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Submitted by:

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RE: COMMENTS ON THE DRAFT NATIONAL VACCINE PLAN

On behalf of Trust for America's Health (TFAH), I am pleased to offer the following comments on the 2020 National Vaccine Plan. TFAH is a nonprofit, nonpartisan public health policy, research and advocacy organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. Our commitment to prevention underlies our support of the National Vaccine Plan and our comments for this rule.

Vaccines are a critical tool in preventing disease and reducing healthcare costs. The Centers for Disease Control and Prevention (CDC) find that since 1994, childhood vaccinations have prevented 419 million illnesses, 26.8 million hospitalizations and 936,000 early deaths¹. They not only save lives, they also save money. Childhood immunizations have saved nearly \$406 billion in direct costs and \$1.88 trillion in total societal costs.

The ongoing measles outbreak, which recently reached the highest levels in 25 years,² illustrates all too grimly the dangers of vaccine skepticism. This outbreak cost the healthcare and public health systems millions of dollars³ and contributed to needless suffering. Public health must have the resources to address vaccine awareness and misinformation issues, in addition to ongoing work to improve access, investigate and control outbreaks, educate providers and monitor vaccine effectiveness. We believe

¹ Centers for Disease Control and Prevention. National Infant Immunization Week. <https://www.cdc.gov/vaccines/events/niiw/overview.html> (accessed May 31, 2019)

² Stack, L. Measles Cases Reach Highest Level in More than 25 Years, C.D.C. Says. The New York Times, May 30, 2019. <https://www.nytimes.com/2019/05/30/health/measles-cases.html> (accessed May 31, 2019).

³ Tuttle, B. "Here's How Much America's 2019 Measles Outbreak is Costing Us." Money, April 30, 2019. <http://money.com/money/5643170/measles-outbreak-2019-cost-vaccine/> (accessed May 31, 2019)

that providers need tools to address misinformation and to answer questions from vaccine-hesitant patients, in a culturally appropriate manner.

Our detailed responses to the questions in the RFI are below.

1. Priorities for the 2020 National Vaccine Plan during 2020–2025. What do you recommend as the top priorities for vaccines and immunizations in the United States? Why are these priorities most important to you?

TFAH encourages the 2020 NVP to prioritize goals, objectives and strategies that will 1) increase coverage and sustained utilization of adult and childhood immunizations; 2) strengthen immunization infrastructure, specifically immunization information system capabilities and improved quality measurement tools to track immunization progress and identify gap areas of immunization coverage; 3) minimize vaccine exemptions for schoolchildren and healthcare workers; and 4) prioritize vaccines globally, considering both global health and the domestic impact of disease outbreaks.

To increase coverage and utilization, TFAH recommends strategies that include:

- a. Significantly increase support for the vaccine infrastructure, outbreak prevention and response. Ensure first-dollar coverage for recommended vaccines under Medicaid, Medicare, and commercial insurance. Public and private payers should ensure that ACIP-recommended vaccines are fully covered, as cost-sharing can be a significant barrier to vaccination. In addition, CDC's immunization program supports state and local immunization programs to increase vaccine rates among uninsured and underinsured adults and children, to respond to outbreaks, to educate the public and to target hard-to-reach populations. In addition, CDC's vaccine program improves vaccine confidence, establishes partnerships, and improves information systems. Funding has not kept up with needs. States have responded by spending immunization dollars to address outbreaks, and to provide vaccines for those who lack health insurance and coverage for certain vaccines, such as HPV. The NVP should recommend increased funding for CDC's immunization program.

- b. Raise awareness about the importance of vaccination and improve vaccine acceptance. Vaccine confidence and hesitancy issues remain a challenge across all sectors of the health care system and our government. Greater attention and effort are needed to drive meaningful improvements in immunization rates among the entire population. The NVP should emphasize the importance of education and encouragement of individuals to be aware of and receive recommended immunizations for themselves and their children. This communication should be strategic, evidence-based, culturally-appropriate and reflect the health literacy, language proficiency and functional and access needs of specific target populations. Providers play an essential role in providing education and

counseling to patients and must have the tools and resources to do this job effectively. Immunization champion programs have demonstrated success at improving immunization coverage rates within provider practices. Additionally, widespread dissemination and implementation of the National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice, to assess, recommend, administer or refer and document the vaccines the patient may (or may not) have received during the office visit, would help bring greater consistency across providers. In order to reinforce the case for vaccines across the life course, the NVP should prioritize gathering and analyzing economic data, including an assessment of the burden of vaccine preventable disease and the direct and indirect costs that can be averted through the use of vaccines.

