ICAN
Informed Consent Action Network

VIA FEDEX

October 12, 2017

U.S. Department of Health & Human Services
HHS Office of the Secretary
Eric D. Hargan
Acting Secretary of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Secretary Hargan:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b).

Americans, including the over 55 organizations listed below, whose members exceed 5 million Americans, are concerned about vaccine safety. The National Childhood Vaccine Injury Act of 1986 (the **1986 Act**) made nearly every aspect of vaccine safety the exclusive responsibility of the Department of Health & Human Services (**HHS**). As the Secretary of HHS (the **Secretary**), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. These specific requests are numbered sequentially in this notice. We would welcome the opportunity to meet and discuss reasonable means for complying with these requests. If that is not possible, the 1986 Act authorizes "a civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty" under the 1986 Act.

I. Background

The 1986 Act granted economic immunity to pharmaceutical companies for injuries caused by their vaccines. (42 U.S.C. § 300aa-11.) The 1986 Act thereby eliminated the market force which drives safety for all other products – actual and potential product liability. Recognizing the unprecedented elimination of this market force, the 1986 Act makes HHS directly responsible for virtually every aspect of vaccine safety. (42 U.S.C. §§ 300aa-2, 300aa-27.)

When the CDC recommends a pediatric vaccine for universal use, it creates for that vaccine's maker a liability free market of 78 million children typically required by law to receive the vaccine. The number of required vaccines has grown rapidly since 1986. In 1983, the CDC recommended that babies under one receive two vaccines: DTP and Polio.[1] As of 2017, the CDC recommends that babies under one receive multiple doses of ten vaccines: DTaP, Polio, Hep B, Rotavirus, Hib, Pneumococcal, Influenza, MMR, Varicella, and Hep A.[2] In total, the current CDC childhood vaccine schedule includes 56 injections of 72 doses of 30 different vaccines.

II. Deficiencies in the Pre-Licensure Safety Review of Pediatric Vaccines

All drugs licensed by the FDA undergo long-term double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. For example: Enbrel's pre-licensure trials followed subjects up to 80 months and controls received a saline injection.[3] Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.[4] Boniva's pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.[5] And even with these long-term studies, drugs are still often recalled.

In contrast, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, of the two Hepatitis B vaccines licensed by the FDA for injection into one-day-old babies, Merck's was licensed after trials that solicited adverse reactions for *only five days* after vaccination and GlaxoSmithKline's was licensed after trials that solicited adverse reactions for *only four days* after vaccination.[6] Similarly, the HiB vaccines sold by these same companies were licensed based on trials which solicited adverse reactions for three and four days, respectively, after vaccination.[7] The only stand-alone polio vaccine was licensed after a mere 48-hour follow-up period.[8]

[1] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
[2] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf
[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf
[6] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[7] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf
[8] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf

Moreover, these trials either had no control group or a control group which received other vaccines as a "placebo."[9] This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.

The 1986 Act expressly requires that you, as the Secretary, "shall make or assure improvements in … the licensing … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(1) Please explain how HHS justifies licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an <u>inert placebo</u>?

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

III. <u>Post-Licensure Surveillance of Vaccine Adverse Events</u>

The lack of pre-licensure safety data leaves the assessment of vaccine safety to the post-licensing period when they are being administered to children in the "real world." To capture vaccine adverse events in the real world, the 1986 Act established the Vaccine Adverse Events Reporting System (**VAERS**) operated by HHS. (42 U.S.C. § 300aa-25.)

In 2016, VAERS received 59,117 reports of adverse vaccine events, including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.[10]

However, only a tiny fraction of adverse vaccine events are reported to VAERS. An HHS-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 7[illegible]00 patients and found that "fewer than 1% of vaccine adverse events are reported."[11] A U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."[12]

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[9] Ibid.

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

[11] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[12] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

Assuming VAERS captures a full 1 percent of adverse events – which is more than is estimated – the VAERS data above from 2016 may reflect that in that year alone there were 5,911,700 adverse vaccine events, including 43,[illegible] deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency room visits.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially avoiding these injuries and deaths.

