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January 13, 2012

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Deputy Assistant Secretary for Health
Director, National Vaccine Program Office
U.S. Department of Health and Human Services
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Room 733G.3
Washington, DC 20201

Dear Dr. Gellin:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults, appreciates the opportunity to comment on the draft report and draft recommendations of the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS) for consideration by the National Vaccine Advisory Committee (NVAC) on achieving the Healthy People 2020 annual coverage goals for influenza vaccination in healthcare personnel (HCP), as published in the Federal Register on December 16, 2011.

The AAP commends the Assistant Secretary for Health, the National Vaccine Program Office and the Healthcare Personnel Influenza Vaccination Subgroup for undertaking the important task of developing recommended strategies for annually achieving 90 percent HCP influenza vaccination coverage, as stated in the Healthy People 2020 goals. Vaccines remain one of the most effective public health interventions and we support efforts to ensure that HCPs that care for our nation's children and adults are themselves vaccinated. Healthcare-associated influenza outbreaks are a common and serious public health problem that contributes significantly to patient morbidity and mortality and creates a financial burden on healthcare systems. Annual immunization of HCP is a matter of patient safety and necessary to significantly reduce healthcare-associated influenza infections.

While AAP generally supports the recommendations of the HCPIVS draft report and the goal of achieving 90 percent influenza vaccination coverage among healthcare personnel, we also strongly believe that the recommendations should make influenza vaccination a requirement for employment.

Although Recommendations One and Two are laudable, many health care employers (HCEs) have implemented such proposals to various degrees and we as a country have still failed to achieve the 90 percent goal of HCP influenza vaccination coverage. Instead of using language that "strongly urges" HCEs and facilities to adopt Recommendations One and Two, it may be more effective if the language "required" HCEs and facilities to incorporate the recommendations.

In addition, for Recommendation Four—for HCEs and facilities that have already implemented Recommendations One, Two and Three and still cannot achieve and maintain the Healthy People 2020 goal of 90 percent influenza coverage among healthcare personnel—we suggest that the Recommendation simply make influenza vaccination a requirement for employment, with the exceptions of those who have medical exemptions and in states that might allow for personal exemptions.

We believe that recent epidemiological research has demonstrated that a compelling case can be made for requiring all employees to receive the influenza vaccination and that such a mandatory approach is ethically justified in the name of patient safety.

The AAP released a Policy Statement in September 2010, “Recommendations for Mandatory Influenza Immunization of All Health Care Personnel,” that listed the following examples of mandatory influenza vaccine policies that resulted in a substantial increase in employee immunization rates, demonstrating the success of implementing a mandatory program.

1. BJC Health care, a large nonprofit health care organization with approximately 26,000 employees, implemented a mandatory influenza immunization program in 2008 after voluntary models failed to increase rates above 80%.ⁱ BJC made influenza immunization a condition of employment as a patient safety initiative. Employees could be granted medical or religious exemptions on review by an occupational medicine professional. Medical exemptions were granted to 321 employees (1.2%), of which 107 were for an egg allergy, 83 for previous allergic reaction or allergy to an influenza vaccine component, and 15 for a history of Guillain-Barré syndrome. Exemptions were granted to 116 other employees, of whom 14 cited pregnancy,ⁱⁱ although it is highly recommended that pregnant women receive influenza vaccine because of the documented increase in risk of serious complications, including death.ⁱⁱⁱ Religious exemptions were granted to 90 employees. The result was an immunization rate of 98.4% for the organization of 25 980 employees. Only 8 employees refused to be vaccinated, and their employment was terminated.^{iv}
2. Seattle's Virginia Mason Medical Center implemented a mandatory influenza immunization program in 2005. The medical center reported a 99% immunization compliance rate among its employees.^v
3. The National Institutes of Health Clinical Center passed a mandatory influenza immunization policy in 2008. The policy required that employees who had patient contact be immunized or complete an online declination statement specifying the reason for refusal. The policy achieved 100% participation in that all 2754 employees who were identified to have direct patient contact were either immunized or formally declined vaccination. Compared with vaccination rates of 40% to 60% from previous years, the organization achieved an immunization rate of 88% (2424) among employees with patient contact. Of employees who formally declined, 36 reported medical contraindications to influenza vaccine, and 294 declined for other reasons such as concerns about adverse effects, belief that they were not at risk of influenza, or perceptions that the vaccine was ineffective or harmful. Philosophical reasons were cited 5 times as frequently as religious reasons for declining vaccination.^{vi}
4. Hospital Corporation of America, which includes 163 hospitals, 112 outpatient centers, and 368 physician practices in 20 states, put a mandatory policy into effect in late 2009. The policy required all employees in contact with patients to either receive the annual influenza vaccine or wear a surgical mask in patient areas. Before the policy, vaccination rates in Hospital

Corporation of America facilities varied from 20% to 70%. This mandatory policy offered influenza vaccine to 140 599 HCP; 96% of these employees complied.^{vii}

In addition, another study was just published this month by the Society for Healthcare Epidemiology of America (see attached) that we recommend be included in the references. The study, “Voluntary to Mandatory: Evolution of Strategies and Attitudes toward Influenza Vaccination of Healthcare Personnel,” highlights well the value of mandatory programs and lack of success with voluntary programs.

Finally, although this is a technical point, we urge you to change language on pages ii and 5, to note that the Advisory Committee on Immunization Practices recommends that all persons 6 months of age and older receive annual influenza vaccination, not “persons > 6 months” as currently written.

As stated earlier, the AAP supports the goal of achieving 90 percent influenza vaccination coverage among health care personnel and commends the Healthcare Personnel Influenza Vaccination Subgroup for undertaking the important task of developing recommended strategies for achieving this goal. Thank you for the opportunity to comment on the draft report and draft recommendations of the Healthcare Personnel Influenza Vaccination Subgroup. If the AAP may be of any further assistance, please don't hesitate to contact Pat Johnson in our Washington, D.C. office at 202/347-8600 or pjohnson@aap.org. We look forward to future collaborations as you move to finalize the recommendations to meet the Healthy People 2020 goal for influenza vaccination in healthcare personnel.

Sincerely,



Robert W. Block, MD, FAAP
President

RWB/pmj

ⁱ Babcock HM, Gemeinhart N, Jones M, Dungan WC, Woeltje KF. Mandatory influenza vaccination of health care workers: translating policy to practice. *Clin Infect Dis*. 2010; 50(4): 459-464

ⁱⁱ Ibid.

ⁱⁱⁱ Pavia AT. Mandate to protect patients from health care-associated influenza. *Clin Infect Dis*. 2010; 50(4): 465-467

^{iv} Babcock HM, Gemeinhart N, Jones M, Dungan WC, Woeltje KF. Mandatory influenza vaccination of health care workers: translating policy to practice. *Clin Infect Dis*. 2010; 50(4): 459-464

^v The Joint Commission. Providing a safer environment for health care personnel and patients through influenza vaccination. Available at: www.jointcommission.org/NR/rdonlyres/814E02F2-1E1C-4D76-9043-DBB3E12A205A/0/Flu_Monograph.pdf. Accessed August 16, 2010.

^{vi} Palmore TN, Vandersluis JP, Morris J, et al. A successful mandatory influenza vaccination campaign using an innovative electronic tracking system. *Infect Control Hosp Epidemiol*. 2009; 30(12): 1137-1142.

^{vii} Tucker ME. Mandating influenza immunization gets the job done. *Lancet*. Available at: www.thelancet.com/H1N1-flu/egmn/0c03ed6d. Accessed July 19, 2010.

American Federation of Labor and Congress of Industrial Organizations



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January 12, 2012

National Vaccine Program Office
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Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

RE: Draft Report and Recommendations of HCPIVS to the NVAC Adult Immunization Working Group on Influenza Coverage for Health Care Personnel

Dear Sir or Madam:

The AFL-CIO is a federation of 57 national and international labor unions representing more than 9 million workers in their workplaces, including workers employed in the healthcare industry. We appreciate the opportunity to submit comments on the draft report and recommendations of the Health Care Personnel Influenza Vaccination Subgroup of the NVAC Adult Immunization Working Group concerned with increasing the rate of influenza vaccination among healthcare workers.

