Exhibit 45

Vaccine Safety Debate
ICAN - Informed Consent Action Network

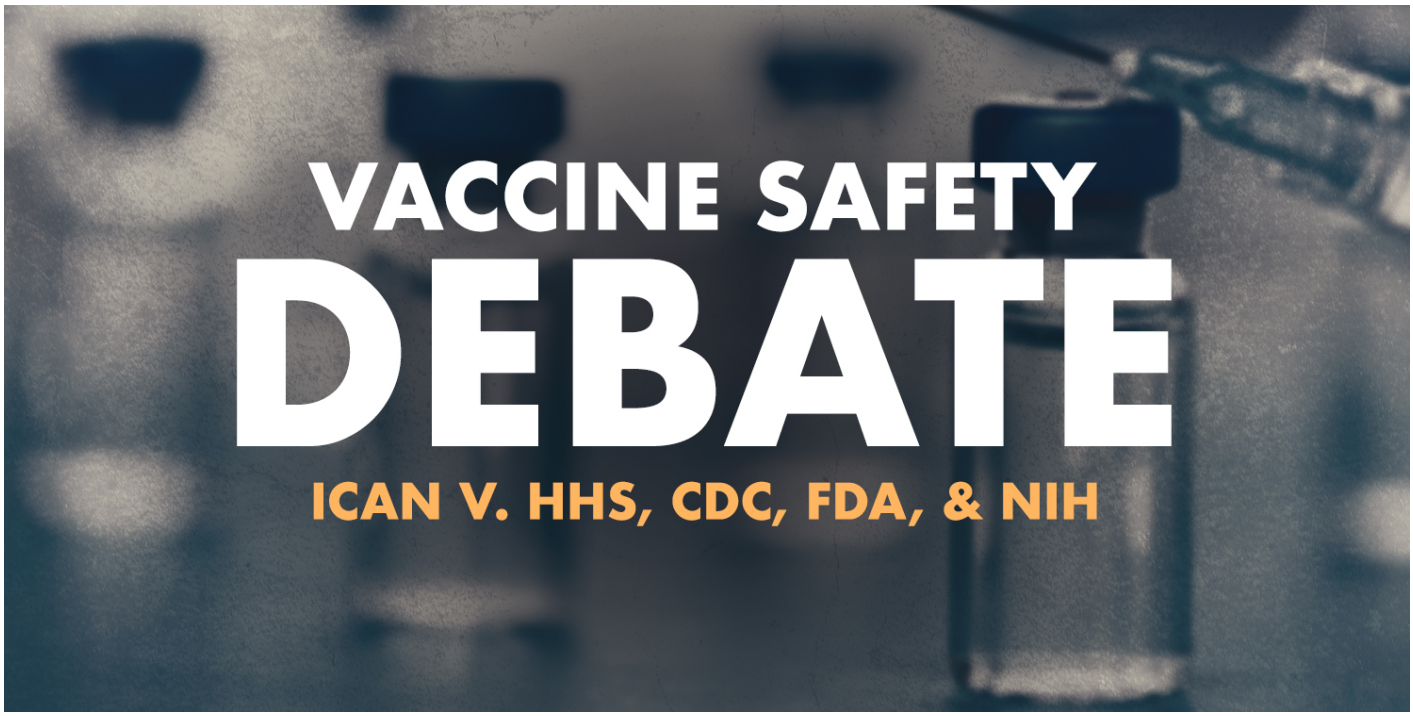
HHS Response heightened serious concerns regarding vaccine safety and the National Childhood Vaccine Injury Act of 1986

https://icandecide.org/article/vaccine-safety-debate/

VACCINES

VACCINE SAFETY DEBATE

June 3, 2021



ICAN vs HHS

On the morning of Tuesday, May 30th, 2017, Robert Kennedy Jr. lead a small delegation of lawyers, scientists, journalists and parents of vaccine injured children onto the campus of the National Institute of Health (NIH), an agency within the United States Department of Health and Human Services (HHS), for a meeting regarding the "Safety Of Vaccines." The meeting was arranged by the newly elected President, Donald Trump, who had expressed concerns about vaccine safety throughout his campaign. Sitting across the long conference room table from the Kennedy delegation were scientists that are considered the world's leading specialists on child health, mental health and vaccines from across the NIH, including:

- Francis Collins – Director of the NIH,

- Anthony Fauci – Director of the National Institute of Allergy and Infectious Disease
- Joshua Gordon – Director of the National Institute of Mental Health,
- Diana Bianchi – Director of the Eunice Kennedy Shriver Institute of Child Health

& Human Development,

- Mary – Sumpter Lapinski – Counselor to the Secretary of Health and Human Services (HHS),
- Linda Birnbaum – Director NIEHS,
- Lawrence Tabak – Principal Deputy Director of NIH, and
- Carrie Wolinetz – NIH Director Chief of Staff.

