STATE OF WEST VIRGINIA
# DEPARTMENT OF HEALTH AND HUMAN RESOURCES

**Bill J. Crouch**
**Cabinet Secretary**

**Rahul Gupta, MD, MPH, MBA, FACP**
**Commissioner**
**State Health Officer**

July 30, 2018

Dear Senator and Delegate :

We are writing in response to your communication dated July 18, 2018, expressing your concerns over a perceived lack of oversight performed by federal government regarding the safety of vaccines in the United States. As we understand, you are making three requests through your joint statement:

1. That the West Virginia Department of Health and Human Resources (DHHR) submit to the legislature evidence that the agency is doing its due diligence regarding mechanisms for vaccine safety reporting and adverse event monitoring;
2. That the Governor include on his call for an upcoming extraordinary Legislative session, legislation adding an exemption from compulsory immunization requirements until "further documentation and data can show that our current vaccination program is not creating harm [to] children"; and
3. That an independent vaccine safety task force be established.

First, we have reviewed the result of litigation in the U.S. District Court for the Southern District of New York styled *Informed Consent Action Network v. U.S. Department of Health & Human Services (HHS)* (18-cv-03215) to which you referred. This case involved an action filed by the Informed Consent Action Network (ICAN) for declaratory and injunctive relief after HHS failed to respond to a Freedom of Information Act (FOIA) request filed with the agency in August 2017. ICAN sued HHS seeking records, if any, responsive to the FOIA request. After the litigation was initiated, HHS

responded by indicating that its search did not locate any responsive records. Because of this response, the parties to the litigation jointly stipulated that all claims asserted in the action were resolved and that the matter could be dismissed. The Court in no way made any finding on whether or not HHS has fulfilled its duties under the law related to vaccine safety. In fact, HHS's failure to provide records showing that it has submitted a report to Congress is not proof that the agency has failed to fulfill its obligation to be an industry watchdog. Indeed, as described below, HHS has acted diligently to ensure vaccine improvements are being made and the products being mandated for our children are unequivocally safe.

We would like to reassure you that the DHHR's Bureau for Public Health, Division of Immunization Services considers vaccine safety a priority for all West Virginia residents. Vaccinations are among the most cost-effective and widely used public health interventions -- one of the ten great public health achievements of the 20th century. Vaccination programs have eradicated smallpox, virtually eliminated poliomyelitis, and reduced vaccine preventable diseases in many developed countries by 98 to 99 percent. Moreover, state vaccination laws have been a great success. The rate of complete immunization of school age children in the United States (more than 95%) is as high or higher than most other developed countries. More importantly, common childhood illnesses, such as measles, pertussis, and polio, which once accounted for a substantial proportion of child morbidity and mortality, have dramatically decreased.

**Vaccine Safety Generally**

Vaccination is a common, memorable event, and association of events in time often signals cause and effect. While some of the sickness or reactions that follow vaccination may be caused by the vaccine, many are unrelated events that occur by coincidence. Therefore, the scientific research that attempts to distinguish true vaccine adverse events from unrelated, chance occurrence is important. Vaccines are held to the highest standard of safety. The United States currently has the safest, most effective vaccine supply in history and monitoring health problems after vaccination is essential to ensure the United States continues to have the safest, most effective vaccine supply in history. Years of testing are required by law before a vaccine can be licensed. Once licensed and in use, vaccines are continuously monitored for safety and efficacy. The Centers for Disease Control and Prevention (CDC) Immunization Safety Office identifies possible vaccine side effects and conducts studies to determine whether a health problem is caused by a specific vaccine. We would like to share with you the following ongoing national vaccination safety obligations which are critical to the safety of West Virginia residents.

**Vaccine Safety Monitoring Activities**

Vaccines are monitored to detect rare reactions. Although vaccines are tested extensively before they are licensed for use in the United States, not enough people are included in the tests to detect reactions that happen only rarely. If serious reactions are found when the vaccine is in widespread use, the vaccine may be withdrawn. Vaccine safety monitoring also makes sure new vaccines are safe for groups such as the elderly, those with chronic medical conditions, and pregnant women. Monitoring vaccine safety also helps to maintain public confidence needed to keep enough people vaccinated to prevent disease outbreaks.

