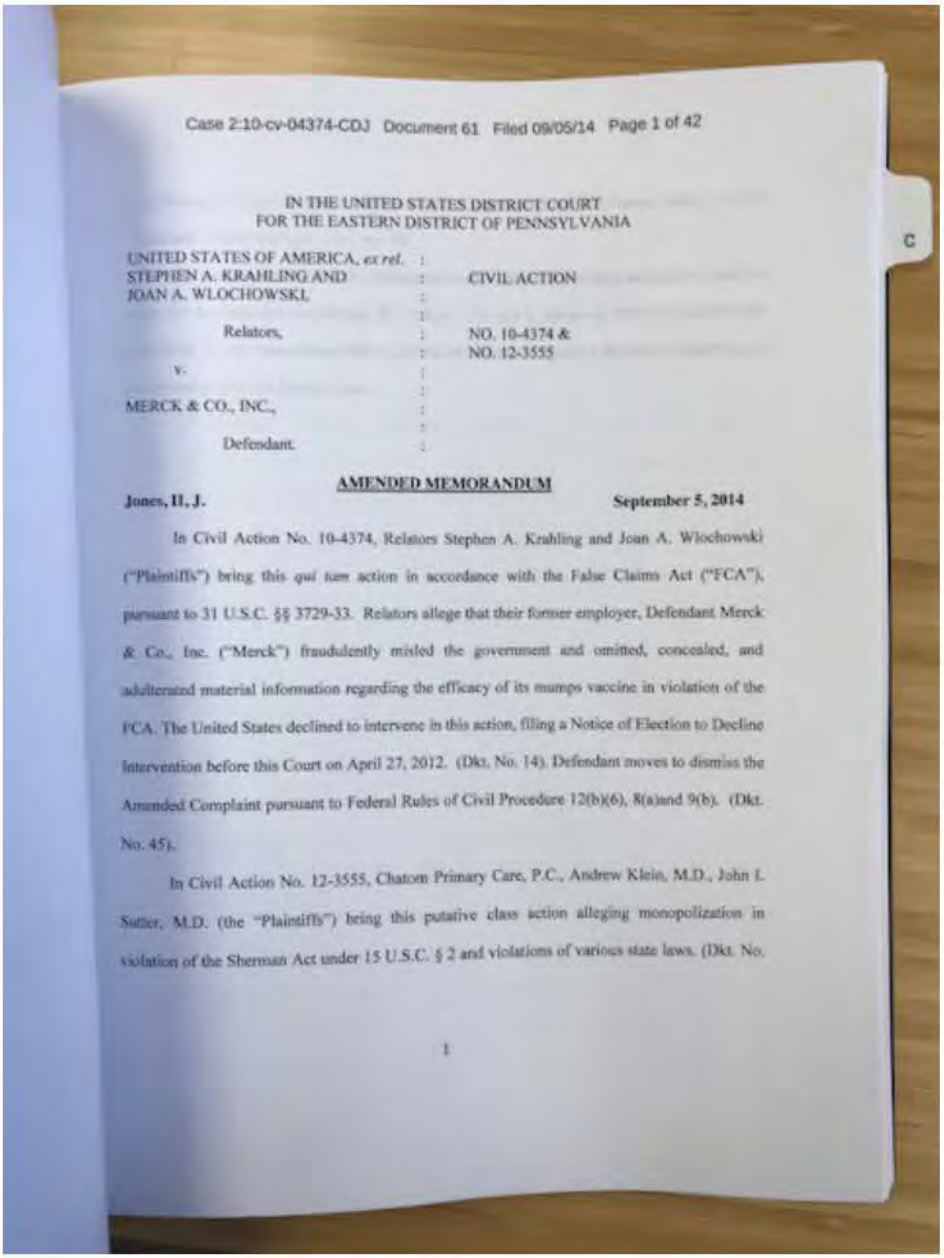
FILED
APR 27 2012
MICHAEL E. KUNZ, Clerk
By ____ Dep. Clerk

Stephen Krahling and Joan Wlochowski bring this *qui tam* action as Relators on behalf of the United States against their former employer, Merck & Co., Inc. ("Merck"), under the False Claims Act, 31 U.S.C. §§ 3729-3733, and allege -- upon knowledge with respect to their own acts and those they personally witnessed, and upon information and belief with respect to all other matters -- as follows:

INTRODUCTION

1. This case is about Merck's efforts for more than a decade to defraud the United States through Merck's ongoing scheme to sell the government a mumps vaccine that is mislabeled, misbranded, adulterated and falsely certified as having an efficacy rate that is significantly higher than it actually is.

2. Specifically, in an effort to maintain its exclusive license to sell the vaccine and its monopoly of the U.S. market for mumps vaccine, Merck has fraudulently represented and continues to falsely represent in its labeling and elsewhere that its mumps vaccine has an



C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

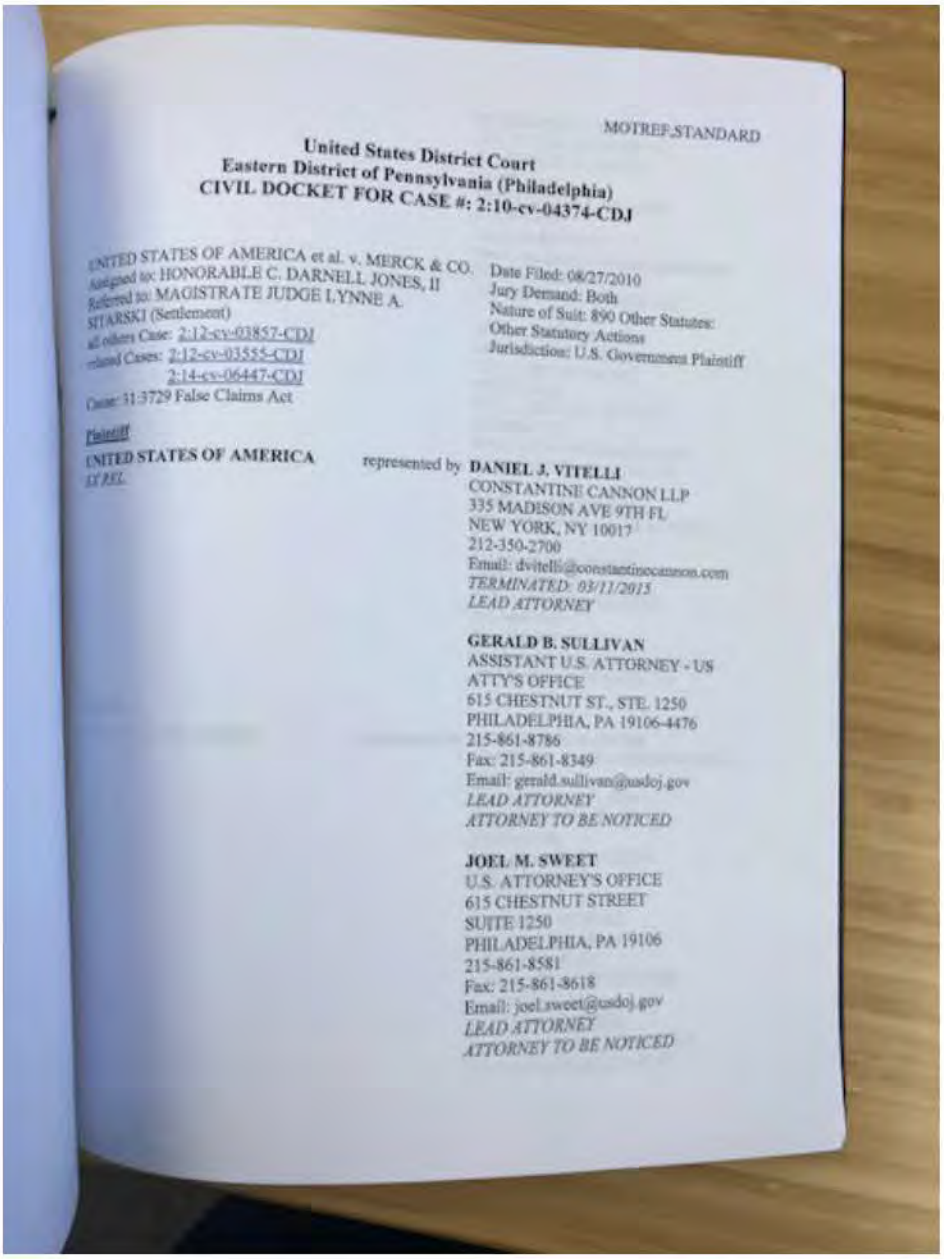
UNITED STATES OF AMERICA, *ex rel.* STEPHEN A. KRAHLING AND JOAN A. WLOCHOWSKI,	:	CIVIL ACTION
Relators,	:	NO. 10-4374 & NO. 12-3555
v.	:	
MERCK & CO., INC.,	:	
Defendant.	:	

AMENDED MEMORANDUM

Jones, II, J. **September 5, 2014**

In Civil Action No. 10-4374, Relators Stephen A. Krahling and Joan A. Wlochowski ("Plaintiffs") bring this *qui tam* action in accordance with the False Claims Act ("FCA"), pursuant to 31 U.S.C. §§ 3729-33. Relators allege that their former employer, Defendant Merck & Co., Inc. ("Merck") fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine in violation of the FCA. The United States declined to intervene in this action, filing a Notice of Election to Decline Intervention before this Court on April 27, 2012. (Dkt. No. 14). Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a)and 9(b). (Dkt. No. 45).

In Civil Action No. 12-3555, Chatom Primary Care, P.C., Andrew Klein, M.D., John L. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No.



MOTREF.STANDARD

United States District Court
Eastern District of Pennsylvania (Philadelphia)
CIVIL DOCKET FOR CASE #: 2:10-cv-04374-CDJ

UNITED STATES OF AMERICA et al. v. MERCK & CO.
Assigned to: HONORABLE C. DARNELL JONES, II
Referred to: MAGISTRATE JUDGE LYNNE A. SITARSKI (Settlement)
all others Case: 2:12-cv-03857-CDJ
related Cases: 2:12-cv-03555-CDJ
2:14-cv-06447-CDJ
Cause: 31:3729 False Claims Act

Date Filed: 08/27/2010
Jury Demand: Both
Nature of Suit: 890 Other Statutes: Other Statutory Actions
Jurisdiction: U.S. Government Plaintiff

Plaintiff

UNITED STATES OF AMERICA
ex rel.

represented by **DANIEL J. VITELLI**
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-350-2700
Email: dvitelli@constantinecannon.com
TERMINATED: 03/11/2015
LEAD ATTORNEY

GERALD B. SULLIVAN
ASSISTANT U.S. ATTORNEY - US ATTY'S OFFICE
615 CHESTNUT ST., STE. 1250
PHILADELPHIA, PA 19106-4476
215-861-8786
Fax: 215-861-8349
Email: gerald.sullivan@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL M. SWEET
U.S. ATTORNEY'S OFFICE
615 CHESTNUT STREET
SUITE 1250
PHILADELPHIA, PA 19106
215-861-8581
Fax: 215-861-8618
Email: joel.sweet@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ICAN
Informed Consent Action Network

July 31, 2018

VIA FEDERAL EXPRESS
Grace M. Lee, MD, MPH
Professor of Pediatrics
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CDJ

12

B

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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Plaintiffs,

v.

Merck & Co., Inc.

Defendant.

Civil Action No. 10-4374 (CDJ)

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

JURY TRIAL DEMANDED

FILED
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MICHAEL E. KUNZ, Clerk
By ____ Dep. Clerk

Stephen Krahling and Joan Wlochowski bring this *qui tam* action as Relators on behalf of the United States against their former employer, Merck & Co., Inc. ("Merck"), under the False Claims Act, 31 U.S.C. §§ 3729-3733, and allege – upon knowledge with respect to their own acts and those they personally witnessed, and upon information and belief with respect to all other matters – as follows:

INTRODUCTION

1. This case is about Merck's efforts for more than a decade to defraud the United States through Merck's ongoing scheme to sell the government a mumps vaccine that is mislabeled, misbranded, adulterated and falsely certified as having an efficacy rate that is significantly higher than it actually is.

2. Specifically, in an effort to maintain its exclusive license to sell the vaccine and its monopoly of the U.S. market for mumps vaccine, Merck has fraudulently represented and continues to falsely represent in its labeling and elsewhere that its mumps vaccine has an

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* STEPHEN A. KRAHLING AND JOAN A. WLOCHOWSKI,	:	CIVIL ACTION
Relators,	:	NO. 10-4374 & NO. 12-3555
v.	:	
MERCK & CO., INC.,	:	
Defendant.	:	

AMENDED MEMORANDUM

Jones, II, J. **September 5, 2014**

In Civil Action No. 10-4374, Relators Stephen A. Krahling and Joan A. Wlochowski ("Plaintiffs") bring this *qui tam* action in accordance with the False Claims Act ("FCA"), pursuant to 31 U.S.C. §§ 3729-33. Relators allege that their former employer, Defendant Merck & Co., Inc. ("Merck") fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine in violation of the FCA. The United States declined to intervene in this action, filing a Notice of Election to Decline Intervention before this Court on April 27, 2012. (Dkt. No. 14). Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a)and 9(b). (Dkt. No. 45).

In Civil Action No. 12-3555, Chatom Primary Care, P.C., Andrew Klein, M.D., John I. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No.

MOTREF,STANDARD

United States District Court
Eastern District of Pennsylvania (Philadelphia)
CIVIL DOCKET FOR CASE #: 2:10-cv-04374-CDJ

UNITED STATES OF AMERICA et al. v. MERCK & CO.
Assigned to: HONORABLE C. DARNELL JONES, II
Referred to: MAGISTRATE JUDGE LYNNE A. SITARSKI (Settlement)
all others Case: 2:12-cv-03857-CDJ
related Cases: 2:12-cv-03555-CDJ
2:14-cv-06447-CDJ
Cause: 31:3729 False Claims Act

Date Filed: 08/27/2010
Jury Demand: Both
Nature of Suit: 890 Other Statutes: Other Statutory Actions
Jurisdiction: U.S. Government Plaintiff

Plaintiff

UNITED STATES OF AMERICA
ET REL

represented by **DANIEL J. VITELLI**
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-350-2700
Email: dvitelli@constantinecannon.com
TERMINATED: 03/11/2015
LEAD ATTORNEY

GERALD B. SULLIVAN
ASSISTANT U.S. ATTORNEY - US ATTY'S OFFICE
615 CHESTNUT ST., STE. 1250
PHILADELPHIA, PA 19106-4476
215-861-8786
Fax: 215-861-8349
Email: gerald.sullivan@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL M. SWEET
U.S. ATTORNEY'S OFFICE
615 CHESTNUT STREET
SUITE 1250
PHILADELPHIA, PA 19106
215-861-8581
Fax: 215-861-8618
Email: joel.sweet@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

__
Grace M. Lee, MD MPH
Associate Chief Medical Officer for Practice Innovation
Professor of Pediatrics
300 Pasteur Drive, G-306B
Stanford, CA 94305
(650) 497-0618 (office)
(650) 305-8030 (cell)

Please send calendar requests to:
Lisa Perry, Executive Assistant
Liperry@stanfordchildrens.org
(650) 724-3664 (office)

Sent from my iPhone

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Mon, 2 Jul 2018 18:53:12 +0000
To: Thomas, Stephanie B. (CDC/OID/NCIRD) (hkp4@cdc.gov)
Subject: FW: Public comment letters
Attachments: Thank you_Woodruff cp edits.docx, Thank you_Severino cp edits.docx, Thank you_Layton cp edits.docx, Thank you_Hastings cp edits.docx, Thank you_Bigtree cp edits.docx

One small issue, I am now a CAPT ☺

From: Pellegrini, Cynthia <CPellegrini@marchofdimes.org>
Sent: Sunday, July 1, 2018 4:30 PM
To: Thomas, Stephanie B. (CDC/OID/NCIRD) <hkp4@cdc.gov>
Cc: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/OID/NCIRD) <aji8@cdc.gov>
Subject: Re: Public comment letters

Steph, these look really marvelous. I made a few tweaks to a couple, things like adding the name of the (b)(6) to the letter to his mom. The only one I made major changes to was the one for Del Bigtree, because he's already gotten the form letter. The others haven't.

Letters with changes are attached in TC. All the others are great.

It's wonderful to know I'm leaving this practice in excellent hands with you all. ☺

All the best,
Cindy

From: Stephanie Thomas <hkp4@cdc.gov>
Date: Friday, June 29, 2018 at 4:25 PM
To: "Pellegrini, Cynthia" <CPellegrini@marchofdimes.org>
Cc: "Cohn, Amanda (CDC/OID/NCIRD)" <anc0@cdc.gov>, "MacNeil, Jessica R. (CDC/OID/NCIRD)" <aji8@cdc.gov>
Subject: Public comment letters

Hi Cindy,
Attached are the response letters for the public comments. Please review and make any changes that you see fit. I wasn't in the room except for the last 2 on Thursday, so I don't know if they spoke of more than what they wrote on their sign-up sheets.

If you are busy or on vacation and don't have time to review these, no problem! Amanda, Jessica and I can make any needed changes.
Thanks and Happy July 4th!

Stephanie

Stephanie B. Thomas
Management Analyst/Committee Management Specialist
Advisory Committee on Immunization Practices (ACIP)
National Center for Immunization and Respiratory Diseases (NCIRD)
Office of the Director (OD)
Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/vaccines/acip/index.html

(b)(6)

Office: [redacted]

Mailing address: 1600 Clifton Road NE/MS-A27/Atlanta, GA 30329-4027

From: Barry, Brooke (CDC/OID/NCIRD)
Sent: Fri, 17 Feb 2017 07:56:12 -0500
To: Messonnier, Nancy (CDC/OID/NCIRD); Cohn, Amanda (CDC/OID/NCIRD)
Subject: FW: summary of event

FYI – I meant to send this yesterday.

From: Katsoyannis, Miranda (CDC/OD/CDCWO)
Sent: Thursday, February 16, 2017 1:06 PM
To: Barry, Brooke (CDC/OID/NCIRD) <bmb8@cdc.gov>; Beauvais, Denise (CDC/OID/NCIRD) <cry2@cdc.gov>; Miller, Rebecca (CDC/OID/NCEZID) <ckq0@cdc.gov>; Nguyen, Lyn (CDC/OID/NCEZID) <ivx1@cdc.gov>
Cc: Pope, Kristin (CDC/OID/NCIRD) <kfp7@cdc.gov>
Subject: summary of event

Hi Folks,
Here is a partner's view of today's event on the Hill. I will also forward our first inquiry from a staffer unfamiliar with vaccine safety issues who is asking for a phone briefing.
Thx,
Randy

Good morning, all –

As you are aware, RFK Jr. and Robert De Niro were scheduled to host a briefing on Capitol Hill this morning. **Robert De Niro did not attend as advertised**, rather, RFK Jr. and the three other speakers from yesterday's press conference (Nico LaHood, Tony Muhammed and Del Bigtree) spoke during the hearing which lasted an hour.

The room was less than half full. By a show of hands prompted by speaker Nico LaHood, San Antonio District Attorney, there were **about 10 congressional staffers in the room. There were no Members of Congress in attendance**. Several dozen people also left about halfway through the briefing, which LaHood commented on as they exited.

It also seems that no MOC sponsored the briefing. In speaking with a senior staff member of the Oversight Committee, it seems most likely that the World Mercury Project rented the room, which is available for rental by any member of the public.

All speakers' talking points closely mimicked those which they spoke to during yesterday's press conference.

RFK Jr. spoke to the World Mercury Project's $100,000 challenge and to the alleged lack of vaccine safety studies available. He frequently conflated the use of "thimerosal," "vaccines," and "mercury" which made it difficult to tell what exactly he was referencing when he made assertions like, "it causes autism."

LaHood asked congressional staffers for a show of hands – there were about 10, all (presumably) under the age of 30. He pointed out their age and emphasized that they may not remember a world without autism, ADHD, OCD etc. but that is not the norm. LaHood implored them to share this information and this plea with their bosses. He also incorrectly cited the most recent autism rate in the United States as 1 in 43 (it's 1 in 68).

Muhammed, of the Nation of Islam, spoke, as he did yesterday, to the alleged disproportionate impact of vaccine injury among minority and poor populations. He also incorrectly asserted that Dr. William Thompson, the CDC whistleblower, is "dying to come before Congress" to testify.

Bigtree, former producer of the daytime TV show "The Doctors" and the film "Vaxxed," closed the event with a highly impassioned speech. He told the crowd, "the blood of these children is on your hands" and that children in the US will continue to die if our legislators do not do their jobs right now.

There was no time remaining for questions.

There has been no media coverage of the briefing thus far.

(b)(6)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 11 Mar 2019 10:25:16 -0400
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FYI

(b)(5) The due date is 3/22. Let me know if we need more time.

-Lyn

Lyn Thi Nguyen, MPH
Public Health Analyst (Policy)
Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329
(b)(6)
(Tel)
(BB)
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

---

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)
Sent: Monday, March 11, 2019 10:23 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Tom Shimabukuro (CDC/OID/NCEZID) (ayv6@cdc.gov) <ayv6@cdc.gov>
Subject: FW: 19-00536-FOIA: Request for Documents

PerStephanie,

Wanted to give you a heads up that we got this FOIA via policy channels. Not sure if you have already gotten this and are already handling from your end. Happy to chat if you have questions.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH
Public Health Analyst (Policy)
Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329

(b)(6)

(Tel)
(BB)
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

From: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>
Sent: Friday, March 8, 2019 5:32 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP) <vhj2@cdc.gov>; Clasp, Samuel (CDC/DDID/NCEZID/DHQP) (CTR) <nss4@cdc.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; DHQP_Policy (CDC) (b)(6)
Cc: Gold, Rebecca (CDC/DDID/NCEZID/OD) <gsy7@cdc.gov>; Richmond-Crum, Malia (CDC/DDID/NCEZID/OD) <jrv8@cdc.gov>; Oliver, Angela (CDC/DDID/NCEZID/OD) <irr7@cdc.gov>
Subject: RE: 19-00536-FOIA: Request for Documents

Lyn

(b)(5)

Amy

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Date: March 8, 2019 at 3:36:48 PM EST
To: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>, Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP) <vhj2@cdc.gov>, Clasp, Samuel (CDC/DDID/NCEZID/DHQP) (CTR) <nss4@cdc.gov>, Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>, DHQP_Policy (CDC) (b)(6)
Cc: Gold, Rebecca (CDC/DDID/NCEZID/OD) <gsy7@cdc.gov>, Richmond-Crum, Malia (CDC/DDID/NCEZID/OD) <jrv8@cdc.gov>, Oliver, Angela (CDC/DDID/NCEZID/OD) <irr7@cdc.gov>
Subject: RE: 19-00536-FOIA: Request for Documents

Amy,

(b)(5)

Thanks.
-Lyn

Lyn Thi Nguyen, MPH
Public Health Analyst (Policy)

Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329
(b)(6)
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

From: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>
Sent: Friday, March 8, 2019 11:58 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP) <vhj2@cdc.gov>; Clasp, Samuel (CDC/DDID/NCEZID/DHQP) (CTR) <nss4@cdc.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; DHQP_Policy (CDC) <(b)(6)
Cc: Gold, Rebecca (CDC/DDID/NCEZID/OD) <gsy7@cdc.gov>; Richmond-Crum, Malia (CDC/DDID/NCEZID/OD) <jrv8@cdc.gov>; Oliver, Angela (CDC/DDID/NCEZID/OD) <irr7@cdc.gov>
Subject: FW: 19-00536-FOIA: Request for Documents

Hey Lyn and Jeremy
You both helped me provide information to NCIRD for the measles hearing last week. Please see below – FOIA request that has gone to NCIRD for action. They would like some information from us. (b)(5)

(b)(5)

Thanks so much!

Amy

Additional background information on this topic (if needed):
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6204a1.htm

MMR vaccine do no and never did contain thimerosal. Additional information on this is on our website: https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html

From: Swartwood, Candice (CDC/DDID/NCIRD/OD) <chj8@cdc.gov>
Sent: Friday, March 8, 2019 8:57 AM
To: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>
Cc: Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; Barry, Brooke (CDC/DDID/NCIRD/OD) <bmb8@cdc.gov>; NCIRD FOIA Requests (CDC) <NCIRDfoiarequests@cdc.gov>
Subject: FW: 19-00536-FOIA: Request for Documents

Hi Amy,

(b)(5)

We will also check with our program folks. Thanks, Candice

From: Jarman Miller, Hannah (CDC/DDID/NCIRD/OD) <oqr0@cdc.gov> **On Behalf Of** NCIRD FOIA Requests (CDC)
Sent: Friday, March 08, 2019 8:51 AM
To: Swartwood, Candice (CDC/DDID/NCIRD/OD) <chj8@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>
Cc: Barry, Brooke (CDC/DDID/NCIRD/OD) <bmb8@cdc.gov>
Subject: FW: 19-00536-FOIA: Request for Documents

Good Morning,

I received a FOIA request from ICAN regarding Nancy's hearing last week. They are requesting studies used to support the statement she made on the risks of encephalitis. Details in the attached. Would we response to this FOIA? Or would is still go out to a division?

Thank you,

Hannah

From: FOIA Requests (CDC) <foiarequests@cdc.gov>
Sent: Friday, March 8, 2019 8:29 AM
To: NCIRD FOIA Requests (CDC) <NCIRDfoiarequests@cdc.gov>
Subject: 19-00536-FOIA: Request for Documents

Request for Documents for Request # '19-00536-FOIA'. Your response due date is: 3/22/2019 12:00:00 AM Message from SENDER: March 8, 2019

19-00536-FOIA. **Due Date March 22, 2019**

Please note the FOIA requester only seeks studies --no emails.

Please read the FOIA request in its entirety and ensure that you search and respond to all parts of the request. CDC programs have 10 work days to search and provide responsive

records. **Notify the FOIA Office by email when all responsive documents and forms have been place in the FOIA share drive.**

If you have any questions or concerns about the request, please contact Mark Harper at 770-488-8154.

All staff have a legal obligation to conduct a reasonable search and provide all materials in-scope of the FOIA request regardless of whether some content can or must be withheld in accordance with FOIA exemptions. The CDC FOIA Office will address release decisions and consult with CDC programs as necessary.

Searching strategies and instructions for Record Holders can be found in the following guide:
Identifying and Providing Documents Responsive to FOIA Requests

Record holders should exercise care in constructing the search strategy and criteria. The FOIA Office has the following suggestions for search criteria to use in this FOIA request:

- *Names (e.g. to/from, author, named in content):*
- *Date or Date Range:*
- *Keywords or phrases (including Boolean criteria such as: and, or, not):*

When documents are located, please return the documents and required form to the CDC FOIA Office (see below) through your organization's FOIA Coordinator. If this request should be forwarded to another C/I/O, federal agency, or state agency, please indicate this on the response sheet.

Required FOIA Form: *The required form may be found on the FOIA intranet page at:*
http://intranet.cdc.gov/ocio/about/foia/index.html

You may also link directly to the form by clicking: http://isp-v-maso-apps/EForms/download.aspx?ID=2003

From: Basket, Michelle (CDC/OID/NCIRD)
Sent: Fri, 31 Mar 2017 14:02:41 -0400
To: Connelly, Erin (CDC/ONDIEH/NCIPC); Messonnier, Nancy (CDC/OID/NCIRD); Craig, Allen (CDC/OID/NCIRD); Barry, Brooke (CDC/OID/NCIRD)
Subject: fyi

From: Vacsafety (b)(6) **On Behalf Of** (b)(6)
Sent: Friday, March 31, 2017 1:39 PM
To: (b)(6)
Subject: Re: [VACSAFETY] Revolution for Truth

Good Afternoon,

Please see a detailed recap of the Revolution for Truth press conference below. The event lasted for an hour longer than the team publicized (9:00 – 11:30 am ET) to accommodate an impromptu Q & A session at the end. Nearly 12,400 viewers tuned in via Facebook Live.