As a representative of healthcare workers, the AFL-CIO believes that all healthcare workers are entitled to a workplace where they are fully protected from exposure to infectious agents such as influenza. In order to achieve this objective, employers must implement a comprehensive infection control program. That program would include an infectious agent hazard analysis; exposure control plan using engineering and workpractice controls along with personal protective equipment; procedures to identify and isolate infected patients; medical surveillance and vaccination of healthcare workers; information and training of healthcare workers; appropriate signage and labeling; housekeeping; and periodic evaluation/revision of the exposure control plan. Such a comprehensive infection control program will protect both healthcare workers and

patients from becoming infected in the workplace with influenza or other infectious agents.

In our view, influenza vaccination of healthcare workers represents an important component of the overall infection control program to protect workers. However, vaccination is only one component and it will not by itself, in the absence of implementing all of the other elements of an infection control program, provide the full degree of protection that workers need. The AFL-CIO supports influenza vaccination of healthcare workers and we encourage healthcare employers to establish effective voluntary programs to achieve high rates of vaccination among its workforce. We do not support, however, mandatory required influenza vaccination programs that compel healthcare workers to become vaccinated under threat of disciplinary action, including discharge, as a means to achieve a vaccination influenza rate target. Mandatory vaccination programs are not necessary in order to achieve high rates of vaccination among healthcare workers.

Recommendation 4 in the draft report from HCPIVS to NVAC states that if healthcare employers cannot achieve the Healthy People 2020 goal of 90% influenza vaccination coverage for healthcare workers, then those employers should “strongly consider an employer requirement for influenza immunization”. We urge NAVC to reject this recommendation requirement outright for the set of reasons that we outline below. Should NVAC not reject this recommendation outright, then we would suggest that it be modified to remove the language requiring healthcare employers to establish mandatory flu vaccination and to add language that stresses the importance of establishing training and information programs on the importance and value of becoming vaccinated. This revised recommendation will assist employers and employees in the healthcare sector in achieving high rates of vaccination without the use of discipline or discharge.

Our opposition to *Recommendation 4* and rationale for urging NVAC to reject it is based on the following arguments:

The Healthy People 2020 Objective Of 90 Percent Seasonal Influenza Vaccination Among Health Care Personnel Is A Goal Rather Than A Mandatory Requirement

The Healthy People 2020 has established goals and objectives for improving the health in the United States, including the setting of a “target” of 90% of health care personnel becoming vaccinated against seasonal influenza. While this target of 90% is laudable, there is no evidence to substantiate that this level of vaccination among health care workers is necessary in order to protect them or patients from becoming infected with the seasonal flu. That said, the 90% target represents an arbitrary, but voluntary, objective that health care employers should seek to achieve. This objective under Healthy People 2020 is not

however, a requirement or mandate. Thus, *Recommendation 4*, which calls for an employer requirement to achieve this goal, violates the spirit and intent of the Healthy People 2020 initiative and as a consequence, should be rejected by NVAC.

The Influenza Vaccine Is Not Very Effective And Mandating Its Use Can Provide Employers And Workers With A False Sense Of Protection From Workplace Influenza Exposures In The Absence Of A Complete Infection Control Program

The influenza vaccine varies widely from year to year in its efficacy and effectiveness depending upon the antigenic match with the influenza strains that are in circulation in any given year. And the effectiveness is determined only after the influenza season is over. As a result, the overall effectiveness of the seasonal influenza virus has recently been estimated to be around 59% (1). Thus, on average, the effectiveness of the seasonal influenza vaccine is far less effective than one would desire in a vaccine. Regardless of the proportion of health care workers who receive the vaccine, many of the recipients are likely to have no effective immunological response – particularly in those flu seasons where the antigenic match is poor and the vaccine effectiveness is low. Mandating the seasonal influenza vaccine that is often not very effective creates an illusion that healthcare workers are being adequately protected when they are not – which further heightens the necessity of implementing comprehensive infection control programs (including seasonal flu vaccination as one of its components). And there appears to be no scientific justification to mandate flu vaccination for healthcare workers in order to protect patients (2). The NVAC should not adopt a recommendation for mandating seasonal flu vaccination when its effectiveness is so poor – and one which requires humans to receive a new vaccination every year.

It is well established that there are serious problems with the effectiveness of the seasonal flu vaccine. In our view, NVAC would be far more effective in addressing this issue by advocating for additional research to generate a more consistently effective seasonal flu vaccine – and one that did not need to be given so frequently – rather than to advocate for required use of an ineffective vaccine that could result in healthcare workers losing their jobs.

Voluntary Programs Alone Can Achieve Sufficiently High Influenza Vaccination Rates That Obviate The Need For Mandatory Requiements

Programs and policies that require seasonal flu vaccination for healthcare workers under threat of discipline or even discharge are not necessary in order to achieve high rates of vaccination within a healthcare sector workforce. It is possible for healthcare employers to achieve seasonal flu vaccination rates in

excess of 90% which can achieve the Healthy People 2020 “target” of 90% without resorting to mandatory programs which places the livelihoods of healthcare workers on the line (3). NVAC would do well to take the high road here by strongly supporting research and case studies that identify the impediments and constructive features of programs that will enhance the rate of flu vaccination among health care workers – rather than to encourage employers to adopt policies that terminate workers.

Unilateral Implementation Of Mandatory Seasonal Influenza Vaccination Programs In Unionized Healthcare Facilities Is A Violation Of The National Labor Relations Act – NVAC Should Not Endorse Illegal Acts By Employers

The establishment of mandatory seasonal influenza programs that require, as a condition of employment, healthcare workers to become vaccinated or suffer discipline or discharge for failing to do so is a term and condition of employment under the National Labor Relations Act. As such, employers with unionized workforces cannot unilaterally implement these mandatory programs without negotiating with the union over the program should the union demand negotiations. This legal requirement in unionized healthcare settings was recently upheld in a decision by the full National Labor Relations Board in *Virginia Mason Hospital and Washington State Nurses Association*, Case 19-CA-30154, August 23, 2011 (4). In our view, NVAC should abandon a recommendation for requiring mandatory programs – and leave that issue, should it arise, to be addressed between the employer and the employee’s representative.

Healthcare Workers Must Be Provided With Medical, Religious And/Or Personal Reasons To Decline Vaccination So That Their Continued Employment Status Is Not Jeopardized

Healthcare workers must be permitted to refuse the annual seasonal influenza vaccination without fear of reprisal for medical, religious, or personal reasons. Such a declination is fully appropriate as part of a comprehensive employer program that is designed to enhance the likelihood of health care workers voluntarily choosing to receive the vaccination. The experience with OSHA’s Bloodborne pathogens standard, which requires employers to provide, but not mandate its use, the hepatitis B vaccine is instructive. The number of cases of hepatitis B among healthcare workers has decreased dramatically despite the fact that workers can decline the vaccine with no reprisals. We think NVAC should adopt a similar posture regarding the seasonal flu vaccine for health care workers.

In closing, we hope that NVAC will adopt our perspective and reject *Recommendation 4* in the report.

Sincerely,

A handwritten signature in cursive script that reads "Bill Kojola".

Bill Kojola
Industrial Hygienist
Safety and Health Department
202-637-5003

REFERENCES

- (1) Osterholm MT, Kelly NS, Sommer A and Belongia EA. Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. *The Lancet Infectious Disease*. Published online October 26, 2011.
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- (3) Hakim H, Gaur AH, and McCullers JA. Motivating factors for high rates of influenza vaccination among healthcare workers. *Vaccine*. In press, 2011.
- (4) National Labor Relations Board. *Virginia Mason Hospital (a Division of Virginia Mason Hospital Center) and Washington State Nurses Association*. Case 19-CA-30154. August 23, 2011.



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January 13, 2012

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Washington, DC 20201

Dear Sir or Madam:

On behalf of our 1.6 million members, including healthcare workers in hospital, nursing home and home care settings, the American Federation of State, County and Municipal Employees (AFSCME) thanks you for the opportunity to comment on the draft developed by the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS) of the National Vaccine Advisory Committee (NVAC), charged with increasing influenza vaccination rates among healthcare workers.

