**VIA ELECTRONIC SUBMISSION**

September 20, 2026

Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
United States Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Re: *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, Docket No. HHS-OS-2026-0332, 91 FR 54724 (Aug. 24, 2026)

Dear Ms. Goss,

We write on behalf of Informed Consent Action Network ("**ICAN**") in response to the U.S. Department of Health and Human Services' ("**HHS**") Request for Information ("**RFI**") concerning the categories used in federal vaccine recommendations and the role that shared clinical decision-making ("**SCDM**") should play within Centers for Disease Control and Prevention's ("**CDC**") vaccine schedule.[1] HHS's recognition of the role that scientific rigor, individual autonomy, informed consent, and public trust play in setting federal vaccine policy is greatly appreciated and cannot be overstated.

## I. Every Vaccination Recommendation and Decision Should be Based on Shared Clinical Decision-Making (SCDM)

The central principle is straightforward: vaccines should be treated like every other medical intervention administered to an individual patient. The appropriate approach, therefore, is SCDM, where there is no "default" decision to vaccinate, but where "the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered" with no "prescribed set of considerations or decision points in the decision-making process."[2]

This process should apply to every vaccine—period.[3] HHS should therefore not treat SCDM as a special category reserved for a subset of vaccines or classes of vaccines; it is the

[1] *See* 91 Fed. Reg. 54724 (Aug. 24, 2026).
[2] *See ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.
[3] It is also critical that all federal guidance, recommendations, and schedules discuss each vaccine independently as opposed to treating them as a class of vaccines. Not all COVID-19 vaccines, for example, are the same. Each individualized vaccine has a different benefit/risk profile and different clinical trial and post-marketing data. HHS should not treat these products as identical simply because they target the same pathogen. The word "vaccine" as used throughout this letter means each individual brand name vaccine.

appropriate clinical process for every vaccine decision. We urge HHS to adopt and implement this principle across the entire federal vaccine recommendation framework.

### A. Ethics and Informed Consent Demand SCDM

The RFI states that personal autonomy, informed consent, and the values and preferences of patients and parents "apply across all vaccine recommendations, including routine ones."[4] However, with the current categories, most of which are "default" decisions to vaccinate, that statement has no practical effect. A federal recommendation should not predetermine the medical decision of any particular patient.

This principle is consistent with ordinary clinical practice and ethics. The Agency for Healthcare Research and Quality ("**AHRQ**") describes SCDM as a collaborative process in which patients and clinicians make healthcare decisions informed by evidence, clinical expertise, and the patient's values, goals, and circumstances.[5] The American Medical Association likewise recognizes informed consent as fundamental to medical ethics.[6] The fact that a vaccine is recommended by public health authorities does not eliminate the need for individualized clinical assessment or informed consent. Each patient's medical history, risk factors, prior reactions, values, and preferences may affect the appropriate decision in ways a population-level recommendation cannot capture.[7]

The current federal framework classifies a majority of vaccine recommendations as a "default" decision to vaccinate.[8] Other medical frameworks reject this approach: Clinical Practice Guidelines, for example, are designed to inform clinician-patient decision-making by presenting the evidence and the likely benefits and harms of available options, without dictating a one-size-fits-all course of care.[9]

There should not be any "routine" or "risk-based" recommendations. Population-level criteria cannot capture every clinically relevant characteristic of each patient, and applying them directly to individual decisions risks creating the false impression that harm-benefit tradeoffs are uniform across everyone who meets a given classification.[10] In reality, individuals within the same risk group often differ substantially in their risk for the relevant outcome and in the balance of benefits and harms of treatment.[11] Population-level classifications should never substitute for the

