National Vaccine Information Center

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National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue SW., Room 733G,
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Attn: HHS Adult Immunization c/o Rebecca Fish

Re: NVIC Public Comment on the NVAC Draft National Adult Immunization Plan

In response to Federal Register Notice 2015-02481, the National Vaccine Information Center (NVIC) submits the following comments on the Draft National Adult Immunization Plan (NAIP). Our comments will be based on the broad themes contained in the draft NAIP for brevity.

Healthy People 2020 Goals & Informed Consent

NVIC opposes the overall use of Healthy People 2020 Goals as the cornerstone for implementing the National Adult Immunization Plan (NAIP). Our opposition is based on the fact that these goals have no "statutory authority to direct the activities of or hold accountable components of the US health system" and many of the goals are created arbitrarily.[1]

Not only does the NAIP not reflect that Healthy People 2020 Goals are aspirational, the implementation of these goals appears to seriously undermine the informed consent ethic.[2] Informed consent has been the ethical principle that has served as the cornerstone of the ethical practice of modern medicine. Informed consent requires that an individual considering a treatment or medical intervention be given full information about its risks and benefits and be able to voluntarily accept, delay or decline the treatment or procedure without being coerced or sanctioned for the decision made. Voluntary use of pharmaceutical products, including vaccines, is not an exception to adherence to the informed consent ethic.[3]

A 2014 paper commissioned by the Institute of Medicine (IOM) noted that "the doctrine of informed consent is a fundamental principle of the U.S. legal system, introduced by case law in 1957...Informed consent and refusal of treatment are recognized as significant legal and ethical rights of patients."[4]

The absence of informed consent protections in the NAIP violates basic human rights. Consent to any medical procedure, including vaccination, must be voluntary and not coerced through financial incentives or sanctions, electronic tracking of patient health care choices, punitive federal and state policies and laws or other societal coercion or sanctions. Informed consent must be given higher priority over adult vaccine uptake goals put forward by the NAIP. These informed consent protections require that flexible medical, religious and conscientious exemptions be included in all vaccine recommendations, policies and laws.

NVIC recommends that the language in the report referencing Healthy People 2020 Goals reflect that these goals are aspirational and, where applicable, are arbitrary. We also recommend that the draft NAIP integrate informed consent protection language throughout the plan in acknowledgement of peer-reviewed research and the federal government's admission that "individuals react differently to vaccines, and there is no way to absolutely predict the reaction of a specific individual to a particular vaccine."[5]

Privacy and Use of EHRs and IISs

The tone of the draft NAIP also raises important privacy concerns. American citizens have a human and constitutional right to privacy. The NAIP recommends the use of electronic health records (EHR) and immunization information systems (IIS) to analyze vaccine uptake and track the vaccination status of all adults. However, we note that the plan does not contain language that protects privacy or that acknowledges the known risks for patient data being hacked (security breaches) by malicious outside entities.[6]

NVIC opposes the NAIP recommendations relating to the use of EHRs and IIS due to the lack of consumer protection language. We recommend that language be added to the NAIP that supports informing consumers of the risk for patient data security breaches, safeguards and protections in place to prevent security breaches, and privacy rights in place for adults opting out of electronic tracking systems.[7] [8]

Additionally, the plan should also include language that supports the use of an audit trail allowing adults to access their medical records with the ability to see who else has accessed it and when it has been accessed to ensure transparency and accountability. NVIC also recommends that the NAIP adopt language supporting consumer choice in the participation in EHR and IIS systems.

Incentivizing of Vaccine Policy

The draft NAIP states that incentives are helpful in encouraging "providers to recommend, provide and maintain records of adult vaccinations."[9]

NVIC opposes incentivizing language in the draft NAIP due to possible penalties incurred by doctors and other healthcare and vaccine providers when adults opt out electronic tracking systems, including the additional pressure that health care providers may experience as a result of incentivizing. While the NAIP doesn't specify what these provider incentives are, EHR incentives appear to be little more than bribes to put pressure on providers to participate in the goals set forth in converting patient data to electronic formats.[10]

"Incentivizing" healthcare and vaccine providers to convince adults to participate in electronic health and vaccine records tracking systems and shared electronic databases unnecessarily burdens providers and sacrifices quality individual healthcare to satisfy governmental vaccine uptake goals.