The idea of automating adverse reaction reporting to VAERS is not new or even difficult to achieve.[13] An agency within HHS, the Agency for Healthcare Research and Quality, sought to do exactly that in 2007 when it provided an approximately $1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.[14] The result was the successful automation of adverse event reports at Harvard Pilgrim:

> *Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions … were identified.*[15]

These results should have been concerning to [illegible]HS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.

After automating adverse events reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

> *Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*[16]

After three years and spending $1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting -- not ignored the requests by the HHS's Harvard grant recipients.

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[13] https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system
[14] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[15] Ibid.
[16] Ibid.

While HHS strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.[17] Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.[18] Capturing "fewer than 1% of vaccine adverse events" thirty years after the passage of the 1986 Act is unacceptable -- and potentially deadly.

The 1986 Act expressly provides that you, as the Secretary, "shall make or assure improvements in … adverse reaction reporting … in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

(3) Please explain why HHS failed to cooperate with Harvard to automate VAERS reporting? And detail any steps that HHS has taken since toward automating VAERS reporting?

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

IV. Identifying What Injuries Are Caused by Vaccines

The first step in assuring safer vaccines is to identify what harms they cause. This would normally be accomplished pre-licensure by long-term, inert-placebo controlled trials – but these are never performed for vaccines. As for post-licensure monitoring, HHS has refused to improve VAERS as discussed above. Hence, assessing which vaccines cause which injuries is mainly left to post-licensure studies. HHS, unfortunately, has neglected to perform these studies.

In 1991, the Institute of Medicine (**IOM**) examined 22 commonly reported serious injuries following the DTP vaccine.[19] The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.[20] The IOM, however, found the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries:

> *Aseptic meningitis; Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome; Erythema multiforme; Autism; Peripheral mononeuropathy; Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*[21]

[17] http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf; https://www.ncbi.nlm.nih.gov/pubmed/26209838; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/
[18] Ibid.
[19] https://www.nap.edu/read/1815/chapter/2#7
[20] Ibid.
[21] Ibid.

The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines" and on the poor design of the few existing studies.[22] It therefore cautioned that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."[23]

In 1994, the IOM issued another report which examined the scientific literature for evidence that could either prove or disprove a causal link between 54 commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.[24] The IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.[25] The IOM, however, found the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> *Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*[26]

As in 1991, this IOM Report again stated, "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[27]

In 2011, more than fifteen years after the IOM Reports in 1991 and 1994, HHS paid the IOM to conduct another assessment regarding vaccine safety.[28] This third IOM Report reviewed the available science with regard to the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and rubella.[29] The IOM located science which "convincingly supports a causal relationship" with 14 of these injuries, including pneumonia, meningitis, hepatitis, MIBE, febrile seizures, and anaphylaxis.[30] The review found sufficient evidence to support "acceptance of a causal relationship" with 4 additional serious injuries.[31]

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

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[22] https://www.nap.edu/read/1815/chapter/2#8
[23] https://www.nap.edu/read/1815/chapter/9
[24] https://www.nap.edu/read/2138/chapter/2#12
[25] https://www.nap.edu/read/2138/chapter/2#12
[26] Ibid.
[27] https://www.nap.edu/read/2138/chapter/12
[28] https://www.nap.edu/read/13164/chapter/2#2
[29] Ibid.
[30] https://www.nap.edu/read/13164/chapter/2#3
[31] Ibid.

Encephalitis, Encephalopathy, Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia, Acute Disseminated Encephalomyelitis, Transverse Myelitis, Optic Neuritis, Neuromyelitis Optica, Multiple Sclerosis, Guillain-Barre Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, Brachial Neuritis, Amyotrophic Lateral Sclerosis, Small Fiber Neuropathy, Chronic Urticaria, Erythema Nodosum, Systemic Lupus Erythematosus, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia, Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura[32]

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence supported a causal relationship for 18 of them, rejected a causal relationship for 5 of them, but for the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found that the science simply had not been performed.[33]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) The first step in reducing adverse reactions is identifying what adverse reactions are caused by vaccine. Given this statutory obligation:

(5) For each of the 38 vaccine-injury pairs reviewed in the 1994 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

(6) For each of the 135 vaccine-injury pairs reviewed in the 2011 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?