While we support the bulk of the *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel*, AFSCME cannot endorse Recommendation # 4 urging that employers require influenza vaccination without allowance for medical, religious and philosophical exemptions, where they are unable to achieve to 90 % compliance. Issues of concern are:

- The use of mandatory vaccination is contrary to the collective bargaining process in union-represented facilities. A new mandatory vaccination policy would be considered a subject of bargaining.
- Efficacy of vaccines for influenza can vary greatly from year to year, and can be as low as 40%. The Centers for Disease Control recently updated its information on vaccine efficacy to be only about 59% in a typical year. Since influenza is an annual vaccination, it should not be compared to the MMR vaccination or even Hepatitis B or pertussis. Individuals, along with the physicians, should have some say if they would want an annual vaccine that may or may not be very effective.
- Although it is generally a very safe vaccine, workers may have a negative outcome from an influenza vaccination even if it isn't as serious as Guillain-Barre syndrome or an allergic reaction. This can be a part of the normal immune response. Many employers use punitive practices such as point systems and discipline for using leave, making it unlikely that employees would be excused for feeling ill after receiving a vaccination. In fact, the HCPIVS does not consider the effects that punitive employer leave policies may have on the rate of influenza transmission or the vaccination rate for healthcare personnel.
- Immunization by itself is not infection control. Good infection control is based on a multi-faceted, systems based approach. Workers' personal actions (getting a shot, hand washing) should not alone be the thrust of any health care organization's policy. AFSCME fears that mandatory vaccination would lead some health care employers to become complacent in other aspects of influenza infection control.

American Federation of State, County and Municipal Employees, AFL-CIO

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National Vaccine Program Office
January 13, 2012
Page 2

- The Occupational Safety and Health Administration (OSHA) has stated it does not believe that there is sufficient evidence to meet the bar necessary to support mandatory vaccination programs.
- There are still shortages of skilled healthcare personnel in many areas of the country. A requirement for an annual vaccination may drive some out of the profession, or make it unattractive to prospective students

Finally, although an admirable goal, a vaccination rate of 90% for healthcare personnel is not necessary to achieve herd immunity within a facility. As an alternative, AFSCME suggests that the NVAC amend Recommendation #4 to incorporate an employer requirement to provide education, modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine. While the HCPIVS frequently cites the importance of healthcare worker education, none of the recommendations actually encourage, or even mention education.

Thank you for considering our comments and concerns as you finalize the recommendations of the Health Care Personnel Influenza Vaccination Subgroup.

Sincerely,



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January 16, 2012

National Vaccine Program Office
US Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination Subgroup
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Dear Subgroup Members:

On behalf of 1.5 million members of the American Federation of Teachers (AFT), I thank you for the opportunity to submit comments on the draft *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel* (15 December 2011, V1.8). The AFT represents over 75,000 healthcare personnel in the AFT Healthcare division. Those healthcare workers include nurses in both acute care and long-term care facilities, school nurses, medical and radiological technologists and environmental service workers among others. We commend the sub-group in addressing both the interests of patient and healthcare personnel (HCP) in their recommendations to the National Vaccine Advisory Committee (NVAC).

The American Federation of Teachers submitted comments to the National Vaccine Program Office draft policy in January 2009. At the time we recommended that the NVP look to the comprehensive regulatory approach developed by OSHA on blood-borne pathogen exposure as a model to improve both healthcare personnel and patient safety. We are heartened that the Assistant Secretary of the Department of Health and Human Services (DHHS) acted upon some of our comments and constituted a working group to produce recommendations for the larger National Vaccine Plan and that DHHS reached out to the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) to participate in the process. As indicated by the Healthcare Personnel Influenza Vaccination Subgroup's (HPIVS) report, consideration was given to a more comprehensive approach to reaching the goal of greater healthcare personnel influenza immunization.

It is our understanding that the sub-group was charged with focusing its recommendations on improving influenza immunization rates of healthcare personnel (HCP) to reach the Healthy People annual goal of 90% influenza vaccine coverage. We believe that the HPIVS recommendations are more nuanced than those in the previous NVP drafts. The current draft recommendations acknowledge that data are lacking and

that more surveillance of HCP immunization should be conducted before universal adoption of HCP mandatory immunization is recommended. However, the report indicates that the majority of the working group leans strongly in favor of mandatory immunization.

We remain unconvinced that mandatory influenza immunization is the most effective and sole approach for reaching the goal of 90% immunization of all healthcare workers. We concur with the first two recommendations of the working group. Comprehensive influenza infection prevention programs are essential for all healthcare facilities and settings; HCP immunization goals should be a part of those programs. However, the AFT believes that the subgroup has not given due consideration to a comprehensive occupational safety and health regulatory approach as an equally effective approach to achieving the 90% goal. Currently, there has been a patch-work of adoption of sound infection control and healthcare worker occupational safety and health programs on the part of healthcare employers. Granted, one may find exemplary models of these programs among larger healthcare employers. Others – especially smaller healthcare employers - however have been slow to take a comprehensive approach to protecting patients and healthcare workers. For instance, too many have neglected the training and information that are promoted in the sub-group report. They have not developed programs to encourage or create incentives for workers with influenza-like illnesses (ILI) to take sick leave and/or be evaluated by a healthcare provider. Others may have adopted the practice of mandatory influenza immunization but have passed on the costs to many low-wage healthcare workers who can ill-afford the economic burden.

We would recommend expanding recommendation three to include other key federal agencies in creating incentives and requirements – especially the Occupational Safety and Health Administration. A comprehensive OSHA standard is the most effective vehicle for bringing the healthcare personnel immunization to scale. The mandate should be the adoption of a comprehensive standard similar to OSHA blood-borne pathogen standard with requirements for training, voluntary immunization and declination after education. When healthcare personnel received training as part of the OSHA blood-borne pathogen standard, they- readily accepted hepatitis vaccine as part of a broad program with the result of improved both worker and patient safety.

The AFT believes that the subgroup can strengthen its recommendations in other areas as well – especially in the arena of research. The subgroup acknowledges the gaps in surveillance and research evidence as well as the lack of standard measures healthcare employers can use to gauge HP immunization. AFT believes that the sub-group should expand the recommendation for research to include vaccine efficacy among healthcare workers. Universal healthcare personnel influenza immunization may be an imperfect

solution for protecting both patients and workers. What little research we have to date¹ indicates that the effectiveness in target populations varies considerably. Those persons with co-morbidities such as diabetes, cardiovascular disease and other chronic illnesses do not readily mount an adequate immune response after vaccination and hence constitute a population at risk for infection after immunization. There is some indication that healthcare workers as a group are less healthy than the general population². A review of healthcare insurance costs for healthcare personnel revealed that HP were more likely to be diagnosed with serious chronic diseases such as asthma, diabetes and heart disease than the general population. HP may need to be considered a vulnerable population with a different set of assumptions made about immune response to seasonal influenza vaccines than those made for a healthy, young population. More research through long-term prospective studies on vaccine efficacy within HP is essential to inform policy recommendations.

Similarly the efficacy of influenza seasonal immunization appears to fluctuate significantly from year to year and no surveillance or research tools exist to gauge efficacy during an influenza season. One researcher estimates the seasonal influenza vaccine efficacy to hover around 59%.³ And we may reasonably anticipate influenza seasons when the antigenic match of the vaccine and the circulating viruses is low. In such seasons, reliance on universal HP immunization may not prove to protect either healthcare workers or patients.

Clearly much more aggressive research is required to gauge vaccine efficacy and immunologic response among healthcare personnel before sweeping policy can be made.

The AFT believes that establishing a mandatory seasonal influenza program is a change to the terms and conditions of employment. Therefore those healthcare employers with unionized workforces cannot unilaterally implement mandatory influenza programs with the consequence of discipline or discharge for those unwilling to do so without negotiating with the union should the union wish to do so. The National Labor Relations Board (NLRB) recently upheld that right in its decision in the Virginia Mason Hospital and Washington State Nurses Association, Case 19-CA-30154, August 23, 2011. In our opinion, a far better seasonal influenza infection control program that includes HP seasonal influenza policies would also result when employers and worker representatives enter negotiations.