The group spoke at length about the conflicts of interest within the CDC and pharmaceutical industry, censorship within the scientific research community and the media, and the stigmatization of parents who question vaccine safety.

We will continue to provide updates on the event as more details are available.

Thanks,
Dominique

Revolution for Truth Press Conference
March 31, 2017
National Press Club – Washington, DC

Participants:

- Brian Hooker
- Toni Bark
- Jennifer Margulis
- Paul Thomas
- Judy Mikovits

The Revolution for Truth team held a press conference this morning titled, "Doctors for Accountability in Medicine and Media", that was moderated by Del Bigtree and featured commentary from Brian Hooker, Toni Bark, Jennifer Margulis, Paul Thomas, Judy Mikovits, and a blogger from Health Impact News. The group spoke at length about **the conflicts of interest within the CDC and pharmaceutical industry, censorship within the scientific research community and the media, and the stigmatization of parents who question vaccine safety.**

Paul Thomas, MD, a Portland-based pediatrician known for his modified vaccine schedule, spoke about the dangers of aluminum in vaccines, which allegedly causes severe developmental delays. He claimed

that the amount of aluminum exceeds federal guidelines for safety, and their nanoparticle form in vaccines makes them incapable of being absorbed. Thomas also noted that vaccines for STD prevention are given too early, as babies don't partake in the risky behaviors that the immunizations protect against, and that immunity from the Hepatitis B vaccine and others wanes before adolescence – rendering them useless. Thomas closed by calling for informed consent for parents, a mechanism for vaccine safety researchers to share their findings freely, and for a longitudinal study to compare health outcomes of vaccinated versus unvaccinated children.

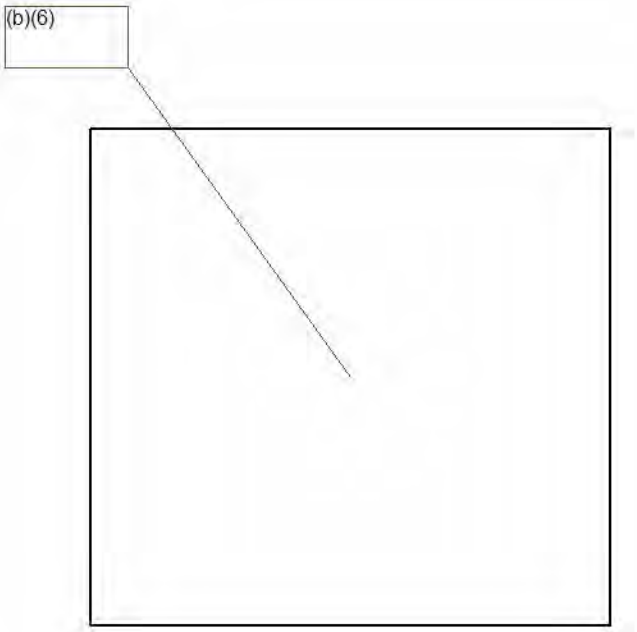
Brian Hooker, PhD, PE, noted anti-vaccine activist and parent of an autistic child, followed Thomas by recounting his involvement within the 'vaccine safety' community since 2001, through the often-told story of his interactions with CDC whistleblower William Thompson. Hooker called for a "robust vaccine safety commission" removed from the CDC's jurisdiction so that logical, safe decisions can be made on the issue. He closed by publicizing the upcoming release of his book, which has been published by Elsevier, and noting the continued censorship of scientific research that challenges the CDC.

A blogger from Health Impact News (Laurie ?) spoke in defense of the term 'vaccine injury,' and rebuked Facebook and other platforms that have framed the issue as "clickbait." The woman then displayed a thick white binder, which allegedly contained thousands of vaccine-injury cases filed in 2016 alone, and she noted that settlements from the NVICP have grown from $114 million in 2015 to $127 million in 2016. The blogger claimed that this information is critical to public health, but it has been largely censored from the media because it could threaten advertising dollars from the pharmaceutical industry. However, she ultimately implored the media against serving financial interests over the pursuit of truth.

Researcher Judy Mikovits, PhD, linked her career in AIDS research to the proliferation of 'vaccine injury' in children by arguing that "kids are the new AIDS patients," as they have allegedly acquired immunodeficiency from environmental factors – specifically vaccines. She claimed that any research alleging a problem with vaccines is destroyed, and she chastised William Thompson and others for rejecting their responsibility to reveal "the truth." Mikovits noted that the medical technology to reverse vaccine damage exists, but claimed that the National Childhood Vaccine Injury Act (NCVIA) of 1986, which exempted vaccine manufacturers from injury claims, has kept this from happening. Mikovits closed by denouncing the HPV vaccine as dangerous, and admitted her initial ignorance to the harms it has allegedly caused as she previously recommended Gardasil to her family members. However, she claims that the vaccine is driving the development of "auto pathogenic strains" of diseases, and is essentially useless because "cervical cancer is not a public health threat."

Jennifer Margulis, author of "Your Baby, Your Way," spoke about how the spirit of fearlessness and truth-seeking in media has been limitless in all areas but vaccine safety, due to financial conflicts. She challenged the press to end their censorship of the topic in order to bring attention to vaccine damage, and she spoke about the need for an independent vaccine safety commission to find unbiased results.

Finally, Toni Bark, MD closed the press conference by explaining how the medical community is largely unaware of the NVICP, which consequently limits the number of vaccine damage claims made by parents. She then detailed the evolution of the vaccine injury reporting procedure, from a table of injuries with set payouts from NVICP to parents' burden of proof for injuries. Bark encouraged parents to make decisions about vaccine scheduling independent of pediatricians and other healthcare practitioners, who are likely uninformed about the alleged dangers of vaccines.


(b)(6)

From: Immunization Action Coalition
Sent: Wed, 26 Jun 2019 13:46:50 +0000
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Subject: IAC Express #1432

Email not displaying correctly? View it in your browser.

IAC EXPRESS

Weekly Immunization News
From the Immunization Action Coalition

Issue 1432: June 26, 2019

TOP STORIES

- Total number of U.S. measles cases for 2019 climbs to 1,077 with 33 new cases reported since last week
- CDC notifies partners and providers of MMR vaccination recommendations for international travelers and for people living in or traveling domestically to areas with ongoing measles outbreaks in the U.S.
- FDA issues Public Health Alert concerning hepatitis A virus contamination of Kroger brand frozen blackberries and Costco Kirkland Signature Brand Three Berry Blend
- CDC publishes report on influenza activity in the U.S. during the 2018–19 season and the composition of the 2019–20 influenza vaccine in this week's *MMWR*
- IAC Spotlight! Explore IAC's "Ask the Experts" web section for answers to more than 1,000 Q&As from CDC experts about

immunize.org

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Video of the Week

Protect Your Child from Danger: This short, animated video from UNICEF shows how some kids, like little daredevils, often put themselves in danger. Although parents can't always do something about the dangers kids get into, they can do something about the dangers that get into kids by childproofing their child with vaccines. Vaccination could save their life.

Visit the VOTW archive

vaccine recommendations, administration, storage and handling, scheduling, and more
- *Washington Post* reports on a foundation that has contributed more than 3 million dollars to anti-vaccine groups in recent years

FEATURED RESOURCES

- Still available! IAC's sturdy laminated 2019 U.S. child/adolescent immunization schedules—order some for your exam rooms today! Bulk purchase prices available.
- IAC's comprehensive *Vaccinating Adults: A Step-by-Step Guide* is available for free download either by chapter or in its entirety (142 pages)

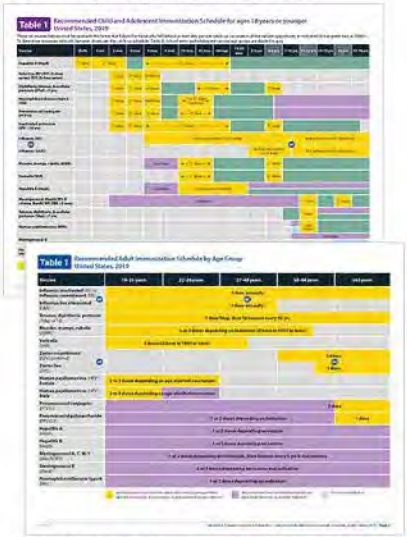
JOURNAL ARTICLES AND NEWSLETTERS

- Vaccine Education Center at Children's Hospital of Philadelphia publishes June issue of its newsletter *Vaccine Update for Healthcare Professionals*
- Two studies find rotavirus vaccine administration may be linked to reduction in type 1 diabetes in children
- CDC publishes "Trends in the Laboratory Detection of Rotavirus before and after Implementation of Routine Rotavirus Vaccination—United States, 2000–2018" in this week's *MMWR*

EDUCATION AND TRAINING

- Reminder: Weekly CDC webinar series on "The Pink Book" chapter

Laminated Schedules



Order laminated child & teen and adult CDC immunization schedules from IAC

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Technically Speaking

Read Dr. Wexler's column for the Vaccine Education Center's monthly newsletter, *Vaccine Update*

Vaccinating Adults: A Step-by-Step Guide

topics runs through September 25; register now

CONFERENCES AND MEETINGS

- Washington State Immunization Summit, hosted by WithinReach and WA State Department of Health, to take place on October 8

TOP STORIES

Total number of U.S. measles cases for 2019 climbs to 1,077 with 33 new cases reported since last week

CDC has posted its latest update on 2019 measles cases in the U.S. on its Measles Cases and Outbreaks web page. The web page shows a preliminary estimate of 1,077 cases across 28 states as of June 20. This is the greatest number of cases reported in the U.S. since 1992 and since measles was declared eliminated from the U.S. in 2000.

The states that have reported cases to CDC are Arizona, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, New Mexico, Nevada, New Hampshire, New Jersey, New York, Oklahoma, Oregon, Pennsylvania, Texas, Tennessee, Virginia, and Washington.

Access additional information about U.S. measles cases in 2019 on CDC's Measles Cases and Outbreaks web page.

Measles outbreaks (defined as 3 or more

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Protect Newborns Guidebook

cases) are currently ongoing in 2019 in the following jurisdictions:

- New York State, Rockland County
- New York City
- California, Butte County
- Pennsylvania
- Washington

Related Links

- CDC's Measles (Rubeola) web section
- CDC's Measles Outbreak Toolkit for Healthcare Providers
- CDC's Measles Outbreak Toolkit for Local/State Health Departments
- IAC's Vaccines: Measles web page
- *IAC Express* Special Edition—Ask the Experts: Issue 1428 (5/30/19)
- IAC's Ask the Experts: Measles, Mumps, and Rubella web page
- IAC's Handouts: Measles web page
- IAC's Measles, Mumps, and Rubella VIS web page

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CDC notifies partners and providers of MMR vaccination recommendations for international travelers and for people living in or traveling domestically to areas with ongoing measles outbreaks in the U.S.

CDC sent by email the following letter to partners and providers on June 17:

Dear Partners and Providers,

Measles cases continue to climb in the United States. The current outbreak began

Comprehensive guide *Hepatitis B: What Hospitals Need to Do to Protect Newborns*

Editorial Information

Editor
Deborah L. Wexler, MD
Managing Editor
Teresa Anderson, DDS, MPH
Consulting Editors
Marian Deegan, JD
Courtnay Londo, MA
Jane Myers, MA, EdM
Assistant Managing Editor
Liv Augusta Anderson, MPP

Abbreviations

AAFP: American Academy of Family Physicians
AAP: American Academy of Pediatrics
ACIP: Advisory Committee on Immunization Practices
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
IAC: Immunization Action Coalition
MMWR: Morbidity and Mortality Weekly Report
NCIRD: National Center for Immunization and Respiratory Diseases
VIS: Vaccine Information Statement
WHO: World Health Organization

with importations into under-vaccinated communities by U.S. residents returning from international travel. With summer travel season here, the Centers for Disease Control and Prevention (CDC) would like to remind you of the MMR vaccination recommendations for international travelers and persons living in or traveling domestically to areas with ongoing measles outbreaks and community-wide transmission.

INTERNATIONAL TRAVEL

The MMR vaccination recommendations for international travel have not changed.

Infants under 12 months old

- *Get an **early dose at 6–11 months***
- *Follow the recommended schedule and get another dose at 12–15 months and a final dose at 4–6 years*

Children over 12 months old

- *Get **first dose immediately***
- *Get second **dose 28 days after first dose***

*Teens and adults with no evidence of immunity**

- *Get **first dose immediately***
- *Get second **dose 28 days after first dose***

** Acceptable presumptive evidence of immunity against measles includes at least one of the following: written documentation of adequate vaccination, laboratory evidence of immunity, laboratory confirmation of measles, or birth in the United States before 1957.*

Patients who need MMR vaccine should be fully vaccinated at least 2 weeks before

departure. If the trip is less than 2 weeks away, and the patient is not protected against measles, give him/her a dose of MMR vaccine. ***Two doses of MMR vaccine provide 97% protection against measles; one dose provides 93% protection.***

DOMESTIC TRAVEL TO OUTBREAK AREAS

CDC's MMR vaccination recommendations for persons residing in or visiting domestic measles outbreak areas within the U.S. have also not changed. You should ensure that people who live in and are traveling to areas in the U.S. where there is ongoing, community-wide transmission of measles are up to date on MMR vaccine. To decide whether to vaccinate an infant visitor less than 12 months of age, follow local health department guidance for the affected area (e.g., if no recommendation was made to vaccinate infant residents, do not vaccinate infant visitors).

Certain areas of New York (state and city) are experiencing large on-going outbreaks, and they have issued guidance for individuals who will spend time in certain communities.

- *See guidance for Rockland County*
- *See guidance for New York City*

Thank you for your continued efforts to protect your communities from measles. For more measles outbreak resources, visit our toolkit [Measles Outbreak Toolkit for Healthcare Providers]. We will soon be adding new resources to that toolkit, including a poster to use in provider offices with travel recommendations for MMR vaccine, as well as short videos with examples of who needs MMR vaccine when, and an interactive MMR vaccine recommendations quiz.

Related Links

- CDC's Measles Outbreak Toolkit for Healthcare Providers web page
- CDC's Measles: Plan for Travel web page
- CDC's Measles Web Graphics web page

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FDA issues Public Health Alert concerning hepatitis A virus contamination of Kroger brand frozen blackberries and Costco Kirkland Signature Brand Three Berry Blend

The Food and Drug Administration (FDA) recently issued a Public Health Alert on June 12 concerning hepatitis A virus contamination of Kroger's Private Selection brand of frozen blackberries and Costco's Kirkland Signature Brand Three Berry Blend. Townsend Farms is the supplier of these frozen blackberry products.

So far, the FDA and CDC have not been made aware of any hepatitis A cases among consumers, but symptoms of the disease can be delayed. The FDA recommends that anyone who has consumed these products and who has not been vaccinated against hepatitis A should consult with their healthcare professional.

Read the FDA full press release, which provides further details about recalled items and recommendations for consumers: Public Health Alert Concerning Hepatitis A Virus Contamination of Kroger Brand Frozen Blackberries and Costco Kirkland Signature Brand Three Berry Blend

Related Links

- *CBS News:* Costco Joins Kroger in Recalling Frozen Berries Due to Hepatitis A Concerns
- CDC: 2016—Multistate Outbreak of Hepatitis A Linked to Frozen Strawberries (Final Update)
- CDC: 2016—Outbreak of Hepatitis A in Hawaii Linked to Raw Scallops
- CDC: Multistate Outbreak of Hepatitis A Virus Infections Linked to Pomegranate Seeds from Turkey (Final Update) (11/28/13)
- CDC: Hepatitis A Outbreaks in the United States
- IAC's Handout: Foodborne Hepatitis A Outbreaks in the U.S. Are Well-documented; Vaccine Provides Lifetime Protection
- IAC's Vaccines: Hepatitis A web page

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CDC publishes report on influenza activity in the U.S. during the 2018–19 season and the composition of the 2019–20 influenza vaccine in this week's *MMWR*

CDC published Update: Influenza Activity in the United States during the 2018–19 Season and Composition of the 2019–20 Influenza Vaccine in the June 21 issue of *MMWR*. A summary made available to the press is reprinted below.

The 2018–19 influenza season in the United States was of moderate severity and lasted 21 weeks, making it the longest season in 10 years. Influenza vaccination is the best way to reduce the risk of influenza and its potentially serious consequences, including hospitalizations in adults and deaths in children. Influenza antiviral medications are an important adjunct to vaccination in the treatment and prevention of influenza. U.S.

influenza-like illness activity began increasing in November 2018, peaked during mid-February, and returned below baseline in mid-April 2019. Influenza A viruses predominated with very little influenza B activity. Two waves of influenza A were notable during this extended season: A(H1N1)pdm09 from October 2018 to mid-February 2019 and A(H3N2) from February through May 2019. Compared to the 2017–18 season, hospitalization rates were lower among adults but higher among children. The majority of A(H1N1)pdm09 and influenza B viruses characterized antigenically and genetically were similar to recommended Northern Hemisphere 2018–2019 cell grown vaccine reference viruses; however, the majority of A(H3N2) viruses were antigenically distinct from the vaccine virus, prompting a change to the 2019–20 Northern Hemisphere A(H3N2) vaccine component to an A/Kansas/14/2017 (H3N2)-like virus.

Access the complete report: Update: Influenza Activity in the United States during the 2018–19 Season and Composition of the 2019–20 Influenza Vaccine

Related Link

- *MMWR* main page provides access to *MMWR Weekly*, *MMWR Recommendations and Reports*, *MMWR Surveillance Summaries*, and *MMWR Supplements*

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IAC Spotlight! Explore IAC's "Ask the Experts" web section for answers to more than 1,000 Q&As from CDC experts about vaccine recommendations, administration, storage and handling, scheduling, and more

IAC's Ask the Experts web section is a

compilation of common as well as challenging questions and answers (Q&As) about vaccines and their administration. William Atkinson, MD, MPH, IAC's associate director for immunization education, manages this web section, with answers provided by experts from CDC's National Center for Immunization and Respiratory Diseases, including Andrew T. Kroger, MD, MPH; Mark S. Freedman, DVM, MPH, DACVPM; Tina S. Objio, MSN, MHA, RN; Candice L. Robinson, MD, MPH; Raymond A. Strikas, MD, MPH, FACP, FIDSA; and JoEllen Wolicki, BSN, RN.

The "Ask the Experts" index page can be found at www.immunize.org/askexperts. Here you will find more than 1,000 Q&As on all vaccines routinely recommended in the United States, as well as information on such topics as administering vaccines, documenting vaccination, scheduling vaccines, vaccine recommendations, precautions and contraindications, storage and handling, travel vaccines, billing and reimbursement, and vaccine safety.

Here are links to some of our most popular pages within the "Ask the Experts" web section:

- Ask the Experts: Measles, Mumps, and Rubella
- Ask the Experts: Diphtheria, Tetanus, Pertussis
- Ask the Experts: Human Papillomavirus (HPV)
- Ask the Experts: Pneumococcal Vaccines (PCV13 and PPSV23)
- Ask the Experts: Zoster (shingles)
- Ask the Experts: Hepatitis A
- Ask the Experts: Hepatitis B
- Ask the Experts: Administering Vaccines
- Ask the Experts: Varicella (chickenpox)

Explore all IAC's "Ask the Experts" Q&As by clicking on the graphic below and bookmarking this valuable resource.

New and updated "Ask the Experts" questions and answers are emailed to *IAC Express* subscribers five times per year. You can access the four most recent *IAC Express* "Ask the Experts" sets of Q&As from the main web page of Ask the Experts in the far-right column.

If you have a question about vaccination that is not covered in the "Ask the Experts" web section, feel free to email it to us at admin@immunize.org.

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Washington Post reports on a foundation that has contributed more than 3 million dollars to anti-vaccine groups in recent years

The Selz Foundation, funded by philanthropists Bernard and Lisa Selz, has provided more than $3 million in the past three years to groups that spread misinformation about vaccines. During this period, the foundation's largest anti-vaccination expenditure went to the Informed Consent Action Network, which advocates for parental choice in vaccines and spreads anti-vaccination messaging. Receiving three-fourths of its income from the Selz Foundation has made the Informed Consent Action Network into the highest-funded anti-vaccine organization in the U.S. The chief executive and public face of the Selz

Foundation, Del Bigtree, who has no medical credentials, has been touring the country to speak publicly in areas with large measles outbreaks, such as Brooklyn and Rockland County, and also has been presenting a weekly live-stream broadcast.

Read the full *Washington Post* story: Meet the New York Couple Donating Millions to the Anti-Vax Movement (6/19/19)

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FEATURED RESOURCES

Still available! IAC's sturdy laminated 2019 U.S. child/adolescent immunization schedules—order some for your exam rooms today! Bulk purchase prices available.

IAC's laminated 2019 U.S. child/adolescent immunization schedule is still available. The adult schedules have sold out. These schedules are covered with a tough coating you can wipe down; they will stand up to a year's worth of use in every area of your healthcare setting where immunizations are given. The child/adolescent schedule is eight pages (i.e., four double-sided pages) and is folded to measure 8.5" x 11".

- Child and Adolescent Laminated Immunization Schedule (0–18 years)

Laminated schedules are printed in color for easy reading. They come complete with essential tables and notes, and they replicate the newly designed CDC schedule format.

PRICING
1–4 copies: $7.50 each
5–19 copies: $5.50 each
20–99 copies: $4.50 each
100–499 copies: $4.00 each
500–999 copies: $3.50 each

For quotes on customizing or placing orders for 1,000 copies or more, call (651) 647-9009 or email us at admininfo@immunize.org.

You can access specific information on the schedule, view an image, order online, or download an order form at the Shop IAC: Laminated Schedules web page.

Related Links

- Child and Adolescent Laminated Immunization Schedule (0–18 years)
- Shop IAC web section
- IAC Order form

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IAC's comprehensive *Vaccinating Adults: A Step-by-Step Guide* is available for free download either by chapter or in its entirety (142 pages)

In late 2017, the Immunization Action Coalition (IAC) announced the publication of its new book, *Vaccinating Adults: A Step-by-Step Guide (Guide)*.

This completely updated "how to" guide on adult immunization provides easy-to-use, practical information covering essential adult immunization activities. It helps vaccine providers enhance their existing adult immunization services or introduce them into any clinical setting. Topics include:

- setting up for vaccination services,
- storing and handling vaccines,
- deciding which people should receive which vaccines,
- administering vaccines,
- documenting vaccinations (including legal issues), and
- understanding financial considerations and billing information.

In addition, the *Guide* is filled with hundreds of web addresses and references to help providers stay up to date on the latest immunization information, both now and in the future.

The *Guide* is available to download/print either by chapter or in its entirety free of charge at www.immunize.org/guide. The downloaded version is suitable for double-sided printing. The National Vaccine Program Office and CDC both supported the development of the *Guide* and provided early technical content review.

The *Guide* is a uniquely valuable resource to

assist providers in increasing adult immunization rates. Be sure to get a copy today!

Related Links

- See *Vaccinating Adults: A Step-by-Step Guide* and all its content
- Free download of entire *Guide* (10.6 MB PDF)
- View the Table of Contents and individual chapters in PDF format:
  – Table of Contents
  – Step 1: Getting Started
  – Step 2: Setting Up for Vaccination Services
  – Step 3: Vaccine Storage and Handling
  – Step 4: Deciding Whom to Vaccinate
  – Step 5: Administering Vaccines
  – Step 6: Documentation and Related Issues
  – Step 7A: Financial Considerations
  – Step 7B: How to Bill for Adult Immunizations
- Promotional flyer for *Vaccinating Adults: A Step-by-Step Guide*
- IAC's educational materials (handouts) onadult immunization

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JOURNAL ARTICLES AND NEWSLETTERS

Vaccine Education Center at Children's Hospital of Philadelphia publishes June issue of its newsletter *Vaccine Update for Healthcare Professionals*

The Vaccine Education Center (VEC) at Children's Hospital of Philadelphia publishes a monthly immunization-focused newsletter titled *Vaccine Update for Healthcare*

Professionals. The June issue includes the following articles:

- News & Views: A Different Approach to Vaccine Refusal Results in a Change of Heart: One Doctor's Experience, by Margaret Stager, MD
- In the Journals: Study Finds That Rotavirus Vaccine Decreases Incidence of Type 1 Diabetes, by Paul A. Offit, MD
- Technically Speaking: Looking for New Tools and Resources to Help Increase Your Clinic's HPV Vaccination Rates? Here Are Some Great Ones! by IAC Executive Director Deborah L. Wexler, MD

Additional resources are available in the full newsletter.

Access the sign-up form to subscribe to *Vaccine Update for Healthcare Professionals*.

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Two studies find rotavirus vaccine administration may be linked to reduction in type 1 diabetes in children

Two studies, one conducted in Australia and one in the U.S., have found that rotavirus vaccination is associated with reduced incidence of type 1 diabetes in children.

Access the two studies:

- *Scientific Reports:* Lower Incidence Rate of Type 1 Diabetes after Receipt of the Rotavirus Vaccine in the United States, 2001–2017 (U.S., 6/13/19)
- *JAMA Pediatrics:* Association of Rotavirus Vaccination with the Incidence of Type 1 Diabetes in Children (Australia, 1/22/19)

Related Links

- *Vaccine Update for Healthcare Professionals:* In the Journals: Study Finds that Rotavirus Vaccine Decreases Incidence of Type 1 Diabetes, by Paul A. Offit, MD (6/18/19)
- *U.S. News & World Reports:* Common Infant Vaccine May Also Shield Kids from Type 1 Diabetes (6/14/19)

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CDC publishes "Trends in the Laboratory Detection of Rotavirus before and after Implementation of Routine Rotavirus Vaccination—United States, 2000–2018" in this week's *MMWR*

CDC published Trends in the Laboratory Detection of Rotavirus before and after Implementation of Routine Rotavirus Vaccination—United States, 2000–2018 in the June 21 issue of *MMWR*. A summary made available to the press is reprinted below.

Rotavirus vaccination has dramatically reduced U.S. disease burden and altered seasonal patterns. Improving coverage and on-time rotavirus vaccination of children is critical to maximize public health benefit. Rotavirus, a common cause of gastroenteritis in young children, is preventable with vaccines used in the United States since 2006. CDC analyzed laboratory testing data for rotavirus collected through national surveillance during the pre-vaccine (2000–2006) and post-vaccine (2007–2018) periods. In the post-vaccine period, we observed a decline in annual rotavirus tests; the annual peak in positive tests declined and the rotavirus season was shorter. A biennial rotavirus seasonal pattern emerged

with alternating years of low and high disease activity. Rotavirus vaccination has dramatically reduced the disease burden. Peak rotavirus activity declined by more than two thirds, from an annual median of 43.1% in the pre-vaccine era to 14.0% in the post-vaccine era; and peak season was shortened from 26 weeks to 9 weeks. These changes have been sustained over 11 post-vaccine–introduction seasons. To maximize the public health impact, efforts to improve coverage and on-time rotavirus vaccination should continue.

Access the complete article: Trends in the Laboratory Detection of Rotavirus before and after Implementation of Routine Rotavirus Vaccination—United States, 2000–2018

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EDUCATION AND TRAINING

Reminder: Weekly CDC webinar series on "The Pink Book" chapter topics runs through September 25; register now

Register for CDC's 15-part, live CE-accredited series of 1-hour webinars designed to provide a chapter-by-chapter overview of the 13th edition of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (also known as "The Pink Book"). Topics include specific vaccines and the diseases they prevent, general recommendations for vaccines, vaccination principles, and immunization strategies for providers.

