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*** VIA EMAIL. VaccinesafetyRFI@hhs.gov ***

ATTENTION: Vaccine Safety Working Group (VSWG), National Vaccine Advisory Committee (NVAC)

RE: Written Comment submitted to NVAC by the **NATIONAL VACCINE INFORMATION CENTER** on the VSWG Draft Report and Recommendations on the Federal Vaccine Safety System

Thank you for the opportunity to provide written comment on the draft report and recommendations of the Vaccine Safety Working Group (VSWG) of the National Vaccine Advisory Committee (NVAC) on behalf of the National Vaccine Information Center (NVIC), a non-profit educational organization founded in 1982. In the past 30 years, NVIC has grown from a small group of parents of DPT vaccine injured children into the leading information resource and voice for hundreds of thousands of educated health care consumers and health care professionals concerned about vaccine safety and protecting the right of informed consent to vaccination.^{1 2 3}

The comprehensive draft summary and analysis developed by the members of the Working Group clearly reflects many hours of deliberation to provide NVAC and the public with an opportunity to reflect upon the current federal system for ensuring vaccines are safe for both individuals and populations and for evaluating and responding to current and emerging vaccine safety issues.

The co-founders of NVIC worked with Congress to create the historic vaccine safety provisions included in the National Childhood Vaccine Injury Act of 1986, an Act that also established the National Vaccine Advisory Committee.^{4 5} NVIC has the longest public record of advocating for reform of the U.S. vaccination system to make it safer, including calling for independent oversight and increased transparency, accountability, vaccine safety research and public engagement.⁶

In the past decade, NVIC has also been committed to public engagement and participatory democracy initiatives that involve vaccine stakeholders and the general public in the evaluation and improvement of vaccine science, regulation and policymaking.⁷ NVIC has a distinguished 23-year public record of providing well informed consumer representatives to serve on committees at the Institute of Medicine (IOM)⁸ and within the Department of Health and Human Services (DHHS), including the Food and Drug Administration (FDA) - Vaccines & Related Biological Products Advisory Committee (VRBPAC); Centers for Disease Control (CDC) and National Vaccine Program Office (NVPO) – National Vaccine Advisory Committee (NVAC), Vaccine Safety Working Group (VSWG) and Vaccine Safety Risk Assessment Working Group (VSRWAG); and the Advisory Commission on Childhood Vaccines (ACCV).^{9 10 11}

NVIC has a number of comments on this comprehensive report and welcomes the opportunity to share our perspective with NVAC. Although there are many items within the body of the report we could comment on, due to length restrictions, we will focus on the draft report recommendations.

Recommendation 8 – Assurance and Accountability

Public trust in vaccine safety is paramount to public trust in public health policies.

It has long been the position of NVIC that existing federal health agencies congressionally funded and charged with the responsibility for (1) conducting scientific research into the development of new vaccines; and (2) creating and implementing legally binding vaccine licensing and testing regulations for pharmaceutical companies producing and marketing vaccines; and (3) making national recommendations for vaccine administration and use; and (4) promoting universal and mandatory use of government recommended vaccines and (5) serving as the legal respondent in plaintiff's petitions for federal vaccine injury compensation,¹² should not also be responsible for vaccine safety oversight.

NVIC is not alone in taking the position that vaccine safety oversight, such as post-licensure surveillance, should be handled by an independent entity outside of DHHS¹³ and there are precedents in other areas of product safety assurance that confirm the validity of treating product or consumer safety as a separate function. These include the National Transportation Safety Board (NTSB) and Consumer Products Safety Commission (CPSC), both of which are independent

Executive Branch entities outside the Cabinet Department structure that obtain funding from Congress and are managed through the Executive Office of the President.

This independent entity would provide oversight on, but not necessarily operation of, the federal Vaccine Adverse Event Reporting System (VAERS) and would take the lead in setting priorities for and oversight of vaccine safety research into the biological mechanisms and high risk factors for vaccine injury and death for the purpose of minimizing vaccine risks for individuals and populations. In addition, this independent entity would be informed by a consumer advisory committee composed of non-governmental, non-industry representatives with the authority to recommend investigations and make special reports to the President on specific vaccine safety issues of public concern.

