June 30, 2026

VIA EMAIL AND FED EX

Karim Mikhail, B. Pharm, MSc
Acting Director
Center for Biologics Evaluation and Research (CBER)
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
[redacted]

Re: *Request for the Immediate Termination of All Center for Biologics Evaluation Research Employees Responsible for Licensure of Routine Childhood Vaccines*

Dear Acting Director Mikhail:

We write on behalf of Informed Consent Action Network ("**ICAN**") requesting that every individual at the Center for Biologics Evaluation and Research ("**CBER**") who has overseen, reviewed, and approved, or otherwise participated in the licensure of any routine injected childhood vaccines on the current CDC schedule be terminated immediately for gross incompetence, dereliction of duty, and inherent conflicts. The basis for this demand is simple: the clinical trials relied upon to license these vaccines were so fundamentally deficient that no competent regulator acting in good faith could have approved them. The evidence, drawn entirely from FDA's own records, package inserts, and company documentation, is damning and undeniable.

I. THE CLINICAL TRIAL RECORD IS ONE OF SYSTEMIC FAILURE

The clinical trials relied upon to license each routine childhood injected vaccine on the CDC schedule did not and could not affirm their safety prior to licensure, including because they did not include a proper control, did not review safety for a sufficient duration after injection, and were underpowered.[1]

[1] **M-M-R II** (https://www.fda.gov/media/75191/download); **Priorix** (https://www.fda.gov/media/189623/download?attachment); **Varivax** (https://www.fda.gov/media/76008/download, note that 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 per milliliter," https://www.ncbi.nlm.nih.gov/pubmed/6325909, https://perma.cc/S8ET-ZBA9, and neomycin is an antibiotic with serious side effects when swallowed, let alone injected, https://www.pdr.net/drug-summary/?drugLabelId=819, https://perma.cc/E8V9-4JN5); **Havrix** (https://www.fda.gov/media/119388/download); **Vaqta** (https://www.fda.gov/media/74519/download, the "Placebo (Alum Diluent)" contained 300µg AAHS and thimerosal, *see* https://www.nejm.org/doi/pdf/10.1056/NEJM199208133270702); **Fluarix (IIV4)** (https://www.fda.gov/media/79278/download, placebo control only used in adult trials but never in trials to license this vaccine for children); **Fluzone (IIV4)** (https://www.fda.gov/media/170019/download); **FluLaval (IIV4)** (https://www.fda.gov/media/115785/download); **Afluria (IIV4)** (https://www.fda.gov/media/117022/download); **Flucelvax (IIV4)** (https://www.fda.gov/media/115862/download, placebo control only used in adult trials but never in trials to license this vaccine for children); **ProQuad** (https://www.fda.gov/media/75195/download, note that in one

As for the control used in these trials (noting that the term "placebo," per FDA's guidance, means an "inert substances with no pharmacologic activity"[2]) there was either no control group, the control group received an injection of a non-inert substance, or the control group received another vaccine that itself was either unlicensed or was never licensed based on a placebo-controlled clinical trial.[3] But even if properly controlled, these trials were typically useless for affirming their safety since safety was often monitored for only days or weeks, or maybe up to six months, after injection, and these were often underpowered.

The reality regarding the pivotal trial relied upon to license each childhood vaccine is confirmed in black and white on FDA's own website and in the pharmaceutical companies' own documentation.

The personnel at CBER who accepted these trials and licensed these products have failed in their most basic duty.

II. THE VACCINE-BY-VACCINE RECORD OF INCOMPETENCE

What follows is the clinical trial record for each routine injected childhood vaccine on the CDC schedule, drawn from FDA records and company package inserts, which your predecessors and colleagues accepted as sufficient for licensure.

A. Hepatitis B Vaccine (Injected on Day of Birth, at 2 Months, and 6 Months)

FDA licensed Recombivax HB for infants and children based on a clinical trial with only 147 healthy infants and in which children were monitored for only 5 days after each dose.[4] There was no control group whatsoever.[5] This was the first vaccine ever licensed using recombinant DNA technology and was described as "the most complex" recombinant product at the time, yet CBER approved it based on 5 days of monitoring in 147 children with no control.[6] The only other hepatitis B vaccine licensed for newborns, Engerix-B, monitored safety for only 4 days after injection.[7]

It may be worth noting that when Heplisav-B was approved in 2017 for adults, it used Engerix-B as a control and the serious adverse event rate for Heplisav-B was 6.2%, which was deemed acceptable because it was similar to the 5.3% rate for Engerix-B—a product that was itself

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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 purport to be in its Clinical Review, http://wayback.archive-it.org/7993/20170723150913/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123800.pdf).