All sessions begin at 12:00 p.m. (ET). This series began on June 5 and will run through September 25, 2019. The next two webinars are scheduled as follows:

- July 10: Immunization Strategies

- July 17: Vaccine Storage and Handling and Administration and Vaccine Administration

Recordings of sessions will be available online within 2 weeks after each webinar.

Information on registration and program details is available on CDC's Pink Book Webinar Series web page.

All the sections of "The Pink Book" (i.e., chapters, appendices, 2017 supplement) are available to download at no charge at www.cdc.gov/vaccines/pubs/pinkbook/index.html. You can also order this resource from the Public Health Foundation for $40 plus shipping and handling.

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CONFERENCES AND MEETINGS

Washington State Immunization Summit, hosted by WithinReach and WA State Department of Health, to take place on October 8

The second annual Washington State Immunization Summit will take place on October 8 in Lynnwood, WA. WithinReach and Washington State Department of Health are co-hosting the summit. The 2019 summit will focus on the measles outbreak, vaccination schedule updates, communicating about vaccines, working with special and at-risk populations, and the Washington State Immunization Information System.

View additional information and register for the summit on the event's website.

Related Link

- For more immunization-related meetings and conferences, see IAC's Calendar of Events

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About *IAC Express*

The Immunization Action Coalition welcomes redistribution of this issue of *IAC Express* or selected articles. When you do so, please add a note that the Immunization Action Coalition is the source of the material and provide a link to this issue.

If you have trouble receiving or displaying *IAC Express* messages, visit our online help section.

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IAC Express Disclaimer

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Our mailing address is
Immunization Action Coalition
2550 University Avenue West, Suite 415 North
Saint Paul, MN 55114

From: Mast, Eric (CDC/CGH/GID)
Sent: Wed, 13 Dec 2017 18:02:07 -0500
To: Wharton, Melinda (CDC/OID/NCIRD)
Cc: Schluter, W. William (CDC/CGH/GID); Gidudu, Jane (CDC/CGH/GID); Weinbaum, Cindy (CDC/OID/NCIRD); Destefano, Frank (CDC/OID/NCEZID); Shefer, Abigail (CDC/CGH/GID)
Subject: ICAN to HHS
Attachments: WebPage.pdf, Letter from Informed Consent Action Network (ICAN)- RE Deaths caused by DTP (003).pdf

Hi Melinda,

We are assisting UNICEF to frame a response to the attached letter from the Informed Consent Action Network which was sent to Tony Lake and to UNICEF country offices.

We are wondering if in your role at NVPO you are aware of (or could get access to) the HHS response to a letter from the Informed Consent Action Network addressed to HHS in October 2017.

Thanks much,

Eric

ICAN
Informed Consent Action Network

VIA FEDEX

October 12, 2017

U.S. Department of Health & Human Services
HHS Office of the Secretary
Eric D. Hargan
Acting Secretary of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Hargan:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b).

Americans, including the over 55 organizations listed below, whose members exceed 5 million Americans, are concerned about vaccine safety. The National Childhood Vaccine Injury Act of 1986 (the **1986 Act**) made nearly every aspect of vaccine safety the exclusive responsibility of the Department of Health & Human Services (**HHS**). As the Secretary of HHS (the **Secretary**), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. These specific requests are numbered sequentially in this notice. We would welcome the opportunity to meet and discuss reasonable means for complying with these requests. If that is not possible, the 1986 Act authorizes "a civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty" under the 1986 Act.

I. Background

The 1986 Act granted economic immunity to pharmaceutical companies for injuries caused by their vaccines. (42 U.S.C. § 300aa-11.) The 1986 Act thereby eliminated the market force which drives safety for all other products – actual and potential product liability. Recognizing the unprecedented elimination of this market force, the 1986 Act makes HHS directly responsible for virtually every aspect of vaccine safety. (42 U.S.C. §§ 300aa-2, 300aa-27.)

When the CDC recommends a pediatric vaccine for universal use, it creates for that vaccine's maker a liability free market of 78 million children typically required by law to receive the vaccine. The number of required vaccines has grown rapidly since 1986. In 1983, the CDC recommended that babies under one receive two vaccines: DTP and Polio.[1] As of 2017, the CDC recommends that babies under one receive multiple doses of ten vaccines: DTaP, Polio, Hep B, Rotavirus, Hib, Pneumococcal, Influenza, MMR, Varicella, and Hep A.[2] In total, the current CDC childhood vaccine schedule includes 56 injections of 73 doses of 30 different vaccines.

II. Deficiencies in the Pre-Licensure Safety Review of Pediatric Vaccines

All drugs licensed by the FDA undergo long-term double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. For example: Enbrel's pre-licensure trials followed subjects up to 80 months and controls received a saline injection.[3] Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.[4] Botox's pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.[5] And even with these long-term studies, drugs are still often recalled.

In contrast, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, of the two Hepatitis B vaccines licensed by the FDA for injection into one-day-old babies, Merck's was licensed after trials that solicited adverse reactions for *only five days* after vaccination and GlaxoSmithKline's was licensed after trials that solicited adverse reactions for *only four days* after vaccination.[6] Similarly, the HiB vaccines sold by these same companies were licensed based on trials which solicited adverse reactions for three and four days, respectively, after vaccination.[7] The only stand-alone polio vaccine was licensed after a mere 48-hour follow-up period.[8]

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[1] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
[2] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf
[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
[6] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[7] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf
[8] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

Moreover, these trials either had no control group or a control group which received other vaccines as a "placebo."[9] This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.

The 1986 Act expressly requires that you, as the Secretary, "shall make or assure improvements in … the licensing … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(1) Please explain how HHS justifies licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an inert placebo?

(2) Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?

III. Post-Licensure Surveillance of Vaccine Adverse Events

The lack of pre-licensure safety data leaves the assessment of vaccine safety to the post-licensing period when they are being administered to children in the "real world." To capture vaccine adverse events in the real world, the 1986 Act established the Vaccine Adverse Events Reporting System (**VAERS**) operated by HHS. (42 U.S.C. § 300aa-25.)

In 2016, VAERS received 59,117 reports of adverse vaccine events, including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.[10]

However, only a tiny fraction of adverse vaccine events are reported to VAERS. An HHS-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 715,000 patients and found that "fewer than 1% of vaccine adverse events are reported."[11] A U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."[12]

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[9] Ibid.
[10] https://wonder.cdc.gov/vaers.html
[11] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[12] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

Assuming VAERS captures a full 1 percent of adverse events – which is more than is estimated – the VAERS data above from 2016 may reflect that in that year alone there were 5,911,700 adverse vaccine events, including 43,200 deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency room visits.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially avoiding these injuries and deaths.

The idea of automating adverse reaction reporting to VAERS is not new or even difficult to achieve.[13] An agency within HHS, the Agency for Healthcare Research and Quality, sought to do exactly that in 2007 when it provided an approximately $1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.[14] The result was the successful automation of adverse event reports at Harvard Pilgrim:

> *Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions … were identified.*[15]

These results should have been concerning to HHS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.

After automating adverse events reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

> *Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*[16]

After three years and spending $1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting -- not ignored the requests by the HHS's Harvard grant recipients.

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[13] https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system
[14] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[15] Ibid.
[16] Ibid.

While HHS strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.[17] Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.[18] Capturing "fewer than 1% of vaccine adverse events" thirty years after the passage of the 1986 Act is unacceptable -- and potentially deadly.

The 1986 Act expressly provides that you, as the Secretary, "shall make or assure improvements in … adverse reaction reporting … in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(3) Please explain why HHS failed to cooperate with Harvard to automate VAERS reporting? And detail any steps that HHS has taken since toward automating VAERS reporting?

(4) Please explain any specific steps taken by HHS to improve adverse reaction reporting to VAERS?

IV. Identifying What Injuries Are Caused by Vaccines

The first step in assuring safer vaccines is to identify what harms they cause. This would normally be accomplished pre-licensure by long-term, inert-placebo controlled trials – but these are never performed for vaccines. As for post-licensure monitoring, HHS has refused to improve VAERS as discussed above. Hence, assessing which vaccines cause which injuries is mainly left to post-licensure studies. HHS, unfortunately, has neglected to perform these studies.

In 1991, the Institute of Medicine (**IOM**) examined 22 commonly reported serious injuries following the DTP vaccine.[19] The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.[20] The IOM, however, found the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries:

> *Aseptic meningitis; Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome; Erythema multiforme; Autism; Peripheral mononeuropathy; Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*[21]

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[17] http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf; https://www.ncbi.nlm.nih.gov/pubmed/26209838; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/

[18] Ibid.

[19] https://www.nap.edu/read/1815/chapter/2#7

[20] Ibid.

[21] Ibid.

The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines" and on the poor design of the few existing studies.[22] It therefore cautioned that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."[23]

In 1994, the IOM issued another report which examined the scientific literature for evidence that could either prove or disprove a causal link between 54 commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.[24] The IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.[25] The IOM, however, found the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> *Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*[26]

As in 1991, this IOM Report again stated, "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[27]

In 2011, more than fifteen years after the IOM Reports in 1991 and 1994, HHS paid the IOM to conduct another assessment regarding vaccine safety.[28] This third IOM Report reviewed the available science with regard to the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and rubella.[29] The IOM located science which "convincingly supports a causal relationship" with 14 of these injuries, including pneumonia, meningitis, hepatitis, MIBE, febrile seizures, and anaphylaxis.[30] The review found sufficient evidence to support "acceptance of a causal relationship" with 4 additional serious injuries.[31]

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

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[22] https://www.nap.edu/read/1815/chapter/2#8
[23] https://www.nap.edu/read/1815/chapter/9
[24] https://www.nap.edu/read/2138/chapter/2#12
[25] https://www.nap.edu/read/2138/chapter/2#12
[26] Ibid.
[27] https://www.nap.edu/read/2138/chapter/12
[28] https://www.nap.edu/read/13164/chapter/2#2
[29] Ibid.
[30] https://www.nap.edu/read/13164/chapter/2#3
[31] Ibid.

Encephalitis, Encephalopathy, Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia, Acute Disseminated Encephalomyelitis, Transverse Myelitis, Optic Neuritis, Neuromyelitis Optica, Multiple Sclerosis, Guillain-Barre Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, Brachial Neuritis, Amyotrophic Lateral Sclerosis, Small Fiber Neuropathy, Chronic Urticaria, Erythema Nodosum, Systemic Lupus Erythematosus, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia, Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura[32]

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence supported a causal relationship for 18 of them, rejected a causal relationship for 5 of them, but for the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found that the science simply had not been performed.[33]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) The first step in reducing adverse reactions is identifying what adverse reactions are caused by vaccine. Given this statutory obligation:

(5) For each of the 38 vaccine-injury pairs reviewed in the 1994 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

(6) For each of the 135 vaccine-injury pairs reviewed in the 2011 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

Further to your duties to identify what injuries are caused by vaccines, the 1986 Act also expressly requires you to "make or assure improvements in … the … recall of reactogenic lots or batches, of vaccines … in order to reduce the risks of adverse reactions to vaccines" and thus each "health care provider who administers a vaccine … shall record … in such person's permanent

[32] Ibid.

[33] Ibid.

medical record … the vaccine manufacturer and lot number." (42 U.S.C. §§ 300aa-25(a), 300aa-27(a)(2).) Since health care providers often fail to record this information:

> **(7) Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?**

V. Identifying Which Children are Susceptible to Vaccine Injury

The IOM has consistently acknowledged there is individual susceptibility to serious vaccine injuries. The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure. HHS, unfortunately, has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 report, stated: "The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."[34] The IOM urged that "research should be encouraged to elucidate the factors that put certain people at risk."[35]

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

> *Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact…*
>
> *Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine… much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.* [36]

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.[37] The IOM again explained that while "most children who experience an adverse reaction to immunization have preexisting susceptibility," the IOM:

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[34] https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9

[35] Ibid.

[36] https://www.nap.edu/read/13164/chapter/5#82

[37] https://www.nap.edu/read/13563/chapter/1

> *found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes.*[38]

HHS had failed to even define the terminology for the study of susceptible subpopulations and hence IOM admonished HHS to "develop a framework that clarifies and standardizes definitions of … populations that are potentially susceptible to adverse events."[39]

The IOM correctly points out in 2011 that given the "widespread use of vaccines" and "state mandates requiring vaccination of children … it is essential that safety concerns receive assiduous attention."[40] This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has never been conducted.

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

> **(8) Please advise when HHS intends to begin conducting research to identify which children are susceptible to serious vaccine injury? If HHS believes it has commenced this research, please detail its activities regarding same?**

VI. Removing Claim "Vaccines Do Not Cause Autism" from the CDC Website

HHS, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that "Vaccines Do Not Cause Autism" even though this broad claim is plainly not supported by the scientific literature.[41]

Indeed, as part of the IOM's 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.[42] The IOM could not locate a single study supporting

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[38] https://www.nap.edu/read/13563/chapter/9#130
[39] Ibid.
[40] https://www.nap.edu/read/13164/chapter/3#28
[41] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[42] https://www.nap.edu/read/13164/chapter/2#2

that DTaP does not cause autism.[43] The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[44] The IOM's full explanation in its 2011 Report for this finding is attached as Appendix B. In fact, the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.[45] No research has been published since 2011 that could change the IOM's conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that there is no causal relationship between vaccines and autism. The CDC nonetheless claims on its website that "Vaccines Do Not Cause Autism."

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive, typically multiple times, by one year of age.[46]

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.[47] Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC's pediatric vaccine schedule cannot support the CDC's overarching declaration that "Vaccines Do Not Cause Autism."

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson[48], recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.[49] Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."[50] Dr. Thompson further stated on that call:

> *I have great shame now when I meet families with kids with autism because I have been part of the problem … the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway*

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[43] https://www.nap.edu/read/13164/chapter/12#545
[44] Ibid.
[45] Ibid. Ironically, this study was disregarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which would be true of any study using VAERS data.
[46] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent. html
[47] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[48] Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC's vaccine safety claims. https://www.ncbi.nlm.nih.gov/pubmed
[49] http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf
[50] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

> *there's still a lot of shame with that. … I am completely ashamed of what I did.*[51]

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.[52]

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."[53] When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"[54]

Former NIH Director Dr. Healy goes on to explain:

> *This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. …*
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> *The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*[55]

The CDC has also failed to address the science supporting a link between vaccines and autism.[56] For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.[57] Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated

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[51] Ibid.
[52] Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. https://doi.org/10.1093/oxfordjournals.aje.a116479
[53] http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/
[54] Ibid.
[55] Ibid.
[56] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[57] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf

children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.[58] There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.[59] Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. Without proper long-term trials comparing those receiving the vaccine to an inert-placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated with unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done. The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP vaccine, let alone the entire vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, are to "develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table." (42 U.S.C. § 300aa-26(a).) This section further provides that:

> The information in such materials shall be based on available data and information … and shall include … (1) a concise description of the benefits of the vaccine, (2) a concise description of the risks associated with the vaccine, (3) a statement of the availability of the National Vaccine Injury Compensation Program, and (4) such other relevant information as may be determined by the Secretary.

(42 U.S.C. § 300aa-26(c).) The VIS produced for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, www.cdc.gov.[60] The CDC website in turn claims that "Vaccines Do Not Cause Autism."[61] Since HHS has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must be "based on available data and information." *Id.* But, based on available data and information, as highlighted by the IOM, HHS cannot validly claim that "Vaccines Do Not Cause Autism." Hence:

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[58] http://www.oatext.com/pdf/JTS-3-186.pdf; http://www.oatext.com/pdf/JTS-3-187.pdf
[59] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf
[60] https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
[61] https://www.cdc.gov/vaccinesafety/concerns/autism.html

(9) Please confirm that HHS shall forthwith remove the claim that "Vaccines Do Not Cause Autism" from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?

VII. Refusal to Conduct Vaccinated Versus Unvaccinated Study

The only scientifically valid way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered and controlled study comparing the rate of all adverse events between vaccinated children and completely unvaccinated children. This is the same type of study required by HHS for every drug pre-licensure. HHS has nonetheless refused to conduct any such study, even retrospectively.

The need for this study is highlighted by the results of a few recent limited vaccinated vs. unvaccinated studies.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.[62] In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.[63] Dr. Aaby's study therefore concluded that: "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[64] More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[65] This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[66]

It is equally troubling that Dr. Abby's study was based on data that had been collecting dust for over 30 years[67] This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science.

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.[68] The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk

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[62] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D

[63] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ Dr. Aaby's study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby's study was one of the few specifically designed to avoid this error.

[64] Ibid.

[65] Ibid.

[66] Ibid.

[67] Ibid.

[68] http://www.oatext.com/pdf/JTS-3-186.pdf

of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.[69] Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.[70]

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.[71] Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.[72] Like the DTP study, the flu vaccine increased susceptibility to other infections.

A properly sized vaccinated versus unvaccinated study is necessary and possible. As stated by the IOM in 2013: "It is possible to make this comparison through analyses of patient information contained in large databases such as VSD."[73] Senior CDC Scientist, Dr. Thompson similarly stated this type of study can and "needs to be done" but that the CDC is "not doing what they should be doing because they're afraid to look for things that might be associated."[74] When vaccine makers are generating over $33 billion in vaccine revenue annually and the CDC is spending over $5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.[75]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Since comparing children receiving the vaccines recommended by the CDC with those that have not received any vaccines is the only scientifically valid way to assess the safety of the CDC's vaccine schedule:

> **(10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of**

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[69] Ibid.

[70] http://www.oatext.com/pdf/JTS-3-187.pdf

[71] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/

[72] Ibid. *See also* http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf (The CDC in 2001 apparently conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not. The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays. Note that while the abstract discusses comparing thimerosal exposure, since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study appears to have primarily compared children receiving Hepatitis B with children that did not receive this vaccine.)

[73] https://www.nap.edu/read/13563/chapter/2#13

[74] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

[75] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf; https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html

fully/partially vaccinated children with completely unvaccinated children?

VIII. Reducing Conflicts of Interest at HHS

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS. The 1986 Act's scheme thus places HHS in charge of two competing duties. On one hand, HHS is responsible for vaccine safety. On the other hand, HHS is required to promote vaccine uptake and defend against any claim they cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense function to such a degree that it has essentially abandoned its vaccine safety function. To restore balance, HHS must take serious steps to create an "ethics firewall" between these competing functions. HHS also must take action with regard to its vaccine committee members and employees that have conflicts with vaccine makers.

HHS Licenses & Recommends Vaccines. With regard to the FDA's Vaccines and Related Biological Products Advisory Committee (**VRBPAC**), which effectively decides whether to license a vaccine, in 2000 the U.S. House Committee on Government Reform (the **Committee**) "determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."[76] The Committee concluded of the VRBPAC: "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."[77]

With regard to the CDC's Advisory Committee on Immunization Practices (**ACIP**), which effectively decides whether to universally recommend a pediatric vaccine, the Committee found that ACIP members routinely fail to disclose conflicts with vaccine makers and when conflicts are disclosed "[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts."[78] The Committee drew focus on the vaccine most recently approved by the ACIP and found extensive and troubling conflicts of interest for most the ACIP members voting to recommend its universal use for children.[79] The Committee was further concerned that "ACIP liaison representatives have numerous ties to

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[76] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf (For instance, "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had significant financial ties to pharmaceutical companies that were developing different versions of the vaccine.")

[77] Ibid.

[78] Ibid.

[79] Ibid. (The Committee's findings were that: (1) The chairman served on Merck's Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a $350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division, a principal investigator for SmithKline and received funds from various vaccine makers; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.)

vaccine manufacturers" but act like voting members of ACIP.[80] The Committee further took issue with the extensive conflicts of interests of members of ACIP's working groups which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.[81] The Committee concluded that ACIP reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[82]

Despite the concerns the Committee expressed in its 2000 report, not much changed. A December 2009 report by the HHS Office of Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for SGEs [a.k.a. **committee members**]".[83] For example, "Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."[84]

In fact, the Inspector General found that the "CDC certified [conflict disclosure forms] with at least one omission in 2007 for 97 percent … of SGEs," "58 percent … of SGEs had at least one potential conflict of interest that CDC did not identify," and when the CDC identified a conflict, it improperly granted broad waivers despite being castigated for this improper practice in 2000.[85] Even worse, "32 percent … of SGEs … had at least one potential conflict of interest that CDC identified but did not resolve" and 13 percent of SGEs were allowed to participate in committee meetings without even having a conflict disclosure form on file.[86]

As the system is set up, an ACIP vote to recommend a vaccine, grants a vaccine manufacturer a liability-free market of 78 million American children, who are legally compelled to receive the vaccine, and billions of taxpayer dollars guaranteeing payment. In such a system, an ACIP vote must be completely insulated from any influence by the vaccine manufacturer. Instead, the opposite appears to be the norm.

HHS Promotes Vaccines. Moreover, while the CDC states on its website -- not less than 130 times -- that "CDC does not accept commercial support," this is simply not true.[87] For example, the British Medical Journal reported in 2015 that: "Despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."[88] As another example, pharmaceutical companies and other private entities, through the "CDC Foundation," can create and fund programs at the CDC (over half a billion dollars' worth to-date), endow positions at the

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[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[84] http://www.nytimes.com/2009/12/18/health/policy/18cdc.html
[85] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf (Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.)
[86] Ibid.
[87] https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main
[88] http://www.bmj.com/content/350/bmj.h2362

CDC, and even place individuals to work at the CDC, paid through "private funding." (42 U.S.C.A. § 280e-11(h)(1), (2).)

Worse, the promotion track for CDC management extends into vaccine makers. The most prominent example is former CDC Director Dr. Julie Gerberding, who headed the agency from 2002 through 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported $2.5 million annual salary and lucrative stock options.[89]

HHS Defends Vaccines. After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with very limited safety data, this very same government agency is mandated to defend against any claim that the vaccine caused harm.

There is no other for-profit product where the very department responsible for regulating that product is statutorily required to promote its uptake and simultaneously defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury. (42 U.S.C. § 300aa-10 *et seq.*)[90] The injured must litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury. (§ 300aa-12.) DOJ and HHS have the government's vast resources, while the injured child must secure a private attorney. (§ 300aa-15.) Moreover, the injured child's damages are limited to $250,000 for death and pain and suffering. (*Id.*)

Worst of all, the injured child must almost always prove "causation" – the biological mechanism by which the vaccine injured the child.[91] Requiring an injured child to prove causation adds insult to injury because had HHS conducted the vaccine safety science it demands as proof in the VICP before licensing a vaccine, the child's injury may have been avoided altogether.

This truly is the epitome of injustice: requiring a child receiving a compulsory pharmaceutical product to medically prove to HHS how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government department, HHS, tasked with this job.[92] As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.[93] It has failed to conduct even one properly sized study comparing vaccinated to

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[89] https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884

[90] *See also* Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)

[91] http://www.gao.gov/assets/670/667136.pdf

[92] See Sections II, III, IV, V, VI, and VII above.

[93] See Section IV above.

unvaccinated children, despite all the resources at its disposal.[94] It is no wonder a single injured child's claim faces a high likelihood of failure in the VICP.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief an insidious intent. Rather, this system eliminates the incentive, and in fact creates a disincentive for HHS and vaccine makers, to conduct research to uncover long term chronic conditions, including the immune and neurological system disorders, which can result from the current vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, have at least equal and arguably greater responsibility for vaccine safety than for vaccine promotion. (42 U.S.C. §§ 300aa-2, 300aa-27.) In accordance with this statutory responsibility:

(11) Please advise if you will:

a. prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?
b. prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?
c. require that vaccine safety advocates comprise half of HHS's vaccine committees?
d. allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?
e. support the creation of a vaccine safety department independent of HHS?
f. support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?

IX. Conclusion

HHS can do better. With hundreds of vaccines in the pipeline it must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will in fact strengthen the vaccine program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to HHS's vaccine program due to safety concerns.

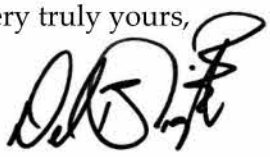
[94] See Section VII above.

Unless HHS performs its vital statutory obligations regarding vaccine safety, and until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injuries. Nor will children injured by vaccines be able to access the services they need. We can do far better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination. The first step in avoiding these harms and helping children already harmed is admitting there are deficiencies and working diligently to improve vaccine safety.

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. These, in fact, reflect nothing more than what Congress already explicitly recognized when passing the 1986 Act: vaccines can and do cause serious injury and HHS needs to work diligently to identify and reduce these harms. If you would like to meet and discuss the foregoing, we would welcome that opportunity and hope to work cooperatively to address these issues.

If that is not possible, Congress, as a final resort to assure vaccine safety, authorized a "civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under" the 1986 Act. (42 U.S.C. § 300aa-31(a).) We are prepared to authorize such an action and this letter constitutes the notice required by 42 U.S.C. § 300aa-31(b). It is, however, our hope that the vaccine safety issues identified herein can be resolved cooperatively, with all interested parties working together toward the common goal of vaccine safety entrusted to HHS under the 1986 Act.

Very truly yours,



Del Bigtree

cc: See Appendix A.
Enclosures: Appendices A to C.