Further to your duties to identify what injuries are caused by vaccines, the 1986 Act also expressly requires you to "make or assure improvements in … the … recall of reactogenic lots or batches, of vaccines … in order to reduce the risks of adverse reactions to vaccines" and thus each "health care provider who administers a vaccine … shall record … in such person's permanent

[32] Ibid.

[33] Ibid.

medical record … the vaccine manufacturer and lot number." (42 U.S.C. §§ 300aa-25(a), 300aa-27(a)(2).) Since health care providers often fail to record this information:

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

V. Identifying Which Children are Susceptible to Vaccine Injury

The IOM has consistently acknowledged there is individual susceptibility to serious vaccine injuries. The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure. HHS, unfortunately, has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 report, stated: "The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."[34] The IOM urged that "research should be encouraged to elucidate the factors that put certain people at risk."[35]

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

> *Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact…*
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> *Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine… much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.* [36]

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.[37] The IOM again explained that while "most children who experience an adverse reaction to immunization have preexisting susceptibility," the IOM:

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[34] https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9

[35] Ibid.

[36] https://www.nap.edu/read/13164/chapter/5#82

[37] https://www.nap.edu/read/13563/chapter/1

> *found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes*.[38]

HHS had failed to even define the terminology for the study of susceptible subpopulations and hence IOM admonished HHS to "develop a framework that clarifies and standardizes definitions of … populations that are potentially susceptible to adverse events."[39]

The IOM correctly points out in 2011 that given the "widespread use of vaccines" and "state mandates requiring vaccination of children … it is essential that safety concerns receive assiduous attention."[40] This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has never been conducted.

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

> **(8) Please advise when HHS intends to begin conducting research to identify which children are susceptible to serious vaccine injury? If HHS believes it has commenced this research, please detail its activities regarding same?**

VI. Removing Claim "Vaccines Do Not Cause Autism" from the CDC Website

HHS, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that "Vaccines Do Not Cause Autism" even though this broad claim is plainly not supported by the scientific literature.[41]

Indeed, as part of the IOM's 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.[42] The IOM could not locate a single study supporting

[38] https://www.nap.edu/read/13563/chapter/9#130
[39] Ibid.
[40] https://www.nap.edu/read/13164/chapter/3#28
[41] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[42] https://www.nap.edu/read/13164/chapter/2#2

that DTaP does not cause autism.[43] The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[44] The IOM's full explanation in its 2011 Report for this finding is attached as Appendix B. In fact, the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.[45] No research has been published since 2011 that could change the IOM's conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that there is no causal relationship between vaccines and autism. The CDC nonetheless claims on its website that "Vaccines Do Not Cause Autism."

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive, typically multiple times, by one year of age.[46]

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.[47] Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC's pediatric vaccine schedule cannot support the CDC's overarching declaration that "Vaccines Do Not Cause Autism."

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson[48], recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.[49] Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."[50] Dr. Thompson further stated on that call:

> *I have great shame now when I meet families with kids with autism because I have been part of the problem … the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway*

[43] https://www.nap.edu/read/13164/chapter/12#545
[44] Ibid.
[45] Ibid. Ironically, this study was disregarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which would be true of any study using VAERS data.
[46] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent. html
[47] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[48] Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC's vaccine safety claims. https://www.ncbi.nlm.nih.gov/pubmed
[49] http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf
[50] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio

> *there's still a lot of shame with that. … I am completely ashamed of what I did.*[51]

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.[52]

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."[53] When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"[54]

Former NIH Director Dr. Healy goes on to explain:

> *This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. …*
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> *The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*[55]

The CDC has also failed to address the science supporting a link between vaccines and autism.[56] For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.[57] Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated

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[51] Ibid.
[52] Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. https://doi.org/10.1093/oxfordjournals.aje.a116479
[53] http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/
[54] Ibid.
[55] Ibid.
[56] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[57] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf

children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.[58] There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.[59] Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. Without proper long-term trials comparing those receiving the vaccine to an inert-placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated with unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done. The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP vaccine, let alone the entire vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, are to "develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table." (42 U.S.C. § 300aa-26(a).) This section further provides that:

> The information in such materials shall be based on available data and information … and shall include … (1) a concise description of the benefits of the vaccine, (2) a concise description of the risks associated with the vaccine, (3) a statement of the availability of the National Vaccine Injury Compensation Program, and (4) such other relevant information as may be determined by the Secretary.