The CDC monitors the safety of vaccines by:

- Performing high-quality vaccine safety research.
- Making determinations about whether vaccines caused reactions in certain cases and helping to learn about preventable risk factors.
- Identifying vaccine adverse events through public health surveillance.

CDC's Immunization Safety Office conducts four primary vaccine safety activities:

- **The Vaccine Adverse Event Reporting System (VAERS)** is a national vaccine safety surveillance program run by CDC and the Food and Drug Administration (FDA). VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur after vaccination. VAERS was created in 1990 in response to the National Childhood Vaccine Injury Act (NCVIA) – 42 U.S.C. § 300aa-26. If any health problem happens after vaccination, anyone – doctors, nurses, vaccine manufacturers, and any member of the general public – can submit a report to VAERS.

- **The Vaccine Safety Datalink (VSD)** is a collaborative project between CDC's Immunization Safety Office and eight health care organizations. The VSD started in 1990 and continues today in order to monitor safety of vaccines and conduct studies about rare and serious adverse events following immunization. The VSD uses electronic health data from each participating site. This includes information on vaccines: the kind of vaccine given to each patient, date of vaccination, and other vaccinations given on the same day. The VSD also uses information on medical illnesses that have been diagnosed at doctors' offices, urgent care visits, emergency department visits, and hospital stays. The VSD conducts vaccine safety studies based on questions or concerns raised from the medical literature and reports to the VAERS. When there are new vaccines that have been

recommended for use in the United States or if there are changes in how a vaccine is recommended, the VSD will monitor the safety of these vaccines. The VSD has a long history of monitoring and evaluating the safety of vaccines. Since 1990, investigators from the VSD have published many studies to address vaccine safety concerns.

- **CDC's Clinical Immunization Safety Assessment (CISA) Project** was established in 2001 to address the unmet vaccine safety clinical research needs of the United States. CISA is a national network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), seven medical research centers, and other partners, which provide a comprehensive vaccine safety public health service to the nation.

- **CDC's Immunization Safety Office (ISO)** prepares for emergencies by ensuring that robust systems are in place to rapidly monitor vaccine safety in the event of an emergency vaccination program.

**Vaccine Information Statements**

As noted above, vaccines are among the most important public health interventions in history, having led to the eradication of smallpox and to significant reductions in the incidence of many other viral and bacterial diseases. But like any medical intervention, vaccines also entail risk. Vaccine reactions are generally mild, but they can, rarely, be severe. When a disease is common and can have serious consequences, the public generally finds that the benefits of a vaccine that can prevent it outweigh the relatively low risk of a severe side effect. But as the incidence of a disease declines, risks from vaccination, which remain relatively constant, can appear more prominent. Ultimately, risks from the vaccine can seem more threatening than risks from the disease.

Providing patients (and the parents of pediatric patients) with accurate information about the benefits and risks of vaccination is important for both ethical and legal reasons. The CDC produces information sheets called "Vaccine Information Statements" (VISs), which describe the risks and benefits of vaccines, and are given to patients at the time of vaccination. The genesis of VISs was a 1974 legal case, and their subsequent history has been determined, in part, by a series of events and decisions that have transformed the earliest materials into those used today. All vaccine providers, public or private, are required by the NCVIA, to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines and each dose of a multi-dose series. It must be given regardless of the age of the recipient.

It is estimated that vaccines have prevented more than 300 million childhood illnesses and more than 700,000 premature deaths between the years 1994 and 2013. While this time period happens to coincide with the introduction of VISs and their continued use, whether VISs have had an impact on vaccine coverage is unknown. However, a recent study looking at acceptance of human papillomavirus (HPV) vaccine reported that CDC's VIS "significantly increased perceptions of vaccine benefits and decreased perceived risks."