Appendix A

A Voice For Choice
A Voice For Choice Advocacy
Christina Hildebrand, President
530 Showers Drive, Suite 7404
Mountain View, CA 94040

Alliance For Natural Health
Gretchen DuBeau, President
3525 Piedmont Road NE B6-310
Atlanta, GA 30305

Arizona Coalition Against Mandated Vaccines
Kelsey Davis, President
Gilbert, AZ 85212

Autism Action Network
John Gilmore, President
550 East Chester Street
Long Beach, NY 11561

Autism Giving Tree
Christina Stafford, M.Ed., BCBA, LBS, President
660 'W' Street
King of Prussia, PA 19406

AutismOne
Ed Arranga, President
1816 West Houston Avenue
Fullerton, CA 92833

The Canary Party
Jennifer Larson, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Colorado Coalition for Vaccine Choice
Fran Sincere, President
125 S. Zephyr
Lakewood, CO 80226

DAIR Foundation
Dawn Loughborough, President
10200 US HWY 290 West
Austin, TX 78736

Elizabeth Birt Center for Autism Law and Advocacy
Kim Mack Rosenberg, President
200 Cabrini Boulevard, Suite 66
New York, NY 10033

Enriched Parenting
Rebecca Fleischman, President
1208 Avenue M, Suite 2323
Brooklyn, NY 11230

Focus for Health Foundation
Shannon Mulvihill, R.N., Executive Director
776 Mountain Boulevard, Suite 202
Watchung, NJ 07069

Georgia Coalition for Vaccine Choice
Sandi Marcus, Founder/CEO
P.O. Box 45
Silver Creek, GA 30173

Health Choice
Mark Blaxil, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Health Choice Massachusetts
Candice Edwards, President
P.O. Box 175
Manchaug, MA 01526

Health Choice Maryland
Emily Tarsell, President
1501 Sulgrave Avenue, Suite 208
Baltimore, MD 21209

Health Choice Connecticut
Dr. Elissa Diamond Fields, President
P.O. Box 29
Roxbury, CT 06783

Health Freedom Florida
Dr. Ryan Fenn & MacKenzie Fraser, Co-Presidents
153 Ivernia Loop
Tallahassee, FL 32312

Health Freedom Idaho
Miste Gardner Karlfeldt, President
1045 S Ancona Ave Ste 140
Eagle, ID 83616

Healthcare Freedom Hawaii
Jessica McCormick &
Natasha Sky, Co-Directors
Mililani, HI 96789

Illinois Coalition for Informed Consent
Jen Suter &
Danielle Olson, Co-Directors
Jacksonville, IL 62650

Indiana for Medical Freedom
Melissa Sura, President
5424 Grapevine Drive
Indianapolis, IN 46235

Informed Choice Washington
Jena Dalpez, President
14106 93rd Avenue NE
Kirkland, WA 98034

Kentucky Vaccine Rights Coalition
Jennifer Benge & Ashley Kennedy, Co-Presidents
899 Corinth Road
Corbin, KY 40701

Know The Vax
Angela Gallagher, President
4553 Aldrich Avenue North
Minneapolis, MN 55412

Learn the Risk
Brandy Vaughan, President
3463 State Street, Suite 182
Santa Barbara, CA 93105

Louisiana Parents for Vaccine Rights
Melisha Dooley &
Sunny Dixon, Co-Directors
413 Toby Lane
Metairie, LA 70003

Maine Coalition for Vaccine Choice
Ginger Taylor, Director
11 High Street
Brunswick, ME 04011

March Against Monsanto
Tami Canal, President
7878 South 1960 East
South Weber, UT 84405

Michigan for Vaccine Choice
Suzanne M. Waltman, President
22615 Francis Street
St. Clair Shores, MI 48082

Minnesota Natural Health Coalition
Lee Beaty, President
1043 Grand Ave, Suite 317
St. Paul MN 55105

Minnesota Natural Health Legal Reform Project
Leo Cashman, President
1043 Grand Ave, Suite 317
St. Paul, MN 55105

Minnesota Vaccine Freedom Coalition
Angela Gallagher, President
4553 Aldrich Avenue North
Minneapolis, MN 55412

Mississippi Parents for Vaccine Rights
MaryJo Perry, President
P.O. Box 141
Pelahatchie, MS 39145

Missouri Parents Against Vaccines
Janessa Baake & Kendal Bourne, Co-Presidents
323 N. Fox Ridge Drive, Suite 204
Raymore, MO 64083

Moms Across America
Zen Honeycutt, President
24000 Alicia Parkway, Suite 17-236
Mission Viejo, CA 92691

Montanans For Medical Freedom
Edna Kent, Director
PO Box 1443
Florence, MT 59833

My Kids, My Choice
Rita Palma, President
2 Purdy Avenue
Baypoint, NY 11705

National Health Freedom Action
Jerri Johnson, President
PMB 218, 2136 Ford Parkway
St. Paul, MN 55116

National Health Freedom Coalition
Roseanne Lindsay, President
PMB 218, 2136 Ford Parkway
St. Paul, MN 55116

New York Alliance for Vaccine Rights
Aimee Villella McBride & Maria Gavriel, Co-Presidents
550 East Chester Street
Long Beach, NY 11561

Ohio Advocates for Medical Freedom
Robert M. Wise, President
P.O. Box 1236
Hartville, OH 44632

Oklahomans for Vaccine and Health Choice
Liza Greve, President
P.O. Box 721356
Norman, OK 73070

Organic Consumers Association
Ronnie Cummins, CEO
6771 South Silver Hill Dr.
Finland, MN 55603

Parents United 4 Kids
Stefanie Fetzer & Shawna Lambert, Co-Presidents
2925 Bonanza
San Clemente, CA 92673

People Advocating Vaccine Education, Inc.
Lisa Jillani, CEO
P.O. Box 690712
Charlotte, NC 28227

Physicians for Informed Consent
Dr. Shira Miller, Executive Director
13749 Riverside Drive
Sherman Oaks, CA 91423

Rogue Recovery
Tyler Dahm, President
3221 West 96th Avenue
Westminster, CO 80031

South Carolina Health Coalition
Jennifer Black & Rebekah Watson, Co-Presidents
1754 Woodruff Road, Suite 112
Greenville, SC 29607

Spectrum Revolution
Catharine Layton, President
357 S. Earlham Street
Orange, CA 92869

Tennessee Coalition for Vaccine Choice
Kristen Odom-Holland, President
P.O. Box 4508
Chattanooga, TN 37405

Vaccine Injury Awareness League
Michelle Ford, President
10866 Washington Blvd, Suite 65
Culver City, CA 90232

Vaccine Safety Council Minnesota
Patti Carroll, President
6533 Flying Cloud Drive, Suite 1200
Eden Prairie, MN 55344

Vermont Coalition for Vaccine Choice
Jennifer Stella, President
P.O. Box 74
Waitsfield, VT 05673

Virginians for Health Freedom
Deborah Hommer, President
P.O. Box 2015
Spotsylvania, VA 22553

West Virginians for Health Freedom
Dr. Chanda Adkins, Director
108 Yorktown Court
Beckley, WV 25801

Weston A. Price Foundation
Sally Fallon Morell, President
PMB 106-380, 4200 Wisconsin Avenue NW
Washington, D.C., 20016

World Mercury Project
Robert F. Kennedy, Jr., Chairman
1227 North Peachtree Parkway, Suite 202
Peachtree City, GA 3026

Appendix B

Adverse Effects of Vaccines

Evidence and Causality

Committee to Review Adverse Effects of Vaccines
Board on Population Health and Public Health Practice
Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,
Editors

INSTITUTE OF MEDICINE
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Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

Mechanistic Evidence

The committee identified one publication reporting the development of ataxia after the administration of DTaP vaccine. Kubota and Takahashi (2008) did not provide evidence of causality beyond a temporal relationship of 2 days between vaccine administration and development of cerebellar symptoms leading to a diagnosis of acute cerebellar ataxia. The publication did not contribute to the weight of mechanistic evidence.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia as lacking.

Causality Conclusion

Conclusion 10.5: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

ACUTE DISSEMINATED ENCEPHALOMYELITIS

Epidemiologic Evidence

No studies were identified in the literature for the committee to evaluate the risk of acute disseminated encephalomyelitis (ADEM) after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, or acellular pertussis antigens alone or in combination.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and ADEM.

Mechanistic Evidence

The committee identified five publications of ADEM developing after the administration of vaccines containing diphtheria toxoid and tetanus toxoid antigens alone or in combination. Four publications did not provide evidence beyond temporality, one of which was deemed too short based on the possible mechanisms involved (Abdul-Ghaffar and Achar, 1994; Bolukbasi and Ozmenoglu, 1999; Hamidon and Raymond, 2003; Rogalewski et al., 2007). In addition, Rogalewski et al. (2007) reported the administration of vaccines against hepatitis B, hepatitis A, and poliovirus in

Appendix C

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Faculty of Medicine
Department of Ophthalmology
& Visual Sciences
Shaw Laboratory
828 West 10th Avenue, Room 386
Vancouver, BC Canada V5Z 1L8

Phone 604 875 4111 Local 68375
Fax 604 875 4376
www.neuraldynamicsubc.ca

June 24, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am writing to you in regard to aluminum adjuvants in vaccines. This subject is one my laboratory works on intensively and therefore one where I feel that I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder (ASD). Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

These studies and the broader existing literature regarding aluminum toxicity, lead almost invariably to the conclusion that aluminum in any chemical form is always neurotoxic when administered to humans. Further, I am convinced that aluminum adjuvants in vaccines may contribute to neurological disorders across the lifespan. In adults, such adjuvant may induce macrophagic myofasciitis, a disease with neuropathological aspects. In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans even though, pursuant to the recommended vaccine schedule published by the Centers for Disease Control (CDC), a baby may be injected with up to 3,675 micrograms of aluminum adjuvant by six months of age.

In regard to the above, it is my belief that the CDC's claim on its website that "Vaccines Do Not Cause Autism" is wholly unsupported. Given this, I remain convinced that much more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is warranted and should be a research priority for the NIH and other funding bodies.

Yours sincerely,

Christopher A. Shaw, Ph.D
Professor
Dept. of Ophthalmology and Visual Sciences
University of British Columbia
828 W. 10th Ave.
Vancouver, British Columbia
Canada, V5Z1M9
Tel: 604-875-4111 (ext. 68373)
Email: cashawlab@gmail.com

Relevant Publications (Shaw Laboratory)

1. Crepeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, giros B, authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective dose neurotoxicity. *Toxicology*. 375:48-57. (2016).

2. Crepeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *J. Inorg. Biochem*. 152:199-205. (2015).

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14. Petrik MS, Wong MC, Tabata RC, Garry RF, and Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *J Neuromolecular Medicine*. 9: 83-100. (2007).

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de recherche biomédicale

UNIVERSITÉ
PARIS-EST

June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants toxicity in humans and animal models. I have been working in this field since the initial description of the AI vaccine-induced macrophagic myofasciitis in 1998. Since that time I have written 40 peer-reviewed scientific publications and one book on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours very sincerely

Romain K. Gherardi
Professor, Neuromuscular Pathology Expert Centre
University Paris-Est, INSERM U955-E10,
Henri Mondor hospital, Créteil France
Contact at the hospital
Tel 00 (33) 1 49812746
romain.gherardi@hmn.aphp.fr

UMR U955 INSERM / UPEC

Team 10
« Biology of the neuromuscular system»

Fred Relaix, director
FrançoisJérome Authier, co-director

Romain Gherardi, former director
Tél. +33 (0)1 49 81 27 42
Fax. +33 (0)1 49 81 27 33
romain .gherardi@inserm.fr

Inserm U955 - Faculté de Médecine
8, rue du Général Sarrail 94010 Créteil Cedex
institutmondor@inserm.fr

Selection of significant publications from our group in the field

Gherardi R. Toxic Story: deux ou trois vérités embarrassantes sur les adjuvants des vaccins. **Actes Sud** (publisher), Paris, 2016, 250 pages

Crépeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, Giros B, Authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. **Toxicology**. 2017 Jan 15;375:48-57.

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Tel: 01782 734080
Fax: 01782 712378
e-mail: c.exley@keele.ac.uk
http://www.keele.ac.uk/aluminium

June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants and aluminum toxicity. I have been working in this field for more than 30 years during which time I have written in excess of 150 peer-reviewed scientific publications on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours faithfully

Christopher Exley PhD
Professor in Bioinorganic Chemistry

Honorary Professor, University of the Highlands and Islands

List of Recent, Relevant and Significant Publications From Our Group

Exley C, Siesjö P & Eriksson H (2010) The immunobiology of aluminium adjuvants: how do they really work? Trends in Immunology 31, 103-109.

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Telephone number +44 (01782) 584211
Fax +44 (01782) 712378

Keele University, Staffordshire, ST5 5BG United Kingdom
Telephone number +44 (01782) 621111 http://www.keele.ac.uk

ICAN
Informed Consent Action Network

VIA FEDEX

December 5, 2017

UNICEF House
Dr. Anthony Lake
Executive Director
3 United Nations Plaza
New York, NY 10017
Telephone: +1(212) 32 67 490
Facsimile: +1(212) 32 67 477

Re: Deaths caused by DTP

Dear Dr. Lake,

UNICEF has been instrumental in vaccination campaigns in many countries, including their prior and ongoing DTP vaccination campaign. We write to bring to your attention an alarming study, published this year, which found that children vaccinated with DTP were 10 times more likely to die in the first six months of life than those children that were unvaccinated.[1] A copy of this study is enclosed.

Dr. Peter Aaby, the lead author of this study, is renowned for studying and promoting vaccines in Africa with over 300 published studies.[2] Dr. Aaby, after concluding that children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated, states:

> "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[3]

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[1] A copy of this study can also be found here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
[2] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/

This study also found that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[4] This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[5]

Unlike most vaccine safety studies in which subjects are not well matched, Dr. Aaby's study is reliable because the subjects were accurately matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. (This issue is explained in detail in a publication by vaccine safety scientists at the U.S. Centers for Disease Control.[6]) Dr. Aaby's study is the only study looking at death from DTP specifically designed to avoid this error.

When an extremely well-designed study from accomplished vaccine proponents at the Research Centre for Vitamins and Vaccines and Institute of Clinical Research at the University of Southern Denmark/Odense University Hospital finds that children receiving a certain product are dying at 10 times the rate of children not receiving that product, prudence dictates pausing the distribution of that product. Please confirm that UNICEF has ceased distributing DTP and kindly advise what research UNICEF is undertaking regarding deaths from DTP vaccine, including identifying the families killed by this vaccine in order to provide them with reparations.

We also note that continued vaccination with DTP without disclosing the findings in Dr. Aaby's study would violate the Nuremberg Code which provides that:

> "The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."[7]

The Nuremberg Code thus draws a sharp line when stating that no human being should receive a medical procedure and/or product without informed consent. Failing to advise

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[4] Ibid.

[5] Ibid.

[6] https://www.ncbi.nlm.nih.gov/pubmed/1415136

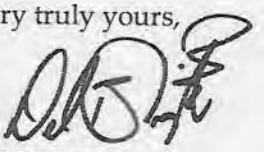
[7] https://history.nih.gov/research/downloads/nuremberg.pdf

the findings of Dr. Aaby's study to parents prior to administering the DTP vaccine would violate this basic human right.

While medical interventions have saved countless lives, the graveyard of history is also replete with once lauded but later abandoned medical inventions and practices. When an issue with a medical procedure is identified, especially when it is killing children, immediate action is necessary. We hope that political and economic considerations will not cloud the clear moral and ethical duty to protect children from death from DTP vaccine.

If UNICEF does not intend to cease distribution of DTP vaccine or at least confirm that parents of children receiving this vaccine are advised of Dr. Aaby's findings, we intend to take appropriate legal action. We look forward to receiving a timely response to this letter so that we can follow-up with all member states cc'd on this communication with regard to what actions UNICEF intends to take in response to Dr. Aaby's extremely concerning finding that children receiving DTP vaccine had a death rate 10 times that of children that were not vaccinated.

Very truly yours,



Del Bigtree

cc: See Appendix A (*Countires Using DTP Vaccine*)

Enclosure: Mogensen S.W., Andersen A., Rodrigues A., Benn C.S., Aaby P., *The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment*, EBioMedicine. 2017;17:192–198.

APPENDIX A

Permanent Mission of Afghanistan to the United Nations
H.E. Mr. Mahmoud Saikal
Permanent Representative
633 Third Avenue, 27th Floor
New York, N.Y. 10017
Phone: (212) 972-1212
Email: info@afghanistan-un.org

Permanent Mission of the Republic of Albania to the United Nations
H.E. Ms. Besiana Kadare
Permanent Representative
320 East 79th Street
New York, N.Y. 10075
Phone: (212) 249-2059
Email: mission.newyork@mfa.gov.al
albania.un@albania-un.org

Permanent Mission of Algeria to the United Nations
H.E. Mr. Sabri Boukadoum
Permanent Representative
326 East 48th Street
New York, N.Y. 10017
Phone: (212) 750-1960
Email: algeria@un.int

Permanent Mission of the Republic of Angola to the United Nations
H.E. Mr. Ismael Abraão Gaspar Martins
Permanent Representative
820 Second Avenue, 12th Floor
New York, N.Y. 10017
Phone: (212) 861-5656
Email: themission@angolaun.org

Permanent Mission of Antigua and Barbuda to the United Nations
H.E. Mr. Walton Alfonso Webson
Permanent Representative
305 East 47th Street, 6th Floor
New York, N.Y. 10017
Phone: (212) 541-4117
Email: unmission@abgov.org

Permanent Mission of Argentina to the United Nations
H.E. Mr. Martín García Moritán
Permanent Representative
One United Nations Plaza, 25th Floor
New York, N.Y. 10017
Phone: (212) 688-6300
Email: enaun@mrecic.gov.ar

Permanent Mission of the Republic of Armenia to the United Nations
H.E. Mr. Zohrab Mnatsakanyan
Permanent Representative
119 East 36th Street
New York, N.Y. 10016
Phone: (212) 686-9079
Email: armenia@un.int

Permanent Mission of the Republic of Azerbaijan to the United Nations
H.E. Mr. Yashar T. Aliyev
Permanent Representative
866 United Nations Plaza, Suite 560 New York, N.Y. 10017
Phone: (212) 371-2559
Email: azerbaijan@un.int

Permanent Mission of the Commonwealth of the Bahamas to the United Nations
H.E. Mr. Elliston Rahming
Permanent Representative
231 East 46th Street
New York, N.Y. 10017
Phone: (212) 421-6925
Email: mission@bahamasny.com

Permanent Mission of the Kingdom of Bahrain to the United Nations
H.E. Mr. Jamal Fares Alrowaiei
Permanent Representative
866 Second Avenue, 14th and 15th Floors
New York, N.Y. 10017
Phone: (212) 223-6200
Email: bahrain1@un.int

Permanent Mission of the People's Republic of Bangladesh to the United Nations
H.E. Mr. Masud Bin Momen
Permanent Representative
820 Second Avenue, 4th Floor
New York, N.Y. 10017
Phone: (212) 867-3434
Email: bangladesh@un.int;
bdpmny@gmail.com;
fsnypmbd@mofa.gov.bd;
z.aynuzzaman@gmail.com

Permanent Mission of Barbados to the United Nations
H.E. Mr. Keith Hamilton Llewellyn Marshall
Permanent Representative
820 Second Avenue, 9th Floor
New York, N.Y. 10017
Phone: (212) 551-4300
Email: prun@foreign.gov.bb;
barbados@un.int

Permanent Mission of the Republic of Belarus to the United Nations
H.E. Mr. Andrei Dapkiunas
Permanent Representative
136 East 67th Street, 4th Floor
New York, N.Y. 10065
Phone: (212) 535-3420
Email: usaun@mfa.gov.by

Permanent Mission of Belize to the United Nations
H.E. Ms. Lois Michele Young
Permanent Representative
675 Third Avenue, Suite 1911
New York, N.Y. 10017
Phone: (212) 986-1240
Email: blzun@belizemission.com
blzun@aol.com

Permanent Mission of the Republic of Benin to the United Nations
H.E. Mr. Jean-Francis Régis Zinsou
Permanent Representative
125 East 38th Street
New York, N.Y. 10016
Phone: (212) 684-1339
Email: beninewyork@gmail.com

Permanent Mission of the Kingdom of Bhutan to the United Nations
H.E. Mrs. Kunzang C. Namgyel
Permanent Representative
343 East 43rd Street
New York, N.Y. 10017
Phone: (212) 682-2268
Email: bhutanmission@pmbny.bt

Permanent Mission of the Plurinational State of Bolivia to the United Nations
H.E. Mr. Sacha Sergio Llorentty Solíz
Permanent Representative
801 Second Avenue, 4th Floor, Suite 402
New York, N.Y. 10017
Phone: (212) 682-8132
Email: missionboliviaun@gmail.com

Permanent Mission of Bosnia and Herzegovina to the United Nations
H.E. Mr. Miloš Vukašinović
Permanent Representative
420 Lexington Avenue, Suites 607 & 608
New York, N.Y. 10170
Phone: (212) 751-9015
Email: bihun@mfa.gov.ba

Permanent Mission of Botswana to the United Nations
H.E. Mr. Charles Thembani Ntwaagae
Permanent Representative
154 East 46th Street
New York, N.Y. 10017
Phone: (212) 889-2277
Email: botswana@un.int

Permanent Mission of Brazil to the United Nations
H.E. Mr. Antonio de Aguiar Patriota
Permanent Representative
747 Third Avenue, 9th Floor
New York, N.Y. 10017-2803
Phone: (212) 372-2600
Email:
Distri.delbrasonu@itamaraty.gov.br
www.un.int/brazil

Permanent Mission of Burkina Faso to the United Nations
H.E. Mr. Yemdaogo Eric Tiare
Permanent Representative
633 Third Avenue, Suite 31A, 31st Floor
New York, N.Y. 10017
Phone: (212) 308-4720
Email: bfapm@un.int

Permanent Mission of the Republic of Burundi to the United Nations
H.E. Mr. Albert Shingiro
Permanent Representative
336 East 45th Street, 12th Floor
New York, N.Y. 10017
Phone: (212) 499-0001
Email: ambabunewyork@yahoo.fr

Permanent Mission of the Republic of Cabo Verde to the United Nations
H.E. Mr. Fernando Jorge Wahnon Ferreira
Permanent Representative
27 East 69th Street
New York, N.Y. 10021
Phone: (212) 472-0333
Email: capeverde@un.int

Permanent Mission of the Kingdom of Cambodia to the United Nations
H.E. Mr. Ry Tuy
Permanent Representative
327 East 58th Street
New York, N.Y. 10022
Phone: (212) 336-0777
Email: cambodia@un.int English

Permanent Mission of the Republic of Cameroon to the United Nations
H.E. Mr. Michel Tommo Monthe
Permanent Representative
22 East 73rd Street
New York, N.Y. 10021
Phone: (212) 794-2295
Email: cameroon.mission@yahoo.com

Permanent Mission of the Central African Republic to the United Nations
H.E. Ms. Ambroisine Kpongo
Permanent Representative
866 United Nations Plaza, Suite 444
New York, N.Y. 10017
Phone: (646) 415-9122
Email: repercaf.ny@gmail.com

Permanent Mission of the Republic of Chad to the United Nations
H.E. Mr. Mahamat Zene Cherif
Permanent Representative
129 East 36th Street
New York, NY 10016
(212) 986-0980
Email: chadmission@gmail.com

Permanent Mission of Chile to the United Nations
H.E. Mr. Cristián Barros Melet
Permanent Representative
One Dag Hammarskjöld Plaza 885
Second Avenue, 40th Floor
New York, N.Y. 10017
Phone: (917) 322-6800
Email: chile.un@minrel.gob.cl

Permanent Mission of Colombia to the United Nations
H.E. Ms. María Emma Mejía Vélez
Permanent Representative
140 East 57th Street, 5th Floor
New York, N.Y. 10022
Phone: (212) 355-7776
Email: colombia@colombiaun.org

Permanent Mission of the Union of the Comoros to the United Nations
H.E. Mr. Mohamed Soilihi Soilih
Permanent Representative
866 United Nations Plaza, Suite 418
New York, N.Y. 10017
Phone: (212) 750-1637
Email: comoros@un.int

Permanent Mission of the Republic of the Congo to the United Nations
H.E. Mr. Raymond Serge Balé
Permanent Representative
14 East 65th Street
New York, N.Y. 10065
Phone: (212) 744-7840
Email: congo@un.int;
mpcongo_onu@hotmail.com

Permanent Mission of Côte d'Ivoire to the United Nations
H.E. Mr. Claude Stanislas Bouah-Kamon
Permanent Representative
800 2nd Avenue, 5th Floor
New York, N.Y. 10017
Phone: (646) 649-5061
Email: cotedivoiremission@yahoo.com

Permanent Mission of Cuba to the United Nations
H.E. Mr. Rodolfo Reyes Rodríguez
Permanent Representative 315 Lexington Avenue
New York, N.Y. 10016
Phone: (212) 689-7215
Email: cuba_onu@cubanmission.com

Permanent Mission of the Democratic People's Republic of Korea to the United Nations
H.E. Mr. Ja Song Nam
Permanent Representative
820 Second Avenue, 13th Floor
New York, N.Y. 10017
Phone: (212) 972-3105
Email: Dprk.un@verizon.net English

Permanent Mission of the Democratic Republic of the Congo to the United Nations
H.E. Mr. Ignace Gata Mavita wa Lufuta
Permanent Representative
866 United Nations Plaza, Suite 511
New York, N.Y. 10017
Phone: (212) 319-8061
Email: missiondrc@gmail.com

Permanent Mission of the Republic of Djibouti to the United Nations
H.E. Mr. Mohamed Siad Doualeh
Permanent Representative
866 United Nations Plaza, Suite 4011
New York, N.Y. 10017
Phone: (212) 753-3163
Email: djibouti@nyct.net

Permanent Mission of the Commonwealth of Dominica to the United Nations
H.E. Mrs. Loreen Ruth Bannis-Roberts
Permanent Representative
800 Second Avenue, Suite 400H
New York, N.Y. 10017
Phone: (212) 949-0853
Email: domun@onecommonwealth.org; dominicaun@gmail.com

Permanent Mission of the Dominican Republic to the United Nations
H.E. Mr. Francisco Antonio Cortorreal
Permanent Representative
144 East 44th Street, 4th Floor
New York, N.Y. 10017
Phone: (212) 867-0833
Email: drun@un.int

Permanent Mission of Ecuador to the United Nations
H.E. Mr. Horacio Sevilla Borja
Permanent Representative
866 United Nations Plaza, Room 516
New York, N.Y. 10017
Phone: (212) 935-1680
Email: ecuador@un.int

Permanent Mission of the Arab Republic of Egypt to the United Nations
H.E. Mr. Amr Abdellatif Aboulatta
Permanent Representative
304 East 44th Street
New York, N.Y. 10017
Phone: (212) 503-0300
Email: egypt@un.int; pr.egypt@un.int

Permanent Mission of El Salvador to the United Nations
H.E. Mr. Rubén Ignacio Zamora Rivas
Permanent Representative
46 Park Avenue
New York, N.Y. 10016
Phone: (212) 679-1616
Email: elsalvador@un.int

Permanent Mission of Equatorial Guinea to the United Nations
H.E. Mr. Anatolio Ndong Mba
Permanent Representative
800 Second Avenue, Suite 305
New York, N.Y. 10017
Phone: (212) 223-2324
Email: equatorialguineamission@yahoo.com

Permanent Mission of Eritrea to the United Nations
H.E. Mr. Girma Asmerom Tesfay
Permanent Representative
800 Second Avenue, 18th Floor
New York, N.Y. 10017
Phone: (212) 687-3390
Email: general@eritrea-unmission.org

Permanent Mission of the Federal Democratic Republic of Ethiopia to the United Nations
H.E. Mr. Tekeda Alemu
Permanent Representative
866 Second Avenue, 3rd Floor
New York, N.Y. 10017
Phone: (212) 421-1830
Email: ethiopia@un.int

Permanent Mission of the Republic of Fiji to the United Nations
H.E. Mr. Peter Thomson
Permanent Representative
801 Second Avenue, 10th Floor
New York, N.Y. 10017
Phone: (212) 687-4130
Email: mission@fijiprun.org

Permanent Mission of the Gabonese Republic to the United Nations
H.E. Mr. Baudelaire Ndong Ella
Permanent Representative
18 East 41st Street, 9th Floor
New York, N.Y. 10017
Phone: (212) 686-9720
Email: info@gabonunmission.com

Permanent Mission of the Islamic Republic of the Gambia to the United Nations
H.E. Mr. Mamadou Tangara
Permanent Representative
336 East 45th Street, 7th Floor
New York, N.Y. 10017
Phone: (212) 949-6640
Email: gambia_un@hotmail.com

Permanent Mission of Georgia to the United Nations
H.E. Mr. Kaha Imnadze
Permanent Representative
One United Nations Plaza, 26th Floor
New York, N.Y. 10017
Phone: (212) 759-1949
Email: geomission.un@mfa.gov.ge

Permanent Mission of Ghana to the United Nations
H.E. Mrs. Martha Ama Akyaa Pobee
Permanent Representative
19 East 47th Street
New York, N.Y. 10017
Phone: (212) 832-1300
Email: ghanaperm@aol.com

Permanent Mission of Grenada to the United Nations
H.E. Ms. Keisha A. McGuire
Permanent Representative
800 Second Avenue, Suite 400K
New York, N.Y. 10017
Phone: (212) 599-0301
Email: grenada@un.int

Permanent Mission of Guatemala to the United Nations
H.E. Mr. Jorge Skinner-Klée
Permanent Representative
57 Park Avenue
New York, N.Y. 10016
Phone: (212) 679-4760
Email: guatemala@un.int; onupnud@minex.gob.gt

Permanent Mission of the Republic of Guinea to the United Nations
H.E. Mr. Mamadi Touré
Permanent Representative
140 East 39th Street
New York, N.Y. 10016
Phone: (212) 687-8115
Email: missionofguinea@aol.com

Permanent Mission of the Republic of Guinea-Bissau to the United Nations
H.E. Mr. João Soares Da Gama
Permanent Representative
336 East 45th Street, 13th Floor
New York, N.Y. 10017
Phone: (212) 896-8311
Email: guinea-bissau@un.int;
guinebissauonu@gmail.com

Permanent Mission of the Republic of Guyana to the United Nations
H.E. Mr. Rudolph Michael Ten-Pow
Permanent Representative 801 Second Avenue, 5th Floor
New York, N.Y. 10017
Phone: (212) 573-5828,
Email: guyana@un.int