¹ Michiels B et al. *A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups*. *Vaccine* 29:9159-9170, 2011

² Thomas Reuters Research Brief. August 2011. *Sicker and Costlier: Healthcare Utilization among US Hospital Employees*.

³ Osterholm MT et al. *Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis*. *The Lancet Infectious Disease*. Published online October 26, 2011.

National Vaccine Program Office
US Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination Subgroup
Page 4

In closing, the AFT believes that HCP influenza immunization alone is an imperfect strategy to guarantee both patient and healthcare worker safety. A better approach in our view is a comprehensive occupational health and infection control plan that includes voluntary immunization, training and education. A regulatory approach is a far more efficient mechanism for reaching scale on healthcare personnel immunization. A regulatory approach will guarantee that many healthcare workers who do not work for large healthcare employers will be offered the vaccine at no cost, education, training and monitoring. Furthermore, we believe that focusing solely on mandatory influenza immunization may have a downside of neglect of other important strategies for reducing patient and worker exposure such as patient isolation, improved ventilation and personal protective equipment and clothing. At the same time, there is a striking need for broader research on vaccine efficacy especially among demographic sub-groups of healthcare personnel.

Again, thank you again for the opportunity to submit comments.

Sincerely,

Darryl Alexander
Program Director
AFT health and safety



American Health Care Association

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January 13, 2012

Jennifer Gordon, Ph.D., National
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Services, 200 Independence Ave. SW.,
Room 733G.3, Washington, DC 20201,
Attn: Jennifer Gordon, Ph.D.

Via Electronic email: nvpo@hhs.gov

**Re: Comments to the Recommendations on Strategies to Achieve the Healthy
People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care
Personnel**

Dear Dr. Gordon:

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) represents nearly 11,000 non-profit and for-profit providers dedicated to continuous improvement in the delivery of professional and compassionate care for our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA/NCAL commends the Department of Health and Human Services (HHS) for preparing Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel. We appreciate the opportunity to offer our comments on the proposed recommendation.

General Comments

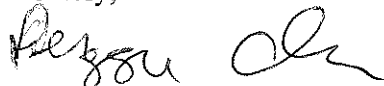
American Health Care Association agrees that all Health Care Personnel (HCP) should be offered the influenza vaccination. AHCA does have the following questions and statements in regards to the recommendations outlined by the NVAC

AHCA/NCAL NVAC Recommendation

- AHCA/NCAL would like to encourage the NVAC Adult Immunization Work Group to develop a template for Health Care Providers that they can develop a written program and implement it in their organization's Infection Control Programs.
- Define the LTC Facility. Does this include the continuum of care like Assisted Living, independent Hospice centers, and Home Health? Or just Skilled Nursing Facilities (SNFs)?
- Identify vaccination priority areas in instances of shortages. What population is on the list to receive the vaccine first? Are HCPs given a priority, then elderly and pediatrics? Or what type of Health Care Setting is a priority or patient type? How does a shortage effect reporting purposes to CMS?
- Specify if an antiviral can be used in cases of shortage, specify the type of patients where the use of antivirals is most effective, and specify whether the administration of an antiviral is appropriate for measurement purposes.
- AHCA/NCAL proposes that if the masks become part of the recommendation then the mask be a surgical type of mask, due to the prohibitive cost of the respirator type of masks. In addition, AHCA/NCAL would like recommend that LTC settings be exempt from this recommendation because when a HCP wears a mask, the mask prohibits communication with the residents/patients of our facilities that have hearing impairment. Keep in mind that nursing facilities are required to provide influenza immunizations to residents. In addition, the use of masks by a HCP can lead to residents who have dementia to become more resistant to care and agitated. Therefore, we encourage the committee to consider the use of Personnel Protective Equipment such as gloves and hand washing to be a substitute for a wearing a mask in the Long Term Care Setting.
- Ensure that employee injury or illness resulting from the vaccine be reported to and paid by National Vaccine Injury Compensation Program. Using additional reporting and compensation systems, like worker's compensation, detracts from having a dedicated and usable source of vaccine-related injury and illness data.

AHCA/NCAL appreciates the opportunity to provide these comments. AHCA/NCAL does support the recommendations that are listed in the report and look forward to working with the committee to address the proposed recommendations.

Sincerely,



Peggy Connorton, MS, LNFA
Manager, LTC Trend Tracker



James L. Madara, MD
Executive Vice President, CEO

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January 17, 2012

Jennifer Gordon, PhD
National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 733-G.3
Washington, DC 20201

Re: Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel

Dear Dr. Gordon:

On behalf of our physician and medical student members, the American Medical Association (AMA) is pleased to provide our support for the five recommendations in the draft report of the Healthcare Personnel Influenza Vaccination Subgroup of the National Vaccine Advisory Committee (NVAC). As noted in the Subgroup's excellent report, influenza infection remains a serious threat to the patients that we serve. Our patients expect that the physician or other healthcare professional who is treating them is protected against influenza, particularly since they are seeing the patient at a time when the patient could potentially be even more vulnerable to the disease.

America's healthcare personnel are on the front lines in the fight against communicable illnesses. The risks are two-fold when this front line does not follow influenza vaccination recommendations. Due to the very nature of the job, healthcare workers run a higher risk of exposure to influenza. Without vaccination, healthcare professionals can transmit influenza to patients in their care. Patients already in fragile health and under the care of a health worker—for example, in a hospital or nursing home—are more likely to be susceptible to the flu and vulnerable to its complications.

While the Healthy People 2020 goal of 90 percent coverage of all healthcare personnel seems to be an ambitious one, the AMA firmly believes that this goal is necessary to optimize patient safety and certainly is achievable. In fact, a recent survey done by the AMA following the 2009 H1N1 influenza pandemic and presented to the NVAC at its February 2010 meeting, indicated that physicians were immunized at an overall rate of almost 94 percent during the 2009-2010 influenza season. Additionally, the recent surveys conducted by the National Foundation for Infectious Diseases and by the Centers for Disease Control and Prevention continue to show improvement in healthcare personnel influenza vaccination coverage rates. Accordingly, the AMA urges all hospitals, health care systems, and health care providers, as a priority, to immunize providers and appropriate patients

Jennifer Gordon, PhD

January 17, 2012

Page 2

as defined by the Advisory Committee on Immunization Practices guidelines against influenza, both for their own protection and to reduce the risk of transmission to others.

Existing AMA policy supports universal influenza vaccination of healthcare workers, and supports universal immunization of healthcare workers against seasonal and pandemic influenza through vaccination programs undertaken by healthcare institutions in conjunction with medical staff leadership. Additionally, the AMA encourages hospitals and skilled nursing facilities to have a system for measuring and maximizing the rate of influenza immunization for health care workers. The AMA also believes that physicians and other health and medical workers (in practice and in training) should set positive examples by assuring that they are completely immunized.

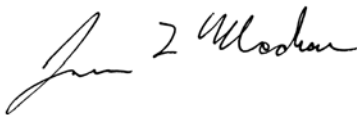
Recommendations 1 through 3 set out important standards for an influenza prevention culture within a medical facility. Significantly, the NVAC subgroup's report clearly delineates that while influenza vaccination is perhaps the most important preventive strategy in such programs, it cannot be the only strategy. Literature has clearly indicated that the most successful influenza prevention programs not only utilize influenza immunization as a critical tool, but they also surround immunization with a culture of education, convenient vaccine access, and implementation of other infection control techniques to prevent the spread of influenza. Finally, the AMA supports the development of a standardized methodology that can be applied across all facilities to measure influenza vaccination rates and to link vaccine coverage levels and quality improvement activities.

The AMA believes that as professionals committed to promoting the welfare of individual patients and the health of the public, and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious disease in healthcare settings. Thus, AMA ethical policy states that physicians have an obligation to accept immunization absent medical contraindication, as recommended by the medical staff leadership or healthcare institution. This is consistent with the subgroup's recommendation that facilities that are unable to achieve the Healthy People 2020 goal of 90 percent influenza vaccination coverage of healthcare personnel in an efficient and timely manner consider an employer requirement for influenza immunization.