No figures are available on the number of paper copies of VISs distributed prior to their availability on the internet; but since then the annual number of downloads from CDC's VIS website has grown substantially. For example, downloads of influenza VISs increased from 113,004 in 2005, to 316,378 in 2010, to 621,054 in 2015; and the number of providers who have registered to receive VIS e-mail updates has grown from fewer than 70,000 in July 2011 to more than 235,000 by February 2017. CDC's Vaccine Information Statements have evolved considerably through several decades of growth and change in the U.S. vaccination program. As future needs and challenges arise, they will undoubtedly continue to evolve, and continue to fulfil their mandate to clearly inform patients about the benefits and risks of all vaccines.

In the past, healthcare providers and public health entities interpreted federal law as a requirement that a paper copy of each VIS had to be handed to the recipient prior to vaccination, and that the recipient must take this copy away with him or her following the vaccination. The evolution of electronic media has resulted in broadening of this interpretation. For example, now:

- A practice may produce permanent, laminated, office copies of each VIS, which may be read by recipients prior to vaccination.
- VISs may be reviewed on a computer monitor (or any video display).
- VISs may be downloaded by the recipient to a smartphone or other electronic device to read at his or her convenience. (VISs have been specially formatted for this purpose.)
- VISs may be made available to be read before the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit or telling them how to download or view a copy from the Internet). These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.
- Providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take away following the vaccination. However, the recipient may decline.

In addition to distributing VISs, providers are required to record specific information in the patient's medical record (which can include an electronic medical record), or in a permanent office log:

- The edition date of the VIS (found on the back at the right bottom corner).
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered).
- The office address and name and title of the person who administers the vaccine.
- The date the vaccine is administered.
- The vaccine manufacturer and lot number.

Regarding your request that the state enact an exemption to its current compulsory immunization requirements until it can be documented that the current vaccination program is not creating harm. Such an exception would essentially negate the state's expressed public policy in favor of compulsory immunization by allowing parents to withhold all vaccines from their children until the state can prove the negative – that vaccinations cause *no* harm. As discussed above, like any medical intervention, there are risks associated with vaccines. Vaccine reactions are generally mild, but they can, be severe. However, incidents of severe reactions are rare. When a disease is common and can have serious consequences, the public generally finds that the benefits of a vaccine that can prevent it outweigh the relatively low risk of a severe side effect. But as the incidence of a disease declines, risks from vaccination, which remain relatively constant, can appear more prominent. Ultimately, risks from the vaccine can seem more threatening than risks from the disease. To allow parents to exempt their children from immunizations until the state proves that there is zero risk associated with the vaccines themselves, will result in the resurgence of diseases that are almost unknown, epidemics of diseases that are nearly under control, and more children getting sick and more dying.

Finally, with regard to the request for a task force, state law already provides for an advisory committee made up of public health nurses, public health officers, primary health care providers, pediatricians, family practice physicians, health care administrators, pharmacists, the Commissioner of the Bureau for Medical Services, representatives of the health insurance industry, the Director of the Public Employees Insurance Agency, representatives of the self-insured industry and a minimum of three consumers. *See W.Va. Code* §16-3-5(d). This advisory committee is charged with the very responsibilities that you are requesting, including making recommendations on the distribution of vaccines, advising the Secretary of DHHR on the changing needs and opportunities for immunization from known diseases for all persons across their life span, and tracking immunization compliance in accordance with federal and state laws.

We remain confident and proud of West Virginia for maintaining its status as a national leader in ensuring the protection from vaccine preventable diseases. We appreciate your engagement in guaranteeing that our state remains a model across the nation in pursuing the best evidence-based strategies while safeguarding the health and safety of our residents.

Sincerely,

Bill J. Crouch
Cabinet Secretary

Rahul Gupta, MD, MPH, MBA, FACP
Commissioner and State Health Officer

cc: The Honorable Jim Justice, Governor