For the past quarter century, NVIC has consistently informed the CDC, FDA, NVAC, ACCV, IOM and Congress about growing public concerns involving the urgent need to fill in gaps in vaccine science, including vaccine adverse event data collection, analysis and response;¹⁴ the urgent need to raise standards for vaccine safety regulation of industry;¹⁵⁻¹⁶ the urgent need to re-examine vaccine risk communication policies;¹⁷ and the urgent need to re-examine vaccine mandates that do not respect informed consent principles or acknowledge biodiversity and place some at higher risk than others for suffering vaccine reactions, injuries and deaths.¹⁸⁻¹⁹ This long-standing need for government health agencies to improve vaccine safety monitoring and research and substantively address the safety of vaccine policies has been well-documented²⁰⁻²⁵ and is being reflected in a number of public opinion polls²⁶⁻²⁸ and scientific surveys²⁹ that give evidence for the increasing number of legitimate questions about vaccine safety being raised by a growing proportion of American parents and the public at large.

Therefore, with regard to Recommendation 8 for Assurance and Accountability, NVIC does not support a further enhanced role for NVAC, the Immunization Safety Task Force (ISTF), NVPO or other existing entities within DHHS in lieu of Option 3 under Recommendation 8: the creation of an independent entity charged with the sole responsibility for vaccine safety oversight that reports directly to the President and Congress. NVIC is in support of this independent oversight entity working with DHHS agencies to facilitate improvements in vaccine safety assurance and accountability that would be implemented by NVPO and other health agencies within DHHS.

NVIC opposes the proposed expanded role of the ISTF as it is currently constituted and operated. ISTF is composed of officials from DHHS, Department of Defense (DOD) and other federal agencies and lacks public representation and transparency, including an apparent shield from Freedom of Information Act (FOIA)³⁰ requests and Federal Advisory Committee Act (FACA)³¹ regulations that apply to advisory committees.

Because there are hundreds of new vaccines being developed,³²⁻³³ many of which likely will be recommended by government for universal use by children and adults, we maintain that adoption of a mechanism for independent vaccine safety oversight is so critical to improving and maintaining public trust that it eclipses all other recommendations in this draft report. Without truly independent and meaningful vaccine safety oversight, implementation of the rest of the recommendations is unlikely to accomplish the goal of securing and maintaining public confidence in the integrity of the national vaccine safety system.

Following are responses to Recommendations 1-7 and 9. They are commented upon in light of the RAND Corporation recommendations cited in the VSWG's draft report.

Recommendation 1 – Leadership

Simply reaffirming the legitimacy of the existing structure will not stem the documented public erosion of trust in the vaccine safety system. A substantive, appropriate response from government is urgently needed.

As described in Option 8.4.3 – **Create an Independent Agency within the Executive Branch to focus on the safety of vaccines**, the creation of an independent entity outside of DHHS (and DOD) would signal to the public that safety concerns reflected in NVAC's Task 1 work have been taken seriously and substantive action is being taken to assure objective oversight of the vaccine safety system. In this context, the federal health agencies named in this recommendation *should assist to inform* the independent entity about operation of the nation's vaccine system but *should not be responsible for oversight* on monitoring the safety of vaccines and the vaccine system.

It appears that the ISTF was created in 2008 and is a shadow committee solely composed of representatives from federal agencies, including DHHS and DOD, and is shielded from transparency, including FOIA requests and FACA regulations. This means the public does not really know what the ISTF is doing. Giving ISTF a major role in vaccine safety oversight, as suggested in this draft recommendation, will not promote public confidence in the transparency, accountability and safety of the nation's mass vaccination system.

The inclusion of entities in 1.2 is sound. However, there is a lack of meaningful consumer/public representation in what appears to be an increasing dominance by existing federal health and defense agencies in the operation of the mandatory vaccination system in the U.S. in the past decade³⁴ without the necessary checks and balances that assure transparency, accountability and public confidence.

The establishment of a standing working group outlined in 1.3 to enhance vaccine safety should ultimately fall under the independent entity outlined in 8.4.3 referenced above to assure transparency and accountability.

Recommendation 2 – Coordination

Subcommittee recommendations for research, post-licensure surveillance, clinical practice communications and stakeholder and public engagement are appropriate but, in most instances, need to be part of the scope of work for an independent agency outlined in 8.4.3.

NVIC does not support the expansion of the recently established ISTF for the reasons already stated above. The ISTF's structure, activities, membership and accomplishments to date appear to be inaccessible to the public other than limited information contained in the short statement found on many government websites such as the one below:

“The Federal Immunization Safety Task Force was established in 2008 to ensure that all federal efforts relevant to immunization safety are coordinated and integrated and that opportunities to enhance synergies across federal government in immunization safety are identified. The Department of Health and Assistant Secretary lead this cross-governmental task forced for Preparedness and Response. The Task Force includes participation from the Department of Veteran Affairs and the Department of Defense. All three Departments are responsible for vaccine research and safety monitoring.”
[\(http://www.flu.gov/individualfamily/vaccination/vsafety/\)](http://www.flu.gov/individualfamily/vaccination/vsafety/)

Recommendation 3 – Research

The goals outlined in the research agenda to close gaps in knowledge about vaccine safety are encouraging. However, use of and dependence on the ISTF will decrease rather than increase public trust. Effective implementation of these goals requires an independent vaccine safety oversight entity to set priorities for and monitor vaccine safety research.

