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Re: Developing the 2020 National Vaccine Plan

As the Institute of Medicine (IOM) noted in [Priorities for the National Vaccine Plan \(2010\)](#), in the U.S., “The starting point for the contemporary vaccine safety system was the National Childhood Vaccine Injury Act of 1986.” The Act had two principal objectives: (1) to provide a federal administrative mechanism alternative to civil litigation to compensate children injured by government licensed and recommended vaccines and (2) “to create a climate of safety through adoption or expansion of optimal public health and clinical practices...and the application of the best science to vaccine safety.”

The Act (Title 3, [P.L. 99-660](#)) established the National Vaccine Program under the Department of Health and Human Services (HHS) with a requirement “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.” Therefore, the Act placed an equal focus on the prevention of infectious diseases and prevention of adverse reactions to vaccines.

Parents of DPT vaccine injured children, who worked with Congress on the 1986 Act and co-founded the non-profit charity known today as the [National Vaccine Information Center](#), were responsible for the inclusion of vaccine safety informing, recording, reporting and research provisions in the Act, which elevated vaccine safety and the prevention of vaccine reactions, injuries and deaths to a national priority for government health agencies, pharmaceutical corporations manufacturing and marketing vaccines, and medical trade associations representing pediatricians and other vaccine providers administering vaccines. The words “safety” and “safe” are repeated over and over again in the text of the Act to emphasize the need “to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines” and “to reduce the risk of any major adverse reactions to the vaccine that may occur.”

It is clear from the legislative history that the intent and purpose of the 1986 Act was not only to protect the national vaccine supply by offering a non-adversarial, less time-consuming and expensive federal compensation system alternative to children injured by government licensed and recommended vaccines, but also to ensure that the government inform the public and doctors about vaccine risks and how to prevent individuals from suffering serious vaccine reactions in order to reduce the need for

compensation. While the first purpose of the Act has been achieved, evidenced by the tripling of the numbers of the HHS recommended childhood vaccines from [23 doses of 7 vaccines](#) in 1986 to [69 doses of 16 vaccines](#) in 2016 and a more than doubling of the numbers of pharmaceutical corporations marketing childhood vaccines in the U.S. from three in 1986 (Merck, Lederle, Connaught) to [six vaccine manufacturers](#) in 2019 (Merck, Pfizer, GlaxoSmithKline, Sanofi Pasteur, Seqirus. Dynavax), the second main purpose of the 1986 Act – to prevent vaccine reactions and reduce vaccine risks - has not been achieved.

Although the 1986 Act placed a dual and equal emphasis on prevention of infectious diseases and prevention of vaccine adverse reactions, in the very first [1994 National Vaccine Plan](#) only four out of 25 “objectives (2.1; 2.2; 2.4; 3.4) and only two out of 14 anticipated “outcomes” addressed prevention of vaccine reactions, injuries and deaths. From the beginning, it was apparent that HHS was not committed to funding research and creating substantive new initiatives to reduce vaccine risks but was - and still is - primarily interested in funding research and creating government programs to develop new vaccines; increase public demand for vaccines; raise vaccination rates among infants and school children; create electronic vaccine tracking registries and surveillance systems to monitor and increase uptake of HHS recommended vaccines; and promote global vaccination programs, even though the purpose of the Act was to protect the U.S. childhood vaccine supply and address vaccine safety issues in U.S. vaccination programs, not fund and [expand global vaccination programs](#).

At the same time between 1987 and 2016, while [peer reviewed studies](#) confirmed that government licensed and recommended childhood vaccines can cause acute and chronic brain and immune system dysfunction and death and that there are significant gaps in scientific knowledge about the biological mechanisms and high risk factors for serious vaccine reactions, HHS and the Department of Justice used rule making authority to weaken the [federal vaccine injury compensation program](#) (VICP) and make it more difficult for vaccine injured children to receive awards. By [ignoring the scientific evidence and intent of the 1986 Act](#), HHS has failed to fulfill the mandate by Congress in 1986 to make vaccines and vaccine policies safer by [defining and reducing vaccine risks to prevent vaccine injury and death](#).

Although the VICP has awarded [\\$4 billion in vaccine injury compensation](#) to date, many children are not being compensated when they suffer chronic brain and immune system damage following vaccination, while the [majority of VICP awards](#) are now being made to adults injured by covered vaccines. Despite the fact that the 1986 Act was created for children, not adults, HHS lobbied Congress to include provisions in the 21st Century Cures Act of 2016 to remove liability from drug companies manufacturing vaccines recommended by HHS for pregnant women, while ignoring [significant scientific knowledge gaps](#) about the biological mechanisms of vaccine injury and death and the potential adverse effects of maternal vaccination on pregnant women and brain and immune system development of the unborn child in utero.

