National Vaccine Information Center

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January 16, 2012 ****VIA EMAIL****

National Vaccine Program Office, US Dept. of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
200 Independence Avenue, SW
Room 733-G.3
Washington, DC 20201
Email nvpo@hhs.gov

Re: Public Comment on Draft Recommendations of The Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) of the National Vaccine Advisory Committee (NVAC)

Dear Committee Members,

We write to you today in opposition to the draft recommendations of the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) of the National Vaccine Advisory Committee (NVAC)[1] regarding influenza vaccination requirements for health care personnel. As the oldest national, non-profit consumer advocacy organization advocating for the institution of vaccine safety and informed consent protections in the public health system, we hear from many health care personnel (HCP), who oppose influenza vaccination requirements for medical, religious and conscientious belief reasons. With this statement, we are voicing their concerns and ours to the NVAC.

The National Vaccine Information Center (NVIC) has historic standing in representing the vaccine injured and vaccine consumers concerned about vaccine safety and the critical need to protect the legal right to informed consent to vaccination in America. NVIC co-founders worked with Congress to insert vaccine safety and informed consent provisions in the historic National Childhood Vaccine Injury Act of 1986.[2] [3] A 501C3 charity founded in 1982, NVIC is supported by more than 30,000 educated health care consumers, including health care professionals, families with healthy children, and those, whose loved ones have experienced vaccine reactions, injuries and deaths. NVIC does not advocate for or against the use of vaccines but defends the human right to exercise informed consent to medical risk-taking, including the right for everyone to have access to full information about infectious diseases and vaccines and the freedom to make voluntary decisions about vaccination.[4]

Vaccines are pharmaceutical products that carry a risk of injury or death, which can be greater for some than others. The Institute of Medicine (IOM) published a landmark report in 2011, *Adverse Effects of Vaccines: Evidence and Causality*, and acknowledged increased susceptibility for individuals, who have unidentified genetic or other biological high risk factors for adverse responses to vaccination that can lead to permanent injury or death.[5] In addition, out of the 27 adverse events reported to be associated with influenza vaccination, for which the IOM committee reviewed evidence in the medical literature to try to determine causation, the committee was unable to make a determination for 23 of the 27 adverse events because there was either an absence of studies or the studies were not methodologically sound enough to prove or disprove causation. [6]

Therefore, a mandatory, one-size-fits all approach to vaccination punishes those at greater genetic and biological risk for suffering harm from vaccines. Mandatory vaccination policies without exemptions also penalize those holding religious or conscientious belief objections to vaccination. It is unfair, irresponsible and unethical for employers to force health care workers to choose between their health, their deeply held spiritual or conscientious beliefs or their job.

In the past two years, we have seen an increase in the number of harassment reports made by health professionals to NVIC. They are reporting they are being threatened and fired from their jobs for declining influenza vaccination [7] even though (1) they have already suffered previous vaccine reactions that their employers refuse to recognize as serious enough to qualify for a medical exemption because those reactions to not adhere to strict CDC contraindication guidelines; or (2) they have a personal or family history of severe allergies, vaccine reactions, autoimmune or neurological disorders that employers reject as qualifiers for a medical exemption because the CDC does not list those medical conditions as a reason to defer vaccination; or (3) they have deeply held spiritual or conscientious beliefs that oppose vaccination but the employer refuses to grant an exemption because the health care worker does not belong to an organized religion or church with a tenet opposing vaccination, which is a violation of constitutional rights.

As a result, these health care professionals – some of them with decades of experience on the front lines caring for patients – find themselves on the street with no job or income during these hard economic times. This should not be allowed to happen in America.

The draft recommendations of the HCPIVS, which advocates requiring mandatory vaccination of health care personnel, violates the ethical principle of informed consent to medical risk-taking. Therefore, NVIC does not support these recommendations or any coercive government or employment policy, which condones the use of harassment and threat of denial of employment or job dismissal as a club to force health care workers with medical, religious or conscientious belief objections to get annual flu shots.