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[4] 91 Fed. Reg. 54724.
[5] *See About Shared Decision Making*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (last visited Aug. 25, 2026), https://www.ahrq.gov/sdm/about/index.html.
[6] *See Opinion 2.1.1 Informed Consent*, AMERICAN MEDICAL ASSOCIATION CODE OF MEDICAL ETHICS (last visited Sept. 3, 2026), https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent.
[7] *See* Anil Makam and Oanh Nguyen, *An Evidence-Based Medicine Approach to Antihyperglycemic Therapy in Diabetes Mellitus to Overcome Overtreatment*, CIRCULATION (Jan. 10, 2017), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.116.022622.
[8] *See ACIP Shared Clinical Decision-Making Recommendations*, *supra* note 2.
[9] *See Clinical Practice Guidelines We Can Trust*, NATIONAL ACADEMIES (2011), https://www.nationalacademies.org/read/13058/chapter/3.
[10] *See* David Kent, et al., *The Predictive Approaches to Treatment effect Heterogeneity (PATH) Statement*, ANNALS OF INTERNAL MEDICINE (Nov. 12, 2019), https://www.acpjournals.org/doi/10.7326/M18-3667.
[11] *See id.*

individualized evaluation of all relevant patient attributes that determines whether an intervention offers a true net benefit to a specific patient.[12]

A clinician should never administer a vaccine based on a government recommendation but rather should only administer every vaccine based on SCDM which allows for informed consent and an evaluation of each individual's medical history, competing risks, and personal values.[13]

### B. Many Childhood Vaccines Do Not Prevent Infection or Transmission and/or Have Limited or Uncertain Community-level Impact

While all vaccines should be administered based on SCDM, without any exception, CDC's existing guidelines *already* provide that most vaccines should be SCDM because they do not meaningfully prevent transmission. As CDC's guidance provides: "ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts."[14]

For example, DTaP, Tdap, IPV, and MenACWY do not meaningfully prevent transmission, as detailed in the following link with supporting citations: https://www.sirillp.com/wp-content/uploads/securepdfs/2026/09/Chapter-9-Vaccines-Amen.pdf. Also see an FDA Briefing Document, dated September 20, 2024, titled *Use of Controlled Human Infection Models to Support Licensure of Pertussis Vaccines* which explains that "aP [acellular pertussis] containing vaccines induce helper T cells (TH2) memory and neutralizing antibody responses that effectively prevent symptomatic disease but fail to prevent colonization and carriage."[15]

In a similar vein, HPV is almost exclusively transmitted through sexual contact, and, in most cases, an 11-year-old is not sexually active and may not face any meaningful near-term exposure risk. The decision to vaccinate at age 11 versus later should therefore be based on individualized considerations—anticipated timing of exposure, medical history, and parental values—rather than a uniform community-wide transmission concern. Hence, even putting the significant risks of this product aside, HPV vaccines should be recommended pursuant to SCDM so that clinicians and parents can evaluate risks, benefits, and timing for the individualized child, rather than applying a one-size-fits-all approach.

As a final example, studies reflect that influenza vaccine has not been shown to meaningfully prevent transmission among children[16] and influenza vaccination during pregnancy involves widely varying clinical circumstances and risk profiles, and patients differ in their medical history, prior vaccine reactions, trimester-specific considerations, and personal values. A meaningful recommendation therefore requires an individualized discussion of expected risks and benefits, available alternatives, and the patient's preferences—not a reflexive "routine"

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[12] *See id.*
[13] *See* Makam, *supra* note 8.
[14] *Id.* (emphasis added).
[15] https://www.fda.gov/media/181937/download.
[16] *See, e.g.*, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004879.pub5/epdf/full; https://pmc.ncbi.nlm.nih.gov/articles/PMC3404712/pdf/cis307.pdf.

assumption. This approach is consistent with an evidence-based framework that prioritizes informed consent and individualized care, especially where community transmission benefits are not the driving rationale for giving this vaccine during pregnancy.

The bottom line is that every vaccine should forthwith be moved to the SCDM category so that they will be administered through counseling based on the individual's circumstances. HHS should **eliminate all categories except for SCDM** and treat all vaccines like every other drug or medical procedure.