c. Minimize vaccine exemptions for schoolchildren and healthcare workers. States should enact policies that enable universal childhood vaccinations to ensure that children, their classmates, educators and the general public are protected from vaccine-preventable diseases. This includes eliminating non-medical exemptions and opposing legislation to expand exemptions. States should ensure medical vaccine exemptions are only given when appropriate and are not used as a de facto personal belief exemption in states where those exemptions have been eliminated. Healthcare personnel should also be required to receive all recommended vaccinations of the Advisory Committee on Immunization Practices (ACIP) in order to protect staff and patients, assure continuity of operations in the event of an outbreak and achieve necessary healthcare infection control. Healthcare facilities should ensure access to vaccines for all staff and contractors and remove barriers for staff receiving vaccines.

d. Globally, malaria, tuberculosis (TB) and HIV vaccines should be priorities, as should Hepatitis C and influenza vaccine research. Malaria, TB and HIV are priorities for TFAH because they represent the world's most prevalent diseases: combined, HIV/AIDS, TB and malaria account for approximately 500 million or more illnesses annually and at least six million deaths.

Developing a vaccine against hepatitis C virus (HCV) also should be a priority, as should increased research into a universal influenza vaccine. Worldwide, an estimated 200 million individuals have HCV. A severe influenza pandemic could result in nearly 2 million American deaths and hundreds of millions more worldwide.

Strengthen and enhance the stability and sustainability of immunization infrastructure.

a. Supporting Immunization Infrastructure. Our nation's immunization infrastructure supports surveillance, reporting and response activities for a wide variety of stakeholders across the health care system. However, the cost of these vital

functions including vaccine purchase; storage; handling and safety; provider and community education and outreach; immunization information systems (IIS) or registries; disease surveillance; and outbreak response are results of the limited budgets of public health programs.

In particular, widespread implementation of health information technology (HIT) and electronic health record (EHR) systems have the potential to improve monitoring of vaccine preventable disease and vaccine coverage rates in real time as well as to facilitate the exchange of data that can improve the quality of preventive care among targeted adult populations, and patient outcomes. Greater utilization and interoperability between EHRs and IIS systems will be integral to improving and maintaining increases in adult immunization rates, and is the first step to identifying gaps where efforts and resources should be directed.

b. Encourage broad adoption of immunization quality measures. Strong and robust immunization infrastructure is critical to quality measurement program efforts to promote quality improvement, adherence and consistent utilization of recommended adult vaccines. TFAH encourages the NVP to strongly support the widespread adoption of quality measurement tools, including Adult Immunization Status (AIS), ESRD and maternal composite measures. Adoption of composite measures that can be electronically reported will provide a sound, reliable and comprehensive means to assess the receipt of routinely recommended adult immunizations while reducing the administrative reporting burden on providers.

2. What changes should be made to the 2010 National Vaccine Plan to make it more current and useful? This could include changes to the goals, objectives, strategies, activities, indicators, and other areas of the plan. Which components of the 2010 National Vaccine Plan worked well and should be maintained?

The 2020 NVP is an opportunity to continue building on the framework laid out in the 2010 NVP and to make it more current and useful in several sections. Given TFAH's priorities, we encourage ODP to maintain 2010 NVP goals 3 and 4 and offer the following specific recommendations:

Goal 3: Support Communications to Enhance Vaccine Decision-Making

Goal 3 of the 2010 NVP has become more relevant than ever. A coordinated approach to provider communication across the health care system, to patients and family members across the life course, and to the public generally is central to the success of all aspects of the NVP.

Moving forward, the 2020 NVP should further strengthen the workflow under goal 3. National immunization campaigns to protect the population against vaccine-preventable diseases have the ability to make a difference, but Goal 3 will be most impactful if and only if barriers to vaccine education and vaccine access have been effectively addressed. Efforts to build and enhance collaborations and partnerships for communication efforts, particularly with state and local partners should remain a high

priority (3.2). Strategies must not only rely on external campaigns but should prioritize stakeholder (3.2.1), cross-agency, and intra-agency collaboration (3.2.2).