Permanent Mission of Haiti to the United Nations
H.E. Mr. Denis Régis
Permanent Representative
815 Second Avenue, 6th Floor
New York, N.Y. 10017
Phone: (212) 370-4840
Email: mphonu.newyork@diplomatie.ht

Permanent Mission of Honduras to the United Nations
H.E. Ms. Mary Elizabeth Flores
Permanent Representative
866 United Nations Plaza, Suite 417
New York, N.Y. 10017
Phone: (212) 752-3370
Email: Ny.honduras@hnun.org

Permanent Mission of India to the United Nations
H.E. Mr. Syed Akbaruddin
Permanent Representative
235 East 43rd Street
New York, N.Y. 10017
Phone: (212) 490-9660
Email: india@un.int
ind_general@indiaun.net

Permanent Mission of the Republic of Indonesia to the United Nations
H.E. Mr. Dian Triansyah Djani
Permanent Representative
325 East 38th Street
New York, N.Y. 10016
Phone: (212) 972-8333
Email: ptri@indonesiamission-ny.org

Permanent Mission of the Islamic Republic of Iran to the United Nations
H.E. Mr. Gholamali Khoshroo
Permanent Representative
622 Third Avenue, 34th Floor
New York, N.Y. 10017
Phone: (212) 687-2020
Email: iran@un.int

Permanent Mission of the Republic of Iraq to the United Nations
H.E. Mr. Mohamed Ali Alhakim
Permanent Representative
14 East 79th Street
New York, N.Y. 10075
Phone: (212) 737-4433
Email: iraqny@un.int

Permanent Mission of Israel to the United Nations
H.E. Mr. Danny Danon
Permanent Representative
800 Second Avenue
New York, N.Y. 10017
Phone: (212) 499-5510
Email: UNInfo@newyork.mfa.gov.il

Permanent Mission of Jamaica to the United Nations
H.E. Mr. E. Courtenay Rattray, CD Permanent Representative
767 Third Avenue, 9th Floor
New York, N.Y. 10017
Phone: (212) 935-7509
Email: jamaica@un.int

Permanent Mission of the Hashemite Kingdom of Jordan to the United Nations
H.E Ms. Sima Sami Bahous
Permanent Representative
866 Second Avenue, 4th Floor
New York, N.Y. 10017
Phone: (212) 832-9553
Email:
missionun@jordanmissionun.com

Permanent Mission of the Republic of Kenya to the United Nations
H.E. Mr. Macharia Kamau Permanent Representative
866 United Nations Plaza, Room 304
New York, N.Y. 10017
Phone: (212) 421-4740
Email: info@kenyaun.org

Permanent Mission of the Republic of Kiribati to the United Nations
H.E. Mrs. Makurita Baaro
Permanent Representative
800 Second Avenue, Suite 400B
New York, N.Y. 10017
Phone: (212) 867-3310
Email: Kimission.newyork@mfa.gov.ki

Permanent Mission of the State of Kuwait to the United Nations
H.E. Mr. Mansour Ayyad SH A Alotaibi
Permanent Representative
321 East 44th Street
New York, N.Y. 10017
Phone: (212) 973-4300
Email: kuwait@kuwaitmissionun.org

Permanent Mission of the Kyrgyz Republic to the United Nations
H.E. Ms. Mirgul Moldoisaeva
Permanent Representative
866 United Nations Plaza, Suite 477
New York, N.Y. 10017
Phone: (212) 486-4214
Email: kyrgyzstan@un.int

Permanent Mission of the Lao People's Democratic Republic to the United Nations
H.E. Mr. Khiane Phansourivong
Permanent Representative
317 East 51st Street
New York, N.Y. 10022
Phone: (212) 832-2734
Email: lao.pr.ny@gmail.com

Permanent Mission of Lebanon to the United Nations
H.E. Mr. Nawaf Salam
Permanent Representative
866 United Nations Plaza, Room 531-533
New York, N.Y. 10017
Phone: (212) 355-5460
Email: contact@lebanonun.org

Permanent Mission of the Kingdom of Lesotho to the United Nations
H.E. Mr. Kelebone Maope
Permanent Representative
815 Second Avenue, 8th Floor
New York, N.Y. 10017
Phone: (212) 661-1690
Email: lesothonewyork@gmail.com

Permanent Mission of the Republic of Liberia to the United Nations
H.E. Mr. Lewis G. Brown
Permanent Representative
866 United Nations Plaza, Suite 480
New York, N.Y. 10017
Phone: (212) 687-1033
Email: 1035 Liberia@un.int

Permanent Mission of the Republic of Madagascar to the United Nations
H.E. Mr. Zina Andrianarivelo-Razafy
Permanent Representative
820 Second Avenue, Suite 800
New York, N.Y. 10017
Phone: (212) 986-9491
Email: repermad@verizon.net

Permanent Mission of the Republic of Malawi to the United Nations
H.E. Mr. Necton D. Mhura
Permanent Representative
866 United Nations Plaza, Suite 486
New York, N.Y. 10017
Phone: (212) 317-8738
Email: MalawiNewyork@aol.com; MalawiU@aol.com

Permanent Mission of the Republic of Maldives to the United Nations
H.E. Mr. Ahmed Sareer
Permanent Representative
801 Second Avenue, Suite 202
New York, N.Y. 10017
Phone: (212) 599-6194
Email: info@maldivesmission.com

Permanent Mission of the Republic of Mali to the United Nations
H.E. Mr. Issa Konfourou
Permanent Representative
111 East 69th Street
New York, N.Y. 10021
Phone: (212) 737-4150
Email: malionu@aol.com

Permanent Mission of the Islamic Republic of Mauritania to the United Nations
H.E. Mr. Mohamed Lemine El Haycen
Permanent Representative
116 East 38th Street
New York, N.Y. 10016
Phone: (212) 252-0113
Email: mauritaniamission@gmail.com

Permanent Mission of the Republic of Mauritius to the United Nations
H.E. Mr. Jagdish Dharamchand Koonjul
Permanent Representative
211 East 43rd St., 22nd Floor
New York, N.Y. 10017
Phone: (212) 949-0190
Email: mauritius@un.int

Permanent Mission of Mexico to the United Nations
H.E. Mr. Juan José Gómez Camacho
Permanent Representative
Two United Nations Plaza, 28th Floor
New York, N.Y. 10017
Phone: (212) 752-0220
Email: onuusr1@sre.gob.mx

Permanent Mission of Mongolia to the United Nations
H.E. Mr. Sukhbold Sukhee
Permanent Representative
6 East 77th Street
New York, N.Y. 10075
Phone: (212) 861-9460
Email: mongolianmission@twcmetrobiz.com

Permanent Mission of the Kingdom of Morocco to the United Nations
H.E. Mr. Omar Hilale
Permanent Representative
866 Second Avenue, 6th and 7th Floors
New York, N.Y. 10017
Phone: (212) 421-1580
Email: morocco.un@maec.gov.ma

Permanent Mission of the Republic of the Union of Myanmar to the United Nations
H.E. Mr. Hau Do Suan
Permanent Representative
10 East 77th Street
New York, N.Y. 10075
Phone: (212) 744-1271
Email: myanmarmission@verizon.net

Permanent Mission of the Republic of Namibia to the United Nations
H.E. Mr. Wilfried I. Emvula
Permanent Representative
135 East 36th Street
New York, N.Y. 10016
Phone: (646) 627-8670
Email: namibia@un.int

Permanent Mission of the Republic of Nauru to the United Nations
H.E. Ms. Marlene Moses
Permanent Representative
801 Second Avenue, Third Floor
New York, N.Y. 10017
Phone: (212) 937-0074
Email: nauru@un.int
nauru@onecommonwealth.org

Permanent Mission of the Federal Democratic Republic of Nepal to the United Nations
H.E. Mr. Durga Prasad Bhattarai
Permanent Representative
820 Second Avenue, Suite 17B (17th Floor)
New York, N.Y. 10017
Phone: (212) 370-3988
Email: nepal@un.int;
nepalmissionusa@gmail.com

Permanent Mission of Nicaragua to the United Nations
H.E. Mrs. María Rubiales de Chamorro
Permanent Representative
820 Second Avenue, 8th Floor
New York, N.Y. 10017
Phone: (212) 490-7997
Email: nicaragua@un.int

Permanent Mission of the Republic of Niger to the United Nations
H.E. Mr. Abdallah Wafy
Permanent Representative
417 East 50th Street
New York, N.Y. 10022
Phone: (212) 421-3260
Email: nigermission@ymail.com

Permanent Mission of Nigeria to the United Nations
828 Second Avenue
New York, N.Y. 10017
Email: permny@nigeriaunmission.org

Permanent Mission of the Sultanate of Oman to the United Nations
H.E. Mr. Khalifa Ali Issa Al Harthy
Permanent Representative
3 Dag Hammarskjöld Plaza
305 East 47th Street, 12th Floor
New York, N.Y. 10017
Phone: (212) 355-3505
Email: oman@un.int

Permanent Mission of Pakistan to the United Nations Pakistan House
H.E. Ms. Maleeha Lodhi
Permanent Representative
8 East 65th Street
New York, N.Y. 10065
Phone: (212) 879-8600
Email: pakistan@un.int

Permanent Mission of Panama to the United Nations
H.E. Ms. Laura Elena Flores Herrera
Permanent Representative
866 United Nations Plaza, Suite 4030
New York, N.Y. 10017
Phone: (212) 421-5420
Email: emb@panama-un.org

Permanent Mission of the Independent State of Papua New Guinea to the United Nations
H.E. Mr. Max Hufanen Rai
Permanent Representative
201 East 42nd Street, Suite 2411
New York, N.Y. 10017
Phone: (212) 557-5001
Email: pngun@pngmission.org

Permanent Mission of Paraguay to the United Nations
801 Second Avenue, 15th Floor, Suite 1501
New York, N.Y. 10017
Phone: (212) 687-3490
Email: paraguay@un.int

Permanent Mission of Peru to the United Nations
H.E. Mr. Gustavo Meza-Cuadra
Permanent Representative
820 Second Avenue, Suite 1600
New York, N.Y. 10017
Phone: (212) 687-3336
Email: onuper@unperu.org

Permanent Mission of the Republic of the Philippines to the United Nations
H.E. Ms. Lourdes Ortiz Yparraguirre
Permanent Representative
556 Fifth Avenue, 5th Floor
New York, N.Y. 10036
Phone: (212) 764-1300
Email: newyorkpm@gmail.com

Permanent Mission of the Republic of Poland to the United Nations
H.E. Mr. Bogusław Winid
Permanent Representative
750 Third Avenue, 30th Floor
New York, N.Y. 10017
Phone: (212) 744-2506
Email: poland.un@msz.gov.pl

Permanent Mission of the State of Qatar to the United Nations
H.E. Ms. Alya Ahmed Saif Al-Thani
Permanent Representative
809 United Nations Plaza, 4th Floor
New York, N.Y. 10017
Phone: (212) 486-9335
Email: pmun@mofa.gov.qa

Permanent Mission of the Republic of Moldova to the United Nations
H.E. Mr. Vlad Lupan
Permanent Representative
35 East 29th Street
New York, N.Y. 10016
Phone: (212) 447-1867
Email: unmoldova@aol.com

Permanent Mission of the Russian Federation to the United Nations
H.E. Mr. Vitaly I. Churkin
Permanent Representative
136 East 67th Street
New York, N.Y. 10065
Phone: (212) 861-4900,
Email: press@russiaun.ru

Permanent Mission of the Republic of Rwanda to the United Nations
124 East 39th Street
New York, N.Y. 10016
Phone: (212) 679-9010
Email: ambanewyork@minaffet.gov.rw
ambanewyork@gmail.com

Permanent Mission of Saint Kitts and Nevis to the United Nations
H.E. Mr. Sam Terence Condor
Permanent Representative
414 East 75th Street, 5th Floor
New York, N.Y. 10021
Phone: (212) 535-1234
Email: sknmission@aol.com

Permanent Mission of Saint Lucia to the United Nations
H.E. Ms. Menissa Rambally
Permanent Representative
800 Second Avenue, 5th Floor
New York, N.Y. 10017
Phone: (212) 697-9360
Email: info@stluciamission.org

Permanent Mission of Saint Vincent and the Grenadines to the United Nations
H.E. Ms. Inga Rhonda King
Permanent Representative
800 Second Avenue, Suite 400F
New York, N.Y. 10017
Phone: (212) 599-0950
Email: mission@svg-un.org;
svgmission@gmail.com

Permanent Mission of the Independent State of Samoa to the United Nations
H.E. Mr. Ali'ioaiga Feturi Elisaia
Permanent Representative
800 Second Avenue, Suite 400J
New York, N.Y. 10017
Phone: (212) 599-6196
Email: office@samoanymission.ws

Permanent Mission of Sao Tome and Principe to the United Nations
H.E. Mr. Carlos Filomeno Agostinho das Neves
Permanent Representative
675 Third Avenue, Suite 1807
New York, NY 10017
Phone: (212) 651-8116
Email: rdstppmun@gmail.com

Permanent Mission of the Republic of Senegal to the United Nations
H.E. Mr. Fodé Seck
Permanent Representative
229 East 44th Street
New York, N.Y. 10017
Phone: (212) 517-9030
Email: senegal.mission@yahoo.fr

Permanent Mission of the Republic of Seychelles to the United Nations
H.E. Ms. Marie-Louise Potter
Permanent Representative
800 Second Avenue, Suite 400G
New York, N.Y. 10017
Phone: (212) 972-1785
Email: seychelles@un.in,
seychellesmissionun@gmail.com

Permanent Mission of the Republic of Sierra Leone to the United Nations
H.E. Mr. Vandi Chidi Minah
Permanent Representative
245 East 49th Street
New York, N.Y. 10017
Phone: (212) 688-1656
Email: sierraleone@un.int

Permanent Mission of Solomon Islands to the United Nations
800 Second Avenue, Suite 400L
New York, N.Y. 10017-4709
Phone: (212) 599-6192
Email: simun@solomons.com

Permanent Mission of the Federal Republic of Somalia to the United Nations
425 East 61st Street, Suite 702
New York, N.Y. 10065
Phone: (212) 688-9410
Email: somalia@un.int

Permanent Mission of the Republic of South Sudan to the United Nations
H.E. Mr. Akuei Bona Malwal
Permanent Representative
336 East 45th Street, 5th Floor
New York, N.Y. 10017
Phone: (212) 937-7977
Email: info@rssun-nyc.org

Permanent Mission of the Democratic Socialist Republic of Sri Lanka to the United Nations
H.E. Mr. Amrith Rohan Perera
Permanent Representative
820 Second Avenue, 2nd Floor
New York, N.Y. 10017
Phone: (212) 986-7040
Email: mail@slmission.com

Permanent Mission of the Republic of the Sudan to the United Nations
H.E. Mr. Omer Dahab Fadl Mohamed
Permanent Representative
305 East 47th Street 3
Dag Hammarskjöld Plaza, 4th Floor New York, N.Y. 10017
Phone: (212) 573-6033
Email: sudan@sudanmission.org

Permanent Mission of the Republic of Suriname to the United Nations
866 United Nations Plaza, Suite 320
New York, N.Y. 10017-1822
Phone: (212) 826-0660
Email: uriname@un.int

Permanent Mission of the Kingdom of Swaziland to the United Nations
H.E. Mr. Zwelethu Mnisi
Permanent Representative
408 East 50th Street
New York, N.Y. 10022
Phone: (212) 371-8910
Email: swaziland@un.int;
swazinymission@yahoo.com

Permanent Mission of the Syrian Arab Republic to the United Nations
H.E. Mr. Bashar Ja'afari
Permanent Representative
820 Second Avenue, 15th Floor
New York, N.Y. 10017
Phone: (212) 661-1313
Email: exesec.syria@gmail.com

Permanent Mission of the Republic of Tajikistan to the United Nations
H.E. Mr. Mahmadamin Mahmadaminov
Permanent Representative
216 East 49th Street, 5th Floor
New York, N.Y. 10017
Phone: (212) 207-3315
Email: tajikistan@un.int;
tajikistanun@aol.com

Permanent Mission of Thailand to the United Nations
H.E. Mr. Virachai Plasai
Permanent Representative
351 East 52nd Street
New York, N.Y. 10022
Phone: (212) 754-2230
Email: thailand@un.int

Permanent Mission of the former Yugoslav Republic of Macedonia to the United Nations
H.E. Mr. Vasile Andonoski
Permanent Representative
866 United Nations Plaza, Suite 570
New York, N.Y. 10017
Phone: (212) 308-8504
Email: newyork@mfa.gov.mk

Permanent Mission of the Democratic Republic of Timor-Leste to the United Nations
H.E. Ms. Maria Helena Lopes de Jesus Pires
Permanent Representative
866 United Nations Plaza, Suite 441
New York, N.Y. 10017
Phone: (212) 759-3675
Email: timor-leste@un.int

Permanent Mission of Togo to the United Nations
H.E. Mr. Kokou Kpayedo
Permanent Representative
336 East 45th Street
New York, N.Y. 10017
Phone: (212) 490-3455
Email: togo@un.int;
togo.mission@yahoo.fr

Permanent Mission of the Kingdom of Tonga to the United Nations
H.E. Mr. Mahe'uli'uli Sandhurst Tupouniua
Permanent Representative 250 East 51st Street
New York, N.Y. 10022
Phone: (917) 369-1025
Email: tongaunmission@gmail.com

Permanent Mission of the Republic of Trinidad and Tobago to the United Nations
H.E. Ms. Pennelope Althea Beckles
Permanent Representative
633 Third Avenue, 12th Floor
New York, N.Y. 10017
Phone: (212) 697-7620
Email: tto@un.int

Permanent Mission of Tunisia to the United Nations
H.E. Mr. Mohamed Khaled Khiari
Permanent Representative
31 Beekman Place
New York, N.Y. 10022
Phone: (212) 751-7503
Email: tunisnyc@nyc.rr.com

Permanent Mission of Turkmenistan to the United Nations
H.E. Mrs. Aksoltan Ataeva
Permanent Representative
866 United Nations Plaza, Suite 540
New York, N.Y. 10017
Phone: (212) 486-8908
Email: turkmenistan@un.int

Permanent Mission of Tuvalu to the United Nations
H.E. Mr. Aunese Makoi Simati
Permanent Representative
800 Second Avenue, Suite 400D
New York, N.Y. 10017
Phone: (212) 490-0534
Email: tuvalu.un@gmail.com

Permanent Mission of the Republic of Uganda to the United Nations
H.E. Mr. Richard Nduhuura
Permanent Representative
336 East 45th Street
New York, N.Y. 10017
Phone: (212) 949-0110
Email: ugandaunny@un.int

Permanent Mission of Ukraine to the United Nations
H.E. Mr. Volodymyr Yelchenko
Permanent Representative
220 East 51st Street
New York, N.Y. 10022
Phone: (212) 759-7003
Email: uno_us@mfa.gov.ua

Permanent Mission of the United Republic of Tanzania to the United Nations
H.E. Mr. Tuvako Nathaniel Manongi
Permanent Representative
307 East 53rd Street, 5th Floor
New York, N.Y. 10022
Phone: (212) 697-3612
Email: tanzania@un.int, tzrepny@aol.com

Permanent Mission of Uruguay to the United Nations
H.E. Mr. Elbio Rosselli
Permanent Representative
866 United Nations Plaza, Suite 322
New York, N.Y. 10017
Phone: (212) 752-8240
Email: urudeleg@mrree.gub.uy

Permanent Mission of the Republic of Uzbekistan to the United Nations
H.E. Mr. Muzaffarbek Madrakhimov
Permanent Representative
801 Second Avenue, 20th Floor
New York, N.Y. 10017
Phone: (212) 486-4242
Email: uzbekistan.un@gmail.com

Permanent Mission of the Republic of Vanuatu to the United Nations
H.E. Mr. Odo Tevi
Permanent Representative
800 Second Avenue, Suite 400C
New York, N.Y. 10017
Phone: (212) 661-4303
Email: vanunmis@aol.com

Permanent Mission of the Bolivarian Republic of Venezuela to the United Nations
H.E. Mr. Rafael Darío Ramírez Carreño
Permanent Representative
335 East 46th Street
New York, N.Y. 10017
Phone: (212) 557-2055
Email: misionvenezuelaonu@gmail.com

Permanent Mission of the Socialist Republic of Viet Nam to the United Nations
H.E. Mrs. Nguyen Phuong Nga
Permanent Representative
866 United Nations Plaza, Suite 435
New York, N.Y. 10017
Phone: (212) 644-0594
Email: info@vietnam-un.org

Permanent Mission of the Republic of Yemen to the United Nations
H.E. Mr. Khaled Hussein Mohamed Alyemany
Permanent Representative
413 East 51st Street
New York, N.Y. 10022
Phone: (212) 355-1730
Email: ymiss-newyork@mofa.gov.ye

Permanent Mission of the Republic of Zambia to the United Nations
H.E. Dr. Mwaba Patricia Kasese-Bota
Permanent Representative
237 East 52nd Street
New York, N.Y. 10022
Phone: (212) 888-5770
Email: zambia@un.int

Permanent Mission of the Republic of Zimbabwe to the United Nations
H.E. Mr. Frederick Musiiwa Makamure Shava
Permanent Representative
128 East 56th Street
New York, N.Y. 10022
Phone: (212) 980-9511
Email: zimnewyork@gmail.com

From: (b)(6)
Sent: Fri, 27 Oct 2017 09:12:11 -0500
To: Cohn, Amanda (CDC/OID/NCIRD)
Subject: Missed You

Sorry I couldn't say hi. I'm working on an email to the director. I'll copy you. I just want to be clear. I don't know anyone from ICAN-before meeting them Wednesday (b)(6)

(b)(6)

(b)(6)

All best,

(b)(6)

From: Vaughn, William (CDC/DDID/NCEZID/DHQP) (CTR)
Sent: Fri, 28 Jun 2019 16:13:02 +0000
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: new Harris poll on vaccine safety

fysa…a new online Harris poll conducted for the American Osteopathic Association about vaccine safety is getting some attention…some info is being promoted by ICAN, with focus on the 45% figure. Pro vaccine folks are also sharing on social media. The full poll isn't posted online that I can find.

https://osteopathic.org/2019/06/24/45-of-american-adults-doubt-vaccine-safety-according-to-survey/
https://www.phillyvoice.com/45-percent-americans-doubt-vaccine-safety-survey/

Although 55% of Americans don't doubt vaccine safety, 45% noted at least one source that caused doubts about the safety of vaccination. The top three doubt-causing sources were online articles (16%), past secrets/wrongdoing by the pharmaceutical industry (16%) and information from medical experts (12%).1

The survey also asked Americans to choose a statement that best represented their feelings about vaccine safety and efficacy. While the vast majority (82%) chose in favor of vaccines, 8% selected responses expressing serious doubt. An additional 9% said they were unsure.2

This survey was conducted online within the United States by The Harris Poll on behalf of AOA from May 28-30, 2019, among 2,007 U.S. adults. This online survey is not based on a probability sample and therefore no estimate of theoretical sampling error can be calculated. For complete survey methodology, including weighting variables and subgroup sample sizes, please contact Jeff Brennan.

Media Contact
Jeff Brennan, Media Relations Manager
312-771-0126 | jbrennan@osteopathic.org

William Vaughn
Health Communications Specialist |Eagle Medical Services, LLC
Communications Lead, Immunization Safety
CDC | Division of Healthcare Quality Promotion
404.718.6776 | hbv2@cdc.gov

From: vinu arumugham
Sent: Thu, 7 Mar 2019 21:20:34 -0800
To: zaoutis@email.chop.edu; Banerjee.Ritu@mayo.edu; ebarnett@bu.edu; jcampbel@som.umaryland.edu; Kourtis, Athena (CDC/DDID/NCEZID/DHQP); noltd@ohsu.edu; chris.nyquist@childrenscolorado.org; Sarah.Brewer@UCDENVER.EDU; dkimberlin@peds.uab.edu; Hbernstein@northwell.edu; Cohn, Amanda (CDC/DDID/NCIRD/OD); Farizo, Karen (FDA/CBER); Fischer, Marc (CDC/DDID/NCEZID/DVBD); natasha.halasa@vanderbilt.edu; lakerley@cheo.on.ca; stevermerj@health.missouri.edu; kct9@cdc.gov
Subject: Retract MMR/autism study; The real vaccine injury table; Rebutting Drs. Hotez, DeStefano and Offit on vaccine safety claims

My comment published in Annals of Internal Medicine explaining why the **Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study** by Hviid et al. should be retracted.

Please see Comments section at: https://annals.org/aim/fullarticle/2727726/measles-mumps-rubella-vaccination-autism-nationwide-cohort-study#article-top

or

https://www.researchgate.net/publication/331586715_Comment_on_Measles_Mumps_Rubella_Vaccination_and_Autism_A_Nationwide_Cohort_Study

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Vaccines and Biologics injury table based on mechanistic evidence – Mar 2019

PDF with hyperlinks: https://zenodo.org/record/2582635/files/viittoc0302http.pdf?download=1

https://doi.org/10.5281/zenodo.2582634

Rebutting Drs. DeStefano and Offit's claims of vaccine safety in: Principal Controversies in Vaccine Safety in the United States

PDF: https://doi.org/10.5281/zenodo.2567372

PDF:https://doi.org/10.5281/zenodo.2582599

Rebutting vaccine safety claims made by Dr. Hotez in Nature Pediatric Research

Vinu Arumugham

Mar 2019

vinucubeacc@gmail.com

This is regarding the article on vaccine preventable diseases by Dr. Hotez (1).

Trust must be earned and cannot be dictated

The medical establishment (ME) admits after billions and decades wasted, it has no answers for the root cause of food allergies, asthma, autism or autoimmune diseases such as type 1 diabetes. Anyone who does not know the root cause of food allergies (2,3), autism (4,5), asthma (6,7) and type 1 diabetes (8–10), is unqualified to make claims about vaccine safety. Since the ME admits they don't know the root cause of all these diseases, they are definitely unqualified to make claims about vaccine safety.

Drs. Pulendran and Ahmed of the Emory Vaccine Center admit that vaccines are based on empirical trial and error approaches with no understanding of the immunological mechanisms (11). Mojsilovic admits that we have no understanding about how vaccine adjuvants work (12).

Professors of medicine, medical journal editors and cardiologists point out that most medical research findings are false, of poor quality and are affected by flagrant conflicts of interest. (13–20)

The US Institute of Medicine committee in their 2011 report (21) on Adverse Effects of Vaccines: Evidence and Causality

wrote:

"The committee concluded the evidence convincingly supports 14 spe-cific vaccine–adverse event relationships. In all but one of these relation-ships, the conclusion was based on strong mechanistic evidence with the epidemiologic evidence rated as either limited confidence or insufficient."

So in an overwhelming 93% (13 of 14) cases, mechanistic studies provided convincing evidence and epidemiological studies failed to do so. At best, epidemiological studies are weak, have numerous sources of confounding and offer little value. At worst, they mislead, sicken millions and setback science by decades (22,23). Epidemiological study results are misinterpreted leading to type II errors (24). The vast majority of vaccine safety claims however, are based on such broken epidemiological studies.

Do you want to show that the rotavirus vaccine **protects** against type 1 diabetes? There's an epidemiological study for that (25).

Do you want to show that the rotavirus vaccine **increases risk** of type 1 diabetes? There's an epidemiological study for that too (26).

There is no science here. This is fraud. You torture an epidemiological study enough, it will confess to **anything**. That is why they are so popular. Vaccine regulators and pharmaceutical companies can get whatever conclusions they like. Unlike other sciences, doctors don't need to **understand** the **mechanism** behind **anything**. It is all about **associations**. This is junk science. No one in their right mind would trust such ridiculous material. Medical science is becoming an oxymoron.