The NAIP should avoid this type of incentivizing, as it puts monetary rewards ahead of consumer privacy and individualized health care.

Instead, the NAIP should encourage healthcare and vaccine providers to inform adults of the opportunity to choose to participate in these electronic tracking systems. However, the decision to participate in these systems must remain voluntary. Policy must *respect consumer choices* relating to the conversion of patient data into an electronic format and the sharing of that information in any state or federal electronic database because that information can also be shared with outside entities under HIPPA regulations, including pharmaceutical companies. Healthcare and vaccine providers should also be protected from financial or other penalties when adults make an informed decision and decline to participate in an electronic health records tracking system.

The NAIP also targets health professions not normally providing vaccinations to adults to become vaccine providers. Health care professionals who at present do not administer vaccines to adults can readily refer them to the many vaccine providers currently doing that, including pharmacists. Government should not be placing pressure on health-related professions to become vaccine providers when there is no demonstrated need for that to be done.

NVIC is opposed to language in the NAIP incentivizing healthcare providers to convince adults to participate in state and federal vaccine tracking systems and shared electronic health record systems that do not contain privacy protections and fail to guarantee that medical information, including vaccination information, will not be used in the future to harass and sanction adults who have not received every dose of every government recommended vaccine. NVIC is also opposed to targeting any healthcare professional to become a vaccine provider and supports the freedom of healthcare professionals to determine what services they offer to the public without pressure and penalties if they decline to participate in government vaccine uptake goals.

We recommend that incentivizing language be removed from the NAIP and that language be added that supports the rights of healthcare providers and all adults to voluntarily choose to participate in governmental vaccine uptake goals outlined in the NAIP to protect patient privacy, safety and trust in the physician-patient relationship.

NVIC supports the addition of language that acknowledges that healthcare providers should inform their patients of the *benefits and risks* of participating in EHR and IIS systems. We also recommend that the NAIP adopt language stating that incentivizing practices are counterproductive to patient privacy and trust when there is no meaningful informed consent and transparency about incentives their healthcare provider accepts.

Vaccine Risks & Injuries

NVIC supports the right of all Americans to have access to and information on preventative healthcare options, including vaccines. However, too often vaccine adverse events, reactions, risks, injuries and deaths are characterized as “rare” by government health officials with little or no detailed information communicated about vaccine risks to balance the detailed information given on vaccine benefits. While the NAIP places an emphasis on adult access to vaccines and raising awareness about adult vaccination, balancing information on the risk for vaccine reactions, injury and death is required to support meaningful informed decision-making.

Not everyone responds to vaccines the same way and the majority of claims compensated by the federal Vaccine Injury Compensation Program (VICP) are now for adult claims.[11] The NAIP is devoid of adult education on vaccine reactions, injury and death, though it supports raising awareness of the VICP with vaccine providers and increased reporting to the federal Vaccine Adverse Event Reporting System (VAERS).

Adults considering use of vaccines have a right to receive full and accurate information not just on vaccine benefits but also on vaccine risks, including injury and death, during their vaccine decision-making process. More importantly, those considering vaccination want this information provided *before* vaccination, as demonstrated in the 2010 federally commissioned report evaluating vaccine provider communication about the Vaccine Injury Compensation Program.

The 2010 Banyan report noted that parents and parents-to-be rely on more than their doctor for information about vaccines and use online resources to obtain vaccine information. Additionally, this report found that they wanted detail when it came to communication from vaccine providers about vaccine risks and benefits. It should be noted that the booklet on the VICP under discussion in that report was 16 pages in length and parents expressed the opinion that it was preferable to receive it during pregnancy and well in advance of appointments where vaccines would be administered.[12]

The Banyan report also noted that, although detail about vaccine risks was preferred, this information was not likely to sway parent and adult decisions to vaccinate.[13] While the report focused on the VICP, it sheds light on adult expectations when it comes to vaccine risk communication during the vaccine decision-making process.