At the head of the table sat Reed Cordish, President Trump's appointed Assistant on Intergovernmental and Technology Initiatives who was tasked with moderating the discussion.

During the two-hour meeting, Kennedy, one of the world's leading authorities on environmental law, laid out a detailed case regarding many of the most glaring concerns with the childhood vaccine program. Kennedy's presentation laid bare:

- The lack of standard safety studies in the pre-licensing phase of vaccine development, including that there isn't a single childhood vaccine given to babies and children that was licensed based on a placebo-controlled clinical trial.
- The ineffective post licensure vaccine injury surveillance system that apparently fails to capture millions of vaccine injuries in the U.S. every year.
- The conflicts of interest inside the government's regulatory agencies which are tasked with conducting safety studies to protect the public from vaccine dangers while simultaneously defending vaccines in cart against people who have been injured by them.
- The disingenuous public mantra by HHS and its health agencies that "Vaccines Are Safe And Effective" despite the more than fifty thousand vaccine injuries and hundreds of deaths reported each year that have resulted in over four billion dollars in legal settlements to date.

Though Kennedy was addressing the brain trust of vaccine science, one wouldn't have guessed it from their confused and often conflicting responses. For instance, when Kennedy claimed that none of the 16 childhood vaccines injected into children had over been through a "gold standard" double blind placebo study to establish safety prior to licensure, one of the scientists objected declaring, "There most certainly are placebo studies! They are conducted in the early stages of vaccine development." When asked to provide proof of those studies another scientist eventually chimed in and proclaimed "Placebo studies are never conducted for vaccines because it is considered unethical." In the end it was clear that the greatest minds of vaccine science were unprepared to answer the basic questions about vaccine safety the Kennedy delegation asked, even though most of the points and questions raised had been culled from HHS's own literature, studies, and websites.

The meeting was adjourned with moans and grunts of disdain from the body of HHS's leading scientists and agency heads who requested time to assemble answers to basic questions regarding vaccine safety. Over the next two months an email exchange between Kennedy and the body of scientists, headed by Francis Collins, revealed that these scientists were utterly incapable of supporting the safety of childhood vaccines or the childhood vaccine schedule HHS aggressively pushes upon every child in this country. Trump's adviser, Reed Cordish, who had continued to referee the discussion between the two sides online, refused to press the scientists for answers to simple questions they were clearly evading. With that, the promise of a thorough discussion on vaccine safety came to a grinding halt and died behind the closed doors of the NIH. From its ashes was born the idea of the HHS Notice.

Kennedy has consistently described himself as pro-vaccine and pro-child health. In speaking with the NIH scientist he was representing all Americans, irrespective of their views on vaccines, by seeking answers to reasonable safety concerns surrounding the dozens of vaccine products that are injected into virtually every child in America. It was difficult to understand whose interests these scientists were representing when they refused to answer Kennedy's questions regarding vaccine safety. More troubling still was the realization that, because the NIH meeting and follow-up emails occurred behind "closed doors," no one in the world would know that the world's top vaccine scientists had just forfeited the Great Vaccine Debate. It was therefore time to repeat this debate in public.

The original HHS Notice compiled all of the questions that had been raised at the NIH along with additional concerns that had transpired from the meeting and email responses. It was delivered by the Informed Consent Action Network (ICAN) to Eric D Hargan, the Secretary of Health and Human Services, on October 12, 2017. Unlike the NIH meeting, which had been conducted in secrecy, the HHS Notice was announced to the public and had signatures representing over 5 million people through more than 50 organizations. This time the world would learn the truth about the questions and issues surrounding the safety of childhood vaccines and the childhood vaccine schedule.