[2] https://www.fda.gov/media/130326/download. *See also* https://www.fda.gov/media/71349/download ("the placebo control design, by … including a group that receives an inert treatment").

[3] *Id*.

[4] https://www.fda.gov/media/74274/download.

[5] *Id*.

[6] https://www.nature.com/articles/d42859-020-00016-5 (https://perma.cc/J44R-UAWG).

[7] https://www.fda.gov/media/119403/download.

licensed without a control group and with only 4 days of safety monitoring.[8] As you are or should be aware, "serious adverse event," as defined by FDA, means death, a life-threatening condition, hospitalization, disability or permanent damage, congenital anomaly, or a required intervention to prevent permanent impairment.[9]

B. DTaP Vaccine (Injected at 2, 4, and 6 Months)

Infanrix was licensed for babies based on trials with no placebo control.[10] Instead, the DTP vaccine was used as a control, and the safety was reviewed for only up to 30 days after injection.[11] The same was the case with Daptacel, the only other DTaP vaccine.[12] DTP itself was not licensed based on a placebo-controlled trial, and studies have repeatedly found that DTP increases mortality in infants—meaning DTP-vaccinated infants die at far higher rates than their equally situated unvaccinated peers.[13] The stark reality is that a product repeatedly shown to increase deaths among babies, DTP, was used as the baseline of safety to license the two current DTaP vaccines.

C. Pneumococcal Vaccine (PCV) (Injected at 2, 4, 6, and 12 Months)

The first PCV vaccine ever licensed for children, Prevnar 7, was licensed in 2000 based on a clinical trial in which the control was another unlicensed experimental vaccine—"an investigational meningococcal group C conjugate vaccine."[14] A group of FDA scientists conceded that comparing Prevnar 7 to an experimental vaccine means "little or no difference between the 2 groups might have been evident" if both vaccines provoked similar adverse effects.[15]

Prevnar 13 was then licensed in 2010 using Prevnar 7 as the control.[16] In Prevnar 13's clinical trial, serious adverse events were reported by 8.2% of Prevnar 13 recipients and 7.2% of Prevnar 7 recipients—among previously healthy infants.[17] Rather than raising alarm, the FDA deemed the product safe because the rates were similar.[18]

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[8] https://www.fda.gov/media/108745/download.

[9] https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

[10] https://www.fda.gov/media/75157/download.

[11] *Id*.

[12] https://www.fda.gov/media/74035/download; https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

[13] https://icandecide.org/wp-content/uploads/2021/06/2021.01.28-Letter-to-Special-Rapporteur-on-Poverty.pdf (https://perma.cc/3KRP-NLVV).

[14] https://labeling.pfizer.com/showlabeling.aspx?id=134.

[15] https://www.ncbi.nlm.nih.gov/pubmed/15479935 (https://perma.cc/QQK3-8CUX).

[16] https://www.fda.gov/files/bioinformatics%20tools/published/Package-Insert---Prevnar-13.pdf.

[17] *Id*.

[18] *Id*.

Vaxneuvance (PCV-15) was then licensed in 2022 using Prevnar 13 as the control, with serious adverse events reported by 9.6% of Vaxneuvance recipients and 8.9% of Prevnar 13 recipients; yet it was deemed safe for licensure because there "were no notable patterns or numerical imbalances between vaccination groups."[19] In 2023, Prevnar 20 (PCV-20) was licensed again using Prevnar 13 as the control, with high rates of serious events in both groups, but was again found to be safe because the rates were found to be similar.[20]

In short, PCV-20 and PCV-15 were licensed using PCV-13 as the control; PCV-13 was licensed using PCV-7 as the control; and PCV-7 was licensed using another unlicensed experimental vaccine as the control—this is a pyramid scheme of safety, and CBER approved every layer of it.