In their 2012 report, the Institute of Medicine (IOM) also highlighted the fact that there is increased individual susceptibility to experiencing vaccine reactions and that there are genetic, biological and environmental risk factors that remain unknown. Language within the NAIP should reflect IOM findings regarding individual susceptibility and more accurately communicate that there are gaps in vaccine safety science and unknown vaccine risk factors that doctors are rarely able to predict.

> *"Vaccinations—like all medical procedures—are neither 100 percent free of risk nor 100 percent effective. Vaccines, in rare cases, can cause illness. Most children who experience an adverse reaction to immunization have a preexisting susceptibility. Some predispositions may be detectable prior to vaccination; others, at least with current technology and practice, are not"* (IOM, 2012, p. 82).[14]

NVIC recommends that language in the NAIP relating to vaccine risk communication be more detailed to meet adult vaccine risk communication expectations and to provide balance, transparency and support informed vaccine decision making. As stated earlier, the NAIP language should also be modified to include informed consent protections with no sanctions when setting goals and objectives around increased government demand for higher adult vaccine uptake.

Enhancements to Safety Systems

In the monitoring of vaccine safety, NVIC supports enhancements that improve vaccine provider reporting of adverse event symptoms following vaccination and vaccine-related injuries and deaths to VAERS, which are acknowledged as being underreported. We would additionally recommend that Objective 1.2 also provide linkage to the VICP due to lack of vaccine consumer awareness of the statute of limitations filing deadlines that govern vaccine injury compensation eligibility. Many vaccine injury claims are dismissed due to plaintiffs missing filing deadlines and exceeding the statute of

limitations. The NAIP should seek to strengthen awareness of the VICP and support vaccine injury compensation of adults (and children) harmed by government recommended vaccines.

Additionally, the Objective 1.3 relating to the VICP would be improved by including input of the Advisory Commission on Childhood Vaccines (ACCV) that monitors and makes recommendations about implementation of the VICP, as well as by integrating findings of the Banyan report that made recommendations on raising public awareness about the existence of the VICP.[15]

NVIC notes that there are significant and increasing vaccine safety science gaps demonstrated by the steady increase in VICP off-the-table vaccine injury and death claims for both adults and children. The expansion in the number of government recommended vaccines during the past three decades has resulted in few compensable vaccine injuries being added to the federal Vaccine Injury Table (VIT). The NVAC's 2011 white paper on the U.S. Vaccine Safety System verifies the depth of the vaccine safety science deficits.

The white paper stated that IOM was unable to make definitive conclusions about more than half of the vaccine-related brain and immune system disorders associated with use of one or more federally recommended vaccines because of conflicting or complete lack of methodologically sound studies in the medical literature. Unfortunately, for 60% of the vaccine-related adverse health outcomes IOM had to state that the evidence was "inadequate to accept or reject a causal association between vaccination and specific adverse events." [16]

The continued expansion of federally recommended vaccines for adults, without complete understanding of vaccine risks underscores the need to close these vaccine safety science research gaps with methodologically sound, unbiased vaccine safety science the public can trust.

Currently the NAIP supports analyzing VICP data, but stronger language is needed to support the closing of long acknowledged vaccine safety science research gaps to lessen the number of VICP claims for off-the-table adult (and child) vaccine injury claims. These off-the-table claims are a direct result of vaccine safety science research gaps highlighted by the IOM and make up the majority of claims filed by consumers with the VICP.

NVIC recommends the NAIP incorporate language strengthening adult vaccine recipient awareness of the VICP and support the funding of quality, independent vaccine safety research using IOM methodology to close vaccine safety research deficits.

Economic Impacts and the Cost of Vaccine Injury & Death

The assumption that higher adult vaccine uptake will reduce health care costs associated with vaccine targeted diseases fails to include goals to develop estimates of the costs related to vaccine reactions, injuries and deaths and their economic impact on society. These benefit risk cost analyses are necessary for the NAIP to achieve stated goals around fully transparent disclosure of vaccine benefits and risks.