The abject failure of the medical establishment in ensuring product safety, is responsible for the rise of measles. 200 years after Jenner, parents are still being forced to choose between vaccine preventable diseases and vaccine induced diseases.

You can fool all the people some of the time and some of the people all the time, but you cannot fool all the people all the time. - Abraham Lincoln.

The vaccine safety movement

Hotez claims "antivaccine" groups are "well-organized" and "well-funded".

The vaccine safety movement, mostly consisting of vaccine injury victims, is as "well-organized" and "well-funded" as the child that exclaimed, the emperor has no clothes.

Humans have co-evolved with measles, chicken pox etc. as with our gut microbiome. Natural chicken pox infection prevents glioma (27) and protects adults against shingles (28). The ME has absolutely failed to understand this larger picture. We certainly don't want kids to die of measles complications but it makes no sense to deprive them of the advantages of infections that we have evolved to depend on for health either. The jab and "eradicate" approach is an oversimplification that has not only failed to eradicate but that also fuels the epidemic of chronic diseases. The focus must be on avoiding measles complications while simultaneously getting the full advantage of a natural infection. The MMR vaccine is an utter failure in that regard.

The insanity of injecting live viruses

We teach kids that a wound must be kept clean to avoid infections. The Flumist vaccine administers live attenuated virus via the same route as a natural influenza infection. In contrast, the route of administration of the MMR vaccine does not match the route of natural infection. The MMR vaccine creates a wound (injection) and infects it with live virus. While an infection is desired to develop immunity, the choice of the route is insane. It injures nerves, destroys natural nerve protection and provides the virus with direct access to the nerves. The result is encephalitis (29), an injury listed on the vaccine injury table of the National Vaccine Injury Compensation

Program (VICP). For every case of encephalitis that is dismissed as rare, how many thousands suffer subclinical nerve/brain damage due to this insanity? Why after 50 years since the introduction of the measles vaccine, are we still injuring our children with this horrible vaccine? Where are the safety improvements as required by law? (30)

Type 1 diabetes

In the ~50 year history of the measles, mumps, rubella (MMR) vaccine, with no safety improvements, I was the first to point out the mechanism by which this GAD65 protein contaminated chick embryo cell culture derived vaccine causes the development of type 1 diabetes (T1D). (8–10,24)

https://www.researchgate.net/publication/318305895_Role_of_MMR_II_vaccine_contamination_with_GAD65_containing_chick_embryo_cell_culture_in_the_etiology_of_type_1_diabetes

My technical report above with more than 20,000 reads is among the most read articles on ResearchGate. It was recommended by 3 diabetes experts and another diabetes expert, Dr. Joseph Cantor of the University of California San Diego added a comment in support.

Influenza

Discussing influenza vaccines, Hotez makes no mention of influenza vaccines causing the development of allergy to the influenza proteins themselves (IgE mediated sensitization) (31–34). This can result in increased severity of influenza disease due to a concurrent allergic reaction to the influenza viral proteins. This is similar to a secondary dengue infection and therefore, similar to dengue shock syndrome (DSS), we have influenza shock syndrome (ISS) (35,36).

"Similarly the overwhelming majority of the children who died in the 2018 US flu epidemic were not vaccinated."

Interestingly, Hotez does not offer a citation for that claim.

In contrast, we find that the vaccinated had a higher probability of severe disease as expected for reasons previously explained (vaccine induced influenza allergy, which results in influenza shock syndrome just like dengue shock syndrome). (36,37) Increasing influenza severity, therefore has an iatrogenic basis. Doctors are making the problem worse, not better (38).

HPV

Hotez writes: "eliminating cervical cancer"

What is the point of eliminating cervical cancer only to replace it with autoimmune diseases that kill just as many? (39)

Autism

"inject fear into parents that vaccines cause autism"

And for good reason because vaccine **do** in fact cause autism. (4) Public discussion is always on the MMR/autism controversy. But we show with strong **mechanistic** evidence that cow's milk protein containing vaccines (DTaP, Prevnar 13, ActHib, not MMR) cause the vast majority of autism cases (4).

"vast cover-up by the CDC and other federal agencies."

The US Department of Health and Human Services (HHS) is required by law to continuously improve vaccine safety and provide a report of such improvements to Congress, every two years. The HHS admitted providing no such report and thus repeatedly breaking the law for 30 years. (30)

Just a few days ago, Dr. Fauci of the National Institutes of Health was caught lying at a Congressional hearing on vaccines. Dr. Fauci claimed that vaccines do not cause encephalitis. The lay audience protested. Dr. Fauci backtracked and changed his response to "rare". So yes, it is most certainly a cover-up. There can be no doubt.

"We have identified at least 99 genes associated with autism"

The vast majority of ASD cases (75%) test positive for folate receptor alpha antibodies (FRAA). These FRAA bind with higher affinity to the bovine folate receptor than human folate receptor. There is no way genes can cause that type of adaptive immune response. Dr. Hotez ignores such inconvenient facts to still mislead the world about the role of genes in ASD. Hughes et al. write that only 10-20% of ASD can be explained by genetic causes (40). Cow's milk protein containing vaccines induce FRAA mediated autism (4).

"the changes in the brains of kids with autism actually begin prenatally, meaning well before a child ever becomes immunized"

It is a misconception that only the child's immunization matters. Mothers are vaccinated with cow's milk containing vaccines as well. So of course they make FRAA too. Majority of FRAA are of the IgG4 subclass that crosses the placenta (41) and damages the fetal brain. So it is of course possible to have prenatal vaccine induced autism.

Doctors are taught that when they hear hoofbeats, they should think horses, not zebras. But Hotez and his genetic autism researcher friends are not even chasing zebras, they are chasing unicorns. That is why after billions and decades wasted, they have nothing to show for it, while tragically, even more children are sickened with dirty vaccines. The vast majority of autism is simply a special case of milk allergy induced by injecting milk protein containing vaccines. This basic immunological concept is a hundred year old Nobel winning discovery (42). Incompetent doctors are ignoring such a basic concept and are continuing to not only sicken our children but attempting to hide the damage they have inflicted. This is the biggest scandal in the history of medicine. Vaccine victims will fight to expose it.

Conclusion

Institutions such as the FDA/CDC/NIH/HHS/AAP are not trusted by a growing number of people. With vaccines sickening more and more people, this will only increase the number of people who don't trust these institutions.

The only way to control these vaccine preventable diseases is to immediately clean up the vaccines and approach these diseases with a view of the big picture.

The spectacular failure of the Dengvaxia vaccine demonstrates that irrational vaccine development with no clue of the immunological mechanisms will backfire with devastating effect. (37)

Vaccines are too important to be left to a bunch of tinkerers. They need to be **engineered** for safety.

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From: Connelly, Erin (CDC/DDID/NCIRD/OD)
Sent: Fri, 31 May 2019 21:22:15 +0000
To: Hall, Bill (HHS/ASPA); Daniel, Katherine Lyon (CDC/OD/OADC); Bonds, Michelle E. (CDC/OD/OADC); Broido, Tara (HHS/OASH)
Subject: Re: How the anti-vaccine movement crept into the GOP mainstream

Thx

Erin Connelly, MPAff
Centers for Disease Control and Prevention

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Date: May 31, 2019 at 4:19:12 PM EDT
To: Daniel, Katherine Lyon (CDC/OD/OADC) <kdl8@cdc.gov>, Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>, Connelly, Erin (CDC/DDID/NCIRD/OD) <efd5@cdc.gov>, Broido, Tara (HHS/OASH) <Tara.Broido@hhs.gov>
Subject: FW: How the anti-vaccine movement crept into the GOP mainstream

Not sure if I passed this along when it came out earlier this week.

From: POLITICO Pro <politicoemail@politicopro.com>
Sent: Sunday, May 26, 2019 9:42 AM
To: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>
Subject: How the anti-vaccine movement crept into the GOP mainstream

How the anti-vaccine movement crept into the GOP mainstream

By Arthur Allen

05/26/2019 09:30 AM EDT

The anti-vaccine movement, which swelled with discredited theories that blamed vaccines for autism and other ills, has morphed and grown into a libertarian political rebellion that is drawing in state Republican officials who distrust government medical mandates.

Anti-vaccine sentiments are as old as vaccines themselves — and it's been nearly 300 years since smallpox immunization began in what is now the United States. Liberal enclaves from Boulder, Colo., to Marin County, Calif., have long been pockets of vaccine skepticism. But the current measles epidemic, with more than 880 cases reported across 25 states of a disease declared eradicated in the U.S. 19 years ago, shows it gaining power within the GOP mainstream.

What's new about the current anti-vaccine movement is the argument that government has no right to force parents to vaccinate their kids before they enter school. While Trump

administration health officials and most Republicans in Congress still back mandatory vaccination, opposition is gaining steam among Republicans in state legislatures.

Among some of these officials, that libertarian demand for medical freedom has displaced the traditional GOP view that it's a civic responsibility to immunize your kids to prevent the spread of disease. As more politicians take an anti-mandate stand, some end up adopting bogus theories about the supposed harms of vaccination — threatening to roll back one of public health's great achievements.

In Kentucky, Gov. Matt Bevin said vaccine mandates were un-American. In Oregon, the state party used vaccine mandates to bash Democrats as violating parental rights. And in the California Senate, all 10 Republicans last Wednesday opposed a measure aimed at stopping bogus medical exemptions from vaccination.

President Donald Trump gave measles vaccination a nine-second endorsement on the White House lawn recently. "They gotta get their shots," he told a press scrum on April 27. In a speech at the World Health Assembly last week, HHS Secretary Alex Azar decried misinformation from "conspiracy groups" that "confuse well-meaning parents."

Azar and other top health officials, at the CDC and elsewhere, have advocated consistently for vaccination. But Trump himself has shown a disdain for scientific and government expertise, and for years — including during his campaign — he backed a debunked claim that childhood shots cause autism.

The arguments of the skeptics — that vaccine-preventable diseases like measles are God's will, a natural process, or even a way of strengthening a child's immune system, that the government and a rapacious pharmaceutical industry are joined in an insidious cover-up of the dangers of vaccines — are varied, and cut across political and geographic spectra, from ultra-liberal bastions of California to the religious conservatism of the South.

The GOP tilt is more pronounced among state lawmakers than among federal ones; many prominent Republicans in Congress including most of the 16 GOP doctors have endorsed vaccines. The most visible and voluble exception is Sen. Rand Paul (R-Ky.), an ophthalmologist who says his own kids were vaccinated but the decision should be left to the parents, not the government.

But in states where legislators have advanced serious efforts to tighten restrictions, such as Maine, Washington, Colorado and Oregon, nearly all of the opponents are Republicans who've taken a medical freedom stance.

"The more they dig into it being about freedom, the more susceptible they become to the theories," said Dave Gorski, a Michigan physician who has tracked the anti-vaccine movement for two decades. "Appeals to freedom are like the gateway drug to pseudoscience."

At the extremes are legislators like Jonathan Stickland, a pro-National Rifle Association, Christian conservative in the Texas Assembly, who has described vaccines as "sorcery" while personally attacking Baylor University scientist Peter Hotez, who has a daughter with autism and

works on vaccines for neglected tropical diseases. "Parental rights mean more to us than your self-enriching 'science,'" Stickland tweeted at Hotez earlier this month.

That same day, the Oregon Republican Party's official Twitter account posted that Oregon Democrats were "ramming forced injections down every Oregon parent's throat."

Other Republican state officials have blamed Central American immigrants for disease outbreaks, echoing a talking point of Fox commentator Lou Dobbs. In fact, experts say, children in many of those countries are more thoroughly vaccinated than their U.S. counterparts against diseases like whooping cough and measles.

In Washington state, the House sponsor of a bill to end exemptions from measles vaccination was state Rep. Paul Harris, a moderate Republican whose district was the epicenter of a measles outbreak. But in the state Senate, the entire 20-member GOP delegation — as well as two Democrats — opposed the bill, although they failed to defeat it. In his signing statement, Gov. Jay Inslee, who is seeking the Democratic presidential nomination, said pointedly, "We believe in science. ... And that is why in Washington state, we are against measles."

In Oregon, where, again, most but not all opposition came from Republicans, Democratic Gov. Kate Brown killed an effort to tighten exemptions as part of a compromise with Republican leaders over a tax bill.

Vaccination was not a partisan issue in the past and even today, in states where vaccination hasn't become politicized, GOP governments are sometimes as likely as Democratic ones to tighten vaccine requirements. Wyoming, for instance, is deeply conservative, but its state health department in a little-noticed decision last year created an immunization registry, added two vaccines to a list of school-entry requirements, and required home-schooled children to be vaccinated if they want to participate in sports or theater.

In neighboring Colorado, though, opposition to vaccine requirements became an attractive issue for conservatives, a minority in the state Legislature. Colorado has one of the country's lowest rates of vaccinated kindergartners, but when Democrats tried to pass a modest bill requiring parents to take their vaccination exemption forms to the health department, hundreds came out to testify against it. The witnesses ranged from conservative Christians to parents with children they think were hurt by vaccines, to "natural living" types who don't want vaccines to muck around with the immune system. But with a few exceptions, it was Republicans who helped stall and kill the bill.

"The antivax messaging has shifted from a focus on questions of safety to things like parental rights and data privacy, and those messages resonate more with conservative lawmakers and play to the GOP political base," said Stephanie Wasserman, executive director of the Colorado Children's Immunization Coalition.

People who prefer whooping cough

Not all that long ago, the anti-vax movement was dominated by the granola-eating, pharma-

distrusting left. Conservative opposition was centered among people who also tended to see water fluoridation as a communist plot. In addition to the political fringes, a few religious sects opposed vaccination for doctrinal reasons — some small churches see them as arrogant interference with God's plans; adherents of Rudolf Steiner, who propounded what he called anthroposophic medicine, think high fevers are key to a child's spiritual growth.

The anti-vaccine club includes people like the former dentist Len Horowitz, who suggested that Ebola and HIV were created in CIA-funded laboratories, and the late Harris Coulter of Washington, D.C., whose books linked the pertussis vaccine to everything from blindness to serial murder and attraction to loud rock music.

A good share of the opposition arises in parents who claim to have seen harm from vaccines in their kids. Autism is often diagnosed around the time of the first measles shot, and while research has thoroughly refuted a causal link, it's hard to shake the convictions — or convincing power — of a parent with a disabled child.

And like any pharmaceutical product, vaccines can, rarely, cause serious adverse events. Scientists at the CDC, FDA and elsewhere get paid to research side effects. Over the years, they have investigated evidence of harm from pertussis and measles shots, and traces of mercury and aluminum in vaccines. They've examined theoretical links to autism, allergies and sudden infant death syndrome — all negative. But the anti-vaccine movement waxes and wanes on political currents that have little to do with the evidence. Since Trump began his ascent in 2015, the movement has been growing.

Paranoia, mysticism and cultural pessimism still contribute to anti-vaccine thinking, but freedom from persecution is increasingly the banner raised in social media and public appearances. At a 13-hour committee vaccine bill hearing in the Colorado House last month, there were a lot of parents like Thomas Olmstead, who called the bill "a step toward the complete erosion of our medical freedom."

Mistrust of government also seems to have underlain the epidemic that struck parts of New York's ultra-Orthodox Jewish community, a crisis that took scientists by surprise. "I can't recall in my time at CDC or since where the Orthodox community was involved in anti-vaccine beliefs," said Walter Orenstein, who led immunization efforts at CDC from 1988 to 2004 — and happens to come from a family of rabbis.

Vaccine resistance has swept into conservative areas of Texas, where parental refusal rates doubled over just a few years. Unsurprisingly, perhaps, rates of refusal increased somewhat in liberal Austin, but the biggest upticks occurred in places like suburban Dallas and Trump-loving West Texas. In Gaines County, midway between Odessa and Lubbock, the percentage of vaccine refuseniks went from 3 percent to 9 percent from 2012 to 2018.

The late feminism opponent Phyllis Schlafly opposed vaccine mandates for years, but she was considered a right-wing gadfly for much of her career. The party has moved toward her. Her son Andrew Schlafly became lead counsel for the Association of American Physicians and Surgeons, a group that's skeptical of vaccination and for a time counted former Trump HHS Secretary Tom Price as a member.

Kentucky's Bevin, a conservative, said in March that he had taken his nine kids to a "chickenpox party" to catch the disease. In the pre-vaccine days, doctors recommended this practice because highly contagious chickenpox has fewer complications in the young, so it was actually safer to get it in childhood than later in life. But the chickenpox vaccine, licensed in 1995, changed that. Science had moved on, but not Bevin. "This is America, and the federal government should not be forcing that on people," he said.

"There's a populist shift, this 'The government is telling me I have to do this,' and then they buy into the conspiracy theories to find motives," said Angie Anderson, a registered Republican with two small children who testified at one of the Colorado hearings — in favor of the bill tightening vaccine requirements. "It plants seeds of doubt and it's gaining traction, and it scares me."

The current measles outbreak can in part be traced back to a 1998 Lancet article by the British gastroenterologist Andrew Wakefield, which linked measles vaccination to autism, setting off a wave of fear. The paper, since disproved and retracted, has become a classic of sorts — frequently employed in college statistics courses to demonstrate bad scientific practice.

Notwithstanding the ridicule, and the fact that Britain stripped him of his medical license in 2010, Wakefield met with Trump during the 2016 campaign, and he's been interviewed by Tucker Carlson. Robert F. Kennedy Jr., who clings to the long-disproven theory that trace mounts of mercury in certain vaccines caused an autism epidemic, says Trump aides after the election promised to appoint him to a committee to investigate HHS' vaccine programs.

Del Bigtree, a former TV journalist, teamed with Kennedy and Wakefield to make a tendentious anti-vaccine film. The three men often speak at rallies in state capitols where bills are under consideration, usually in the company of a few Republican state legislators.

The growing clout of the anti-vaccine movement is visible even at the CDC, where hundreds of vaccine opponents show up to speak during public comment periods at thrice-annual meetings of the Advisory Committee on Immunization Practices, the CDC's key immunization overseer.

"I don't tune them out, but the concerns they have — safety, appropriateness of vaccine trials — don't raise a red flag with me," said committee Chairman José Romero, a University of Arkansas pediatrician. "I wish the public would understand that the safety of these vaccines is looked at many times along the way to their children."

To view online:
https://protect2.fireeye.com/url?k=f9bd824d-a5e88b9d-f9bdb372-0cc47a6a52de-99a8d15e9a14cdc6&u=https://subscriber.politicopro.com/education/article/2019/05/how-the-anti-vaccine-movement-crept-into-the-gop-mainstream-1472439

POLITICOPRO

From: Fontenot, Monique (OS/ASPA)
Sent: Mon, 20 Aug 2018 17:11:57 +0000
To: Bonds, Michelle E. (CDC/OD/OADC)
Subject: RE: Kennedy/Bigtree lawsuit settlement

Hi Michelle,

Ok, if not, it may be ASPR. Just let me know and I will forward to them.

Thanks in advance.

Monique S. Fontenot
Office of the Assistant Secretary for Public Affairs
Department of Health and Human Services
(202) 260-7141
monique.fontenot@hhs.gov

From: Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Sent: Monday, August 20, 2018 1:09 PM
To: OS Media (HHS/ASPA) <media@hhs.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>
Cc: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: Re: Kennedy/Bigtree lawsuit settlement

Will check but I don't think it would be CDC.

From: OS Media (HHS/ASPA) <media@hhs.gov>
Date: August 20, 2018 at 11:59:37 AM EDT
To: Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>, Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>, Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Cc: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: FW: Kennedy/Bigtree lawsuit settlement

Hello CDC team,

Would this inquiry be directed to you for response?

From: David Taub <dtaub@gvwire.com>
Sent: Monday, August 20, 2018 11:55 AM
To: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: Kennedy/Bigtree lawsuit settlement

Did HHS ever release a statement regarding the settlement of a lawsuit filed by Del Bigtree and Robert Kennedy Jr. over HHS not adhering to the 1986 vaccine safety report law?

If not, can you please provide details of the suit and a statement?

Thank you,

David Taub
Senior Reporter
GV Wire | GVWire.com
Fresno, CA
Twitter: @TaubGVWire
P: 559-492-4037

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From: Bonds, Michelle E. (CDC/OD/OADC)
Sent: Mon, 20 Aug 2018 17:32:10 +0000
To: Burden, Bernadette (CDC/OD/OADC)
Subject: RE: Kennedy/Bigtree lawsuit settlement

Check with OGC first

From: Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>
Date: August 20, 2018 at 1:31:32 PM EDT
To: Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: RE: Kennedy/Bigtree lawsuit settlement

Michelle,

I can send along to NCIRD. Or are you handling?

B.

From: Bonds, Michelle E. (CDC/OD/OADC)
Sent: Monday, August 20, 2018 1:09 PM
To: OS Media (HHS/ASPA) <media@hhs.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>
Cc: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: Re: Kennedy/Bigtree lawsuit settlement

Will check but I don't think it would be CDC.

From: OS Media (HHS/ASPA) <media@hhs.gov>
Date: August 20, 2018 at 11:59:37 AM EDT
To: Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>, Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>, Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Cc: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: FW: Kennedy/Bigtree lawsuit settlement

Hello CDC team,

Would this inquiry be directed to you for response?

From: David Taub <dtaub@gvwire.com>
Sent: Monday, August 20, 2018 11:55 AM
To: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: Kennedy/Bigtree lawsuit settlement

Did HHS ever release a statement regarding the settlement of a lawsuit filed by Del Bigtree and Robert Kennedy Jr. over HHS not adhering to the 1986 vaccine safety report law?

If not, can you please provide details of the suit and a statement?

Thank you,

David Taub
Senior Reporter
GV Wire | GVWire.com
Fresno, CA
Twitter: @TaubGVWire
P: 559-492-4037

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From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 24 Jul 2018 12:10:58 +0000
To: Barry, Brooke (CDC/OID/NCIRD)
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Hmmm, thanks.

From: Barry, Brooke (CDC/OID/NCIRD)
Sent: Tuesday, July 24, 2018 8:00 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

FYI - just wanted to share. I haven't had a chance to read through all these emails...lots of people are aware of this.

From: Shanley, Edwin (CDC/OID/NCIRD) <ets5@cdc.gov>
Date: July 24, 2018 at 7:54:28 AM EDT
To: McMillen, Amy (CDC/OID/NCEZID) <auh1@cdc.gov>, Beauvais, Denise (CDC/OID/NCIRD) <cry2@cdc.gov>
Cc: Barry, Brooke (CDC/OID/NCIRD) <bmb8@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Thanks Amy!
Exec Sec sent us some correspondence received by HHS on this topic. I attached my response to Brooke and Denise. As you may recall, in NCIRD's response to this FOIA request (FOIA 18-00585) (May 2018), we argued that the requester was misinterpreting the legislation.
-Eddie

From: McMillen, Amy (CDC/OID/NCEZID)
Sent: Tuesday, July 24, 2018 7:31 AM
To: Beauvais, Denise (CDC/OID/NCIRD) <cry2@cdc.gov>; Shanley, Edwin (CDC/OID/NCIRD) <ets5@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Good Morning – making sure you are in the loop since this came in when I was there.
amy

From: Brouillette, Colleen (CDC/OID/NCEZID) (CTR)
Sent: Monday, July 23, 2018 4:43 PM
To: Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>

Cc: McMillen, Amy (CDC/OID/NCEZID) <auh1@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Jane,

Just wanted to make you aware of a Snopes request around that FOIA we discussed…three months ago maybe… it was the one about Reports to Congress on vaccines. If you scroll to the bottom of this thread, you'll see that Kristen Shatynski got the email. Then it was sent to Laura Kemper and then Lauren Hoffman in IMAC. It might be helpful for us to provide what we ultimately responded with. Let me know what you think.

Colleen

From: Nguyen, Lyn (CDC/OID/NCEZID)
Sent: Monday, July 23, 2018 4:30 PM
To: Brouillette, Colleen (CDC/OID/NCEZID) (CTR) <mfi3@cdc.gov>; McMillen, Amy (CDC/OID/NCEZID) <auh1@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

FYI

Lyn Thi Nguyen, MPH
Acting Associate Director for Policy
Division of Healthcare Quality Promotion/NCEZID
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, MS A-07
Atlanta, GA 30329
(Tel) 404.639.7391
(BB) 404.386.3994
(Fax) 404-718-1900
(E-mail) ivx1@cdc.gov
Telework Mondays and Fridays - please contact by BB and e-mail

---

From: Vaughn, William (CDC/OID/NCEZID) (CTR)
Sent: Monday, July 23, 2018 4:23 PM
To: Destefano, Frank (CDC/OID/NCEZID) <fxd1@cdc.gov>; Shimabukuro, Tom (CDC/OID/NCEZID) <ayv6@cdc.gov>; Nguyen, Lyn (CDC/OID/NCEZID) <ivx1@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

FYSA…this is regarding the RFKjr/Del Bigtree FOIA request we've seen; no action being requested from ISO at this time…

From: Nordlund, Kristen (CDC/OID/NCIRD)
Sent: Monday, July 23, 2018 4:15 PM
To: Kelly, Bertram (CDC/OD/OADC) <msy5@cdc.gov>; Skinner, Thomas W. (CDC/OID/NCEZID) <tws3@cdc.gov>
Cc: Vaughn, William (CDC/OID/NCEZID) (CTR) <hbv2@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Thanks, we're aware of it.

From: Kelly, Bertram (CDC/OD/OADC)
Sent: Monday, July 23, 2018 4:14 PM
To: Nordlund, Kristen (CDC/OID/NCIRD) <hok4@cdc.gov>; Skinner, Thomas W. (CDC/OID/NCEZID) <tws3@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Tom and Kristen,

Kathy wants to make sure you are aware of this conversation. Nothing to do on CDC's part at the moment, but they want you to have awareness.

Thx
Bert

From: Harben, Kathy (CDC/OD/OADC)
Sent: Monday, July 23, 2018 4:10 PM
To: Kelly, Bertram (CDC/OD/OADC) <msy5@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

No discussion. They unfortunately left you off the chain last night—the answer is in attached. Please do give Kristen/Ian and NCEZID a heads up.

From: Kelly, Bertram (CDC/OD/OADC)
Sent: Monday, July 23, 2018 4:07 PM
To: Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Was there a discussion on this topic this morning? Does Immunization Safety need to engage?

Let me know how I can assist.

bk

From: Harben, Kathy (CDC/OD/OADC)
Sent: Saturday, July 21, 2018 8:38 PM
To: Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>; Riedford, Daniel G. (CDC/OCOO/OD) <dgr0@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Kelly, Bertram (CDC/OD/OADC) <msy5@cdc.gov>
Subject: Re: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Thanks Paige, agree we should discuss Monday. Adding Bert for awareness.

From: Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>
Date: July 21, 2018 at 7:40:24 PM EDT
To: Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>, Riedford, Daniel G. (CDC/OCOO/OD) <dgr0@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>, Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>, Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>, Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Subject: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Hi all
We can discuss Monday- will need to check and see if CDC has any FOIA requests on Vaccine Safety (improvements)?

The email at the bottom (Snopes) links to the lawsuit mentioned.
Thanks
Paige

From: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Date: July 21, 2018 at 8:44:39 AM EDT
To: Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>, Caudwell, Kerry M. (CDC/OD/OCS) <cli9@cdc.gov>, CDC OD OCOS IMAC <CDCOD_OCOS_IMAC@cdc.gov>, Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>, Kennedy, Veronica (CDC/OD/OCS) <bvo3@cdc.gov>
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

See below media inquiry (Snopes) that Katerina has asked us to research regarding RTCs on vaccine safety. Although it is media it is also Oversight (House E and C), Julia will search Activator Monday and reach out to her contact in OA. I think [(b)(5)] HHS indicates ASL says that they already checked with CDCW— not sure who they reached out to and no one checked with us, but they might have checked with OA. Interesting how this one was routed— through leg. lanes and don't see ASPA here even though it's media. Also relates to a FOIA request..... maybe we can discuss on Monday morning.