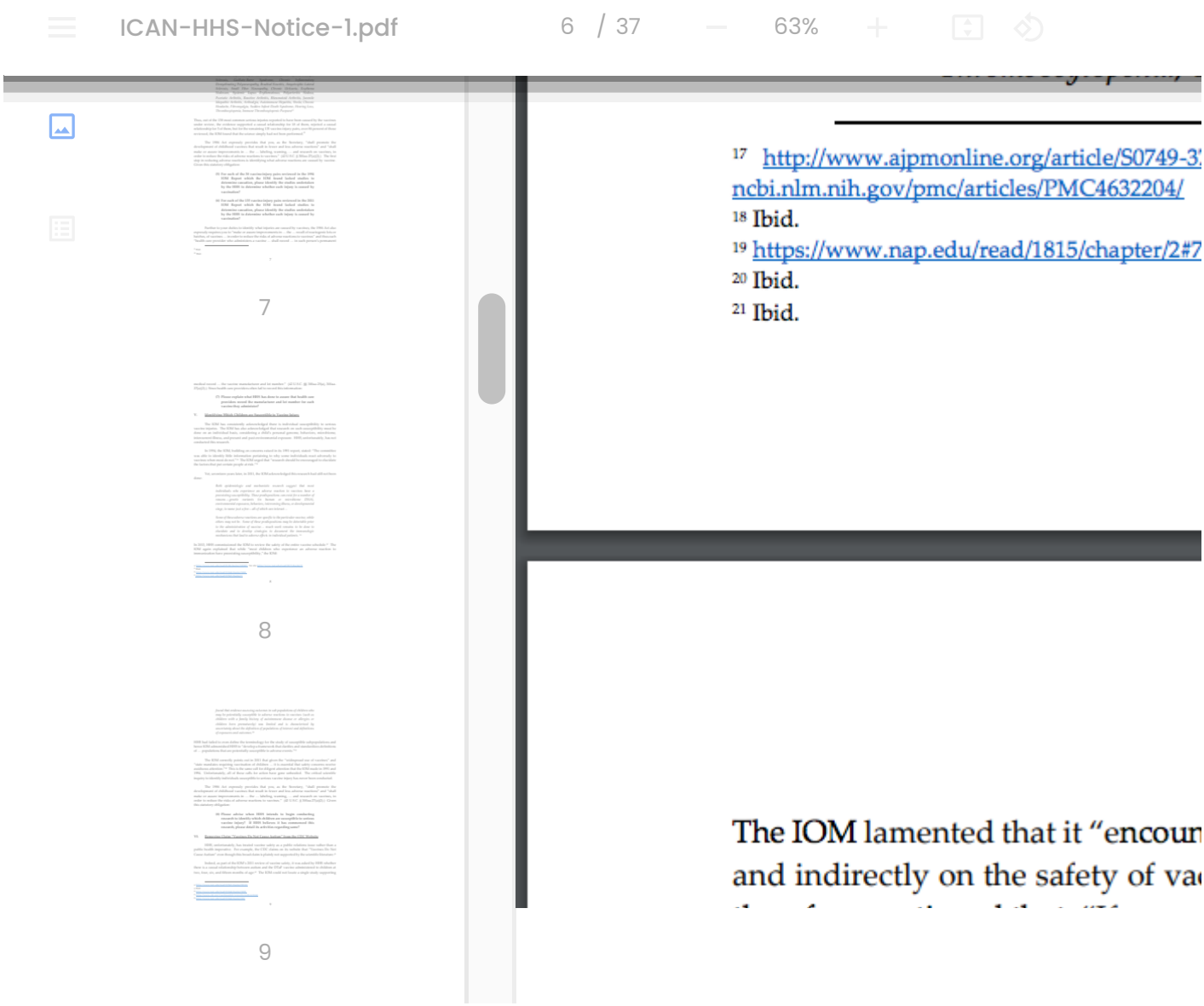
In January of 2018, ICAN received the HHS Response letter. It was a collaboration by multiple agencies within HHS, including CDC, FDA, NIH, and HRSA which made numerous unsupported conclusory assertions, misstatements, and referenced, directly and indirectly, numerous studies aimed at addressing some of the concerns put forth in the HHS Notice. ICAN spent nearly a year doing its due diligence, researching every assertion made by HHS and reading every one of the studies HHS cited to write the detailed ICAN Reply to HHS. In its reply, ICAN described HHS's failure to support many of its most basic claims regarding vaccine safety as well as point out the plainly false and dangerous claims perpetuated by the childhood vaccine program and exemplified by the HHS Response.