D. Hib Vaccine (Injected at 2, 4, 6, and 12 Months)

Not one of the three licensed Hib vaccines was licensed based on a placebo-controlled trial. ActHIB's trial used an unspecified hepatitis B vaccine as a control (itself not licensed based on a placebo trial) and had only 30 days of safety review, during which 3.4% of participants experienced a serious adverse event, but none was assessed by the investigators (Sanofi) as related to the study vaccines.[21] Hiberix's trial used ActHIB as a control with 31 days of safety review.[22] PedvaxHIB used an unlicensed vaccine as a control with only 3 days of safety review after injection.[23]

E. Polio Vaccine (Injected at 2, 4, 6, and 48 Months)

IPOL, the sole stand-alone polio vaccine in the United States, was licensed in 1990 based on a trial with no control—let alone a placebo control—with only 3 days of safety review after injection.[24] Sanofi itself reported: "Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants."[25] Of course no causal relationship could be established in a trial that was utterly useless for determining safety. IPOL is a completely different product from the Salk vaccine, using immortalized monkey kidney cells, among other material differences which would explain why neither Sanofi nor FDA relied on the Salk vaccine's safety or efficacy to license IPOL.[26]

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[19] https://www.fda.gov/media/150819/download.

[20] https://www.fda.gov/media/149987/download; https://www.fda.gov/media/150459/download.

[21] https://www.fda.gov/media/74395/download; http://wayback.archive-it.org/7993/20170723144656/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244597.pdf at 8.

[22] https://www.fda.gov/media/77017/download.

[23] https://www.fda.gov/media/80438/download at 6-8.

[24] https://www.fda.gov/media/75695/download at 14-17.

[25] *Id*. at 15.

[26] https://www.fda.gov/media/75695/download; https://pubmed.ncbi.nlm.nih.gov/6740101/ (https://perma.cc/29KM-2ZHE); https://www.culturecollections.org.uk/products/cell-cultures/ecacc-cell-line-profiles/vero/ (https://perma.cc/ML7G-3387); https://www.atcc.org/products/all/ccl-81.aspx#characteristics (https://perma.cc/WEV7-V5WY).

F. Influenza Vaccine (Injected Starting at 6 Months, Then Annually)

None of the trials for the initial licensed version of each influenza vaccine for children included a placebo control group.[27] The formulation changes annually, and each new formulation is licensed without any clinical trials. The safety of many influenza vaccines rests on a trial that used Fluzone (IIV3) as a control, but Fluzone was itself licensed based on a small trial without any control.[28] Worse, an efficacy trial for Fluzone conducted after licensure found that in the second year of the study "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 drainage tubes.[29]

G. Hepatitis A Vaccine (Injected at 12 Months and 18 Months)

Havrix, licensed in 1995, and Vaqta, licensed in 1996, were the first two hepatitis A vaccines ever licensed in the United States.[30] There was no excuse not to use a placebo control group, yet neither trial did. For Havrix, the control was Engerix-B, the hepatitis B vaccine licensed after only 5 days of safety monitoring.[31] For Vaqta, the control was an injection of AAHS (a proprietary aluminum adjuvant) and thimerosal.[32]

H. Varicella Vaccine (Chicken Pox) Vaccine (Injected at 12 Months)

Varivax, the first and only vaccine licensed for chicken pox in 1995, was not licensed based upon a placebo-controlled trial despite being the first vaccine for this disease. Although the package insert claims safety was reviewed against a "placebo" control, only 465 children received the purported "placebo."[33] Merck's peer-reviewed article makes clear this "placebo" was not a placebo at all, but rather an injection of "lyophilized stabilizer containing approximately 45 mg of neomycin per milliliter."[34] Neomycin is an antibiotic with a long list of serious adverse reactions, including hearing loss, kidney damage, and nerve damage.[35]

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[27] *See* influenza vaccines, *supra* note 1.

[28] *Id*.

[29] https://www.ncbi.nlm.nih.gov/pubmed/14506120 (https://perma.cc/BG8X-U4Z8).

[30] https://www.fda.gov/media/119388/download; https://www.fda.gov/media/74519/download.

[31] https://www.fda.gov/media/119388/download.

[32] https://www.fda.gov/media/74519/download (The "Placebo (Alum Diluent)" contained 300µg AAHS and thimerosal, https://www.nejm.org/doi/full/10.1056/NEJM199208133270702); http://wayback.archive-it.org/7993/20170723025039/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110035.pdf.

[33] https://www.fda.gov/media/76008/download; https://www.ncbi.nlm.nih.gov/pubmed/6325909 (https://perma.cc/N7DS-XKP7).

[34] *Id*.

[35] https://www.pdr.net/drug-summary/?drugLabelId=819 (https://perma.cc/E8V9-4JN5).