Finally, the AMA lauds the subgroup's recommendation that research into new influenza vaccine technology be continued. While the existing influenza vaccine is very safe and effective, it is not a perfect vaccine. The development of a new vaccine that no longer requires annual vaccination would be a significant boost to improving not only healthcare personnel influenza immunization rates, but also rates among the general public.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD



AMERICAN OSTEOPATHIC ASSOCIATION

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January 13, 2012

Jennifer Gordon, PhD
National Vaccine Program Office
US Department of Health and Human Services
200 Independence Avenue, SW
Room 733G.3
Washington, DC 20201

Attn: Healthcare Personnel Influenza Vaccination

Dear Dr. Gordon:

Thank you for the opportunity to comment on the December 2011 draft report on healthcare personnel influenza vaccination. The American Osteopathic Association (AOA) represents more than 78,000 osteopathic physicians nationwide. Approximately 65% of practicing osteopathic physicians work in primary care areas such as pediatrics, family practice, obstetrics and gynecology, and internal medicine. Many DOs fill a critical need for patients by practicing in rural and other medically underserved communities.

The AOA does understand the significance of influenza vaccination. In 2009, we approved policies which state that we support and recommend influenza vaccinations for all health care workers and educators according to the guidelines of the Centers for Disease Control and Prevention (CDC), and that all osteopathic medical schools have an ongoing influenza vaccination program for students.

We understand that this report does not outline the scope or contents of employer requirements for vaccination of health care personnel and that the decision for such requirements should be made by the health care employer. We concur and believe that this decision is best made at each individual employer and/or facility level. However, we do have concerns with any final recommendations which would require universal mandatory influenza vaccination of health care personnel without voluntary efforts first. If mandated in all circumstances such a requirement could result in additional administrative burden for health care employers and facilities.

We understand that the Centers for Medicare and Medicaid Services (CMS) plans to require reporting of health care worker vaccination rates in acute care hospitals beginning in January 2013 and those that fail to report will have a payment reduction as a penalty for not reporting. Given the current uncertain and challenging financial climate, health care personnel and facilities cannot afford to continually take on additional unfunded mandates or absorb more payment reductions.

We do have suggestions that could be implemented to educate employees and assist facilities with this important issue: Information on influenza vaccination should be provided to all employees during the employee orientation process. By providing information on vaccination during orientation, health care personnel would “get in the habit” of being vaccinated each year and would receive current and up-to-date vaccine information that could be shared with their patients. In addition, as part of planning and training for a potential epidemic, hospitals and other facilities should also consider synchronizing their vaccination programs with their biological disaster planning exercises.

Thank you for the opportunity to provide comments. We look forward to working with HHS on this and other issues of importance to the osteopathic community.

Respectfully,

A handwritten signature in cursive script, appearing to read "Martin S. Levine, DO". The signature is written in black ink and is positioned below the word "Respectfully,".

Martin S. Levine, DO
President

Protect, Prevent, Live Well

January 13, 2012

Jennifer Gordon, Ph.D.
National Vaccine Program Office, US Dept. of Health and Human Services
200 Independence Avenue, SW
Room 733-G.3
Washington, DC 20201

RE: Comments on FR Document 2011-32308, draft report and recommendations of the Health Care Personnel Influenza Subgroup of the National Vaccine Advisory Committee

Dear Dr. Gordon,

The American Public Health Association (APHA), the oldest and most diverse organization of public health professionals and advocates in the world dedicated to promoting and protecting the health of the public and our communities, appreciates the opportunity to provide comments on the draft report and recommendations of the Health Care Personnel Influenza Subgroup of the National Vaccine Advisory Committee (NVAC).

APHA commends the NVAC for its development of draft recommendations to achieve the annual Healthy People 2020 goal of 90 percent influenza vaccine coverage for health care personnel. The report and recommendations clearly demonstrate the essential role immunization of health workers plays in preventing influenza transmission, especially in health care settings. These individuals may be exposed to influenza and transmit infection to patients, coworkers, or community members even if they themselves do not develop symptoms or illness. Of particular concern is transmission to patients, who due to weakened immune systems, are at heightened risk for complications and morbidity from influenza infection. Additionally, transmission to other health workers in their workplace can impact capacity to provide services. APHA has longstanding support for employers and workplaces requiring vaccination of health workers without a documented medical contraindication to the vaccine as a strategy to reduce and prevent the spread of influenza, including 2010 adopted policy 201014, [Annual Influenza Vaccination Requirements for Health Workers](#). APHA also supports employers requiring influenza vaccination of health workers as a precondition of employment, and on a continuing annual basis.

As you move forward with these recommendations, we encourage the NVAC to broaden the definition of health care personnel to include those working outside of traditional health care facilities. This includes workers in community-based residential settings, senior centers, community health workers, and those providing care in schools. Home care workers in particular are less likely to have employer-paid health insurance to cover an influenza vaccination.

Additionally, workers in these environments do not share the benefits of medically-outfitted licensed facilities or doctors' offices, leaving them at additional risk for infection without vaccination.

Achieving 90 percent influenza vaccination coverage is an important goal; however, the timing of a mandatory vaccination policy for personnel will vary among health care settings. Slower uptake of vaccinations among workers may require some employers to initiate a vaccination requirement sooner than others in order to achieve the 90 percent coverage goal in a timely manner, particularly if the rate of improvement with other strategies is slow. We agree with NVAC that requirements for influenza vaccination are the most effective mechanism to rapidly reach and maintain the 90 percent coverage goal, and also recognize that education campaigns and vigorous outreach to staff may be sufficient for some employers without a mandatory program. Health care employers and facilities should ensure their vaccination programs and policies reflect the specific needs of their employees and environment. Continuing evaluation is essential.

We support the NVAC recommendation that health care employers and facilities implement annual education campaigns on the importance, safety, and efficacy of influenza vaccination, and work to oppose anti-vaccine or anti-mandate efforts that misinform health care workers or the public on this issue. Misinformation on the severity of influenza, the effectiveness and safety of the vaccine, workplace risks of transmission, and other issues may lead health care workers to refuse or delay vaccination. Correcting these falsities is a shared responsibility of HHS and individual health care employers and facilities and should be a priority when implementing a vaccination program.

It is also important to demonstrate the shared benefits of individual vaccination for coworkers, patients, and their communities. Lowering the spread of influenza affects the health of all involved parties. While health workers may want to assert their individual rights to decide about the vaccine, choosing to work in health care brings responsibility. Addressing this responsibility to the community and demonstrating their influential role in public perception about influenza prevention and the impact of their behavior on the broader health care system should be used as a motivating factor to receive the influenza vaccine.

Thank you for the opportunity to provide comments on this report and the NVAC's draft recommendations. We look forward to working with the public health community to ensure the goals of Healthy People 2020 are achieved.

Sincerely,

A handwritten signature in black ink, appearing to read "Georges C. Benjamin". The signature is fluid and cursive, written in a professional style.

Georges C. Benjamin, MD, FACP, FACEP (E)
Executive Director



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January 13, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 733G.3
Washington, D.C. 20201
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

Re: Comments on the Draft Report and Draft Recommendations of the Health Care Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel

Dear Dr. Gordon:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of greater than 14,000 infection preventionists, wishes to thank the National Vaccine Advisory Committee (NVAC) and the Health Care Personnel Influenza Vaccination Subgroup (HCPiVS) for the opportunity to provide input into their "Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Healthcare Personnel."

We strongly support the report's recommendations and the underlying Healthy People 2020 Annual goal. As you may know, in January 2011 APIC recommended that acute care hospitals, long term care, and other facilities that employ healthcare personnel (as defined in the August 2009 MMWR) require annual influenza immunization as a condition of employment unless there are compelling medical contraindications.

Our position called for individuals exempted from annual vaccination due to medical contraindications to be educated on the importance of careful adherence to all of the non-vaccine related Healthcare Infection Control Practices Advisory Committee (HICPAC) prevention strategies, including hand hygiene and cough etiquette. We further said they may be required to wear a surgical mask when contact with patients or susceptible employees was likely.