Mortality and serious complications associated with many of the vaccine-targeted infectious diseases were in decline prior to the introduction of vaccines.[17] Information on pre-vaccine era declines in disease complications and mortality and associated health care cost reductions should be included in the NAIP to more accurately and transparently evaluate vaccine effectiveness and economic benefits resulting from universal use of government recommended vaccines by all adults.

NVIC also notes that economic impacts vary from disease to disease and vaccine to vaccine. These variances are not reflected in the draft NAIP, but are instead put into a one-size-fits-all statement that does not realistically portray economic impact of universal vaccine use by adults.

For example, the CDC presented information during its 2011 public engagement on meningococcal vaccine demonstrating that it is not economically feasible to promote routine meningococcal vaccination. The subsequent CDC sponsored stakeholder report noted that access to vaccines is important, as are education efforts to raise awareness of their availability. However the report also voiced the need for a "broader and more nuanced set of ACIP recommendation options… an option that would allow for broad education and access without making meningococcal vaccination routine for all children." [18] It follows that meningococcal vaccine is no more financially feasible to recommend for adults than it is for children.

Other examples of varied economic impact are HPV and influenza vaccines. According to the CDC's 2004 report, HPV is transmitted through sexual activity with the vast majority of individuals infected with HPV clearing and resolving HPV infection on their own without clinical consequences or intervention.[19] The HPV vaccine series costs $390 (or more) per person,[20] while the incidence of HPV associated cancers is less that 1% of the U.S. population.[21]

The CDC has noted that cervical cancer is the most important outcome in HPV related cancers[22] and that half of deaths in the U.S. from cervical cancer are associated with delayed or lack of pap test screening. The CDC considers pap tests to be an important screening measure in the early diagnosis and prevention of cervical cancer [23] and the American Cancer Society notes that early diagnosis and treatment of cervical cancer is connected with high survival and cure rates.[24]

We note that pap screening costs between $20 and $30[25] and is recommended regardless of HPV vaccination status.[26] NVIC questions the economic feasibility and impacts associated with universal adult use of HPV vaccine when weighed against other routine preventative measures that cost far less. Cervical cancer impacts approximately 12,000 women in the U.S. and has a mortality rate of roughly 4,100 per year, with half of those deaths potentially preventable by pap screenings.[27]

HPV vaccine is an example of the NAIP's lack of specificity and nuance when making statements on the economic impact of adult use of federally recommended vaccines where other preventative measures, such as pap screening, may have larger positive economic impacts. The NAIP also fails to acknowledge that the majority of HPV infections resolve without consequence or intervention, which put into question the need for universal adult HPV vaccine use recommendations.

Influenza vaccine effectiveness varies from year to year, with only 20 to 25 percent of Americans contracting influenza in most flu seasons and with large variability in influenza vaccine effectiveness from season to season, depending upon whether influenza strains selected for the vaccine match the most prevalent circulating strains. [28] According to the CDC, from 2005-2015 the influenza vaccine's overall effectiveness ranged from 10% in 2005 to 60% in 2010.[29] This is important information considering that the leading vaccine injury currently compensated by the VICP is for adults who have suffered Guillain Barre Syndrome (GBS – causes paralysis) after flu shots. [30] The NAIP contains no mention of the costs of injury associated with adult influenza vaccine injuries and deaths.

NVIC also questions the economic feasibility of federal recommendations for 320 million Americans[31] to get an annual flu shot, which costs about $20,[32] given influenza vaccine's lack of effectiveness and the likelihood that only 20-25 percent of Americans will ever contract a strain of influenza targeted by the vaccine.

While there is a need to educate adults about the availability of government recommended adult vaccines, the application of a one-size-fits-all economic impact statement in NAIP is very questionable and requires much more evidence-based support.