This book contains all three of the documents listed above: The HHS Notice, The HHS Response and the ICAN Reply to HHS. The reader who is interested in getting to the heart of the issue quickly can skip ahead to the third chapter and read the final document in the series, the ICAN Reply to HHS. It is self-explanatory and contains excerpts from the original documents to clearly understand the context behind each discussion.

For the more discerning reader, all of the documents and citations have been supplied in this book so that you can see the clear support for every assertion made, which you will note almost all came from HHS's own documents.

This is not fiction. This is not a textbook. This is the official debate on one of the most important subjects in the world – – the safety of our children.

Get a cup of tea or coffee, and get ready to finally read the great vaccine debate so you can make a truly informed decision the next time you need to decide whether to vaccinate yourself or your child.



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

JAN 18 2018

Mr. Del Bigtree
Informed Consent Action Network
10200 US HWY 290 W, Suite 301
Austin, Texas 78736

Dear Mr. Bigtree:

Acting Secretary Hargan has asked me to thank you for your letter expressing interest in vaccine safety and in and the federal policies guiding the licensing, recommendation, and safety monitoring of immunizations, and to respond to you directly.

The Department of Health and Human Services has a far-reaching mission to enhance and protect the health of all Americans. Vaccines are held to the highest standard of safety to both protect people from adverse reactions and enhance their health by preventing a number of serious diseases. I am proud to report that data show the United States currently has the safest supply in history.

I have provided responses to your specific questions in the enclosure to this letter. Thank you for the opportunity to address your concerns.

Sincerely yours,

Melinda Wharton

Melinda Wharton, MD, MPH
Acting Director, National Vaccine Program Office

Enclosure

HHS Responses to Questions and Comments from Mr. Bigtree

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. In addition, there appears to be a misunderstanding regarding the term "solicited" adverse events. Typically, in vaccine trials, 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. Please be assured that vaccine safety is carefully examined regardless of whether there is a placebo included in the clinical trials. Once vaccines are approved, the safety is also carefully monitored, in some cases by manufacturer-conducted post-marketing studies by Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), or the Post-licensure Rapid Immunization Safety Monitoring System (PRISM), as well as other mechanisms.

(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?

Inert placebo controls are not required to understand the safety profile of a new vaccine, and are thus not required. In some cases, inclusion of placebo control groups is considered unethical. Even in the absence of a placebo, control groups can be useful in evaluating whether the incidence of a specific observed adverse event exceeds that which would be expected without administration of the new vaccine. Serious adverse events are always carefully evaluated by FDA to determine potential association with vaccination regardless of their rate of incidence in the control group. In cases where an active control is used, the adverse event profile of that control group is usually known and the findings of the study are reviewed in the context of that knowledge.

(2) Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?

Data relied upon in licensing infant use of hepatitis B vaccines is summarized in the respective package inserts. Furthermore, pediatric data from other countries and in the literature, support the safety of these vaccines in infants. The recommendation for all children to receive these vaccines was made by the Advisory Committee for

Immunization Practices. Their reasoning is summarized in a *Morbidity and Mortality Weekly Report* at https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm. Follow-up studies support the safety of infant vaccination with hepatitis B vaccines.

(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?

On June 30, 2017, the Centers for Disease Control and Prevention (CDC) and FDA implemented a revised reporting form and a new process for submitting reports to the VAERS for non-manufacturer reports. Persons reporting adverse events are now able to use the VAERS 2.0 online reporting tool to submit reports directly online; alternatively, they may download and complete the writable and savable VAERS 2.0 form and submit it using an electronic document upload feature. Vaccine manufacturers submit VAERS reports electronically through the FDA Electronic Submissions Gateway (ESG). With VAERS 2.0 and the FDA ESG, multiple electronic options exist for VAERS reporting.

In addition, CDC is developing the next generation of spontaneous reporting mechanisms for the VAERS. Following its initial work with Harvard, CDC completed a successful proof of concept study with Harvard and other partners that takes advantage of electronic health records (EHR) and computer algorithms to facilitate direct reporting from EHR systems. You can read about that study at https://academic.oup.com/cid/article/61/6/864/451758. CDC continues to explore options to further develop this capability.