Like the 1994 National Vaccine Plan, the [2010 National Vaccine Plan](#) has suffered from a continuing lack of attention by HHS to defining and reducing vaccine risks to prevent vaccine reactions, a purpose that was so integral to the 1986 Act. In fact, in 2010 HHS accurately characterized the U.S. vaccination system in the 21st century as a business “enterprise,” which had the effect of turning the National Vaccine Plan into a government operated vaccine marketing plan for the pharmaceutical industry: “The 2010 National

Vaccine Plan provides a vision for the U.S. vaccine and immunization enterprise for the next decade.”

The [National Vaccine Advisory Committee \(NVAC\)](#), which is under the direction of the Assistant Secretary of Health, was also created under the 1986 National Childhood Vaccine Injury Act. Like the National Vaccine Program, NVAC was given a dual mission “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.” However, rather than supporting vaccine safety science research and federal programs that prioritize prevention of vaccine reactions, NVAC has consistently demonstrated a preference for using taxpayer money to market vaccines for pharmaceutical corporations and enlist state governments, doctors and medical facilities, as well as NGO’s, including churches and faith-based organizations, to market and promote required use of federally recommended vaccines by all children and adults.

An example is NVAC’s [The National Adult Immunization Plan: A Path to Implementation](#) published in 2012, which was expanded and [adopted in 2016](#) by the National Vaccine Program Office (NVPO) and linked to Healthy People 2020 performance goals, for which HHS has no statutory authority to arbitrarily set and require those operating the U.S. health care system to meet. None of the four main goals for the Adult Vaccination Plan address vaccine safety or preventing vaccine reactions. Instead, the Number One priority, goal and objective of NVAC’s plan for vaccinating all adults is focused on government operated electronic surveillance systems “to increase the use of electronic health records and immunization system registries (IIS) to collect and track adult immunizations.” There are [no mechanisms included in the Plan](#) for protecting the privacy and informed consent rights of adults, protecting personal data from security breaches, or prohibiting use of these electronic surveillance and vaccine tracking systems by government officials, doctors, employers and other entities with access to the data to punish adults for failing to receive all vaccines that are developed, licensed, recommended and promoted for mandatory use by HHS.

Additionally, the National Adult Immunization Plan being implemented by HHS calls for all doctors and medical facilities to make compliance with federally recommended vaccinations “standard of care,” which is one reason so many adults, like so many children, are [being denied medical care](#) if they decline even one vaccination recommended by the Advisory Committee on Immunization Practices (ACIP), [regardless of whether they have had previous vaccine reactions or injuries](#). Goals of the National Adult Immunization Plan, which is part of the National Vaccine Program and Plan, seek to persuade employers to require all employees to receive federally recommended vaccines and enlist faith based organizations and other NGOs to market vaccines to adults with virtually no attention paid to preventing vaccine reactions or protecting the legal right for Americans to exercise voluntary, [informed consent](#) to vaccination.

With only 30 days notice for the public to submit comprehensive comments to HHS about the 2020-2025 National Vaccine Plan and virtually no prior public engagement over the past five years by HHS with NGOs that publicly articulate concerns about the safety of the US. vaccination system, following is a brief summary of additional observations by the [National Vaccine Information Center \(NVIC\)](#), which is the oldest and largest consumer-led organization in the U.S. dedicated to preventing vaccine injuries and deaths:

Top Priorities for the 2020-2025 National Vaccine Plan. Due to the historic negligence by HHS to make reducing vaccine risks and preventing vaccine reactions a priority, the top priority of the 2020-2025 National Vaccine Plan should be to *Reform and Expand Vaccine Safety Research to Define Vaccine Risks and Prevent Vaccine Injuries and Deaths*. The vast majority of the studies listed by HHS as “[Vaccine Safety Publications](#)” are epidemiological studies or vaccine policy analyses designed to affirm current HHS vaccine policy and minimize the significance of vaccine reactions and the potential negative effects on health, while almost none are bench science studies designed to investigate the biological mechanisms for and the genetic, epigenetic and environmental risk factors for [increased individual susceptibility](#) to adverse responses to vaccines. Of particular interest to parents of minor children is quality scientific evidence to [demonstrate the safety of the childhood vaccine schedule](#).