## II. Every Vaccine Recommendation Must Be Backed by Adequate Clinical Trial Data

The RFI asks how recommendation categories should be structured when randomized controlled trial ("**RCT**") evidence is limited, absent, infeasible, or unethical to obtain.[17] HHS should ensure that no vaccine product is recommended, in any category, by the federal government in this scenario. Whether FDA chooses to license a product in the absence of adequate clinical trial data is a separate question but, regardless of licensure, the federal government must assure that it only recommends vaccine products for which there is adequate RCT data available.

### A. Initial Recommendations or Renewal Recommendations for Each Vaccine Must Be Backed by Adequate Clinical Trial Data

Any recommendation, including an SCDM recommendation, for any vaccine product must only be made where the clinical trial relied upon to license that vaccine, at a minimum:

1. Was **randomized** and **double-blinded** so that all researchers and everyone else involved in conducting the study were not aware of which participants received the experimental vaccine and which received the control;

2. Had a **safety review period** after administration of each dose of at least one year for adults, two years for children, three years preschoolers and toddlers, and four years for infants during which period all adverse events were captured and reported to FDA along with underlying medical records, with the exception of minor events;

3. Was sufficiently **powered** to determine that the vaccine prevents more deaths from the target disease than it causes; and

4. Had a **control** group that received a placebo or another vaccine for the same proposed indication that was licensed per the foregoing requirements, including that the trial had a placebo control.[18]

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[17] *See* 91 Fed. Reg. 54,724.

[18] https://www.ncbi.nlm.nih.gov/pubmed/1330942 (https://perma.cc/T9NY-8NM2) ("a placebo is a pharmacologically inactive substance"); https://www.cdc.gov/vaccines/glossary/#heading-p (https://perma.cc/VR3G-NXNV) (Per CDC's vaccine glossary, a "placebo" is: "A substance or treatment that has no effect on living beings, usually used as a comparison to vaccine or medicine in clinical trials."); https://www.fda.gov/media/130326/download ("Placebos, defined as inert substances with no pharmacologic activity, are commonly used in double-blind, randomized controlled clinical trials."); https://www.fda.gov/media/71349/download ("the placebo control design, by … including a group that receives an inert treatment…").

If vaccines that have historically been recommended by the federal government have not met the above requirements, the government should no longer recommend those products. If a new vaccine is under consideration for a recommendation by the government, it should only be considered if it has met the above requirements.

### B. All Recommendations Concerning Timing of Vaccination, Age of Vaccination, and/or Catch-up Schedules Must Be Backed by Adequate Clinical Trial Data

Similarly, any government recommendation concerning the timing of vaccination, age of vaccination or the catch-up schedule for vaccination should have clinical trial data that meets the requirements listed in Section A, above. Those clinical trials should support any specific recommendation as to when vaccines are given, whether they are given concomitantly, and should establish the overall safety and efficacy of a child receiving the catch-up schedule of vaccines. Absent such clinical trial data, no recommendation should be made.

## III. Every Recommendation Should Be Revisited Every Year

### A. Adequate Safety and Causality Analyses Must Be Performed in Order to Maintain Recommendation

Once a vaccine is recommended by the government, that recommendation should be revisited every year. This will allow for a new assessment of any additional post-marketing data that becomes available and/or any changes that might affect the recommendation.

At the one-year review, at the very least, HHS should require, for each vaccine recommended, that the most commonly claimed injuries from that vaccine are clearly identified and that sufficient and adequate studies are done to conduct a causality assessment. The 2012 IOM report, *Adverse Effects of Vaccines: Evidence and Causality*, laid out a framework for assessing whether vaccines cause specific adverse events.[19] Just as IOM used epidemiologic evidence and mechanistic evidence, so too should HHS to evaluate whether each vaccine's recommendation should remain in place given the results of such an analysis.

In the event that any commonly claimed injury is identified but there are inadequate studies to reach a causality conclusion on whether the vaccine does or does not cause that harm, any recommendation for that vaccine should be withdrawn until the studies have been conducted to reach a causality conclusion.