(4) Please explain any specific steps taken by HHS to improve adverse reaction reporting to VAERS?

Please see my response to question #3.

(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?

Please refer to the latest review of the "Safety of Vaccines Used for Routine Immunization in the United States" published in 2014 at https://www.ahrq.gov/research/findings/evidence-based-reports/vaccinestp.html. This report reviewed and accepted the findings of the 2011 Institute of Medicine report and provides an independent, systematic review of the literature published after that report on the safety of vaccines recommended for routine immunization of children, adolescents,

and adults in the United States. The report, highlighted in the July 2014 issue of *Pediatrics*, provides the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States. The report concludes that the risk of rare adverse events must be weighed against the protective benefits that vaccines provide. Furthermore, the Centers for Disease Control and Prevention (CDC) has been working to address several of the vaccine-injury pairs that have been identified in the reports mentioned above. A list of CDC vaccine safety publications can be found at: https://www.cdc.gov/vaccinesafety/research/publications/index.html.

(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?

Please see response to question #5.

(7) Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?

Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program (VICP) are required under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), as amended, to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine. This provision of the Vaccine Act applies to any vaccine for which there is a routine recommendation for childhood vaccination, even if many or most doses of the vaccine are administered to adults (e.g., influenza vaccine). In addition, the provider is required to record the edition date of the Vaccine Information Statement (VIS) distributed and the date those materials were provided.

The Advisory Committee on Immunization Practices (ACIP) also issued "General Best Practice Guidelines for Immunization" at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/records.html. This report provides information for clinicians and other health care providers about concerns that commonly arise when vaccinating persons of various ages, and includes a chapter on vaccination records that reinforces the Vaccine Act's requirement to record in the recipient's medical record (or a permanent office log or file) the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine.

(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?

HHS is currently supporting several initiatives that focus on advancing research on the fields of precision vaccinology (vaccine formulations tailored on the individual immune reactivity status) and adversomics (the study of vaccine adverse reactions using immunogenomics and systems biology approaches). Two examples are listed below:

- https://www.immuneprofiling.org/hipc/page/showPage?pg=about
- https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.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?

Vaccines are held to strict standards of safety. Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:

- https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf
- http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx
- http://www.jpeds.com/article/S0022-3476(13)00144-3/pdf?ext=.pdf
  http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx

While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at https://iacc.hhs.gov/publications/strategic-plan/2017/.

(10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of fully/partially vaccinated with completely unvaccinated children?

HHS tasked the Institute of Medicine (IOM) to identify research approaches, methodologies, and study designs that could address questions about the safety of the current schedule. This report is the most comprehensive examination of the immunization schedule to date and can be found at http://nationalacademies.org/HMD/Reports/2013/The-Childhood-Immunization-Schedule-and-Safety.aspx. The IOM committee uncovered no evidence of major safety concerns associated with adherence to the childhood immunization schedule. The committee also cited ethical concerns about conducting a new study to compare the health outcomes of vaccinated children with their fully unvaccinated counterparts, as this would intentionally leave unvaccinated people and the communities they live in subject to increased risk of death and illness.

Should signals arise that there may be need for investigation, however, the report offers a framework for conducting safety research using existing or new data collection systems. One of the systems that the IOM report considered best suited to conduct these types of studies is CDC's Vaccine Safety Datalink (VSD). In response to the IOM report, CDC commissioned a white paper on the feasibility of conducting studies of the safety of the vaccine schedule in VSD. This report states, "Additionally, CDC has started conducting some of the studies mentioned in the white paper." Additional information on the white paper can be found at: https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety_web.pdf.

(11) Please advise if you will:

a. prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?

HHS employs a thorough process for soliciting and vetting candidates for advisory committees to minimize any potential for financial conflicts of interest and works to identify all potential financial conflicts related to the particular matter before a committee. In accordance with 18 U.S.C. § 208(b)(1) and (b)(3), a member of an HHS vaccine advisory committee may be granted a waiver to allow individuals with potentially conflicting financial interests to participate in meetings where it concludes, after close scrutiny, that certain criteria are met. See 18 U.S.C. § 208 for more information.

b. prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?