(42 U.S.C. § 300aa-26(c).) The VIS produced for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, www.cdc.gov.[60] The CDC website in turn claims that "Vaccines Do Not Cause Autism."[61] Since HHS has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must be "based on available data and information." *Id*. But, based on available data and information, as highlighted by the IOM, HHS cannot validly claim that "Vaccines Do Not Cause Autism." Hence:

[58] http://www.oatext.com/pdf/JTS-3-186.pdf; http://www.oatext.com/pdf/JTS-3-187.pdf
[59] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf
[60] https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
[61] https://www.cdc.gov/vaccinesafety/concerns/autism.html

(9) Please confirm that HHS shall forthwith remove the claim that "Vaccines Do Not Cause Autism" from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?

VII. Refusal to Conduct Vaccinated Versus Unvaccinated Study

The only scientifically valid way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered and controlled study comparing the rate of all adverse events between vaccinated children and completely unvaccinated children. This is the same type of study required by HHS for every drug pre-licensure. HHS has nonetheless refused to conduct any such study, even retrospectively.

The need for this study is highlighted by the results of a few recent limited vaccinated vs. unvaccinated studies.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.[62] In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.[63] Dr. Aaby's study therefore concluded that: "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[64] More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[65] This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[66]

It is equally troubling that Dr. Abby's study was based on data that had been collecting dust for over 30 years[67] This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science.

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.[68] The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk

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[62] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D

[63] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ Dr. Aaby's study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby's study was one of the few specifically designed to avoid this error.

[64] Ibid.

[65] Ibid.

[66] Ibid.

[67] Ibid.

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

of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.[69] Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.[70]

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.[71] Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.[72] Like the DTP study, the flu vaccine increased susceptibility to other infections.

A properly sized vaccinated versus unvaccinated study is necessary and possible. As stated by the IOM in 2013: "It is possible to make this comparison through analyses of patient information contained in large databases such as VSD."[73] Senior CDC Scientist, Dr. Thompson similarly stated this type of study can and "needs to be done" but that the CDC is "not doing what they should be doing because they're afraid to look for things that might be associated."[74] When vaccine makers are generating over $33 billion in vaccine revenue annually and the CDC is spending over $5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.[75]

The 1986 Act expressly provides that you, as the Secretary, "shall promote the development of childhood vaccines that result in fewer and less adverse reactions" and "shall make or assure improvements in … the … labeling, warning, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." (42 U.S.C. § 300aa-27(a)(2).) Since comparing children receiving the vaccines recommended by the CDC with those that have not received any vaccines is the only scientifically valid way to assess the safety of the CDC's vaccine schedule:

> **(10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of**

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[69] Ibid.

[70] http://www.oatext.com/pdf/JTS-3-187.pdf

[71] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/

[72] Ibid. *See also* http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf (The CDC in 2001 apparently conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not. The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays. Note that while the abstract discusses comparing thimerosal exposure, since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study appears to have primarily compared children receiving Hepatitis B with children that did not receive this vaccine.)

[73] https://www.nap.edu/read/13563/chapter/2#13

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

[75] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf; https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html

fully/partially vaccinated children with completely unvaccinated children?

VIII. Reducing Conflicts of Interest at HHS

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS. The 1986 Act's scheme thus places HHS in charge of two competing duties. On one hand, HHS is responsible for vaccine safety. On the other hand, HHS is required to promote vaccine uptake and defend against any claim they cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense function to such a degree that it has essentially abandoned its vaccine safety function. To restore balance, HHS must take serious steps to create an "ethics firewall" between these competing functions. HHS also must take action with regard to its vaccine committee members and employees that have conflicts with vaccine makers.