From: "Kemper, Laura (HHS/ASL)" <Laura.Kemper@hhs.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network
Date: 20 July 2018 16:42
To: "Shipley, Samuel (HHS/IOS)" <Samuel.Shipley@HHS.GOV>, "Horska, Katerina (HHS/IOS)" <Katerina.Horska@hhs.gov>, "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>

(b)(5)

Hi Sam, Katerina, and Kat-

[redacted]

Thanks, Laura

From: Shatynski, Kristen [mailto:Kristen.Shatynski@mail.house.gov]
Sent: Friday, July 20, 2018 4:11 PM
To: Kemper, Laura (HHS/ASL)
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

What I hope to be the last request for the day. Do you all have any insights into these alleged reports to the Committee on vaccine safety? Are there any public reports we can give to them?

Sent from my iPhone

Begin forwarded message:

From: "Sherman, Jennifer" <Jennifer.Sherman@mail.house.gov>
Date: July 20, 2018 at 4:03:30 PM EDT
To: "Trent, Josh" <Josh.Trent@mail.house.gov>, "Shatynski, Kristen" <Kristen.Shatynski@mail.house.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network

Hey guys – See below from Snopes. EACC = Energy and Commerce Committee.

From: Alex Kasprak <alex@snopes.com>
Sent: Friday, July 20, 2018 2:38 PM
To: Sherman, Jennifer <Jennifer.Sherman@mail.house.gov>
Subject: Media Inquiry from Snopes.com / Informed Consent Action Network

Hello Jennifer,

The EACC press line gave me your contact info. I am a reporter for Snopes.com looking into claims made by the vaccine-safety group Informed Consent Action Network (ICAN) in a recent court filing. In a press release about a FOIA lawsuit by that group, ICAN asserts that their request for documents demonstrated that "HHS never, not even once, submitted a single biennial report to [the Energy and Commerce Committee] detailing the improvements in vaccine safety." I was wondering if this was a factual characterization of HHS's reporting to the EACC?

Thanks for your help,

Alex

860-539-9007
alex@snopes.com

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Fri, 20 Jul 2018 02:07:17 +0000
To: PAUL HENRY HUNTER
Subject: Re: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

I just received it too....

From: PAUL HENRY HUNTER <phhunter@wisc.edu>
Date: July 19, 2018 at 10:06:24 PM EDT
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Fwd: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS

Dear Amanda,
Just curious if other ACIP members got a similar message to the one below.

Sincerely,
Paul Hunter MD
phhunter@wisc.edu, 414-550-2524, www.linkedin.com/in/paulhuntermd
Director, Ambulatory Acting Internship
Associate Director for Public Health and Community Projects
Wisconsin Academy of Rural Medicine
Associate Professor of Family Medicine and Community Health
University of Wisconsin School of Medicine and Public Health
==========

Begin forwarded message:

From: Amanda Dumenigo <amanda@horsense.net>
Subject: NY Court rules in favor of Del Bigtree and Robert F. Kennedy, Jr. Against US Department of Health & Human Services, HHS
Date: July 19, 2018 at 8:57:04 PM CDT
To: "phhunter@wisc.edu" <phhunter@wisc.edu>

ICAN
Informed Consent Action Network

For additional information and interviews please contact

Amanda Dumenigo, Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400

For Immediate Release:
July 2018
Dear Mr. Hunter,

We wanted to inform you that vaccine safety expert and producer of the controversial film, Vaxxed, Del Bigtree, was awarded court ordered relief in lawsuit by his non-profit, The Informed Consent Action Network, ICAN, against the U.S. Department of Health and Human Services.
On Monday, June 9th, the United States District Court for the Southern District of New York signed a Stipulation granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN), the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr..

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

In 1986, the Pharmaceutical Industry was under the strain of so many lawsuits for injuries caused by vaccines they were struggling to make a profit. They threatened to stop producing vaccines unless the U.S. government protected them from liability for damages caused by their vaccines. The US Government gave in to the pressure and passed the 1986 Vaccine Injury Compensation Act, which gave unprecedented legal immunity to all vaccine makers, eviscerating the free market incentive to remedy the very safety issues that had landed them in court to begin with. Recognizing that this would leave an unavoidable gap in vaccine safety testing, the US Congress charged the Secretary of Health and Human Services with the explicit responsibility of testing vaccines for safety and working to reduce the adverse events caused by all vaccines.

In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

ICAN was therefore forced to file a lawsuit to inspire HHS to either provide copies of its biannual vaccine safety reports to Congress or admit it never filed these reports. As a result of the lawsuit, HHS has signed a court order admitting that it never, not even once,

submitted a single biannual report to Congress detailing the improvements in vaccine safety for 30 years.

Given that HHS is the primary scientific body mandated to protect American citizens from the adverse events caused by vaccines, and given that this lawsuit reveals that they are unable to produce a single report, under court order, to verify *any* work towards safer vaccines, the American people must now be made aware that the vaccines that are mandated upon millions of children, may in fact be dangerous to there health.

For an interview with Emmy award winning producer of The Doctors television show, producer of the award winning documentary Vaxxed, and President of The INFORMED CONSENT ACTION NETWORK which filed the lawsuit contact: Amanda Dumenigo,
Media & Public Relations, ICAN amanda@icandecide.org 305-528-1920 or
Catharine Layton, C.O.O., ICAN cat@icandecide.org 714-360-3400.

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Thu, 22 Feb 2018 15:13:35 +0000
To: Shefer, Abigail (CDC/CGH/GID)
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Thanks.

Frank DeStefano, MD, MPH

From: Shefer, Abigail (CDC/CGH/GID)
Sent: Wednesday, February 21, 2018 2:52 PM
To: Destefano, Frank (CDC/OID/NCEZID) <fxd1@cdc.gov>
Cc: Shimabukuro, Tom (CDC/OID/NCEZID) <ayv6@cdc.gov>
Subject: Fwd: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Whoops. Frank I think I got wrong email for you...

From: Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>
Date: February 21, 2018 at 2:50:00 PM EST
To: Shimabukuro, Tom (CDC/OID/NCEZID) <ayv6@cdc.gov>, DeStefano, Frank (NIP) <CORP/NIP1/fxd1@cdc.gov>
Subject: Fwd: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

FYI. I don't know if this was ever shared with you.

From: Robin Nandy <rnandy@unicef.org>
Date: February 13, 2018 at 11:05:01 AM EST
To: Ana Maria Henao-Restrepo <henaorestrepoa@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>, hombachj@who.int <hombachj@who.int>, Zuber, Patrick (CDC who.int) <zuberp@who.int>, Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>, Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>, Diana Chang Blanc <changblancd@who.int>, Martin Howell FRIEDE <friedem@who.int>, Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>, Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>, Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>, Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>, Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>, Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>, Vertefeuille,

John F. (CDC/CGH/GID) <dki4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Colleagues

Please find attached letter that went out today. There were substantial delays from our side and multiple reviewers. But happy to let you know that no further changes were made compared to the version we settled on. The only change is that it went out from our Chief of Health rather than our Deputy Executive Director. Given that the content of the letter is technical, there was a feeling among management that it was best for it to go out from the Head of our Health Section.

I will keep you informed if we get a response from Mr Bigtree. I do not think that this is the end of the story. More episodes to come, I'm sure.

Thanks again to you all for your collaboration.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
(b)(6)
3 United Nations Plaza
New York, NY 10017
USA
Tel:
Mob:
Email:

From: Ana Maria Henao-Restrepo [mailto:henaorestrepoa@icloud.com]
Sent: Friday, January 26, 2018 3:16 PM
To: Robin Nandy <rnandy@unicef.org>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Thanks to you for this very inclusive and collaborative effort!

Warm regards

Ana María

Sent from my iPhone

On 26 Jan 2018, at 20:56, Robin Nandy <rnandy@unicef.org> wrote:

Thanks Ana Maria and Will

Hope this is okay, Will?

Please find attached final draft which I am sending 'up'.

I will circulate the final signed version when it does go out.

I would like to reiterate how much I appreciate WHO and CDC guidance and inputs on this.

Good weekend all.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [mailto:henaorestrepoa@icloud.com]
Sent: Friday, January 26, 2018 1:01 PM
To: Robin Nandy <rnandy@unicef.org>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID)

<slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Yes we believe this statement is important as it accurately reflect the conclusions from the SAGE and the evidence findings ....

Our preference is therefore for it to remain...

Kind regards
Ana María

Sent from my iPhone

On 26 Jan 2018, at 16:50, Robin Nandy <rnandy@unicef.org> wrote:

Dear **Will and Steve (Cochi)**

Many thanks for your prompt responses. On your two comments, the second one is straightforward and I will incorporate in the next iteration.

On your first comment on the sentence reading "***Regarding the possible non-specific effect of DTP on all-cause mortality, the available data neither exclude nor confirm the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality***."

I think Ana Maria was keen to include this as it is the language used in the SAGE review and the need to have language in the letter consistent with it. However, I will look forward to additional comments, particularly from WHO colleagues.

Ana Maria, Martin

Your thoughts and guidance please.

Again, thanks to all for their patience on the multiple back and forth on this. I feel we are nearly there ☺

Regards

Robin

Dr. Robin Nandy

Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Schluter, W. William (CDC/CGH/GID) [mailto:wbs8@cdc.gov]
Sent: Friday, January 26, 2018 8:42 AM
To: Robin Nandy <rnandy@unicef.org>; Ana Maria Henao-Restrepo <henaorestrepoa@icloud.com>
Cc: hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin:
Sorry, if I am raising issues you've already considered. Two minor edits noted in the attached. Overall, the message is clear and powerful.
Kind regards,
Will

From: Robin Nandy [mailto:rnandy@unicef.org]
Sent: Friday, January 26, 2018 5:49 AM
To: Ana Maria Henao-Restrepo <henaorestrepoa@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dki4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE
Importance: High

Dear Ana Maria, Steve and Will

Many thanks for your inputs. Please be assured that your inputs are very much appreciated and the letter is based on the inputs provided previously. The aim of additional edits was to reduce

length, ensure flow and keep it focused and to the point while retaining language consistent with SAGE recommendations. Your current round of inputs really helps to get us there.

Please find herewith, the next iteration based on your comments. I would appreciate your review and endorsement of this version following which I will submit it to our Executive Office. As mentioned earlier, I would like both WHO and CDC to be comfortable with the content of this letter.

I truly appreciate your support in this process.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [mailto:henaorestrepoa@icloud.com]
Sent: Wednesday, January 24, 2018 7:49 AM
To: Robin Nandy <rnandy@unicef.org>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; slc1@cdc.gov; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Laura Conklin (CDC/OID/NCIRD) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Thanks for sharing this revised version.
We fully understand the need for internal clearance and buy in at UNICEF.

However, please allow us to provide some additional comments.

As stated by you there are 'sensitivities' and we believe our strength comes form the independent evidence based process that we all have followed and adhere to.

Therefore, the attached comments are suggestions to use same or similar language to that of SAGE and to also ensure any detail technical comments is aligned with what the conclusions of the review are.

(I have spend over 4 years on this topic and come to realise how critical this is.)

As stated in the document we are not proposing that all the text is included but that key proposed terms (in bold) are maintain throughout.

We trust you received these comments in the constructive spirit that inspired them.

Kind regards,

Ana Maria

On 24 Jan 2018, at 13:01, Robin Nandy <rnandy@unicef.org> wrote:

Dear Colleagues

As you can imagine, given the sensitivities with this letter, it has gone through extensive review inhouse. Attached herewith is the latest iteration.

We have tried to ensure that the main messages are retained and the letter is factually accurate based on extensive inputs provided by yourselves.

Could you take a quick read to see if you are comfortable with this version and if you would like to see any changes. We are all implicated in this and I want to ensure that you are all comfortable with the content.

We would like to have closure on this asap - it has already dragged on far too long, largely due to the process on our end.

I look forward to hearing from you.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza

New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [mailto:henaorestrepoa@icloud.com]
Sent: Monday, January 8, 2018 6:43 PM
To: Robin Nandy <rnandy@unicef.org>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; slc1@cdc.gov; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Laura Conklin (CDC/OID/NCIRD) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Please find attached a proposed revised version of the letter for your consideration.
In brief, I have added statements re benefits of DTP and revised the TORs and roles of the various WHO committees.
Moreover, the text regarding the recommendations was adjusted to be more aligned -in my view- the original recommendations.

I hope this is helpful.

Other colleagues will certainly add additional comments or modifications.

Kind regards,

Ana Maria

(PS Happy 2018 to all..!)

On 29 Dec 2017, at 19:54, Robin Nandy <rnandy@unicef.org> wrote:

Thanks Will. I will look forward to further inputs from colleagues. At our end, we are thinking that the counterfactual argument may also be worth making - the potential impact on not using the DTP vaccine.

I guess many colleagues are on leave and it is also after hours in Geneva - so we will have to pick it up in the new year.

Here's wishing all colleagues a very happy, successful and prosperous new year.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: (b)(6)
Mob (b)(6)
Email: rnandy@unicef.org

From: Schluter, W. William (CDC/CGH/GID) [mailto:wbs8@cdc.gov]
Sent: Friday, December 29, 2017 9:34 AM
To: Robin Nandy <rnandy@unicef.org>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>
Cc: Diana Chang Blanc <changblancd@who.int>; FRIEDE, Martin Howell <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dki4@cdc.gov>
Subject: RE: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin:
I agree with your assessment that the letter may need to be strengthened in the third paragraph. I'll leave it to others to suggest specific language.
Kind regards,
Will

From: Robin Nandy [mailto:rnandy@unicef.org]
Sent: Thursday, December 28, 2017 4:15 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>
Cc: Diana Chang Blanc <changblancd@who.int>; FRIEDE, Martin Howell <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dki4@cdc.gov>
Subject: RE: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths

caused by DTP URGENT PLEASE
Importance: High

Dear Ana Maria, Joachim, Patrick, Steve, Kim and Will

I know that many of you may be on leave this week. However, I wanted to update you on where the letter in response to the ICON letter on child deaths due to DTP is at.

Attached is the most current version in the final stages of clearance in our Executive Office. I also attach the version that was developed with your inputs, which I am indeed grateful for.

Reading this attached version, we are feeling that the response may not be strong enough. Can we provide further details on why we cannot prove or disprove this claim despite the fact that this issues has been followed since 2001, the lack of RCT on the NSE of DTP and also what the status of ongoing research on the subject is? Can we strengthen the response so that we do not leave ourselves open to additional questions and criticisms. Also, our response is likely to be posted on the ICON website.

Any further inputs and thoughts you may have will be much appreciated. We would like to finalize and send out the response asap as country missions, notably the Nigeria mission have inquired how UNICEF is going to respond to this message.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: (b)(6)
Mob:
Email

<ED Response DTP Dec 2017 DRAFT4.docx>

<ED Response DTP Dec 2017 FINAL DRAFT.docx>

From: Cohn, Amanda (CDC/OID/NCIRD)
Sent: Tue, 24 Jul 2018 12:19:58 +0000
To: Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: anticipated regret

Wow. On another note, have you seen the ICAN lawsuit emails in your NVPO hat?

Amanda

From: Wharton, Melinda (CDC/OID/NCIRD)
Sent: Tuesday, July 24, 2018 8:16 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>; Connelly, Erin (CDC/OID/NCIRD) <efd5@cdc.gov>
Subject: anticipated regret

I saw this on Facebook this morning. Apparently it is from (originally) the Northern Rivers Vaccination Association - http://www.nrvs.info/

From: Messonnier, Nancy (CDC/OID/NCIRD)
Sent: Fri, 31 Aug 2018 18:34:38 +0000
To: Cozart, Barbara (CDC/OID/NCIRD)
Subject: RE: APPROVAL NEEDED - Amanda Cohn International Travel Oct 4-5

ok

From: Cozart, Barbara (CDC/OID/NCIRD)
Sent: Friday, August 31, 2018 2:14 PM
To: Messonnier, Nancy (CDC/OID/NCIRD) <nar5@cdc.gov>
Subject: APPROVAL NEEDED - Amanda Cohn International Travel Oct 4-5
Importance: High

It's not on the travel calendar so new to me. Do you approve? Amanda said she'll be putting it into the system today so need quick turnaround please.

Amanda Cohn TDY London 'NITAG Stakeholder Meeting', Oct 4-5, 2018

From: Henry, Corey P. (CDC/OID/NCIRD) (CTR)
Sent: Friday, August 31, 2018 1:56 PM
To: Cozart, Barbara (CDC/OID/NCIRD) <wjn4@cdc.gov>
Cc: Wright, Victoria (CDC/OID/NCIRD) <vdc4@cdc.gov>
Subject: FW: Invitation: NITAG Stakeholder Meeting, 4-5 October 2018

Hey Barbara,

Forwarding this to you. Can you see if Dr. Messonnier approves? Xan already is aware of it.

Regards,

Corey P. Henry
PROGRAM ANALYST/FATA
CHEROKEE NATION ASSURANCE
NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)
CDC/NCIRD/OD/OAS/NCT Events TRAVEL-DOMESTIC | Centers for Disease Control and Prevention
1600 Clifton Rd NE, Bldg. 24, Room 8117.2, Mailstop A-27, Atlanta, GA 30333
Office: 404.718.8893 | Email: CPHenry@cdc.gov
NCT Events Team Lead: Detrice Dumas, iiu3@cdc.gov

From: Wright, Victoria (CDC/OID/NCIRD)
Sent: Friday, August 31, 2018 11:49 AM
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Cc: Thomas, Stephanie B. (CDC/OID/NCIRD) <hkp4@cdc.gov>; Henry, Corey P. (CDC/OID/NCIRD) (CTR) <xcb9@cdc.gov>
Subject: RE: Invitation: NITAG Stakeholder Meeting, 4-5 October 2018

From: Nordlund, Kristen (CDC/OID/NCIRD)
Sent: Fri, 24 Aug 2018 12:38:51 -0400
To: Messonnier, Nancy (CDC/OID/NCIRD); Connelly, Erin (CDC/OID/NCIRD)
Cc: Wharton, Melinda (CDC/OID/NCIRD)
Subject: Re: can you track this

I'll call and see what I can get.

From: Messonnier, Nancy (CDC/OID/NCIRD) <nar5@cdc.gov>
Date: August 24, 2018 at 12:34:03 PM EDT
To: Nordlund, Kristen (CDC/OID/NCIRD) <hok4@cdc.gov>, Connelly, Erin (CDC/OID/NCIRD) <efd5@cdc.gov>
Cc: Wharton, Melinda (CDC/OID/NCIRD) <mew2@cdc.gov>
Subject: can you track this

(b)(5)

Thanks.

From: OS Media (HHS/ASPA) <media@hhs.gov>
Date: August 20, 2018 at 11:59:37 AM EDT
To: Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>, Burden, Bernadette (CDC/OD/OADC) <btb8@cdc.gov>, Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>
Cc: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: FW: Kennedy/Bigtree lawsuit settlement
Hello CDC team,
Would this inquiry be directed to you for response?
From: David Taub <dtaub@gvwire.com>
Sent: Monday, August 20, 2018 11:55 AM
To: OS Media (HHS/ASPA) <media@hhs.gov>
Subject: Kennedy/Bigtree lawsuit settlement

(b)(5)

Thank you,
David Taub
Senior Reporter

GV Wire | GVWire.com
Fresno, CA
Twitter: @TaubGVWire
P: 559-492-4037
Sign up for GV Wire's morning newsletter

Follow us on Facebook and Twitter

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Tue, 12 Mar 2019 18:15:25 +0000
To: Sharon Frey; Romero, Jose
Subject: RE: CDF

Thank you! It sounds like all members are receiving the same package..

From: Sharon Frey <sharon.frey@health.slu.edu>
Sent: Tuesday, March 12, 2019 2:06 PM
To: Romero, Jose <RomeroJose@uams.edu>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Sharon Frey <sharon.frey@health.slu.edu>
Subject: Re: CDF

Hi,

Just letting you know I received another thick FedEx packet related to safety today, this time from ICAN(informed consent action network) and signed by Del Bigtree.

Regards,

Sharon

Sharon E. Frey, M.D.
Ralph Kinsella Endowed Chair in Internal Medicine
Professor and Associate Director of Clinical Research
Clinical Director, Center for Vaccine Development
Division of Infectious Diseases, Allergy and Immunology
Saint Louis University Medical School
1100 S. Grand Blvd (DRC- Rm 827)
St. Louis, MO 63104
ph: 314-977-5500
fax: 314-771-3816

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Wed, 1 Aug 2018 14:08:45 -0400
To: Riedford, Daniel G. (CDC/OCOO/OD); Flynn, Paige (CDC/OD/OCS); Bonds, Michelle E. (CDC/OD/OADC); Viana, Bruno A. (CDC/OCOO/OD)
Cc: Holloway, Rachel (CDC/OCOO/OD); Harben, Kathy (CDC/OD/OADC); Heldman, Amy B. (CDC/OD/OADC)
Subject: RE: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

It was part of another chain. ☺

From: Riedford, Daniel G. (CDC/OCOO/OD)
Sent: Wednesday, August 01, 2018 2:08 PM
To: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>
Subject: RE: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Wednesday, August 1, 2018 1:57 PM
To: Riedford, Daniel G. (CDC/OCOO/OD) <dgr0@cdc.gov>; Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>
Subject: RE: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

(b)(5) Lauren

From: Riedford, Daniel G. (CDC/OCOO/OD)
Sent: Wednesday, August 01, 2018 1:54 PM
To: Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>

Subject: RE: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety
Importance: High

(b)(5)

(b)(5)

A copy is attached.

From: Flynn, Paige (CDC/OD/OCS)
Sent: Wednesday, July 25, 2018 8:59 AM
To: Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>; Riedford, Daniel G. (CDC/OCOO/OD) <dgr0@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Subject: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

FYI

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Wednesday, July 25, 2018 8:57 AM
To: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

Lauren

From: Katsoyannis, Miranda (CDC/OD/CDCWO)
Sent: Monday, July 23, 2018 5:14 PM
To: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

(b)(5)

[redacted]

Randy Katsoyannis
202-245-0618

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Monday, July 23, 2018 5:06 PM
To: Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

[redacted]

From: Bigham, Jane E. (CDC/OD/CDCWO)
Sent: Monday, July 23, 2018 5:03 PM
To: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>

Cc: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Hi Lauren,

EZID forwarded the chain below. We received this from Laura Kemper as well and were pinged regarding the FOIA request a few months back. Just wanted to touch base with you and make sure we were all on the same page.

Randy is the lead on vaccine safety issues in our office. We recall not having anything for this FOIA request - and don't recall an RTC.

Thanks!
Jane

From: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Date: July 21, 2018 at 8:44:39 AM EDT
To: Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>, Caudwell, Kerry M. (CDC/OD/OCS) <cli9@cdc.gov>, CDC OD OCOS IMAC <CDCOD_OCOS_IMAC@cdc.gov>, Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>, Kennedy, Veronica (CDC/OD/OCS) <bvo3@cdc.gov>
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

See below media inquiry (Snopes) that Katerina has asked us to research regarding RTCs on vaccine safety. Although it is media it is also Oversight (House E and C), Julia will search Activator Monday and reach out to her contact in OA. I think (b)(5) HHS indicates ASL says that they already checked with CDCW- not sure who they reached out to and no one checked with us, but they might have checked with OA. Interesting how this one was routed-through leg. lanes and don't see ASPA here even though it's media. Also relates to a FOIA request..... maybe we can discuss on Monday morning.

From: "Kemper, Laura (HHS/ASL)" <Laura.Kemper@hhs.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network
Date: 20 July 2018 16:42
To: "Shipley, Samuel (HHS/IOS)" <Samuel.Shipley@HHS.GOV>, "Horska, Katerina (HHS/IOS)" <Katerina.Horska@hhs.gov>, "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
Hi Sam, Katerina, and Kat-

Wasn't sure who to check with on this. See email below. Could ExecSec check on whether we've sent any RTC over the years dealing with vaccine safety?

Thanks, Laura

From: Shatynski, Kristen [mailto:Kristen.Shatynski@mail.house.gov]
Sent: Friday, July 20, 2018 4:11 PM
To: Kemper, Laura (HHS/ASL)
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

What I hope to be the last request for the day. Do you all have any insights into these alleged reports to the Committee on vaccine safety? Are there any public reports we can give to them?

Sent from my iPhone

Begin forwarded message:

From: "Sherman, Jennifer" <Jennifer.Sherman@mail.house.gov>
Date: July 20, 2018 at 4:03:30 PM EDT
To: "Trent, Josh" <Josh.Trent@mail.house.gov>, "Shatynski, Kristen" <Kristen.Shatynski@mail.house.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network

Hey guys - See below from Snopes. EACC = Energy and Commerce Committee.

From: Alex Kasprak <alex@snopes.com>
Sent: Friday, July 20, 2018 2:38 PM
To: Sherman, Jennifer <Jennifer.Sherman@mail.house.gov>
Subject: Media Inquiry from Snopes.com / Informed Consent Action Network

Hello Jennifer,

The EACC press line gave me your contact info. I am a reporter for Snopes.com looking into claims made by the vaccine-safety group Informed Consent Action Network (ICAN) in a recent court filing. In a press release about a FOIA lawsuit by that group, ICAN asserts that their request for documents demonstrated that "HHS never, not even once, submitted a single biennial report to [the Energy and Commerce Committee] detailing the improvements in vaccine safety." I was wondering if this was a factual characterization of HHS's reporting to the EACC?

Thanks for your help,

Alex

860-539-9007
alex@snopes.com

From: Bonds, Michelle E. (CDC/OD/OADC)
Sent: Wed, 25 Jul 2018 13:51:25 +0000
To: Flynn, Paige (CDC/OD/OCS); Viana, Bruno A. (CDC/OCOO/OD); Riedford, Daniel G. (CDC/OCOO/OD)
Cc: Holloway, Rachel (CDC/OCOO/OD); Harben, Kathy (CDC/OD/OADC); Heldman, Amy B. (CDC/OD/OADC); Hoffmann, Lauren (CDC/OD/OCS)
Subject: RE: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Good to know. thx

From: Flynn, Paige (CDC/OD/OCS)
Sent: Wednesday, July 25, 2018 8:59 AM
To: Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Viana, Bruno A. (CDC/OCOO/OD) <cqy8@cdc.gov>; Riedford, Daniel G. (CDC/OCOO/OD) <dgr0@cdc.gov>
Cc: Holloway, Rachel (CDC/OCOO/OD) <khx1@cdc.gov>; Harben, Kathy (CDC/OD/OADC) <kxh9@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Subject: Closing loop: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

FYI

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Wednesday, July 25, 2018 8:57 AM
To: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Just closing the loop with you. As anticipated, the search turned up no RTCs on this topic. We told HHS Exec Sec that yesterday and they let ASL know.

Lauren

From: Katsoyannis, Miranda (CDC/OD/CDCWO)
Sent: Monday, July 23, 2018 5:14 PM
To: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

(b)(5)

(b)(5)

Randy Katsoyannis
(b)(6)

From: Hoffmann, Lauren (CDC/OD/OCS)
Sent: Monday, July 23, 2018 5:06 PM
To: Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>
Cc: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: RE: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

We don't expect to find anything, but all we are doing is searching Activator to confirm there is no report. I also told HHS to check with HRSA. We also searched FOIAs and have a similar request, but not this one.

From: Bigham, Jane E. (CDC/OD/CDCWO)
Sent: Monday, July 23, 2018 5:03 PM
To: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Cc: Katsoyannis, Miranda (CDC/OD/CDCWO) <mtk7@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network - Vaccine safety

Hi Lauren,

EZID forwarded the chain below. We received this from Laura Kemper as well and were pinged regarding the FOIA request a few months back. Just wanted to touch base with you and make sure we were all on the same page.