The current federal ethics laws and regulations do not provide HHS or any other federal agency the authority to restrict the future employment of a career federal employee or an advisory committee member after they leave federal service. However, there are some restrictions on communication by former employees back to their federal agency, such as

a lifetime ban on communicating or appearing before the government on behalf of their new employer or anyone else regarding specific policy matters in which they participated personally and substantially during their entire government service. See 18 U.S.C § 207(a)(1) for more information. There are a number of other exceptions that may apply as well including restrictions on representations to the government for matters under the former employee's official responsibility and restrictions that apply to senior-level government officials.

Federal advisory committee members and career federal employees are prohibited from participating personally and substantially in a particular government matter that will affect their financial interests, as well as the financial interests of their spouse or minor child, general partner, or groups or people covered by 18 U.S.C. § 208. Many federal employees, depending on their duties, must file financial disclosure reports to help identify and mitigate potential conflicts of interest with the employees' duties. See 5 CFR Part 2634. Additionally, special government employees serving on advisory committees must report certain financial interests before attending committee meetings. *See* 5 CFR § 2634.904(a)(2). A 208(b)(3) waiver may be granted to such committee members, based on a determination that the need for the service outweighs the potential for a conflict of interest.

c. require that vaccine safety advocates comprise half of HHS's vaccine committees?

The Vaccine Act defines memberships for the NVAC and ACCV. See 42 U.S.C. §§ 300aa-5 and 300aa-19. The VRBPAC charter states that "Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry." You can learn more about the VRBAC charter at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm129571.htm. The ACIP charter provides that "the committee shall consist of 15 members, including the Chair. Members and the Chair shall be selected by the Secretary, HHS, from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs." You can find out more about the ACIP by reading the charter at

https://www.cdc.gov/vaccines/acip/committee/charter.html. New members are selected based on the candidate's qualifications and their ability to contribute to the specific objectives or needs of the committee, with an overall goal of ensuring a diverse committee that reflects the charge.

d. allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?

The United States has a robust vaccine safety system that closely and constantly monitors the safety of vaccines. Several agencies within HHS dedicate a significant portion of their budgets and expertise to collaboratively ensure that vaccination efforts are as safe as possible. Due to the significant progress made in the last few years to monitor side effects and conduct relevant vaccine safety research, HHS does not foresee drastically changing current budget allocations in this area. However, this could change pending a vaccine safety signal. Likewise, advances in the development of new vaccines or ways of administering immunizations may require additional vaccine safety funding.

To address comments you made in your letter about vaccine monitoring, I want to clarify a few things. The Vaccine Adverse Event Reporting System (VAERS) is a national system to collect reports of adverse events that happen after vaccination. The adverse events reported to this system are not necessarily caused by vaccination and may or may not be a condition that occurred by chance alone, so they must be further investigated. For more information, please visit: https://vaers.hhs.gov/.

HHS places a priority on vaccine safety. To fulfill public health and regulatory functions, the Centers for Disease Control and Prevention (CDC) and FDA use the Vaccine Safety Datalink (VSD) and Post-licensure Rapid Immunization Safety Monitoring System (PRISM) to evaluate if adverse events are related to vaccination. You can find more details about VSD and PRISM at:
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html and
http://onlinelibrary.wiley.com/doi/10.1002/pds.2323/abstract.

e. support the creation of a vaccine safety department independent of HHS?

HHS works in close partnership with other federal, state and local agencies, as well as private entities to monitor and communicate about the safety of U.S. vaccines. To adequately address safety-related issues, strengthen the system that monitors the safety of vaccines throughout production and use, and advance the safety profile of vaccines, the expertise of several groups within HHS is required. For example, FDA regulates vaccine clinical trials, licenses vaccines, and monitors vaccine safety after vaccine use and the Health Resources and Services Administration runs the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program. As HHS plays a significant and cross-cutting role in vaccine safety, the diverse federal

vaccine safety portfolio is coordinated at HHS to leverage collaboration among the many groups, inside and outside of HHS, involved in vaccine and immunization activities.