A second priority should be *Support Communications to Protect Voluntary, Informed Consent to Vaccination*. [Informed consent](#) is the gold standard for the ethical practice of medicine and should be a cornerstone of public health policy and law. The majority of vaccine communications programs developed by HHS since the first National Vaccine Plan have been designed to ignore vaccine reactions and the importance of identifying and reducing vaccine risks in order to strongly [promote use of HHS recommended vaccines](#) by all children and, now, all adults, rather than facilitate informed and voluntary vaccine decision making.

Changes to the 2010 National Vaccine Plan. The 2010 National Vaccine Plan’s [Goal 1](#) to *Develop New and Improved Vaccines* links development of new and improved vaccines for “domestic and global health priorities” to [public-private business partnerships](#) between HHS and global vaccine manufacturers, the Bill and Melinda Gates Foundation and the “Global HIV Enterprise.” In fact, the National Vaccine Program and Adult Immunization Program is now being managed by a new [Office of Infectious Disease and HIV/AIDS Policy \(ODIP\)](#), perhaps in preparation for an upcoming global campaign for mandated use of an HIV/AIDS vaccine as soon as it is licensed by HHS and recommended for all children and adults by the World Health Organization (WHO) and HHS. The goal of developing new and improved vaccines in the 2020-2025 National Vaccine Plan, including funding for vaccine development programs, should be confined to vaccines for domestic use in conformance with the purpose of the 1986 Act. Although Objective 1.4 to *Increase understanding of the host immune system* under Goal 1 is an extremely important scientific research priority, strategies for meeting this objective have not been adequately implemented in the 2010 Plan and should remain in the 2020-2015 Plan and be met.

The current objectives of the 2010 National Vaccine Plan’s [Goal 2](#) *Enhance the Vaccine Safety System* and important objectives and strategies for 2.2, 2.3, 2.4, 2.5 2.6 and 2.7 have not been met and should be revised, expanded and met in the 2020-025 National Vaccine Plan.

[Goal 3](#) to *Support communications to enhance informed vaccine decision-making* and objectives and strategies for achieving this goal have not been appropriately designed and fail to acknowledge the importance of voluntary, informed consent to vaccination. HHS has concentrated almost all of its activities in this area on conducting studies to identify reasons why Americans are not following HHS vaccine recommendations and devising ways to force compliance with HHS vaccine policies, rather than funding

studies to better define biological and other high risk factors for susceptibility to vaccine reactions in order to create credible information for the public to better inform vaccine decision making. The current approach by HHS to this goal fails to instill public trust in HHS vaccine policies. In the 2020-2025 National Vaccine Plan, this goal and strategies should be revised and appropriately implemented.

[Goal 4](#) of the 2010 National Vaccine Plan *Ensure a Stable Supply of, Access to, and Better Use of Recommended Vaccines in the United States* has been heavily focused on creation of state and national electronic surveillance and vaccine tracking systems to enforce compliance with HHS vaccine policies, rather than addressing fundamental gaps in vaccine science to increase public confidence in HHS policies. This goal should be revised in the 2020-2025 National Vaccine Plan to be more responsive to factors that affect vaccine use in the U.S.

[Goal 5](#) of the 2010 National Vaccine Plan *Increase global prevention of death and disease through safe and effective vaccination* should be removed from the 2020-2025 National Vaccine Plan. As stated previously, the 1986 National Childhood Vaccine Injury Act, which created the National Vaccine Program, was designed to protect the domestic vaccine supply and prevent vaccine reactions, [not advocate for funding and creation of global vaccine marketing campaigns](#) and create global surveillance and electronic vaccine tracking systems.

The [National Vaccine Information Center has long maintained](#) that there are inherent conflicts of interest in requiring the same government agency responsible for vaccine research, development, licensing, policymaking, promotion, and administration of the Vaccine Injury Compensation Program to also be responsible for vaccine safety research and oversight. The fact that to date, the National Vaccine Plan has failed to live up to the expectations and requirements of the vaccine safety provisions secured by parents of vaccine injured children in the National Childhood Vaccine Injury Act may well reflect that inherent conflict of interest.

Whatever the reasons that the National Vaccine Plan has failed to fulfill the 1986 Act's mandate to focus equally on "optimal prevention of adverse reactions to vaccines," HHS should take steps to correct that failure in the 2020-2025 National Vaccine Plan.

Sincerely,



Barbara Loe Fisher,
Co-founder & President