NVIC maintains it is important for government to reaffirm, in accordance with the National Childhood Vaccine Injury Act of 1986, that vaccine research conducted by the government is meant to ***“induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.”***³⁵

Public trust in the nation's vaccine program can only be secured and maintained if individuals voluntarily agreeing to be vaccinated have a high degree of confidence that the scientific knowledge base exists to identify individuals at high risk for suffering vaccine reactions. Additionally, the societal impact, including impact on healthcare costs for individual families and our nation resulting from chronic illness potentially caused by vaccine complications, has yet to be fully acknowledged. These potential costs are not included in vaccine risk/benefit calculations currently used to support federal recommendations for universal use of 69 doses of 16 vaccines by all children using the same schedule from day of birth through age 18.

Therefore, to further strengthen this draft report's research recommendation, statements should be added about elevating vaccine safety research to a higher program funding priority. The budget for research to close vaccine safety research funding gaps needs to be on par with money spent to develop new vaccines and to promote universal use of existing vaccines. This report should also reaffirm the need to address vaccine safety knowledge gaps identified by NVAC's Task 1 recommendations for the CDC's Immunization Safety Office (ISO) five-year research agenda³⁶ and add any NVAC Task 1 research recommendations that are not included in the ISO research agenda.

Research recommendations in this report should also address the well-documented need for basic science research into biological mechanisms for vaccine induced brain and immune dysfunction for the purpose of identifying high risk factors for vaccine complications leading to chronic poor health or death in individuals and special populations.^{37 38} Placing a higher priority on basic science research will close knowledge gaps that have grown along with the expanding vaccine schedules in the past two decades. Continuing almost exclusive reliance on epidemiological studies is insufficient to identify causal relationships between certain vaccines and adverse events in smaller, at-risk populations. Failure to address these long standing basic science knowledge gaps may well serve to unfairly penalize and cause avoidable suffering for special populations within our genetically diverse society, who are disproportionately bearing excess vaccine risk burdens.

Research recommendations in this report should address the need for longitudinal research into the potential latent adverse effects of vaccines leading to chronic illness, including (1) evaluation of potential common biological and other risk denominators among individuals awarded federal vaccine injury compensation;^{39 40} and (2) prospective evaluation of

morbidity and mortality health outcomes, as well as measurement of changes in immune and brain function over time, in fully vaccinated and unvaccinated individuals.⁴¹

In harnessing technology of the 21st century, routine clinician use of electronic medical records software has the potential to improve detection and reporting of AEFI's to VAERS. This request is consistent with the vaccine safety provisions of the National Childhood Vaccine Injury Act of 1986 that require providers to report serious health problems following vaccination to VAERS as a way to monitor and improve vaccine safety.

To secure and maintain public confidence in the quality and integrity of vaccine safety research, it should be conducted by scientists without significant financial and professional ties to vaccine manufacturers^{42 43 44 45 46} or government health agencies. Investigators must use sound methodology that reduces bias and the datasets they use must be made available so their work can be replicated and validated by other independent investigators. On-going systematic reviews of the medical literature to obtain additional information on research quality and outcomes is needed, in addition to public access to government-held data for the purpose of replicating studies DHHS (and DOD) officials publish regarding the safety of vaccines.

The lack of transparency and inability of independent researchers to replicate and validate government studies that do or do not confirm vaccine risks has been a major concern articulated by vaccine safety advocates. The IOM noted this legitimate concern in a 2005 report examining the Vaccine Safety Datalink (VSD) managed by the CDC: ***“Ensuring the independence, transparency and fairness of VSD research activities is important for ensuring public trust in the VSD as a tool for addressing critical vaccine safety questions.”***

Public access and transparency recommendations from the IOM's 2005 report should be adopted for all vaccine safety databases, including the VSD and biological specimen repositories. This task would be best accomplished in conjunction with oversight by the independent entity option in Recommendation 8, as discussed earlier.