To address your point about conducting research to uncover long-term adverse events, HHS both conducts research in this area and funds outside research in this area. For example, after a safety signal in Europe indicated an increased risk of narcolepsy, a chronic neurological disorder caused by the brain's inability to normally regulate sleep-wake cycles, after vaccination with a monovalent 2009 H1N1 influenza vaccine, CDC began research to determine if there was a safety issue not only in the United States but globally as well. To respond to this signal, an international team of researchers conducted a dynamic retrospective cohort study to estimate incidence rates of narcolepsy diagnoses using a common protocol on electronic data in seven countries during 2003–2013. For the case control study, conducted according to a common protocol in six countries, cases were identified from sleep center records. Overall, the results of this study did not support an association between receipt of the 2009 H1N1 vaccine and narcolepsy. The successful completion of this study proves that the United States has the infrastructure to not only investigate vaccine safety signals at a local level, but to also collaborate with international partners when such signal is of global concern.

f. support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?
The National Vaccine Injury Compensation Program (VICP) does vital work to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. According to the VICP website, over 5000 petitions were compensated, supply shortages of vaccines have been reduced, and pricing of vaccines stabilized since the program was enacted. Likewise, this program provides an alternative to civil litigation that includes attorney fees and costs. Although the Vaccine Act provides liability protections to manufacturers of covered vaccines in many circumstances, these protections are not absolute. The Vaccine Act provides that there are instances when a manufacturer of a covered vaccine is not protected from liability by the Act, such as when an individual files a petition and is requesting damages of $1,000 or less. In such a case, a civil suit against an administrator may be permitted to be filed in state or Federal court without first filing a petition in the VICP.

Further, a repeal of the National Childhood Vaccine Injury Act of 1986 is unlikely. Congress recently passed the 21st Century Cures Act (Public Law 114-255), which made several amendments to the Vaccine Act. The amendments expand the VICP's coverage to include new vaccines that previously were not covered by the VICP (vaccines recommended by the CDC for routine administration in pregnant women) and make clear

that vaccine-injury claims may be filed both with respect to injuries alleged to have been sustained by women receiving covered vaccines during pregnancy and with respect to injuries alleged to have been sustained by live-born children who were in utero at the time those women were administered such vaccines.

ICAN
Informed Consent Action Network

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-27; 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. ...

[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)
Infalmmatory 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

[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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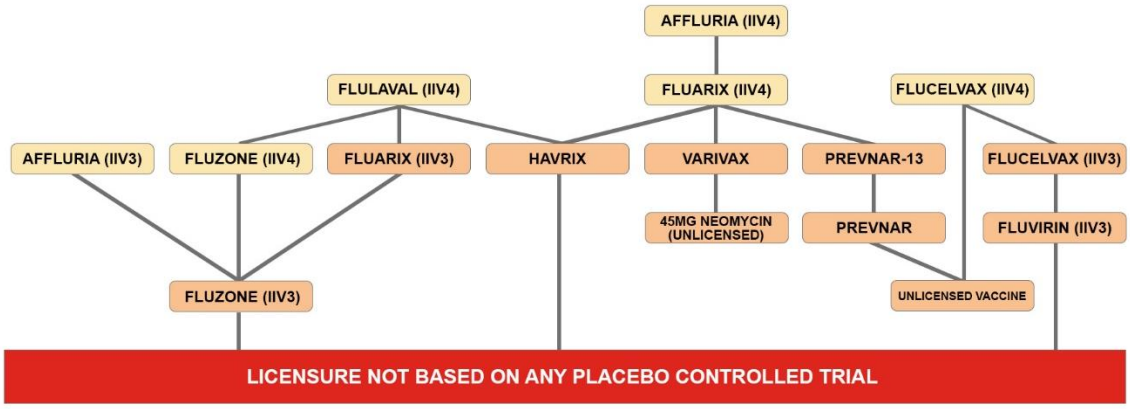
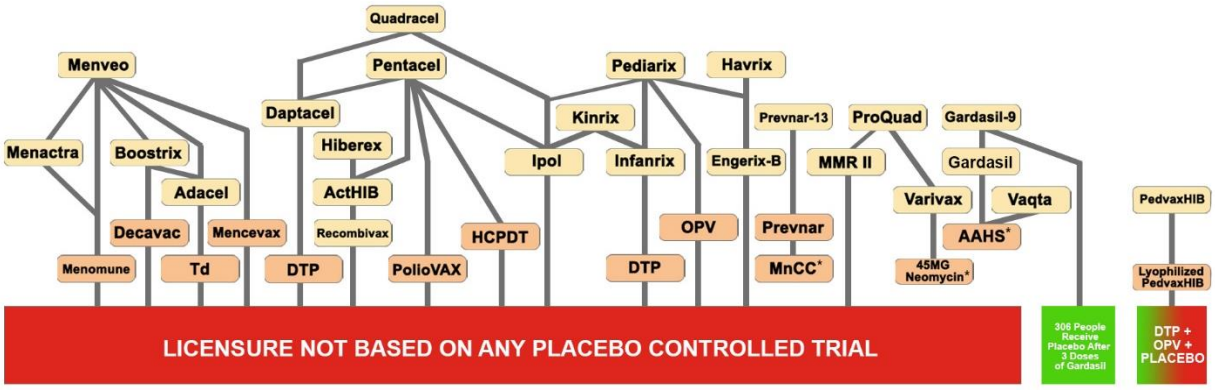
[87] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[88] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[89] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf
[90] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/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:



*Unlicensed

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

[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

[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,

[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;

[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]

[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

[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,

[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.

[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

[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

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.

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[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."

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[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.

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[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.

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[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.

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[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

[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?*

[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

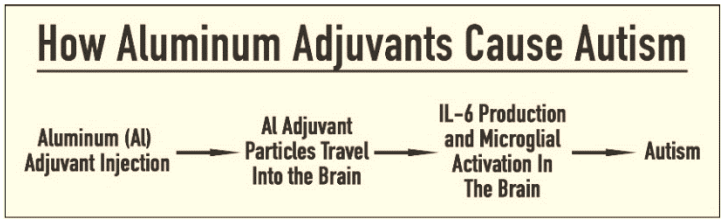
> Dr. Kelley: Yes. They also say there is no proven association.
>
> *Lawyer: Do you agree with the position of the American Academy of Pediatrics?*
>
> Dr. Kelley: I agree with their position as a public health measure. I don't agree with it scientifically.
>
> *Lawyer: You are actually arguing for 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

[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

[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

[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

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

[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

[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

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

[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] http://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=AsOSF5hqCQc&t=356s&index=25&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2 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

[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-doctorsa-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.

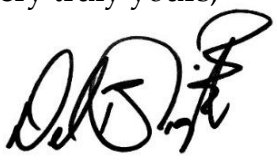
Since vaccine products are injected dozens of times into nearly every baby and child in America and are typically required by law to attend school, they should be tested for safety prior to licensure in extremely well designed clinical trials. Instead the opposite is true. Without impeccable clinical 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.

[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

March 12, 2020

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:

In our letter of October 12, 2017, we notified the Department of Health & Human Services (**HHS**) about a number of serious concerns regarding how 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]

HHS responded to our letter in a reply dated January 18, 2018. That letter was reviewed and cleared by the following agencies within HHS: the Centers for Disease Control and Prevention (**CDC**), the Food & Drug Administration (**FDA**), the National Institutes of Health (**NIH**), the Office of the General Counsel (**OGC**), the Human Resources & Services Administration (**HRSA**), and the Agency for Healthcare Research and Quality (**AHRQ**).[3]

After carefully reviewing the extensive information provided in HHS's reply, ICAN responded by letter dated December 31, 2018.[4] ICAN provided detailed information, mostly from HHS's own primary sources, as to why HHS's reply of January 18, 2018 either did not address or heightened the serious concerns raised in ICAN's prior letter. In that regard, we submitted a number of follow-up questions in Appendix A to that letter.

[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] https://icandecide.org/hhs/vaccines-safety-12-31-18.pdf

It has now been over 13 months since ICAN submitted these follow-up questions and concerns regarding vaccine safety. Nonetheless, HHS has failed to respond to the questions posed in our letter of December 31, 2018, nor to any of the substance in that letter.

HHS's failure and/or apparent inability to respond to ICAN's simple vaccine safety questions and concerns provides further support that the Secretary of HHS has failed to fulfill his vaccine safety obligations pursuant to the 1986 Act.

Absent a substantive response to the questions and substance of our December 31, 2018letter within sixty days of this notice, an action against the Secretary of HHS shall be filed pursuant to 42 U.S.C. § 300aa-31.

For your convenience, copies of the three prior letters are enclosed herein.

ICAN reserves all rights. Govern yourself accordingly.

Very truly yours,

Del Bigtree
President

Enclosures