### B. Safety Surveillance Systems Must Be Fixed to Enable Adequate Safety Analyses

In order to identify the most commonly claimed injuries for each vaccine and conduct an adequate causality assessment as discussed above, proper surveillance systems must exist.

[19] https://www.ncbi.nlm.nih.gov/books/NBK190024/.

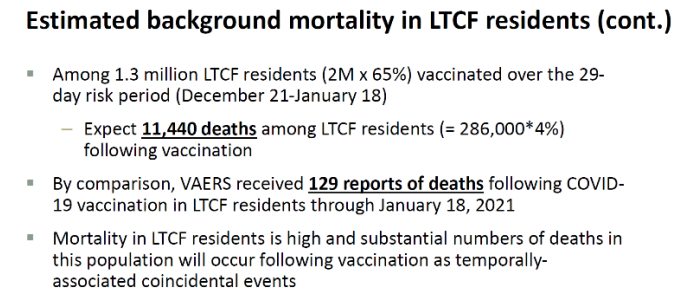
CDC lists 4 "vaccine safety systems" that it relies upon: VAERS, V-safe, CISA, and VSD.[20] Each of these systems has critical and severe limitations and issues that render them inadequate for assessing safety.

### *1. VAERS*

VAERS, the Vaccine Adverse Event Reporting System, has numerous problems, one of which is severe underreporting. An AHRQ-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."[21] 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.[22]

Two recent real-world reflections of this underreporting are seen when looking at reporting of anaphylaxis cases and death after COVID-19 vaccination. According to CDC, "Anaphylaxis occurs [after COVID-19 vaccination] at a rate of approximately 5 cases per one million vaccine doses administered" based on events reported to VAERS.[23] This is in stark contrast to a study at Mass General Brigham that assessed anaphylaxis in a clinical setting after the administration of COVID-19 vaccines and found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[24] This is equivalent to 50 times more cases than what VAERS and CDC are reporting for a condition that occurs almost immediately after vaccination and which vaccine providers are repeatedly advised to report.

A January 27, 2021 ACIP meeting again brought into clear focus this incredible level of under reporting for even cases of death. During that meeting, Tom Shimabukuro, then of CDC's COVID-19 Vaccine Safety Task Force, Vaccine Safety Team, explained that it was expected that 11,440 deaths from long term care facilities (LTCF) would be reported to VAERS given the number of deaths that would naturally occur during the period directly after COVID-19 vaccination in these facilities:[25]




[20] *See* https://www.cdc.gov/vaccine-safety-systems/index.html.
[21] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[22] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.
[23] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.
[24] https://jamanetwork.com/journals/jama/fullarticle/2777417.
[25] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf.

Instead, VAERS only received 129 reports of deaths following COVID-19 vaccination in LTCF (or 1.1%). This again reflects the serious under reporting to VAERS, even for deaths, and is consistent with the study cited above. This is especially troubling since the need to report to VAERS for deaths after COVID-19 has been repeatedly reiterated to vaccination providers and is required by law.[26] If anaphylaxis and death are being underreported, consider the level of underreporting for serious adverse events that do not occur immediately after any vaccination or are not easily identified. This should seriously concern HHS, CDC, and FDA and must be addressed. There are serious safety signals that are likely being missed for all vaccines. Ignoring and casting aside these issues in the drive to vaccinate and promote vaccine confidence may eventually be the undoing of the very confidence HHS seeks to instill. Unless and until underreporting to VAERS is addressed, underreporting to a passive signal detection system will continue to blind health agencies, medical professionals, and patients from what is really occurring in the clinic and will render true informed consent impossible.

The first step to fix it is, at the least, to automate hospital and clinical medical records to automatically send VAERS reports for all clinically significant events occurring within a window of time after vaccination. This already exists for other purposes. It can be done for vaccines as well, which is clear from CDC's own publications on this topic and pages 31 to 34 of ICAN's letter exchange with HHS on this issue available here: https://icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf .

### *2. V-safe*

V-safe was a new safety surveillance system—a smartphone-based tool—rolled out with the COVID vaccines. CDC assured the public, "COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in U.S. history."[27] The V-safe Protocol explained that: "The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[28] V-safe was launched in December 2020 and nine million of the approximately 10 million V-safe users registered between December 2020 and April 2021.[29] The data submitted by 10 million V-safe users, therefore, is likely a good reflection of the experience of the larger population of 270 million Americans who received at least one dose of a COVID-19 vaccine.

V-safe collected data in two ways: the first was check-the-box options limited to (a) symptoms and (b) health impacts. The second allowed users to enter information in free-text fields, up to a certain character limit. As CDC explains: "Any side effects from getting the vaccine are

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[26] See the Fact Sheet for Healthcare Providers Administering Vaccine for each of the three authorized vaccines available at https://www.fda.gov/media/144413/download; https://www.fda.gov/media/144637/download; and https://www.fda.gov/media/146304/download ("The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS): … • serious adverse events* (irrespective of attribution to vaccination)… • cases of COVID-19 that result in hospitalization or death.").

[27] https://web.archive.org/web/20211021222012/https:/www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

[28] https://web.archive.org/web/20210102024902/https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[29] https://icandecide.org/v-safe-data/ (https://perma.cc/2UG6-L8R8).

normal signs the body is building protection."[30] Meaning, the check-the-box symptoms data collected was effectively useless for assessing safety of COVID-19 vaccines. Indeed, the 10 million V-safe users reported over 70 million check-the-box symptoms, and this did not raise any concern for CDC as seen from numerous studies CDC published with high rates of symptoms.[31]

Other than the list of 10 symptoms, the only other check-the-box safety information collected was whether users reported needing medical care, missed school or work, or could not perform normal daily activities (health impact data). If a user selected that he needed medical care, the user was asked to select whether he sought telehealth, urgent care, emergency care, or was hospitalized. The health impact data was collected weekly for the first six weeks after injection and then at 3, 6, and 12 months. In contrast, the check-the-box symptoms data was collected for only the first week after injection. Since CDC dubbed V-safe a "real time" surveillance program, it *must be* the health impact data that it planned to use to rapidly detect any safety issues.[32]

Since 2021, CDC has published more than 40 studies to support its claim that COVID-19 vaccines are safe. The main data used in these studies are the health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. The studies formed the core of CDC's support for the safety of COVID-19 vaccines. However, CDC in all these studies only reports the *first week* of health impact data after injection. Reporting to the public only the first week of health impact data is, at best, highly misleading because CDC is well aware that injuries from COVID-19 vaccines can occur long after the first week.[33]

When the check-the-box data was finally obtained via a Freedom of Information Act ("**FOIA**") lawsuit, it showed that 7.7% of V-safe users reported needing medical care after a COVID-19 vaccine and an additional 25% of V-safe users reported missing school or work or being unable to do normal activities after the injection.[34] That finding was jaw dropping. It showed that nearly 1 in 13 people sought medical care after a COVID-19 vaccine. Worse, on average, each person seeking medical care sought it 2 to 3 times, and approximately 75% of medical care visits were reported as urgent care, emergency room, or hospitalization.

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[30] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html (https://perma.cc/SNU3-4FKR).

[31] See, among others https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm (https://perma.cc/34EP-T9QT); https://www.cdc.gov/mmwr/volumes/70/wr/mm7039e4.htm (https://perma.cc/5FKF-N9F8); https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm (https://perma.cc/R6SF-DX35).

[32] https://web.archive.org/web/20220101081450/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (V-safe "information helps CDC monitor the safety of COVID-19 vaccines in near real time.");
https://web.archive.org/web/20230125013322/https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html ("This information [from V-safe] helps us [CDC] communicate timely and transparent information about the safety of vaccines to public health officials, healthcare providers, and the public.").

[33] For example, myocarditis can arise at least 42 days after vaccination. https://pubmed.ncbi.nlm.nih.gov/34614329/ at Figure 1 (https://perma.cc/JW7L-J5PF). Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. https://web.archive.org/web/20211216171853/https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.