This draft report also recommends more polling to identify specific public concerns and perceptions about vaccine safety without adequately summarizing existing information on this subject. The 2005 IOM report, as well as information obtained from 2009 public engagement meetings sponsored by CDC/NVAC to gauge public opinion about pandemic H1N1 influenza vaccination programs,⁴⁷ as well as more recent polls and published studies,⁴⁸ have clearly identified trends and reasons for erosion of public trust in the vaccine safety system.

Recommendation 4 – Post-Licensure Surveillance

While the draft report states that little is known about the extent of public awareness of VAERS, it should contain a stronger statement regarding the need for all vaccine providers to report to VAERS to strengthen post-licensure vaccine safety surveillance. If providers do not report, then potential vaccine safety signals cannot be detected.⁴⁹

There have been studies indicate that AEFI's reported to VAERS may represent less than 10 percent or even less than 1 percent of all vaccine adverse events that occur in the U.S.^{50 51} Since the 1986 Vaccine Injury Act was passed and VAERS became operational in 1990, NVIC has been notified by many families that vaccine providers become angry when asked questions about vaccine reactions and often refuse to report serious health problems resulting in hospitalizations, injuries and deaths following vaccination to VAERS.⁵² Parents say that vaccine providers dismiss vaccine-associated adverse health outcomes as a “coincidence.”

Vaccine provider failure to report AEFI's to VAERS can result in failure to properly identify, treat and acknowledge vaccine-related health problems appropriately, thus creating an opportunity for re-vaccination that could result in more severe injury. The addition of many new vaccines to the federally recommended list of vaccines in the past two decades, many of which are given simultaneously to populations that may not have been included in pre-licensure clinical trials, increases the urgent need for all vaccine providers to report AEFI's to VAERS. Vaccine providers should be instructed to report, regardless if they do not personally believe the adverse health outcome is causally related to the vaccination recently administered.

Post marketing surveillance is a key component of an effective vaccine safety system and NVIC supports legal enforcement of the vaccine safety provisions in the 1986 National Childhood Vaccine Injury Act, including mandatory reporting by vaccine providers to VAERS.

Recommendation 9 – Clinical Practice

NVIC supports Recommendation 5.2 regarding bar coding of vaccines. However, for reasons previously stated, NVIC does not support a role for ISTF as it is currently configured that includes creating and disseminating information to clinicians

about how to identify, evaluate, manage and report vaccine adverse events. There are other professional groups that should be part of this activity and an important function like this should be monitored by an independent entity charged with oversight of vaccine safety as outlined in Option 3 of Recommendation 8.4.

Recommendations 6 & 7: Communications and Stakeholder/Public Engagement

Communication with the public about vaccination should be clear, simple and honest. It is essential that the public be made aware of vaccine safety research gaps, what assumptions about safety are being made and what is known and is not known about potential vaccine benefits and risks^{53 54} in alignment with Goal 3 of the National Vaccine Plan

Vaccine risk communication should be grounded in transparency, honesty and respect for the right to informed consent to medical risk taking.⁵⁵ The public, especially parents being asked to trust government-produced vaccine benefit and risk information, expect public health policies to acknowledge the precautionary principle.⁵⁶

For example, the Vaccines.gov website referred to in the draft report could be improved by including information about vaccine risks. The emphasis on promoting routine use of vaccines to reach public health goals should be balanced with language that empowers patients and parents to make well-educated vaccine decisions that includes reducing individual risks.⁵⁷ Respect for the public's intelligence and diversity of values and perceptions is key to good communication with the public.⁵⁸

Finally, as it relates to public participation in public health policymaking, the public needs more representation.⁵⁹ The public is not well represented on vaccine licensing and policymaking committees within DHHS. Committees managed by the NVPO, FDA and CDC are dominated by representatives from federal agencies, the pharmaceutical industry and individuals, whose vaccine-related professional work is funded by government health agencies or pharmaceutical companies manufacturing vaccines. Expanding the number of voting members with a diversity of expertise and perspectives, who are free from ties to vaccine manufacturers and government vaccine research grants, is needed to secure public trust and confidence in the integrity and safety of the vaccine system. This includes an urgent need to expand the number of well-informed consumer voting members representing a diversity of perspectives.

Recommendation 9 – Cost evaluation of recommendations.

NVIC supports the NVACs efforts to determine costs on enhancement of the existing vaccine safety system, as well as evaluation of the funding of option 8.4.3.

NVIC is also supportive of the CDC's ongoing public engagement initiatives and thanks the members of the VSWG for their dedicated work collecting information for and preparing this draft report and recommendations.

Respectfully submitted,

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