APIC also supported the CMS rule requiring facilities to report HCP influenza vaccination rates through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). At the time the CMS rule was proposed, most hospitals did not use the CDC/NHSN module to collect HCP influenza vaccination rates because the current CDC/NHSN module was redundant and labor intensive, but instead used their own databases, usually maintained by the Employee/Occupational Health Department, to collect vaccination data. However, a new NHSN module has recently been endorsed by the National Quality Forum (NQF) and is expected to be available for use in August 2012. APIC supports use of NHSN to capture HCP influenza vaccination rates in order to capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for HCP, and the elements within yearly influenza campaigns that succeed or require improvement.



It remains our belief that these requirements should be part of a comprehensive strategy which incorporates all of the recommendations for influenza vaccination of HCP of HICPAC and the Advisory Committee on Immunization Practices (ACIP) for influenza vaccination of HCP.

Again, we wish to thank you for the opportunity to comment. We applaud NVAC for its efforts to develop sound recommendations on improving HCP influenza vaccination, consistent with the Healthy People 2020 goal, thus improving the safety of patients and HCP.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell N. Olmsted", is written over a light gray rectangular background.

Russell N. Olmsted, MPH, CIC
2011 APIC President

Healthcare Personnel Influenza Immunization

FR Doc 2011-32308 Filed 12-16-11

The Association of American Physicians and Surgeons (AAPS), a national organization of physicians in all specialties founded in 1943 to preserve the sanctity of the patient-physician relationship, objects strenuously to any coercion of healthcare personnel to receive influenza immunization.

It is a fundamental human right not to be subjected to medical interventions without fully informed consent.

Like all medical interventions, influenza vaccination has risks as well as benefits. Safety testing has been limited, especially concerning long-term health effects of repeated vaccination. It is known that serious adverse effects sometimes occur, and may lead to death or chronic disability. Benefits have been difficult to demonstrate. Benefits to patient populations linked to vaccination rates of personnel, if demonstrable at all, are small. Outside of study populations such as long-term care facilities, benefits are largely hypothetical.

The majority of healthcare workers decline annual influenza vaccination. The government has no constitutional authority to impose medical interventions on individuals, even if put to a majority vote. In the case of influenza vaccination, a majority vote of the affected individuals would apparently be negative. With what justification do “stakeholders” of Healthy People 2020, which is apparently a public-private partnership without specific statutory authorization or oversight, advocate overruling Americans’ decision about their own health, even Americans who are medical professionals?

The draft document itself reveals the poor quality of the evidence backing this recommendation. Estimates of annual “influenza-associated deaths” vary 13 fold, from 3,000 to 49,000. This likely reflects annual variation in influenza prevalence as well as uncertain diagnostic criteria. Whatever causes this wide variation will vastly outweigh any effect of higher immunization rates, since efficacy under the best conditions is likely no better than 70%. Of the alleged 200,000 hospitalizations “for respiratory illnesses and heart conditions associated with seasonal influenza infections,” we have no idea how many involve vaccine-preventable influenza. The proportion that resulted from contact with unimmunized medical workers is also unknown but probably very small.

The statement that “immunization is the most effective method for preventing infection from influenza and possible hospitalization or death” is an assertion unsupported by evidence. Better handwashing and respiratory hygiene, vitamin D supplementation, use of ultraviolet lights to decontaminate air in enclosed areas, or other methods have not been tested in comparison with immunization.

Notably, recommendations do not include better safety testing of vaccine. This would include measures of health in vaccinated and unvaccinated populations, including prevalence of

allergies and autoimmune conditions. It might also include measures of mercury levels in tissues, since influenza vaccine contains mercury in thimerosal, a known neurotoxin that accumulates in the body. Quantitative comparisons of mercury exposure from medical treatments with environmental exposures that are of concern to the Environmental Protection Agency (EPA) should be part of informed consent. All vaccine components should be tested for potential allergy-inducing adjuvant effects, whether or not they are intended as adjuvants.

Respectfully submitted,
Jane M. Orient, M.D., Executive Director
Association of American Physicians and Surgeons
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Association of Community Health Nursing Educators

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Jennifer Gordon, PhD
AAAS Science and Technology Policy Fellow
National Vaccine Program Office
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. Gordon,

The Executive Committee of the Association of Community Health Nursing Educators, ACHNE, commends the National Vaccine Advisory Committee's for the thoughtfulness of its December 15, 2012 draft *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel*. ACHNE, a member of the Quad Council of Public Health Nursing Organizations and an organization that promotes excellence in community and public health nursing education, research, and practice, supports the five recommendations of NVAC's draft report.

ACHNE supports the inclusion of public health ethics and nursing ethics as a necessary part of undergraduate and graduate community/public health nursing curricula. We consider that employer-initiated requirements for influenza vaccination (if they are determined to be necessary for the timely, efficient achievement of the goal of 90% Healthy People 2020 influenza vaccination coverage goal for health care personnel) are consistent with public health ethics and with the Nurses Code of Ethics. Additionally, such a requirement is in line with other employer requirements that safeguard the health of populations served.

Community/public health nurses will likely be involved in development, implementation, and evaluation of comprehensive vaccination programs for health care personnel. We look forward to sharing information about this report and its recommendations with public health nursing educators and with our students. Thank you for the opportunity to give input into this important document.

Sincerely,

Susan Swider
President
Association of Community Health Nursing Educators

10200 W 44th Ave #304
Wheat Ridge CO 80033



Submitted via email to nvpo@hhs.gov

January 16, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

RE: Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee [NVAC] on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel [76 FR 78659]

The Association of Flight Attendants – Communications Workers of America, AFL-CIO (AFA) represents nearly 60,000 flight attendants at 23 airlines. AFA welcomes this opportunity to comment on the draft report and recommendations of the NVAC subgroup.

Flight attendants are trained in many healthcare-related tasks and frequently called upon to provide or support patient care giving activities in the performance of their duties as first responders on board commercial air transport airplanes. As such, the flight attendant profession is clearly a component of the broader healthcare community, and AFA members may therefore be affected should the NVAC subgroup draft recommendations drive substantive changes to government and private employer vaccination and illness prevention policies. Regarding the subject NVAC subgroup report, AFA supports in particular the following draft recommendations:

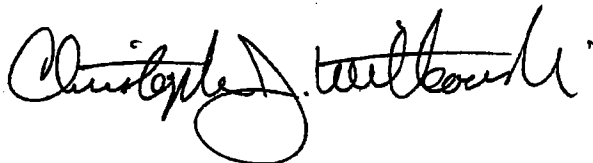
- Recommendation 1, that “facilities establish comprehensive influenza infection prevention programs as recommended by the CDC [Centers for Disease Control and Prevention] ...” AFA agrees with the need for effective vaccines and prevention programs to protect the health of workers. This is especially important for flight attendants, who are in continual and close contact with the public while working and passing through various densely-populated locations that include airplane cabins, airports, shuttle buses / people movers and hotels.
- Recommendation 2, that “facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs...” This is a common sense proposal.
- Recommendation 3, that efforts be continued to “standardize the methodology used to measure HCP [health care personnel] influenza vaccination rates...” AFA agrees that measuring and reporting rates improve vaccination levels.
- Recommendation 5, which encourages “ongoing efforts to develop new and improved influenza vaccines and vaccine technologies...” AFA is aware that studies (particularly in the aftermath of the H1N1 pandemic) have generated uncertainty as to whether influenza vaccines are as effective as they should be. This recommendation if followed should help to improve the effectiveness of vaccines and further limit the spread of influenza within worker populations.



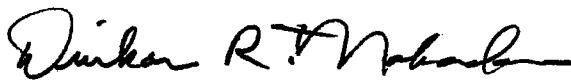
However, regarding Recommendation 4, AFA does not support making influenza vaccination a condition of employment for HCP. As stated in the draft report, this is a controversial and hotly debated recommendation. It is also one that if adopted will have significant, career-altering consequences for workers who object strongly (for whatever reason) to influenza vaccination. AFA argues that there are numerous reasons not to *require* influenza vaccination of employees, including: 1) The Healthy People 2020 goal of 90% coverage of HCP cited in the NVAC subgroup draft report is simply a goal, not a requirement, and scientific evidence supporting the stated value of 90% is apparently lacking; 2) Influenza vaccines are generally less effective than desirable, given the numerous strains of influenza in circulation; and 3) Comprehensive illness prevention programs that incorporate employee training and information, hazard analysis, exposure controls, medical surveillance and *voluntary* vaccination (paid for by the employer) are sufficient to minimize the risks to worker and public health posed by circulating strains of influenza.