Meaningful improvements in vaccine utilization and coverage rates can only be achieved with a strong foundation that incorporates the latest research and communication strategies. Tools to disseminate vaccine information—including publication of evidence-based recommendations, use of mass and social media, provider education and training, and support of non-federal stakeholder partners—are proven ways to educate and drive adult immunization demand. Public and private payers have an important role to play in communication efforts through things such as the Medicare Handbook and Medicare Learning Network (MLN) publications. In addition, reminder messages (postcard/text/email) to patients are reliable methods to communicate immunization information to providers and patients.

The 2020 NVP should also emphasize initiatives aimed at boosting immunization rates for minority, at-risk, and vulnerable populations across the life course (3.4). Communication and engagement should be strategic, evidence-based, culturally appropriate and reflect the health literacy, language proficiency and functional and access needs of specific target populations. Special attention should be paid to communicating the risk and cost of vaccine preventable disease with the goal of establishing vaccination as a routine part of preventive care and building confidence in vaccination as a societal norm (3.4).

The NVP should also prioritize improving the lines of communication between state and local vaccine program managers, third party payers, and key decision and policy makers (3.5). Ensuring that policy makers at all levels of government have current information on vaccine benefits and risks; economics related to vaccination; as well as an understanding of public knowledge and attitudes toward immunization will help to better inform the policymaking process (3.5). It is especially important for key decision-makers to have data on the direct and indirect costs and benefits of vaccinations across the life course (3.5.3).

2010 NVP Goal 4 — Ensure a Stable Supply of, Access to, and Better Use of Recommended Vaccines in the United States

Significant progress has been made to ensure the supply and delivery of vaccines over the last decade. The 2020 NVP should emphasize objectives to improve access to and utilization of vaccines across the life course. While tremendous progress has been made in access to childhood immunization, adults seeking access to and coverage for vaccines encounter a confusing health care system that presents multiple barriers, including lack of information about recommended vaccines, financial hurdles, as well as technological and logistical obstacles.

TFAH supports increasing the pool of providers who immunize. As new vaccines are approved, reaching target populations will be critical. States can expand certain health care providers' roles and scopes of practice to increase the pool of professionals who

provide vaccines, such as pharmacists and paramedics. All insurance plans should consider including pharmacists and other complementary providers in-network, and providers should receive equal payment for vaccine administration services for their adult and pediatric populations.

3. What are the goals, objectives, and strategies for each of your top priority areas? Are there any goals in the current strategy that should be discarded or revised? Which ones and why?

TFAH sees the value of carrying over many of the 2010 NVP goals, objectives and strategies to the proposed 2020 plan. Streamlining and assigning specific actions and benchmarks to stakeholders in the immunization community could help to improve the actionability and accountability of the plan in the implementation phase. As this process moves forward, we would encourage the plan to include strategies that are targeted across the life course and to identify specific strategies that will potentially benefit the various plan stakeholders seeking to make progress toward the various goals and objectives outlined in the plan.

Increased partnerships for communication efforts will be especially important. We share NVPs goals of reducing barriers and improving access to vaccines. Tremendous work is taking place across the country to identify the barriers and challenges around adult vaccines. NVP should prioritize collaborations with stakeholders to disseminate information and to learn from current outreach and best practices.

The NVP should also prioritize efforts to reduce financial barriers to vaccination. This includes efforts to ensure that out-of-pocket costs do not represent a significant barrier to adults and that providers are adequately compensated for the purchase and administration of ACIP-recommended vaccines.

A strong immunization infrastructure, including robustly supported and comprehensive immunization information systems should be the backbone of several of the goals outlined in the 2020 NVP. This infrastructure should have the capacity to deliver accurate and timely immunization coverage information on routinely administered vaccines and easily transmit immunization encounters and quality reporting measures. The NVP should prioritize the completeness of, and communication between IIS and EHRs to monitor vaccine coverage and efforts to support the adoption of interoperable health information technology and EHRs for immunization.

TFAH is committed to improving our nation's immunization infrastructure and would encourage increased and predictable discretionary funding through CDC for state and local immunization programs administered by public health departments, as well as broader investment from federal stakeholders within and outside of the Department of Health and Human Services that rely upon these services and systems, including the Centers for Medicare and Medicaid Services, the Departments of Defense and Veterans Affairs, among others.

