National Vaccine Information Center

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Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality (AHRQ)
5600 Fishers Lane,
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Re: Federal Register Notice 85 FR 21855 - Request for Supplemental Evidence and Data Submissions - Supplemental Evidence and Data Request on Safety of Vaccines Used for Routine Immunization in the United States

Attention: EPC SEADs Coordinator

The charitable non-profit National Vaccine Information Center (NVIC), founded by parents of vaccine injured children in 1982 to prevent vaccine injuries and deaths through public education, has called for methodologically sound scientific studies to evaluate health outcomes post vaccination ever since our work with Congress to secure informing, recording, reporting and research provisions in the National Childhood Vaccine Injury Act of 1986.[1] [2]

Within that federal law is language emphasizing the need to develop institutional mechanisms for increasing vaccine safety and reducing the occurrence of vaccine injuries and deaths, which cannot be achieved without a comprehensive understanding of the biological mechanisms for vaccine injury and death and identification of individuals with genetic, epigenetic, environmental and other risk factors for increased susceptibility to adverse responses to vaccination.

In response to the AHRQ's request, below is a summary of concerns relating to questions outlined within the Federal Register notice.

Findings by the Institute of Medicine, National Academies of Science

After the 1986 National Childhood Vaccine Injury Act became law in 1986, the National Academy of Sciences Institute of Medicine (IOM), which was renamed the Health and Medicine Division (HMD) in 2015, was contracted by the U.S. Department of Health and Human Services (HHS) to convene physician committees to review epidemiological and biological mechanism evidence related to vaccine safety. In 1991, [3] and 1994,[4] [5] IOM published landmark reports on whole cell pertussis, tetanus and diphtheria vaccines in DPT; rubella, measles, mumps vaccines in MMR; and polio, HIB and hepatitis B vaccines. Those IOM reviews were conducted in response to a vaccine safety research provision included in the 1986 Act at the request of parents of vaccine injured children for an independent evaluation of evidence for vaccine safety.

Continuing to respond to the mandate by Congress in the 1986 Act for DHHS to review and improve vaccine safety, between 1995 and 1998 with HHS funding, the IOM convened the Vaccine Safety Forum composed of vaccine stakeholders and held public workshops to discuss vaccine safety issues of concern to the public.[6] In 1997, IOM published several reports summarizing discussions during the public workshops held by the Vaccine Safety Forum and addressed better ways

to detect and respond to vaccine adverse events; ideas for scientific research to identify individual susceptibility to vaccine reactions and better understand the biological mechanisms for and possible means of preventing adverse health outcomes after vaccination, and how to engage in effective vaccine risk communication.[7] [8]

Between 2001 and 2005, the IOM was contracted by HHS to convene physician committees to evaluate the safety of vaccines and vaccine programs within the context of public health policies and goals. IOM held a public meeting on Jan. 11, 2001[9] and published a series of nine physician committee reports on topics such as multiple vaccinations and immune dysfunction;[10] the safety of Thimerosal containing vaccines and neurodevelopmental disorders;[11] hepatitis B vaccine and demyelinating neurological disorders[12] and included a review of emerging vaccine safety research concerns.[13]

However, the 2012 IOM report, Adverse Effects of Vaccines: Evidence & Causality, is one of the most important independent vaccine safety evidence reviews since 1991 and 1994, because the IOM physician committee evaluated both the biological mechanisms and epidemiological evidence for the safety of eight vaccines that are federally recommended and mandated by states for children and adults.

While there was historic official confirmation by the scientific community in the 1991 and 1994 IOM reports that vaccines can cause brain and immune system dysfunction and death, those reports also highlighted vaccine science gaps that prevent a complete understanding and evaluation of adverse responses to vaccination.[14] [15] The 2012 report funded by DHHS and conducted by IOM importantly re-affirmed that fact and also, once again, clearly acknowledged biodiversity and the fact that there is increased individual susceptibility for harm from vaccination.[16] The acknowledgement that certain biological genetic, epigenetic and environmental factors can increase the risk of vaccine injury but doctors cannot reliably predict who will be harmed by vaccination because of current knowledge gaps, should have stimulated interest and secured support within DHHS for funding independent scientific research that will help reduce vaccine risks for those who are most vulnerable to suffering life-altering chronic health conditions and disabilities or dying as a result of receiving of one or more vaccinations.