Randy is the lead on vaccine safety issues in our office. We recall not having anything for this FOIA request - and don't recall an RTC.

Thanks!
Jane

From: Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>
Date: July 21, 2018 at 8:44:39 AM EDT
To: Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>, Caudwell, Kerry M. (CDC/OD/OCS) <cli9@cdc.gov>, CDC OD OCOS IMAC <CDCOD_OCOS_IMAC@cdc.gov>, Flynn, Paige (CDC/OD/OCS) <ijf4@cdc.gov>, Kennedy, Veronica (CDC/OD/OCS) <bvo3@cdc.gov>
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

See below media inquiry (Snopes) that Katerina has asked us to research regarding RTCs on vaccine safety. Although it is media it is also Oversight (House E and C), Julia will search Activator Monday and reach out to her contact in OA. I think we should alert OADC, programs and others before responding. HHS indicates ASL says that they already checked with CDCW- not sure who they reached out to and no one checked with us, but they might have checked with OA. Interesting how this one was routed-through leg. lanes and don't see ASPA here even though it's media. Also relates to a FOIA request..... maybe we can discuss on Monday morning.

From: "Kemper, Laura (HHS/ASL)" <Laura.Kemper@hhs.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network
Date: 20 July 2018 16:42
To: "Shipley, Samuel (HHS/IOS)" <Samuel.Shipley@HHS.GOV>, "Horska,

Katerina (HHS/IOS)" <Katerina.Horska@hhs.gov>, "Malliou, Ekaterini (OS/IOS)" <Ekaterini.Malliou@hhs.gov>
Hi Sam, Katerina, and Kat-

Wasn't sure who to check with on this. See email below. Could ExecSec check on whether we've sent any RTC over the years dealing with vaccine safety?

Thanks, Laura

From: Shatynski, Kristen [mailto:Kristen.Shatynski@mail.house.gov]
Sent: Friday, July 20, 2018 4:11 PM
To: Kemper, Laura (HHS/ASL)
Subject: Fwd: Media Inquiry from Snopes.com / Informed Consent Action Network

What I hope to be the last request for the day. Do you all have any insights into these alleged reports to the Committee on vaccine safety? Are there any public reports we can give to them?

Sent from my iPhone

Begin forwarded message:

From: "Sherman, Jennifer" <Jennifer.Sherman@mail.house.gov>
Date: July 20, 2018 at 4:03:30 PM EDT
To: "Trent, Josh" <Josh.Trent@mail.house.gov>, "Shatynski, Kristen" <Kristen.Shatynski@mail.house.gov>
Subject: FW: Media Inquiry from Snopes.com / Informed Consent Action Network

Hey guys - See below from Snopes. EACC = Energy and Commerce Committee.

From: Alex Kasprak <alex@snopes.com>
Sent: Friday, July 20, 2018 2:38 PM
To: Sherman, Jennifer <Jennifer.Sherman@mail.house.gov>
Subject: Media Inquiry from Snopes.com / Informed Consent Action Network

Hello Jennifer,

The EACC press line gave me your contact info. I am a reporter for Snopes.com looking into claims made by the vaccine-safety group Informed Consent Action Network (ICAN) in a recent court filing. In a press release about a FOIA lawsuit by that group, ICAN asserts that their request for documents demonstrated that "HHS never, not even once, submitted a single biennial report to [the Energy and Commerce Committee] detailing the improvements in vaccine safety." I was wondering if this was a factual characterization of HHS's reporting to the EACC?

Thanks for your help,

Alex

860-539-9007
alex@snopes.com

From: Andrea Woodruff
Sent: Thu, 26 Oct 2017 13:04:24 -0400
To: Cohn, Amanda (CDC/OID/NCIRD)
Subject: Re: Common ground

I'm sure you have seen this.
http://icandecide.com/white-papers/ICAN-HHS-Notice.pdf

Sent from my iPhone

On Oct 26, 2017, at 12:40 PM, Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov> wrote:

Will do, thank you! I'll come say hello after the meeting, but I can't see where you are sitting.

From: Andrea Woodruff <andrea.o.woodruff@gmail.com>
Date: October 26, 2017 at 12:19:06 PM EDT
To: Cohn, Amanda (CDC/OID/NCIRD) <anc0@cdc.gov>
Subject: Fwd: Common ground

Please forward this to Dr. Bennett.

I know you have a wealth of knowledge.
I see kids affected by all sorts of things. Vaccines are only one of my list of suspects.
The idea for all these vaccine recommendations save lives led me to these questions.
My main concern is vaccinating pregnant women with TDaP and Flu. I believe that people have the right to their own healthcare choices. My concerns are mine, but others may have their own.
My concern is that women are being coerced through access to employment, education, and/or healthcare without adequate studies.
The influenza vaccination efficacy is poor. How many lives are we really saving in the US? If I only look at data, where do I look.
For pertussis, are we spreading this illness.
https://www.researchgate.net/publication/279306290_Asymptomatic_transmission_and_the_resurgence_of_Bordetella_pertussis
Again, what data to I look at to prove or disprove if this is happening? I'm to the point where I don't believe much anymore. I feel more comfortable with public data.
TDAP has aluminum and polysorbate 80. Polysorbate 80 opens the blood brain barrier.
Aluminum and tetanus toxin are neurotoxins.
We may save lives, but do we understand the costs? Doesn't recommending vaccines without adequate studies set us all up for major liability? (I count myself here as a tax payer and stockholder.)
Please help me balance my thoughts.
Sincerely,
Andrea Woodruff

Sent from my iPhone

From: vinu arumugham
Sent: Thu, 28 Mar 2019 00:22:29 -0700
To: kathryn.edwards@vanderbilt.edu; janet.englund@seattlechildrens.org; Leonard.R.Friedland@gsk.com; LRFriedland@comcast.net; david.greenberg@sanofipasteur.com; hjanes@fredhutch.org; kkotloff@medicine.umaryland.edu; ofer.levy@childrens.harvard.edu; sarah.long@drexelmed.edu; Lynfield, Ruth (CDC state.mn.us); pmcinnes@mail.nih.gov; asmonto@umich.edu; psm9@pitt.edu; hanae@bcm.edu; mhsawyer@ucsd.edu; Wharton, Melinda (CDC/DDID/NCIRD/ISD); Hunter-Thomas, Serina (FDA/CBER); rosanna.harvey@fda.hhs.gov; ljohnson@ap.org; Slater, Jay (FDA/CBER); Woo, Jane (FDA/CBER); Hess, Maureen (FDA/CBER); Forshee, Richard (FDA/CBER); Walderhaug, Mark O (FDA/CBER); CBER OCOD Consumer Account; Destefano, Frank (CDC/DDID/NCEZID/DHQP); Thompson, Mark (CDC/DDID/NCIRD/ID); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Walker, Tanja Y. (CDC/DDID/NCIRD/ISD); Secretary@HHS.gov; Gottlieb, Scott (FDA); Redfield, Robert R. (CDC/OD); DIRECTOR'S INCOMING (CDC); francis.collins@nih.gov; Rolfes, Melissa (CDC/DDID/NCIRD/ID); Doyle, Joshua (CDC/DDID/NCIRD/ID); Blanton, Lenee (CDC/DDID/NCIRD/ID); Jernigan, Daniel B. (CDC/DDID/NCIRD/ID); Katz, Jackie M. (CDC/DDID/NCIRD/ID); Tumpey, Terrence (CDC/DDID/NCIRD/ID); Wentworth, David E. (CDC/DDID/NCIRD/ID); sharplessne@nih.hhs.gov; Emelia.Benjamin@bmc.org; mjessup@leducq.com; tavori@ohsu.edu; jessica.lilley@vanderbilt.edu; web@beasleyallen.com
Subject: Comment #2 on MMR/autism study; Failure to refute ASIA; Censorship of Prof. Lujan's work; Textbook Vaccine/allergy death

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My comments published in Annals of Internal Medicine explaining why the **Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study** by Hviid et al. should be retracted.

Please see Comments section at: https://annals.org/aim/fullarticle/2727726/measles-mumps-rubella-vaccination-autism-nationwide-cohort-study#article-top

or

Comment #2: Authors' inability to address vaccine content variation effect and lack of control for multiple mechanisms is very troubling

https://www.researchgate.net/publication/331916430_Authors'_inability_to_address_vaccine_content_variation_effect_and_lack_of_control_for_multiple_mechanisms_is_very_troubling_Comment_on_Measles_Mumps_Rubella_Vaccination_and_Autism_A_Nationwide_Cohort

Comment #1: MMR and autism study is fundamentally flawed

https://www.researchgate.net/publication/331586715_Comment_on_Measles_Mumps_Rubella_Vaccination_and_Autism_A_Nationwide_Cohort_Study

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Ameratunga et al. fail to refute Autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA)

https://doi.org/10.5281/zenodo.2596908

https://www.researchgate.net/publication/331829086_Ameratunga_et_al_fail_to_refute_Autoimmuneautoinflammatory_syndrome_induced_by_adjuvants_ASIA

Pulling the wool over your eyes: Sheep study is the latest victim of corruption and censorship of vaccine safety science

https://doi.org/10.5281/zenodo.2600655

Fish allergy death of 11-year-old Cameron Jean-Pierre: Textbook case of vaccine induced IgE mediated allergy

Regarding:

https://abc7ny.com/parents-speaks-out-after-boy-dies-from-smell-of-cooking-fish/5004794/

How do they create peanut allergy in sheep in the laboratory?

They immunize (vaccinate) sheep with peanut extract + aluminum adjuvant.

Induction of Allergic Responses to Peanut Allergen in Sheep

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3526581/

"sheep were sensitised separately with a crude PN extract and OVA. The immunisation protocol involved 3 subcutaneous (s.c.) injections at 2-week intervals and a 4th 'boost' injection after a rest period of 4 weeks. Each injection comprised either 100 µg of solubilised crude PN extract or 100 µg of OVA prepared in a total of 1 ml sterile saline with 50 µl of a commercial aluminium adjuvant (alum); Rehydragel ® LV- Aluminium hydroxide (Reheis Inc/NJ, USA)."

How did doctors create fish protein allergy in Cameron Jean-Pierre?

The US National Academy of Medicine reports in:

- Finding a Path to Safety in Food Allergy, p. 241

"Allergens in Vaccines, Medications, and Dietary Supplements

Physicians and patients with food allergy must consider potential food allergen exposures in vaccines, medications, and dietary supplement prod- ucts (e.g., vitamins, probiotics), which are not regulated by labelling laws. Also, excipients (i.e., substances added to medications to improve various characteristics) may be food or derived from foods (Kelso, 2014). These include **milk proteins; soy derivatives; oils from sesame, peanut, fish or soy; and beef or fish gelatin.** The medications involved include vaccines; anesthetics; and oral, topical, and injected medications. With perhaps the exception of gelatin, reactions appear to be rare overall, likely because little residual protein is included in the final preparation of these items. The specific risk for each medication is not known.

Vaccines also may contain food allergens, such as egg protein or gelatin."

They injected him with fish protein containing vaccines most of which contain aluminum adjuvant.

How many children like Cameron Jean-Pierre have to die before we put an end to this murderous assault on our children, by our doctors?

Vaccines and Biologics injury table based on mechanistic evidence – Mar 2019

PDF with hyperlinks: https://zenodo.org/record/2582635/files/viittoc0302http.pdf?download=1

https://doi.org/10.5281/zenodo.2582634

Rebutting Drs. DeStefano and Offit's claims of vaccine safety in: Principal Controversies in Vaccine Safety in the United States

PDF: https://doi.org/10.5281/zenodo.2567372

PDF:https://doi.org/10.5281/zenodo.2582599

Rebutting vaccine safety claims made by Dr. Hotez in Nature Pediatric Research

Vinu Arumugham

Mar 2019

vinucubeacc@gmail.com

This is regarding the article on vaccine preventable diseases by Dr. Hotez (1).

Trust must be earned and cannot be dictated

The medical establishment (ME) admits after billions and decades wasted, it has no answers for the root cause of food allergies, asthma, autism or autoimmune diseases such as type 1 diabetes. Anyone who does not know the root cause of food allergies (2,3), autism (4,5), asthma (6,7) and type 1 diabetes (8–10), is unqualified to make claims about vaccine safety. Since the ME admits they don't know the root cause of all these diseases, they are definitely unqualified to make claims about vaccine safety.

Drs. Pulendran and Ahmed of the Emory Vaccine Center admit that vaccines are based on empirical trial and error approaches with no understanding of the immunological mechanisms (11). Mojsilovic admits that we have no understanding about how vaccine adjuvants work (12).

Professors of medicine, medical journal editors and cardiologists point out that most medical research findings are false, of poor quality and are affected by flagrant conflicts of interest. (13–20)

The US Institute of Medicine committee in their 2011 report (21) on Adverse Effects of Vaccines: Evidence and Causality

wrote:

"The committee concluded the evidence convincingly supports 14 spe-cific vaccine–adverse event relationships. In all but one of these relation-ships, the conclusion was based on strong mechanistic evidence with the epidemiologic evidence rated as either limited confidence or insufficient."

So in an overwhelming 93% (13 of 14) cases, mechanistic studies provided convincing evidence and epidemiological studies failed to do so. At best, epidemiological studies are weak, have numerous sources of confounding and offer little value. At worst, they mislead, sicken millions and setback science by decades (22,23). Epidemiological study results are misinterpreted leading to type II errors (24). The vast majority of vaccine safety claims however, are based on such broken epidemiological studies.

Do you want to show that the rotavirus vaccine **protects** against type 1 diabetes? There's an epidemiological study for that (25).

Do you want to show that the rotavirus vaccine **increases risk** of type 1 diabetes? There's an epidemiological study for that too (26).

There is no science here. This is fraud. You torture an epidemiological study enough, it will confess to **anything**. That is why they are so popular. Vaccine regulators and pharmaceutical companies can get whatever conclusions they like. Unlike other sciences, doctors don't need to **understand** the **mechanism** behind **anything**. It is all about **associations**. This is junk science. No one in their right mind would trust such ridiculous material. Medical science is becoming an oxymoron.

The abject failure of the medical establishment in ensuring product safety, is responsible for the rise of measles. 200 years after Jenner, parents are still being forced to choose between vaccine preventable diseases and vaccine induced diseases.

You can fool all the people some of the time and some of the people all the time, but you cannot fool all the people all the time. - Abraham Lincoln.

The vaccine safety movement

Hotez claims "antivaccine" groups are "well-organized" and "well-funded".

The vaccine safety movement, mostly consisting of vaccine injury victims, is as "well-organized" and "well-funded" as the child that exclaimed, the emperor has no clothes.

Humans have co-evolved with measles, chicken pox etc. as with our gut microbiome. Natural chicken pox infection prevents glioma (27) and protects adults against shingles (28). The ME has absolutely failed to understand this larger picture. We certainly don't want kids to die of measles complications but it makes no sense to deprive them of the advantages of infections that we have evolved to depend on for health either. The jab and "eradicate" approach is an oversimplification that has not only failed to eradicate but that also fuels the epidemic of chronic diseases. The focus must be on avoiding measles complications while simultaneously getting the full advantage of a natural infection. The MMR vaccine is an utter failure in that regard.

The insanity of injecting live viruses

We teach kids that a wound must be kept clean to avoid infections. The Flumist vaccine administers live attenuated virus via the same route as a natural influenza infection. In contrast, the route of administration of the MMR vaccine does not match the route of natural infection. The MMR vaccine creates a wound (injection) and infects it with live virus. While an infection is desired to develop immunity, the choice of the route is insane. It injures nerves, destroys natural nerve protection and provides the virus with direct access to the nerves. The result is encephalitis (29), an injury listed on the vaccine injury table of the National Vaccine Injury Compensation Program (VICP). For every case of encephalitis that is dismissed as rare, how many thousands suffer subclinical nerve/brain damage due to this insanity? Why after 50 years since the

introduction of the measles vaccine, are we still injuring our children with this horrible vaccine? Where are the safety improvements as required by law? (30)

Type 1 diabetes

In the ~50 year history of the measles, mumps, rubella (MMR) vaccine, with no safety improvements, I was the first to point out the mechanism by which this GAD65 protein contaminated chick embryo cell culture derived vaccine causes the development of type 1 diabetes (T1D). (8–10,24)

https://www.researchgate.net/publication/318305895_Role_of_MMR_II_vaccine_contamination_with_GAD65_containing_chick_embryo_cell_culture_in_the_etiology_of_type_1_diabetes

My technical report above with more than 20,000 reads is among the most read articles on ResearchGate. It was recommended by 3 diabetes experts and another diabetes expert, Dr. Joseph Cantor of the University of California San Diego added a comment in support.

Influenza

Discussing influenza vaccines, Hotez makes no mention of influenza vaccines causing the development of allergy to the influenza proteins themselves (IgE mediated sensitization) (31–34). This can result in increased severity of influenza disease due to a concurrent allergic reaction to the influenza viral proteins. This is similar to a secondary dengue infection and therefore, similar to dengue shock syndrome (DSS), we have influenza shock syndrome (ISS) (35,36).

"Similarly the overwhelming majority of the children who died in the 2018 US flu epidemic were not vaccinated."

Interestingly, Hotez does not offer a citation for that claim.

In contrast, we find that the vaccinated had a higher probability of severe disease as expected for reasons previously explained (vaccine induced influenza allergy, which results in influenza shock syndrome just like dengue shock syndrome). (36,37) Increasing influenza severity, therefore has an iatrogenic basis. Doctors are making the problem worse, not better (38).

HPV

Hotez writes: "eliminating cervical cancer"

What is the point of eliminating cervical cancer only to replace it with autoimmune diseases that kill just as many? (39)

Autism

“inject fear into parents that vaccines cause autism”

And for good reason because vaccine **do** in fact cause autism. (4) Public discussion is always on the MMR/autism controversy. But we show with strong **mechanistic** evidence that cow’s milk protein containing vaccines (DTaP, Prevnar 13, ActHib, not MMR) cause the vast majority of autism cases (4).

“vast cover-up by the CDC and other federal agencies.”

The US Department of Health and Human Services (HHS) is required by law to continuously improve vaccine safety and provide a report of such improvements to Congress, every two years. The HHS admitted providing no such report and thus repeatedly breaking the law for 30 years. (30)

Just a few days ago, Dr. Fauci of the National Institutes of Health was caught lying at a Congressional hearing on vaccines. Dr. Fauci claimed that vaccines do not cause encephalitis. The lay audience protested. Dr. Fauci backtracked and changed his response to “rare”. So yes, it is most certainly a cover-up. There can be no doubt.

“We have identified at least 99 genes associated with autism”

The vast majority of ASD cases (75%) test positive for folate receptor alpha antibodies (FRAA). These FRAA bind with higher affinity to the bovine folate receptor than human folate receptor. There is no way genes can cause that type of adaptive immune response. Dr. Hotez ignores such inconvenient facts to still mislead the world about the role of genes in ASD. Hughes et al. write that only 10-20% of ASD can be explained by genetic causes (40). Cow’s milk protein containing vaccines induce FRAA mediated autism (4).

“the changes in the brains of kids with autism actually begin prenatally, meaning well before a child ever becomes immunized”

It is a misconception that only the child’s immunization matters. Mothers are vaccinated with cow’s milk containing vaccines as well. So of course they make FRAA too. Majority of FRAA are of the IgG4 subclass that crosses the placenta (41) and damages the fetal brain. So it is of course possible to have prenatal vaccine induced autism.

Doctors are taught that when they hear hoofbeats, they should think horses, not zebras. But Hotez and his genetic autism researcher friends are not even chasing zebras, they are chasing

unicorns. That is why after billions and decades wasted, they have nothing to show for it, while tragically, even more children are sickened with dirty vaccines. The vast majority of autism is simply a special case of milk allergy induced by injecting milk protein containing vaccines. This basic immunological concept is a hundred year old Nobel winning discovery (42). Incompetent doctors are ignoring such a basic concept and are continuing to not only sicken our children but attempting to hide the damage they have inflicted. This is the biggest scandal in the history of medicine. Vaccine victims will fight to expose it.

Conclusion

Institutions such as the FDA/CDC/NIH/HHS/AAP are not trusted by a growing number of people. With vaccines sickening more and more people, this will only increase the number of people who don't trust these institutions.

The only way to control these vaccine preventable diseases is to immediately clean up the vaccines and approach these diseases with a view of the big picture.

The spectacular failure of the Dengvaxia vaccine demonstrates that irrational vaccine development with no clue of the immunological mechanisms will backfire with devastating effect. (37)

Vaccines are too important to be left to a bunch of tinkerers. They need to be **engineered** for safety.

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From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 27 Aug 2019 15:51:41 +0000
To: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Subject: RE: ELAINE and JOHN: FOR YOUR REVIEW and INPUT: Response Jacob Kophamer_ DHQP - DUE ASAP
Attachments: Email 00423908 14 8 2019 (003).pdf_Incoming.pdf, Response Jacob Kophamer_ DHQP response.docx

Thanks Bonita! John and Elaine – some context below.

Per the email thread below, HHS received a public correspondence from an individual who is part of the Parents for the Modernization of VAERS Reporting group (https://www.facebook.com/uhpamv/posts/1366355516847588). The letter (attached PDF) was assigned to me/ DHQP/ISO for a response and will be reviewed and cross-cleared by NCIRD and FDA after we send back up the clearance chain. Can you review the draft response that William and I revised from EZID policy and let us know if you have any additional edits/comments/suggestions? Like other policy/comms request, we try to keep this at high levels, but I am not sure if we are still working with FDA to further improve/modernize VAERS via linking EHRs and systems.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH

Public Health Analyst (Policy)

Division of Healthcare Quality Promotion/NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(Fax) 404-718-1900

(E-mail) ivx1@cdc.gov

Telework Mondays and Fridays - please contact by BB and e-mail

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From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Sent: Tuesday, August 27, 2019 11:49 AM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
Subject: ELAINE and JOHN: FOR YOUR REVIEW and INPUT: Response Jacob Kophamer_ DHQP - DUE ASAP

Elaine and John – for your review and response - due ASAP.

Thanks,

Bonita
498-0646

From: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
Sent: Tuesday, August 27, 2019 11:38 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: Re: FOR YOUR REVIEW and INPUT: Response Jacob Kophamer_ DHQP - DUE ASAP

Elaine and John Su should be able to review. Thanks

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 27, 2019 11:31:58 AM
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: FW: FOR YOUR REVIEW and INPUT: Response Jacob Kophamer_ DHQP - DUE ASAP

Frank and Bonita,

With so many people out of the office today, I was wondering if there is someone in ISO who can review the draft response to this controlled correspondence. CDC OD wants a response ASAP and I was told HHS will not allow an official extension. I spoke to William on this request and also had him review what I revised this AM. We were also discussing the reference to the Harvard work since we both recalled the topic, but not sure what we should be saying. Based on a previous inquiry from Del BT which we had provided 2 years ago (b)(5)

(b)(5)

Let me know if you are able to review and have edits/comments to what was drafted.

Thanks.

-Lyn

Lyn Thi Nguyen, MPH

Public Health Analyst (Policy)

Division of Healthcare Quality Promotion/NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(b)(6)

(b)(6)

(Fax) 404-718-1900

(E-mail) ivx1@cdc.gov

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From: Vaughn, William (CDC/DDID/NCEZID/DHQP) (CTR) <hbv2@cdc.gov>
Sent: Tuesday, August 27, 2019 10:53 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Subject: RE: FOR YOUR REVIEW and INPUT: Response Jacob Kophamer_ DHQP

Hey there…this looks good. So two pages on the HHS VAERS website specifically address some of the concerns in the letters...the latest disclaimer language is in the draft…have added the link to the healthcare provider guidance page (btw, very findable via Google, too). Let's chat when you a minute… thx, William

VAERS reporting guidance for physicians:
https://vaers.hhs.gov/resources/infoproviders.html

New disclaimer that explains limitations, and multi-system approach:
https://vaers.hhs.gov/data.html

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Wed, 13 Mar 2019 13:26:29 +0000
To: Miles, Carla (CDC/DDID/NCIRD/OD) (CTR)
Subject: Re: Good morning!

Is it from ICAN? If so, I have the same folder :)

From: Miles, Carla (CDC/DDID/NCIRD/OD) (CTR) <yiv8@cdc.gov>
Date: March 13, 2019 at 8:49:44 AM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: Good morning!

I have a folder on my desk for you from Dr. Messonnier. I didn't want to leave it on your desk – are you in your office?

Carla Miles
Contractor (Cherokee Nation Assurance)

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases (NCIRD)
Influenza Coordination Unit
1600 Clifton Road
Atlanta, GA USA 30333
Office: 404 639-2941
Cell: 404 432-1524
Telework: Tuesday/Friday

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Thu, 2 May 2019 15:09:49 +0000
To: Eisenberg, Emily (CDC/DDID/NCIRD/ID)
Subject: RE: ICAN packets

We are not collecting them, and I don't think systematically collecting names but I am keeping a semi-list. They have gone out far and wide…

From: Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>
Sent: Thursday, May 2, 2019 11:08 AM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: ICAN packets

Hi there Amanda – Steve Redd got an ICAN package too – it is on my desk. Do I just trash it, or are we collecting them somewhere or reporting individual recipients?

Emily Eisenberg Lobelo, ScD, MSJ
On Detail
Sr. Advisor, Office of the Director
CDC/Deputy Director for Public Health Service and Implementation Science
Phone: 404.639.1187, BB: 678.640.7692

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Mon, 11 Mar 2019 15:58:44 +0000
To: Romero, Jose; Lee, Grace
Cc: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD)
Subject: RE: ICAN

Thanks Jose for the heads up. No further action.

From: Romero, Jose <RomeroJose@uams.edu>
Sent: Monday, March 11, 2019 11:56 AM
To: Lee, Grace <GMLee@stanfordchildrens.org>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Subject: FW: ICAN

Grace:

Sorry I forgot to cc you.

JRR

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: "Romero, Jose" <RomeroJose@uams.edu>
Date: Monday, March 11, 2019 at 10:55 AM
To: "Cohn, Amanda (CDC/DDID/NCIRD/OD)" <anc0@cdc.gov>, Jessica MacNeil <aji8@cdc.gov>
Cc: "Hargrove, Tamara" <THargrove@uams.edu>
Subject: ICAN

Amanda and Jessica:

I just received a FedEx from Informed Consent Action Network re: HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 USC 300aa-31(b) and 300aa-31. Both documents are lengthy.

I suspect you as well as members of the ACIP have or will receive this. I am on inpatient service this week and will most likely not get to these until this weekend. Please let me know if there is something I MUST do at this time.

José

José R. Romero, MD, FAAP, FIDSA, FPIDS
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases
Director, Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and
Arkansas Children's Hospital

Arkansas Children's Hospital
1 Children's Way
Slot 512-11
Little Rock, AR 72202-3591

Tel: 501-364-1416
Fax: 501-364-3551
Email: RomeroJose@uams.edu

From: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Sent: Wed, 24 Apr 2019 21:29:20 +0000
To: Schluter, W. William (CDC/DDPHSIS/CGH/GID)
Subject: RE: ICAN

Can I call you in 10 minutes?

From: Schluter, W. William (CDC/DDPHSIS/CGH/GID) <wbs8@cdc.gov>
Date: April 24, 2019 at 5:23:11 PM EDT
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: RE: ICAN

Yes. Are you available now?

W. William Schluter, MD, MSPH
Director
Global Immunization Division
Center for Global Health
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS A04
Atlanta, GA 30329
Office telephone: 404-553-7314

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Sent: Wednesday, April 24, 2019 5:09 PM
To: Schluter, W. William (CDC/DDPHSIS/CGH/GID) <wbs8@cdc.gov>
Subject: ICAN

Do you have a minute to touch base about the packets I heard gid staff received? Ncird staff also received them.