[34] https://icandecide.org/v-safe-data/ (https://perma.cc/F26E-EUY7).

Since V-safe was supposed to assess safety and the only metric that really assessed safety was seeking medical care, if 1 in 13 V-safe users seeking medical care an average of 2 to 3 times each was not enough to declare a safety issue, it is plain V-safe was not created or designed to *ever* find a safety issue. It was created, as has been CDC's practice, to publicly claim it is assessing safety; in reality it is just another system designed to affirm CDC's *a priori* belief and policy that vaccines are safe.

CDC could have made V-safe a rapid and robust safety system by simply including check-the-box options for harms that COVID-19 vaccines can or were suspected to cause. Instead, it purposely chose to not include any of these adverse events of special interests, or their symptoms, as check-the-box options. Instead, it relegated any potential reporting of these harms to the free-text fields, knowing full well that, among other issues, fewer people would report issues in a free-text field (versus a check-the-box option) and this free-text data would be more difficult to standardize. CDC did not design V-safe with the interest of the public in mind – it designed V-safe to ensure that it would affirm its policy that COVID-19 vaccines are safe. This must be changed.

### *3. CISA*

CDC regularly claims that CISA, or Clinical Immunization Safety Assessment, is a critical part of the safety monitoring of vaccines. CDC describes CISA as: "a national collaborating network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), eight medical research centers, and other partners" that was established "to improve the understanding of adverse events following immunization at the individual patient level."[35] CISA, like the other safety surveillance programs, is also not used to assess, but rather to affirm, safety.

For one, as CDC states, "CISA provides consultations for U.S. healthcare providers with complex vaccine safety questions about their patients."[36] ICAN has heard time and again during the COVID-19 vaccine rollout that many people who suffered adverse events after their vaccination were not believed or being treated by their doctors. No one in the medical field would acknowledge that the injury could potentially be a vaccine injury and so those people were unable to utilize CISA as it provides consultations only to healthcare providers and not to individual patients.

Moreover, the Principal Investigator of CISA, Dr. Kathryn Edwards,[37] has also been a paid advisor to Pfizer, was compensated by numerous other pharmaceutical companies as consultant and/or advisor, and was also one of five members of the Pfizer COVID-19 vaccine trial's data safety monitoring board.[38] As explained by bioethicist Arthur Caplan, these boards are "very powerful. They're key guardians of science and safety and are as important if not more important than the FDA."[39] Dr. Edwards had a close look at the Pfizer vaccine trial and the ability to stop the

[35] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.

[36] *Id.*

[37] https://www.vumc.org/vvrp/person/kathryn-m-edwards-md.

[38] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

[39] https://www.cnn.com/2020/10/03/health/dsmb-role-coronavirus-vaccine-trial/index.html.

trial if there were safety concerns. Following the release of that same product, she was consulting with healthcare providers as to whether or not that same product was the cause of their patients' serious injuries. This conflict alone renders the entire CISA program unreliable.

### *4. VSD*

The VSD, or Vaccine Safety Datalink, is a database that contains the vaccination history and medical diagnostic codes (which would reflect what medical conditions a person may have) for over 10 million Americans. While this system could be helpful in assessing vaccine safety, it currently is not. Instead of being used to improve safety, it is used as a tool to silence vaccine critics and expand vaccine recommendations, even for unlicensed off-label uses.

Until around 2001, the VSD was maintained at CDC. Until that time, independent scientists were able to obtain access to the VSD at the request of members of Congress and through other legal means. The issue for CDC is that those scientists' studies found that vaccines cause various harms. CDC could not have that. So, CDC moved the VSD to a health industry trade association in 2001 to avoid having the VSD data subject to FOIA, and to assure that only the scientists and studies it approves, and whose results conform with CDC's policy that vaccines are safe and effective, may utilize the VSD and get published.[40]

This means any study published using the VSD cannot be relied upon due to selection bias, since only studies matching CDC's beliefs are published. If ten other studies using VSD on the same issue did not match CDC's policies, they simply would not have been published. This selection bias renders any study published using the VSD unreliable because there may be a dozen other similar studies that reached the opposite result that simply were not published.