Similar findings pointing out knowledge and research gaps in vaccine science were echoed in the 2013 report published by the IOM with DHHS funding, which examined evidence for the safety of the federally recommended vaccine schedule for infants and children between birth and six years old. After IOM held a public workshop to discuss vaccine stakeholder concerns,[17] [18] the report published by IOM identified fewer than 40 studies specifically addressing the safety of the early childhood vaccine schedule. The IOM committee tasked with reviewing evidence for the safety of the schedule that pediatricians use to vaccinate infants and children noted the following:

- Few 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 has directly examined health outcomes and stakeholder concerns in precisely the way that the committee was charged to address its statement of task;"
- "No studies have compared the differences in health outcomes that some stakeholders questioned between entirely unimmunized populations 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;"
- "The committee believes that although the available evidence is reassuring, 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;" and
- "Providers are encouraged to explain to parents how each new vaccine is extensively tested when it is approved for inclusion in the recommended immunization schedule. However, when providers are asked if the entire immunization schedule has been tested to determine if it is the best possible schedule, meaning that it offers the most benefits and the fewest risks, they have very few data on which to base their response;"

Inherent Conflicts of Interest

After the IOM issued their report on the early childhood vaccine schedule in 2013, DHHS contracted RAND Corporation to conduct a "systematic review of the literature" on the safety of federally recommended vaccines. Authors of the DHHS-funded RAND review concluded that "the evidence showed that vaccines are very safe" and serious vaccine reactions are "extremely rare." The review, which was requested and funded by the National Program Office (NVPO) in the Office of the Secretary for Health through the federal Agency for Healthcare Research and Quality (AHRQ)[19] was published July 1, 2014 in Pediatrics, and largely ignored vaccine safety research and knowledge gaps identified and documented in over 20 years of published reports by the IOM.

In the DHHS-funded RAND vaccine safety review, 9 out of 10 study authors were employed by RAND, which has served primarily as a Department of Defense (DOD) contractor since the corporation was founded in 1948.[20]

- Of the seven members of the Technical Expert Panel assisting with design of the federally funded study, two were high ranking DHHS officials responsible for ensuring vaccine safety; two are employed by health care maintenance corporations that partner with DHHS to provide electronic patient medical records for DHHS to conduct vaccine safety studies; and one is an academic vaccine researcher with significant DHHS funding ties;

- Of the four peer reviewers asked to review the federally funded study, two were DHHS employees (one is a high ranking CDC official responsible for ensuring vaccine safety) and one is a Department of Veteran Affairs employee;

- A conflict of interest disclaimer for technical experts and peer reviewers of the report stated that those individuals "must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts of interest may be retained."

Due to these conflicts of interest, the DHHS/RAND review of vaccine safety science did nothing to reassure educated health care consumers that vaccine reactions are rare, that most federally recommended vaccines are safe for everyone, and that there is no urgent need for additional vaccine safety research to be conducted or for one-size-fits-all vaccine policies and laws to be reformed to prevent vaccine injuries and deaths.

Assuring Trust

Since 1982, NVIC has advocated that well-designed, independent, on-going scientific studies must be conducted to: (1) define the various biological mechanisms involved in vaccine injury and death: (2) identify genetic and other biological high risk factors for suffering chronic brain and immune system dysfunction after vaccination; and (3) evaluate short and long-term health outcomes of individuals, who use many vaccines, and those, who use fewer or no vaccines, to evaluate any differences in health outcomes.

Being able to define increased individual susceptibility to adverse responses to vaccination is critical to securing the public's trust[21] in the soundness, fairness and safety of national vaccine policies. In order to secure and maintain public confidence, vaccine safety research must be conducted by scientists without significant financial and professional ties to vaccine manufacturers[22] [23] [24] [25] or government health agencies. On-going systematic vaccine safety reviews require that same level of transparency and independence.

Preventing vaccine injuries and deaths often takes a back seat and is left out of the parent-pediatrician and patient-vaccine administrator encounters altogether.[26] [27] Federal vaccine policies and state vaccine mandates, which fail to acknowledge biodiversity and the fact that we are not all the same and do not all respond the same way to vaccines - just as we do not all respond the same way to prescription drugs[28] - is logically viewed by parents as inherently unequal, unsafe and unethical when the risk of vaccine injury or death for their child turns out to be 100 percent.[29]

Trust in the recommendations of public health officials and doctors implementing "no exceptions" vaccine policies continues to erode when government agencies and medical trade organizations refuse to acknowledge biodiversity or

support methodologically sound vaccine safety research to fill in scientific knowledge gaps documented in two decades of reports published by the IOM, while lobbying to remove informed consent protections and vaccine exemptions in state vaccine laws and supporting removal of all civil liability from vaccine manufacturers and vaccine administrators for vaccine injuries and deaths.[30] [31] [32] [33] The continued inherent conflicts of interest within federal agencies that have developed public-private business partnerships with the pharmaceutical industry to create new vaccines, while simultaneously being legally responsible for licensing vaccines and ensuring their safety and also making national vaccine use policies, as well as determining who can or cannot receive federal vaccine injury compensation, does not instill confidence that a vaccine safety review conducted by AHRQ will be thorough, transparent or completely honest.

The National Vaccine Information Center (NVIC) does not support a review of vaccine safety evidence conducted by the AHRQ, due to inherent conflicts of interest and lack of independence. It is NVIC's position that vaccine safety reviews funded by the federal government must be free from the influence of industry and federal agencies responsible for developing, licensing, making policy for and promoting mandated use of federally recommended vaccines while, additionally, being responsible for determining who does and does not receive vaccine injury compensation.

Regards,

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Co-founder and President

Theresa Wrangham
Executive Director

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