In conclusion, AFA supports Recommendations 1, 2, 3 and 5 of the NVAC subgroup draft report, but urges rejection of Recommendation 4 (or, at the very least, deletion of that part of the recommendation that influenza vaccination be a condition of employment for HCP.) Thank you for considering AFA's comments regarding these issues of importance to flight attendants.

Sincerely,



Christopher J. Witkowski
Director
Air Safety, Health and Security Department



Dinkar R. Mokadam, CIH
OSHA Specialist
Air Safety, Health and Security Department



January 16, 2012

Jennifer Gordon, Ph.D.
National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201
Attn: Healthcare Personnel Influenza Vaccination

Dear Dr. Gordon:

The Association of Immunization Managers (AIM), representing the 64 federally-funded state, territorial and urban area immunization programs, is writing to provide comment on the National Vaccine Advisory Committee (NVAC) recommendations for achieving the Healthy People 2020 goal of 90% influenza vaccine coverage of healthcare personnel. We commend NVAC for addressing this need and thank you for the opportunity to provide input.

AIM fully supports the NVAC recommendations for comprehensive and specific strategies to improve influenza vaccination rates in healthcare personnel. We hope that additional resources will become available to implement the strategies and evaluate their success. The document very clearly demonstrates the need for improved infection prevention in healthcare facilities and the evidence supporting comprehensive education and vaccination programs as recommended by the Centers for Disease Control and Prevention.

AIM believes that Recommendation 4 must be strengthened in order to achieve the 90% vaccination goal. Many institutions have enacted comprehensive education and vaccination programs yet still failed to reach the 90% coverage goal. Organizations that have required vaccination as a condition of employment have achieved the goal (as documented by the National Influenza Vaccine Summit). NVAC recommendations should be for healthcare employers and facilities to “enact” rather than “strongly consider” a requirement for influenza immunization.

Thank you again for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Claire Hannan".

Claire Hannan, MPH
Executive Director

ANAC

ASSOCIATION OF NURSES IN AIDS CARE

January 16, 2012

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

Dear Ms. Gordon:

The Association of Nurses in AIDS Care (ANAC) strongly supports the *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel* proposed by the NVAC Adult Immunization Working Group. ANAC's mission is to provide professional development, continuing education and advocacy for and on behalf of not only its nearly 2,000 members, but also nurses working in any aspect of HIV and HIV-related care, prevention and treatment. ANAC submits the following comments in support of this draft guidance.

ANAC firmly believes that every health care consumer has the right to assume that health care personnel and the agencies that employ health care personnel will take all measures to prevent the transmission of communicable pathogens. Health care personnel have an obligation to prevent harm to those for whom they care and must adhere to primary prevention practices, including immunization against those diseases for which safe and effective vaccines exist.

Since 1984, the U.S. Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) have recommended immunization against influenza for health care workers (HCWs), recognizing their risk of workplace exposure. The Hospital Infection Control Practices Advisory Committee (HICPAC) likewise made this recommendation to prevent nosocomial influenza transmission to patients, which has been documented in both acute care hospitals and long-term care facilities.

In 1989, the American Public Health Association (APHA) recommended requiring immunization of laboratory and health care personnel and students against all vaccine-preventable diseases, including influenza. More recently, over a dozen other professional associations, have similarly recommended influenza vaccination requirements for HCWs to protect personnel themselves as well as the patients with whom they come in contact. In 2011, ANAC adopted a position statement that outlines its support for mandatory annual influenza vaccination of all health workers.

ANAC's position statement, along with the others, **highlights the ethical responsibility of health care providers to prevent harm to those for whom they care.** Ethicists agree that mandates are appropriate when there is a clear public or community benefit and voluntary approaches are not adequate. With rare exception,

they maintain that influenza vaccination is such a situation. Some ethicists also maintain that the bioethical principle of justice precludes conscientious objection to vaccination or refusal for personal reasons.

As such, **ANAC emphasizes its support for the HCPIVS recommendation for a mandate as a condition of health care employment and credentialing unless a documented medical contraindication to influenza vaccine exists.** The responsibility to protect patients from nosocomial infection is shared by both health personnel and the organizations that employ them. The rationale for making vaccination a condition of employment (or volunteering or consulting) in a health care setting is to enhance and ensure patient and staff safety. Requiring influenza vaccination is congruent with long-existing, widely used standards of prevention practice when health care personnel can be vectors of airborne or droplet infection.

Influenza is a contagious respiratory infection that, despite the availability of safe and effective vaccines, remains a major cause of death and disease. It is the most common vaccine-preventable disease in the U.S. and around the world, with as many as 80,000 reported deaths in the U.S. in some years. People with immunocompromising conditions are especially susceptible to severe illness from influenza and influenza mortality is greater among people with chronic medical problems. Influenza can trigger the complications of diseases such as diabetes, cardiovascular disease, and renal and liver problems – conditions highly prevalent among people with HIV infection. With increasing age, the HIV-affected population experiences many chronic conditions that both heighten the risks associated with influenza infection and further reduce immune response to vaccine.

Hospitalized patients who develop nosocomial influenza have a high mortality rate. Unvaccinated health care personnel have been implicated as sources of influenza infections in deadly outbreaks among adults and children in both acute and long-term care settings. It has been estimated that in some years, about 25% of health personnel can be infected with influenza, which is readily spread from person to person when a host coughs or sneezes, and less efficiently by indirect contact – both by persons who have no symptoms and are unwitting vectors and also those who work while feeling ill, even with flu-like symptoms during flu season, a well-documented occurrence among health personnel. The National Patient Safety Foundation reports that institutions requiring staff influenza vaccination show an 88% reduction in workforce infection and a 41% lower influenza-related patient mortality.

To maintain Joint Commission accreditation, hospitals, long-term care facilities, and home health providers must not only offer vaccine and monitor staff coverage each year, but also continually take steps to raise staff vaccination rates the following year.

Not surprisingly, mandatory approaches have yielded the highest reported rates for any intervention designed to improve vaccination coverage. Reports suggest that even the most successful voluntary programs, including those with aggressive campaigns that employ proven best practices confront a ceiling effect below 80%, much less than the Healthy People 2020 goal of 90% coverage goal. CDC recently reported that staff vaccination

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rates against seasonal flu were twice as high when health care employers required vaccination as when they recommended but did not require it. Indeed, most researchers and other experts conclude that mandatory approaches are needed to consistently achieve > 70% vaccination coverage.

ANAC fully supports NVAC's recommendation for the integration of influenza vaccination programs into existing infection prevention programs or occupational health programs. ANAC does not support exemptions for other than medical contraindications, and therefore it is ANAC's position that allowing an individual to decline after education and individualized counseling should be regarded as a last resort, not a routine option. Health care employers have a responsibility to offer influenza vaccination at no cost, and to make it available to health care personnel at convenient times and locations, thereby ensuring that opting out of getting the vaccine is a more difficult choice.

Primary prevention by vaccination is the most effective and efficient means of protection against influenza. Other measures, such as hand hygiene and barrier precautions, are complementary protective steps, *not* alternatives to pre-exposure immunization. While ensuring that symptomatic staff remain away from work until recovered is essential, it is even more important to prevent their infection since influenza's silent 1-to-4-day incubation period allows the host to infect others before feeling ill and often without being aware of having been exposed. About 20% of cases will remain asymptomatic but still be infectious. Since unvaccinated clusters within a work unit, facility, or other group setting may compromise a group's protection (herd immunity), allowing exemptions for other than the very small (< 0.1%) number of people who have real medical contraindications to influenza vaccination limits the effectiveness of a vaccination program and should be discouraged.

Immunization of health personnel against influenza is thus an essential part of health care employer's and personnel's culture of safety – both for those seeking care and for those providing care.

Please note that ANAC's complete position statement on this topic is included with these comments, following the references pages. If you have any questions, or need additional information, please contact me at 330-670-0101.