HHS Licenses & Recommends Vaccines. With regard to the FDA's Vaccines and Related Biological Products Advisory Committee (**VRBPAC**), which effectively decides whether to license a vaccine, in 2000 the U.S. House Committee on Government Reform (the **Committee**) "determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."[76] The Committee concluded of the VRBPAC: "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."[77]

With regard to the CDC's Advisory Committee on Immunization Practices (**ACIP**), which effectively decides whether to universally recommend a pediatric vaccine, the Committee found that ACIP members routinely fail to disclose conflicts with vaccine makers and when conflicts are disclosed "[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts."[78] The Committee drew focus on the vaccine most recently approved by the ACIP and found extensive and troubling conflicts of interest for most the ACIP members voting to recommend its universal use for children.[79] The Committee was further concerned that "ACIP liaison representatives have numerous ties to

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[76] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf (For instance, "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had significant financial ties to pharmaceutical companies that were developing different versions of the vaccine.")

[77] Ibid.

[78] Ibid.

[79] Ibid. (The Committee's findings were that: (1) The chairman served on Merck's Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a $350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division, a principal investigator for SmithKline and received funds from various vaccine makers; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.)

vaccine manufacturers" but act like voting members of ACIP.[80] The Committee further took issue with the extensive conflicts of interests of members of ACIP's working groups which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.[81] The Committee concluded that ACIP reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[82]

Despite the concerns the Committee expressed in its 2000 report, not much changed. A December 2009 report by the HHS Office of Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for SGEs [a.k.a. **committee members**]".[83] For example, "Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."[84]

In fact, the Inspector General found that the "CDC certified [conflict disclosure forms] with at least one omission in 2007 for 97 percent … of SGEs," "58 percent … of SGEs had at least one potential conflict of interest that CDC did not identify," and when the CDC identified a conflict, it improperly granted broad waivers despite being castigated for this improper practice in 2000.[85] Even worse, "32 percent … of SGEs … had at least one potential conflict of interest that CDC identified but did not resolve" and 13 percent of SGEs were allowed to participate in committee meetings without even having a conflict disclosure form on file.[86]

As the system is set up, an ACIP vote to recommend a vaccine, grants a vaccine manufacturer a liability-free market of 78 million American children, who are legally compelled to receive the vaccine, and billions of taxpayer dollars guaranteeing payment. In such a system, an ACIP vote must be completely insulated from any influence by the vaccine manufacturer. Instead, the opposite appears to be the norm.

HHS Promotes Vaccines. Moreover, while the CDC states on its website -- not less than 130 times -- that "CDC does not accept commercial support," this is simply not true.[87] For example, the British Medical Journal reported in 2015 that: "Despite the agency's disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking."[88] As another example, pharmaceutical companies and other private entities, through the "CDC Foundation," can create and fund programs at the CDC (over half a billion dollars' worth to-date), endow positions at the

[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[84] http://www.nytimes.com/2009/12/18/health/policy/18cdc.html
[85] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf (Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.)
[86] Ibid.
[87] https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main
[88] http://www.bmj.com/content/350/bmj.h2362

CDC, and even place individuals to work at the CDC, paid through "private funding." (42 U.S.C.A. § 280e-11(h)(1), (2).)

Worse, the promotion track for CDC management extends into vaccine makers. The most prominent example is former CDC Director Dr. Julie Gerberding, who headed the agency from 2002 through 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported $2.5 million annual salary and lucrative stock options.[89]

HHS Defends Vaccines. After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with very limited safety data, this very same government agency is mandated to defend against any claim that the vaccine caused harm.

There is no other for-profit product where the very department responsible for regulating that product is statutorily required to promote its uptake and simultaneously defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury. (42 U.S.C. § 300aa-10 *et seq*.)[90] The injured must litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury. (§ 300aa-12.) DOJ and HHS have the government's vast resources, while the injured child must secure a private attorney. (§ 300aa-15.) Moreover, the injured child's damages are limited to $250,000 for death and pain and suffering. (*Id*.)

Worst of all, the injured child must almost always prove "causation" – the biological mechanism by which the vaccine injured the child.[91] Requiring an injured child to prove causation adds insult to injury because had HHS conducted the vaccine safety science it demands as proof in the VICP before licensing a vaccine, the child's injury may have been avoided altogether.