I. MMR Vaccine (Injected at 12 Months and 48 Months)

Merck's MMR-II was licensed in 1978 based on a clinical trial with only 834 children, no control group whatsoever, and only 42 days of safety review after injection.[36] During the trial, approximately one-third of participants developed gastrointestinal issues and one-third developed respiratory issues, but without a control group, these reactions were written off.[37] This was a novel product that, among other differences from MMR-I, contains hundreds of billions of pieces of human DNA and cellular material from the cultured cell line of an aborted fetus, yet no proper safety trial was conducted.[38]

When a later trial for GSK's Priorix (MMR-RIT), licensed in 2022, used MMR-II as a control with 6 months of safety review, both vaccine groups showed high rates of serious adverse events, emergency room visits, and new onset of chronic diseases including autoimmune disorders, asthma, type I diabetes, vasculitis, celiac disease, thrombocytopenia, and allergies.[39] Rather than raising alarm, the FDA deemed Priorix safe because it had the same level of harm as the control group receiving MMR-II. These serious harms were not disclosed in the package insert but were buried in a supplemental table in a journal article.[40]

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[36] https://sirillp.com/MMR-clinical-trial (https://perma.cc/RRE8-WDQ5).

[37] *Id*.

[38] Because viruses multiply in cells, living cells are used to grow viruses for vaccine production. The rubella virus used in MMR-II is grown on the cultured cell line of an aborted fetus, listed as "WI-38 human diploid lung fibroblasts" in the ingredients of MMR-II as portions of these cells end up in each vial of MMR-II. https://web.archive.org/web/20241120002123/https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. As explained by a company that sells this aborted fetal cell line: "WI-38 cell line is the first human diploid cell line to be used in human vaccine preparation. WI-38 cells were isolated from the lung tissue of a 3-month-old, female, embryo." https://www.atcc.org/products/ccl-75 (https://perma.cc/H6XR-QFXN). Dr. Stanley Plotkin deposition, https://icandecide.org/plotkintranscript/ at 328 (https://perma.cc/7WCZ-G2TC). *See also* https://soundchoice.org/wp-content/uploads/2021/01/epidemiologic-molecular-relationship-vaccine-manufacture-autism-prevalence.pdf (https://perma.cc/2E38-QEYA); https://pubmed.ncbi.nlm.nih.gov/26103708/ (https://perma.cc/E6TH-2LK8) (*See* Table 3, reflecting an average of 142 nanograms of single-stranded DNA and 35 nanograms of double-stranded DNA in the rubella vaccine component of each dose of MMR-II). Doing the math, 150 nanograms of double-stranded DNA broken down into 215 base pair fragments equals approximately 646 billion pieces of human DNA from an aborted fetal cell line in each vial of MMR-II. https://www.technologynetworks.com/tn/tools/copynumbercalculator. Doing this same math for 150 nanograms of single-stranded DNA equals 1.3 trillion pieces inside each vial of MMR-II. *Id.* In addition to the human DNA, there is also an unspecified amount of human cellular debris in each dose of MMR-II. *See also* https://thehighwire.com/ark-videos/aborted-fetal-tissue-in-vaccines/.

[39] https://pmc.ncbi.nlm.nih.gov/articles/PMC7192400/#sec20 at Supplementary Table 6 (https://perma.cc/JA5Y-Y94M); https://pmc.ncbi.nlm.nih.gov/articles/instance/7192400/bin/piz010_suppl_supplementary_materials.docx.

[40] https://pmc.ncbi.nlm.nih.gov/articles/PMC7192400/#sec20 (https://perma.cc/JA5Y-Y94M); https://pmc.ncbi.nlm.nih.gov/articles/instance/7192400/bin/piz010_suppl_supplementary_materials.docx.

J. HPV Vaccine (Injected Starting at 9 Years of Age)

The first Gardasil vaccine, licensed in 2006, was tested in a trial in which 10,706 girls and women received Gardasil.[41] Neither of the control groups received a placebo.[42] Of the control subjects, 9,092 received an injection of AAHS (a known neurotoxic and cytotoxic aluminum adjuvant), and only 320 received what the package insert falsely labeled as "saline placebo"—which actually contained L-histidine, polysorbate 80, sodium borate, and yeast protein.[43]

During the six-month safety review, 2.3% of the women and girls in both the Gardasil group and the combined control group developed a systemic autoimmune disorder.[44] AAHS is used to induce autoimmunity in laboratory animals and has been implicated in various autoimmune conditions in humans.[45] Since the control group itself received AAHS, this ingredient could have caused the autoimmune disorders seen in both groups, rendering any safety comparison meaningless. Gardasil 9 was then licensed based on a trial in which a few hundred participants did finally receive a saline injection, but only after receiving three doses of the original Gardasil – hence again not a placebo control group.[46]

K. Tdap Vaccine (Injected at 11 Years and Older)

Adacel and Boostrix, both licensed in 2005, were licensed without a placebo-controlled trial.[47] Both used Decavac vaccine as the control, which itself was not licensed based on a placebo-controlled trial.[48]

L. Meningococcal ACWY Vaccine

Menomune was licensed without a placebo-controlled trial.[49] Menactra was then licensed using Menomune as the control.[50] In a remarkable circularity, the safety section of the package insert for Menomune references the trial for Menactra, meaning the same clinical trial is relied upon in the package insert for each to support its safety.