If that were not reason enough to discount any study using the VSD, every study published using the VSD violates the most basic scientific standards and process because the underlying data are almost never available for inspection by the public and other scientists.[41] Refusal to make these data available is another reason to not rely on any VSD study, as they cannot be reproduced by independent scientists. The lack of transparency and reproducibility violates core features of the scientific method. Consider that HHS regulations provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but yet CDC does not apply this same standard to its own VSD studies.[42] It gets worse because the secret studies that CDC performs using the VSD with secret data are virtually all squarely aimed at increasing vaccine uptake.

What the VSD should be used for is to assess the actual safety of vaccines, including the long-term impact of vaccination. As CDC has even acknowledged, public stakeholders "have expressed more concerns about long-term than short-term health outcomes" and "long-term health outcomes have been less well-studied in the context of vaccine safety," but VSD is currently geared toward assessing short-term, and not long-term, health outcomes:

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

[41] https://www.cdc.gov/vaccine-safety-systems/vsd/access-use.html (https://perma.cc/7L2Y-AU7V).

[42] https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information (https://perma.cc/RR3R-3JDT).

> The current safety surveillance systems such as the VSD … 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.[43]

When these studies are finally conducted—as they must be—they should not be conducted by CDC's Immunization Safety Office which works to increase vaccine uptake, communicates about setting policy with pharma companies, and has even been accused by a Senior Scientist at CDC of fraudulently modifying results of prior vaccine studies, including for the purpose of avoiding liability for HHS in Vaccine Court.[44] Nor should the studies be conducted by any organization that would suffer any financial and/or reputational harm from a finding that vaccines can cause certain harms, which would, of course, disqualify HHS or its subagencies from conducting these studies. This is because any finding that vaccines cause, for example, 1 in 5 cases of either allergic rhinitis, ADHD, learning disabilities, or neurodevelopmental delay, all of which studies have found to be related to vaccination, would result in trillions of dollars of liability and a loss of public confidence in HHS and its subagencies.[45]

There is a simple solution that should happen immediately: HHS and CDC, if confident in the safety of childhood vaccines (and if they care at all about preventing harm to children from vaccine products), must simply make the deidentified data in the VSD available to the public (especially given that it is paid for by taxpayers). This way, independent scientists can conduct vaccine safety studies.[46]

## IV. Conclusion

Vaccines should be treated like every other medical intervention. The appropriate approach is one in which the physician and patient/parent consider the patient's particular circumstances, the available evidence, the benefits and risks of the vaccine, reasonable alternatives, and the patient's values and preferences, including religious beliefs. No vaccine should earn the recommendation of the federal government absent adequate clinical trial data and safety assessments. Every recommendation should be revisited every year with an adequate post-marketing analysis of both safety—using improved and effective safety surveillance systems—and efficacy.

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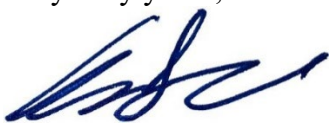
[43] https://www.cdc.gov/vaccine-safety/media/pdfs/white-paper-safety-508.pdf (https://perma.cc/GPK4-BL55).
[44] https://icandecide.org/article/whistleblower-william-thompson-reveals-mmr-vaccines-association-with-autism/ (https://perma.cc/58WB-NLXA).
[45] http://www.oatext.com/pdf/JTS-3-186.pdf (https://perma.cc/8A26-67EC).
[46] The FDA has a system called Post-licensure Rapid Immunization Safety Monitoring System which is of even more limited use than the VSD and suffers from the same issues as VSD and far more. For example, CDC explains it is used "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." https://www.cdc.gov/vaccine-safety/media/pdfs/white-paper-safety-508.pdf (https://perma.cc/GPK4-BL55).

We respectfully urge HHS to adopt these reforms to promote transparent, evidence-based recommendations while preserving meaningful individual and parental choice.

Very truly yours,



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