This truly is the epitome of injustice: requiring a child receiving a compulsory pharmaceutical product to medically prove to HHS how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government department, HHS, tasked with this job.[92] As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.[93] It has failed to conduct even one properly sized study comparing vaccinated to

[89] https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884
[90] *See also* Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)
[91] http://www.gao.gov/assets/670/667136.pdf
[92] See Sections II, III, IV, V, VI, and VII above.
[93] See Section IV above.

unvaccinated children, despite all the resources at its disposal.[94] It is no wonder a single injured child's claim faces a high likelihood of failure in the VICP.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief an insidious intent. Rather, this system eliminates the incentive, and in fact creates a disincentive for HHS and vaccine makers, to conduct research to uncover long term chronic conditions, including the immune and neurological system disorders, which can result from the current vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, have at least equal and arguably greater responsibility for vaccine safety than for vaccine promotion. (42 U.S.C. §§ 300aa-2, 300aa-27.) In accordance with this statutory responsibility:

(11) Please advise if you will:

a. prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?
b. prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?
c. require that vaccine safety advocates comprise half of HHS's vaccine committees?
d. allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?
e. support the creation of a vaccine safety department independent of HHS?
f. support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?

IX. Conclusion

HHS can do better. With hundreds of vaccines in the pipeline it must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will in fact strengthen the vaccine program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to HHS's vaccine program due to safety concerns.

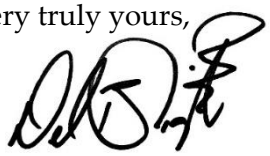
[94] See Section VII above.

Unless HHS performs its vital statutory obligations regarding vaccine safety, and until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injuries. Nor will children injured by vaccines be able to access the services they need. We can do far better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination. The first step in avoiding these harms and helping children already harmed is admitting there are deficiencies and working diligently to improve vaccine safety.

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. These, in fact, reflect nothing more than what Congress already explicitly recognized when passing the 1986 Act: vaccines can and do cause serious injury and HHS needs to work diligently to identify and reduce these harms. If you would like to meet and discuss the foregoing, we would welcome that opportunity and hope to work cooperatively to address these issues.

If that is not possible, Congress, as a final resort to assure vaccine safety, authorized a "civil action … against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under" the 1986 Act. (42 U.S.C. § 300aa-31(a).) We are prepared to authorize such an action and this letter constitutes the notice required by 42 U.S.C. § 300aa-31(b). It is, however, our hope that the vaccine safety issues identified herein can be resolved cooperatively, with all interested parties working together toward the common goal of vaccine safety entrusted to HHS under the 1986 Act.

Very truly yours,



Del Bigtree

cc: See Appendix A.
Enclosures: Appendices A to C.

Appendix A

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Appendix B

Adverse Effects of Vaccines

Evidence and Causality

Committee to Review Adverse Effects of Vaccines

Board on Population Health and Public Health Practice

Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,
Editors

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

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Adverse Effects of Vaccines: Evidence and Causality

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

Mechanistic Evidence

The committee identified one publication reporting the development of ataxia after the administration of DTaP vaccine. Kubota and Takahashi (2008) did not provide evidence of causality beyond a temporal relationship of 2 days between vaccine administration and development of cerebellar symptoms leading to a diagnosis of acute cerebellar ataxia. The publication did not contribute to the weight of mechanistic evidence.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia as lacking.

Causality Conclusion

Conclusion 10.5: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

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

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Adverse Effects of Vaccines: Evidence and Causality

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

ACUTE DISSEMINATED ENCEPHALOMYELITIS

Epidemiologic Evidence

No studies were identified in the literature for the committee to evaluate the risk of acute disseminated encephalomyelitis (ADEM) after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, or acellular pertussis antigens alone or in combination.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and ADEM.