It is important to note that HCPIVS members also appear to be troubled by the coercive nature of proposed mandatory influenza vaccination policies for health care personnel as a condition of employment. Review of the history of the committee's draft recommendations reveals that the majority of HCPIVS members favor in-house education programs informing health care workers about influenza; reasonable infection control measures and easy access to influenza vaccine. However, most committee members do not favor mandatory influenza vaccination policies that fail to include informed consent protections and vaccine exemptions.

In fact, the majority of committee members (89% or 24 of 27) indicated they support the inclusion of exemptions to influenza vaccination for health care personnel. Specifically, 29% (7 of 24 members) opposed influenza vaccination requirements for health care workers; 29% (7 of 24 members) supported medical, religious and philosophical exemptions; 41% (10 of 24 members) supported a medical exemption and 11% (3 of 27 members) did not respond.[8]

The following overarching themes identified by the committee, which establish the foundation of the committee's recommendations, lack foundational merit due to inadequate supporting evidence:

- ***Theme 1: Influenza is a significant public health issue.*** – Out of 308 million Americans, CDC estimated that only about 12,000 deaths were associated with influenza in 2009, a pandemic year in which influenza morbidity and mortality was very closely monitored,[9] which is in sharp contrast with the CDC's recently revised public statement (included in these draft recommendations) that the U.S. has "3,000 to 49,000 influenza-associated deaths each year." With more than 200 viruses known to cause influenza and influenza-like illness, the CDC's top influenza expert stated in 2003 at an FDA meeting that 80% of flu-like illness reported during the "flu season" is not caused by type A or type B influenza.[10] Other experts estimate that influenza vaccines, which only contain three strains of influenza type A and B viruses, are protective at best against only about 10% of all circulating viruses that cause influenza-like symptoms.[11]

  The draft recommendation's utilization of CDC's recently revised estimates for influenza-associated deaths to demonstrate that influenza is a significant public health threat, which

requires a “no exceptions” mandatory vaccination policy for health care personnel, is misleading. The inference made by using the CDC’s influenza mortality estimates, which also include deaths associated with influenza-like illnesses that have not been lab confirmed as type A or type B influenza, is that higher uptake of influenza vaccine would reduce annual mortality from type A and type B influenza. Scientific evidence does not support such an inference.

With regard to residents in long-term care facilities (LTCFs), an independent systematic review of the medical literature by the Cochrane Collaboration found no evidence that vaccinating health care workers prevents laboratory-confirmed influenza, pneumonia, and death from pneumonia of the elderly in LTCFs. The same review also found that winter influenza is responsible for less than 10% of deaths of individuals over 60.[12]

In fact, research shows that influenza rarely kills healthy people under age 65, and that only 5 to 20 percent of Americans may experience type A or type B influenza in an average flu season,[13] with the majority having uncomplicated cases.

While people with chronic medical conditions are at risk for influenza complications and death, an independent, systematic review of the medical literature revealed that asymptomatic individuals may shed influenza virus, but that transmission of influenza has been inferred and studies have not conclusively determined that asymptomatic and pre-symptomatic people do effectively transmit influenza to others.[14] At the same time, there is considerable body of evidence demonstrating that influenza transmission can be prevented or reduced in home and health care settings with traditional public health interventions, including hand washing, masking, and separating sick and healthy persons.[15] [16] [17]

Many assertions made by the committee within this theme are grossly overstated and not consistent with scientific evidence about influenza vaccine effectiveness or reliance on influenza vaccination as the primary influenza-prevention intervention in health care settings.

- ***Theme 2: Immunization is the most effective way to protect patients and HCP from influenza infections –*** A 2010 review of the medical literature on this topic found that there is an absence of accurate data on rates of laboratory-proven influenza in healthcare workers.[18] While influenza vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP), systematic reviews of influenza vaccine research has shown that most influenza studies are poorly designed and have failed to demonstrate influenza vaccine effectiveness and safety.[19] [20]

  A more recent systematic review of studies, published in *The Lancet in* October 2011, found that influenza vaccine is less than 70 percent effective in preventing influenza [21] and, like all pharmaceutical products, the CDC warns that use of influenza vaccine is not without risk of vaccine injury.[22]

  The current scientific evidence, some of it referenced in this statement, does not support the committee’s central argument that influenza vaccine is the most effective and safe way to prevent health care personnel from transmitting type A and B influenza strains to patients. In fact, when vaccinated health care workers start exhibiting flu symptoms, they and their employers may be more likely to assume they are <u>not</u> infected with type A or type B influenza when the opposite may be true. This a priori assumption, based on misplaced faith in the effectiveness of influenza vaccine, could have unintended consequences for health care workers and patients alike.