As mentioned previously, vaccines also have known and unknown risks. Health care costs associated with vaccine reactions, hospitalizations, injuries and deaths are notably absent from the NAIP and clearly must be included for accuracy and transparency. Economic impacts and factors that need to be included in the NAIP are the costs of closing existing vaccine safety science research gaps; costs of vaccine safety research to prevent vaccine injury and death for new vaccines; costs associated with vaccine reactions, injuries and deaths and costs associated with compensating individuals and families who have experienced vaccine injuries and/or died as a result of a vaccine reaction.

NVIC recommends that these associated costs be more accurately reflected and included in the NAIP. We also recommend that costs associated with established declines in disease complications and mortality prior to vaccine introduction and widespread use be factored into the NAIP language relating to economic impacts and effectiveness of vaccines to ensure accuracy.

Partnering with Employers, Community and Faith-Based Organizations

The NAIP also seeks to partner with organizations, employers and faith-based communities to assist with adult awareness of the government recommended adult vaccination schedule, offering of vaccines and strong encouragement to use all federally recommended vaccines.

NVIC notes that it is not the purview of these groups to increase vaccine uptake or to provide vaccines to their employees, members and congregations. While many of these groups may be willing to assist in NAIP goals, crafting of language with regard to the participation of these groups must clearly indicate that participation is optional. The NAIP should ensure that there are no sanctions for groups choosing not to participate in what is traditionally the role of government health agencies, public health clinics and private physicians and not the responsibility of employers, community organizations or churches.

As stated earlier, informed consent protections must be provided, including acknowledgment of the fact that that peer reviewed science and government health agencies recognize that no vaccine is 100 percent safe and that some individuals can be harmed by them. NAIP partners must also be informed that the vaccine policies they choose to create to meet NAIP adult vaccine uptake goals should include flexible medical, religious and conscientious belief exemptions that allow for their members and/or employees to delay or decline one or more vaccines without sanctions.

NVIC recommends the addition of language clearly supporting that NAIP partners adopt informed consent protections for their members and employees when considering the creation of their own vaccine policies. We additionally recommend that language promoting partnerships between government and employers, as well as churches and other community and faith-based organizations be clearly described as voluntary.

Transparency and Independent Monitoring and Evaluation

Lastly, NVIC expresses deep concern about the "vested interest" held by members of the Adult Interagency Task Force (AIFT). This task force was created to improve coordination and collaboration across federal agencies during the 2009 H1N1 efforts. The NAIP recommends using the AIFT to implement an Adult Immunization Implementation Plan.

The use of this task force to monitor progress on the implementation of the NAIP without representation on the task force of those with no vested interest in vaccine uptake is likely to further endorse a one-size-fits-all approach to vaccination that lacks informed consent protections for Americans.

The current draft of the NAIP already demonstrates a lack of consumer protection, including a lack of respect for the human right to informed consent to medical risk taking, including the right to accept, delay or decline one or more vaccines. A higher priority on the prevention of vaccine injury and death and informed consent to vaccination is needed in the NAIP to balance the aggressive nature of government promotion of vaccination and electronic tracking of adults to meet NAIP objectives.

NVIC has historically supported the institution of an independent public oversight mechanism in the federal government to monitor vaccine research, development, regulation, policymaking and promotion by federal and state public health agencies, as well as to conduct and oversee independent, non-governmental monitoring of adverse health events associated with vaccination.

Adult vaccination policies must incorporate measures that allow adults to make informed and voluntary vaccination decisions without sanction, as is allowed with all other medical procedures and use of pharmaceutical products that carry risks that can be greater for some people than other people. The public health agenda outlined in the NAIP cannot be allowed to supersede the informed consent rights of adults to achieve a numerical adult vaccine uptake goal set by government health officials. Each adult American should be allowed to determine what risk they are willing to accept when considering vaccination and should not be sanctioned for the decision they make.

We appreciate the opportunity to provide these comments to the NVAC and request that these concerns be addressed and the NAIP be modified accordingly.

Respectfully submitted,

s/s Barbara Loe Fisher
Barbara Loe Fisher,
President & Co-Founder

Theresa Wrangham
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