Mechanistic Evidence

The committee identified five publications of ADEM developing after the administration of vaccines containing diphtheria toxoid and tetanus toxoid antigens alone or in combination. Four publications did not provide evidence beyond temporality, one of which was deemed too short based on the possible mechanisms involved (Abdul-Ghaffar and Achar, 1994; Bolukbasi and Ozmenoglu, 1999; Hamidon and Raymond, 2003; Rogalewski et al., 2007). In addition, Rogalewski et al. (2007) reported the administration of vaccines against hepatitis B, hepatitis A, and poliovirus in

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Appendix C

a place of mind
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June 24, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am writing to you in regard to aluminum adjuvants in vaccines. This subject is one my laboratory works on intensively and therefore one where I feel that I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder (ASD). Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

These studies and the broader existing literature regarding aluminum toxicity, lead almost invariably to the conclusion that aluminum in any chemical form is always neurotoxic when administered to humans. Further, I am convinced that aluminum adjuvants in vaccines may contribute to neurological disorders across the lifespan. In adults, such adjuvant may induce macrophagic myofasciitis, a disease with neuropathological aspects. In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans even though, pursuant to the recommended vaccine schedule published by the Centers for Disease Control (CDC), a baby may be injected with up to 3,675 micrograms of aluminum adjuvant by six months of age.

In regard to the above, it is my belief that the CDC's claim on its website that "Vaccines Do Not Cause Autism" is wholly unsupported. Given this, I remain convinced that much more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is warranted and should be a research priority for the NIH and other funding bodies.

Yours sincerely,

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Relevant Publications (Shaw Laboratory)

1. Crepeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, giros B, authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective dose neurotoxicity. *Toxicology*. 375:48-57. (2016).

2. Crepeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *J. Inorg. Biochem*. 152:199-205. (2015).

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June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants toxicity in humans and animal models. I have been working in this field since the initial description of the AI vaccine-induced macrophagic myofasciitis in 1998. Since that time I have written 40 peer-reviewed scientific publications and one book on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours very sincerely

Romain K. Gherardi
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Selection of significant publications from our group in the field

Gherardi R. Toxic Story: deux ou trois vérités embarrassantes sur les adjuvants des vaccins. **Actes Sud** (publisher), Paris, 2016, 250 pages

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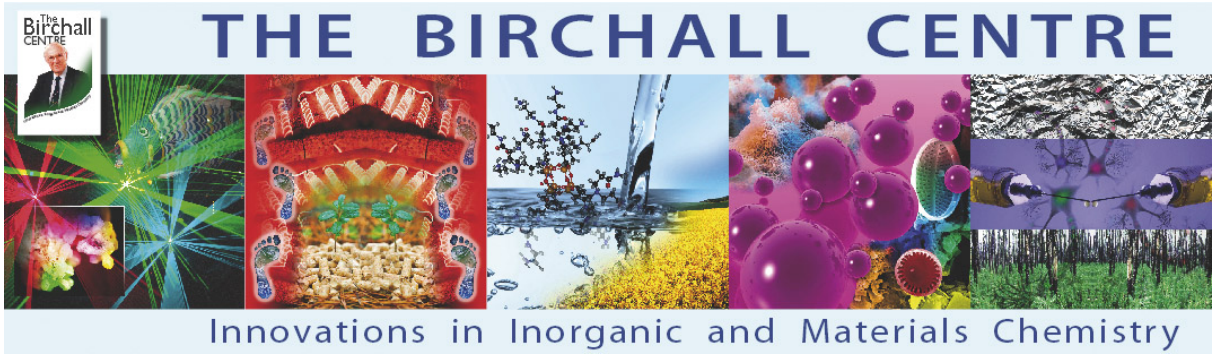

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June 15, 2017

United States Department of Health & Human Services
National Institutes of Health
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Centers for Disease Control & Prevention
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

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The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours faithfully

Christopher Exley PhD
Professor in Bioinorganic Chemistry

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List of Recent, Relevant and Significant Publications From Our Group

Exley C, Siesjö P & Eriksson H (2010) The immunobiology of aluminium adjuvants: how do they really work? Trends in Immunology 31, 103-109.

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Exley C (2014) Why industry propaganda and political interference cannot disguise the inevitable role played by human exposure to aluminium in neurodegenerative diseases, including Alzheimer's disease. Frontiers in Neurology **5**:212. doi: 10.3389/fneur.2014.00212.

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