- ***Theme 3: In spite of long- standing recommendations for all HCP to receive vaccination against influenza, HCP immunization rates are well below the Healthy People 2020 goal. –*** Recent research and public opinion surveys demonstrate that vaccine hesitancy is on the increase among educated consumers and it is primarily due to concerns about vaccine safety. The HCPIVS report makes no mention of the rise in influenza vaccine injury reports to the federal Vaccine Adverse Events Reporting System (VAERS) [23] and the rise in influenza vaccine injury claims filed with the Vaccine Injury Compensation Program (VICP).

The fact that influenza vaccine injury reports and compensation claims are increasing should be of great concern to NVAC in light of information provided by the staff of the Chief Medical Office (CMO) of the Federal Division of Vaccine Injury Compensation (DVIC) in 2011. According to Dr. Rosemary Johann-Liang, DVIC CMO, the number of vaccine injury claims filed in 2010 with the federal Vaccine Injury Compensation Program (VICP) have almost tripled in comparison to claims filed from 2001-2007, with the increase in claims largely due to adult influenza vaccine injury claims.[24]

Health care professionals are among the most well-educated and aware of the risks and complications of infectious diseases and vaccines. Therefore, the NVAC should take seriously the fact that studies reveal about 60% of HCPs do not want to be vaccinated for influenza and are concerned about the vaccine's ineffectiveness and side effects.[25]

Additionally, another critical issue not addressed by the committee's recommendations is the potential for liability exposure to health care facilities when a health care professional, who is forced to get vaccinated as a condition of employment, is permanently injured after an influenza vaccine reaction. Taxpayers will also face an additional financial burden when health care workers become vaccine injured and file workman compensation claims or file unemployment claims, when they are fired for failing to show proof they have gotten an annual flu shot.

How will health care workers be compensated for an on-the-job influenza vaccine injury that occurs because of mandatory vaccination policies that violate informed consent rights and fail to include adequate medical, religious or conscientious belief exemptions? Will workers fired for noncompliance have the ability to draw unemployment benefits? These are concerns that the committee's report fails to address in pursuit of the shortsighted Healthy People 2020 goal, which is primarily defined by numbers of people vaccinated.

Because NVIC's mission for three decades has been to prevent vaccine injuries and deaths through public education and defend the informed consent ethic, we maintain that the informed consent rights of America's health care professionals should not be violated by the institution of mandatory influenza vaccination requirements by employers, which fail to provide flexible exemptions for medical, religious and conscientious belief objections. At the end of the day, threatening and forcing America's health care personnel to get annual flu shots or be fired [26] will only serve to further erode public trust in vaccines and public health policies.[27] [28] [29]

We know that NVIC is not alone in our opposition to the institution by employers of coercive influenza vaccination policies that strip health care personnel of their informed consent rights. In December 2011 the Association of American Physicians and Surgeons (AAPS) stated their opposition as follows:

*"AAPS, a national organization of physicians in all specialties, objects to the mandatory immunization of health care workers (HCWs). Fewer than half of American HCWs choose to be immunized annually against influenza. We believe that the professional judgment of these workers should be respected."*

In conclusion, NVIC maintains that health care professionals should be given access to full and accurate information on influenza and influenza vaccine and be allowed to exercise voluntary, informed consent to vaccination and not be subjected to harassment, coercion, intimidation or threatened with termination for declining to get an annual flu shot. We urge the committee to include recommendations for flexible medical, religious and conscientious belief exemptions in vaccination policies instituted by employers for health care personnel.

Respectfully,

*Barbara Loe Fisher*

Barbara Loe Fisher
Co-founder & President

*Theresa K. Wrangham*

Theresa K. Wrangham,
Executive Director

## References


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