There should also be close collaboration and coordination across federal agencies on efforts where there are implications for disease outbreaks and vaccinations. For instance, the nationwide opioid epidemic has resulted in a concurrent rise in the number of cases of Hepatitis A and B. Response efforts have severely strained federal, state and local resources and budgets. Improved collaboration and coordination across the viral hepatitis and immunization divisions will help to address some of this burden and improve response efforts aimed at containing these outbreaks.

Similarly, as our health system increasingly turns to the use of quality reporting and improvement tools in clinical practice, immunization should be prominently featured across these programs. Efforts to strengthen and support the dissemination and adoption of federal benchmarks and measures to encourage improved monitoring and reporting on immunization activities will help drive increased adult immunization rates and should also be considered a core strategy. Measures that consider the application of adult immunization standards across health care settings should be highlighted as a means to expand the consistent availability of immunizations as well as the use of IIS and quality improvement programs.

Finally, as discussed in our response to question 1, TFAH would like to see minimization of vaccine exemptions for school children and healthcare workers to prevent outbreaks like those that we have seen with measles, as well as increased attention to malaria, tuberculosis (TB) and HIV vaccines, and development of HCV and influenza vaccines.

4. What indicators can be used to measure your top priorities and goals? Are there any indicators in the 2010 National Vaccine Plan or the National Adult Immunization Plan (<https://www.hhs.gov/sites/default/files/nvpo/national-adult-immunizationplan/naip.pdf>) that should continue to be used? If so, which ones, and why?

A focused, concerted approach to adult immunization will need clear benchmarks and expectations of success. We recommend the NVP include an implementation plan that will show how goals, objectives, strategies will be met as well as who will be responsible for working together on the different activities for implementation.

The NVP should drive government resource allocation in terms of federal dollars, time and resources. Immunizations must be a national effort that involves multiple federal partners. The plan should incorporate efforts to coordinate with other partners within HHS, including CDC, CMS, HRSA, IHS, VA, DOD, to inform vaccine policy implementation. The NVP should outline a structure for interagency cooperation to ensure that implementation of vaccine efforts are integrated, comprehensive, efficient and effective.

The elements of the NVP should be harmonized with other federal government objectives. In cases where there are associated Healthy People 2030 goals, there should be alignment with NVP targets. We also encourage the NVP to prioritize

surveillance data to more accurately evaluate coverage gaps and disparities, particularly among minority and vulnerable populations. Another example would be to set forth specific strategies around immunization quality that correspond with CMS quality roadmap goals and objectives.

We also encourage the NVP to prioritize timely surveillance data to more accurately evaluate coverage gaps and disparities, particularly among minority and vulnerable populations. This is essential to implementing policies and strategies aimed at improving the impact and effectiveness of adult immunization efforts to increase and expand coverage.

Access to a real-time immunization dashboard could serve to highlight immunization champions as well as identify current and emerging coverage gaps in immunization in particular areas or among specific age groups or other subpopulations. This knowledge would inform policies and help to effectively target activities and resources where they are needed most.

When possible, immunization data should also tie in to related surveillance systems. For example, there has been a rise in hepatitis with the increase in opioid use, and this data should be cross referenced.

5. Identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the 2020 National Vaccine Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles that you or your organization might have in the 2020 National Vaccine Plan.

Successful implementation of the NVP will rest in large part on our shared commitment to several principles: educating all adults about the incredible benefits that vaccines provide for themselves and their children; making vaccines available to everyone, from all backgrounds; and simplifying the vaccine delivery process.

We agree with the Stakeholder Engagement Diagram as set forth in the National Vaccine Plan Development 2020 recommendations from the National Vaccine Access Coalition in September 2019. HHS, in particular ODP, has a long history of working with federal and non-federal partners to devise the NVP and to develop strategies that work towards implementation.

The NVP should consider new partners, including larger health systems, medical groups and Community Health Centers. External service providers for older adults, senior centers and employers have an important role in enacting the strategies of the plan.

TFAH recommends that the members of the National Vaccine Advisory Committee be tasked with responsibilities around enacting objectives and strategies. Workgroups could be created based on what is recommended in the plan across the lifespan to help oversee the various issues. Federal and non-federal partners should also be tasked with specific goals and priorities within the NVP.

Conclusion

Thank you very much for the opportunity to provide comments on the NVP. We are very much committed to the use of vaccines for individuals of all ages domestically and globally, and look forward to working with your office on the NVP in the future. If you have any questions, please contact Cecelia Thomas at cthomas@tfah.org