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[41] https://www.fda.gov/media/186364/download; https://www.clinicaltrials.gov/study/NCT00092547.

[42] *Id*.

[43] *Id*.

[44] https://www.fda.gov/media/74350/download.

[45] https://www.wiley.com/en-us/Vaccines+and+Autoimmunity-p-9781118663431; https://pubmed.ncbi.nlm.nih.gov/25923134/ (https://perma.cc/822U-GQQV).

[46] https://www.fda.gov/media/90249/download; https://clinicaltrials.gov/study/NCT01047345?tab=results.

[47] https://www.fda.gov/media/119862/download; https://www.fda.gov/media/124002/download.

[48] *Id*.

[49] https://web.archive.org/web/20240622065910/https://www.fda.gov/media/83562/download; https://www.fda.gov/media/75619/download.

[50] *Id*.

The pyramid scheme continued when Menveo was licensed in 2010 using Menomune and Menactra as controls; MenQuadfi was then licensed in 2020 using Menveo and Menactra as controls.[51] At the bottom of this pyramid, there is no safety baseline.

III. THE ETHICAL FAILURE COMPOUNDS THE SCIENTIFIC FAILURE

The reality is that not a single routine injected childhood vaccine on the CDC schedule (save Covid-19 vaccines) was licensed based on a placebo-controlled trial, nor when another vaccine was used as a control was the control vaccine licensed based on a placebo-controlled trial. So on and so forth. This reality is brought into sharp relief by the fact that even where no licensed vaccine existed—such as the first vaccines for chicken pox, hepatitis A (both licensed in 1995), and HPV (licensed in 2006)—no placebo was used. There was no legitimate reason to not use a placebo in those trials yet it simply was not done.

This reality raises serious ethical concerns. As researchers from the University of Oxford have explained: "In some trials placebos were omitted on ethical grounds. This is illogical because studies destined to produce unreliable results should themselves be considered unethical."[52]

Injecting a vaccine into millions of children in an uncontrolled setting without first assessing its safety in a placebo-controlled trial is, to any objective and reasonable observer, grossly unethical conduct.[53] Even worse, by failing to require placebo-controlled trials, FDA gave itself a convenient way to consistently discount even widespread claims of vaccine injury by claiming causation had not been proven, knowing full well causation will likely never be proven without a placebo-controlled trial.

IV. CONCLUSION: IMMEDIATE TERMINATION IS REQUIRED

The record above is not conjecture. It is drawn entirely from FDA's own records, FDA approved documents, and peer-reviewed publications. It demonstrates that the clinical trials relied upon to license each routine injected childhood vaccine on the CDC schedule did not and could not determine the vaccine's safety profile prior to licensure due to, among other issues, improper controls, limited safety review, and lack of power. (While the foregoing is more than sufficient to prove this grave issue, for a more fulsome treatment, see Chapter 10 of *Vaccines Amen: The Religion of Vaccines*.)

Any CBER official who reviewed and accepted these trials as adequate to license pharmaceutical products for injection into millions of healthy infants and children was either grossly incompetent or derelict in their duty to protect the public. There is no third option. No competent regulator could review a trial with 147 children, 5 days of monitoring, and no control group, and conclude the product was safe for every newborn in America. No competent regulator

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[51] https://www.fda.gov/media/78514/download; https://www.fda.gov/media/137306/download.

[52] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1113953/ (https://perma.cc/QC3S-GEWG).

[53] https://research.unc.edu/human-research-ethics/resources/ccm3_019064/ (https://perma.cc/2NHF-DXF7) ("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").

could accept a pyramid scheme of safety in which each vaccine is deemed safe only because it is as safe as another vaccine that was itself never properly trialed for licensure.

We therefore demand that every individual at CBER who has been involved in the review and licensure of any routine injected childhood vaccine be immediately terminated. The health and safety of America's children demand nothing less.

Very truly yours,

SIRI & GLIMSTAD LLP

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