Sincerely,

Kimberly Carbaugh
Interim Chief Operating Officer

Encl: References

ANAC's Position Statement on Requiring Annual Immunization of Health Workers Against Influenza

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ASSOCIATION OF NURSES IN AIDS CARE
POSITION STATEMENT
Support for Requiring Annual Immunization of Health Workers Against Influenza
Adopted by the ANAC Board of Directors February 2011

Position:

Based on the evidence, it is the position of the Association of Nurses in AIDS Care that

- **The health care consumer has the right to assume that health workers in all settings where service is provided, and the agencies that employ them, will take all measures to prevent transmission of communicable pathogens**
- **Health workers have a responsibility to prevent harm to those for whom they care and to their coworkers, and therefore must adhere to recommended primary prevention practices, including immunization against those for which safe and effective vaccines exist.**
- **Health workers should be immunized against seasonal influenza each year unless they have a medically documented contraindication to the available vaccines.**
- **Healthcare organizations should require staff, regardless of pay status (i.e., whether or not they receive remuneration for their services), to be immunized against seasonal influenza unless there is medical documentation of a contraindication. This recommendation applies to all types of facilities and services, including inpatient and outpatient acute and chronic care, long-term residential care, home care, rehabilitation, counseling and other services, including independent private practitioners. It applies to all staff who may come in contact with service recipients as well as staff who routinely come in contact with such staff (e.g., in staff cafeterias, administrative offices, etc.).**
- **Healthcare employers have the responsibility to offer vaccine to staff at no cost and to facilitate vaccine administration at worksites or other convenient locations and times. Thus, requirements should not place additional burden on workers, who should also be able to submit documentation of having received vaccination from other providers or facilities.**
- **Service providers should publicly post their staff vaccination policy.**
- **Getting vaccinated must be easier and more convenient for staff than opting out and, if exemptions are allowed, the procedures for obtaining one must be as rigorous as for getting the vaccine. Neither the perfunctory signing of a form nor online declination is adequate.**
- **Unvaccinated staff should be identified and, regardless of symptoms, when there is influenza in the community, should be reassigned or expected to implement barrier**

precautions (such as masks) when within a specified proximity of potentially susceptible service recipients.

Statement of Concern:

The responsibility to protect patients from nosocomial infection is shared by both health workers and the organizations that employ them. The rationale for making vaccination a condition of employment (or volunteering or consulting) in a healthcare organization is to enhance and ensure patient and staff safety. Requiring influenza vaccination is congruent with long-existing, widely used standards of prevention practice when health workers can be vectors of airborne or droplet infection.

Accumulated data demonstrating vaccine efficacy and safety support making annual vaccination a requirement, particularly since experience and research repeatedly demonstrate that knowledge is not enough to ensure either healthful behavior or consistent adherence to good infection control practice. Thus, education remains a key component of both voluntary and mandatory vaccination programs, but even mandatory education cannot be expected to achieve adequate influenza vaccine uptake by health workers. Whereas health workers may choose to pursue other individual health behaviors, the potential impact of their vaccination choices is a critical concern for the populations and individuals they serve.

Influenza is a contagious respiratory infection that, despite the availability of safe and effective vaccines, remains a major cause of death and disease. It is the most common vaccine-preventable disease in the U.S. and around the world, with as many as 80,000 reported deaths in the U.S. in some years. People with immunocompromising conditions are especially susceptible to severe illness from influenza and influenza mortality is greater among people with chronic medical problems. Influenza can trigger the complications of diseases such as diabetes, cardiovascular disease, and renal and liver problems – conditions highly prevalent among people with HIV infection. With increasing age, the HIV-affected population experiences many chronic conditions that both heighten the risks associated with influenza infection and further reduce immune response to vaccine.

Hospitalized patients who develop nosocomial influenza have a high mortality rate. Unvaccinated healthcare workers have been implicated as sources of influenza infections in deadly outbreaks among adults and children in both acute and long-term care settings. It has been estimated that in some years, about 25% of health workers can be infected with influenza, which is readily spread from person to person when a host coughs or sneezes, and less efficiently by indirect contact – both by persons who have no symptoms and are unwitting vectors and also those who work while feeling ill, even with flu-like symptoms during flu season, a well-documented occurrence among health workers. The National Patient Safety Foundation reports that institutions requiring staff influenza vaccination show an 88% reduction in workforce infection and a 41% lower influenza-related patient mortality.^x

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While ensuring that symptomatic staff remain away from work until recovered is essential, it is even more important to prevent their infection since influenza's silent 1-to-4-day incubation period allows the host to infect others before feeling ill and often without being aware of having been exposed. About 20% of cases will remain asymptomatic but still be infectious. Since unvaccinated clusters within a work unit, facility, or other group setting may compromise a group's protection (herd immunity), allowing exemptions for other than the very small (< 0.1%) number of people who have medical contraindications to influenza vaccination limits the effectiveness of a vaccination program and should be discouraged. For this reason, allowing an individual to decline after education and individualized counseling should be regarded as a last resort, not a routine option. Primary prevention by vaccination is the most effective and efficient means of protection against influenza. Other measures, such as hand hygiene and barrier precautions, are complementary protective steps, *not* alternatives to pre-exposure immunization. Immunization of health workers against influenza is thus an essential part of healthcare providers' culture of safety – both for those seeking care and for those providing care.

Background:

Since 1984, the U.S. Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) have recommended immunization against influenza for health care workers (HCWs), recognizing their risk of workplace exposure. The Hospital Infection Control Practices Advisory Committee (HICPAC) likewise made this recommendation to prevent nosocomial influenza transmission to patients, which has been documented in both acute care hospitals and long-term care facilities.

In 1989, the American Public Health Association (APHA) recommended requiring immunization of laboratory and healthcare workers and students against all vaccine-preventable diseases, including influenza. More recently, other professional associations, have similarly recommended influenza vaccination requirements for HCWs to protect workers themselves as well as the patients with whom they come in contact: American College of Physicians (ACP), Association of Practitioners of Infection Control (ACIP), National Patient Safety Foundation (NPSF), Infectious Diseases Society of America (IDSA), Society of Hospital Epidemiologists of America (SHEA), and the American Academy of Pediatrics (AAP).

These position statements highlight the ethical responsibility of healthcare providers to prevent harm to those for whom they care. Ethicists agree that mandates are appropriate when there is a clear public or community benefit and voluntary approaches are not adequate. With rare exception, they maintain that influenza vaccination is such a situation. Some ethicists emphasize that the bioethical principle of justice precludes conscientious objection to vaccination or refusal for personal reasons.

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By 2008, 15 states had issued requirements for health worker influenza immunization and, by mid-2010, over 60 institutions across at least 20 states reported successfully implementing mandatory programs. To maintain Joint Commission accreditation, hospitals, long-term care facilities, and home health providers must not only offer vaccine and monitor staff coverage each year, but also continually take steps to raise staff vaccination rates the following year.

Not surprisingly, mandatory approaches have yielded the highest reported rates for any intervention designed to improve vaccination coverage. Reports suggest that even the most successful voluntary programs, including those with aggressive campaigns that employ proven best practices confront a ceiling effect below 80%, much less the 98% coverage needed for herd immunity. CDC recently reported that staff vaccination rates against seasonal flu were twice as high when healthcare employers required vaccination as when they recommended but did not require it. Indeed, most researchers and journal editors conclude that mandatory approaches are needed to consistently achieve > 70% vaccination coverage,

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Association Of State And Territorial Health Officials
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(202) 371-9090 | www.astho.org

January 16, 2012

National Vaccine Program Office
Department of Health and Human Services
200 Independence Avenue, SW, Room 733G.3
Washington, DC 20201

Re: Healthcare Personnel Influenza Vaccination

Dear Ms. Gordon:

The Association of State and Territorial Health Officials (ASTHO) appreciates the opportunity to comment on the *Recommendations on Strategies to Achieve the Healthy People 2020 Annual goal of 90% Influenza Vaccine Coverage for Health Care Personnel* draft report.

ASTHO is a national nonprofit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 100,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and promoting excellence in state-based public health practice. ASTHO takes a great interest in the national policies that prevent the spread of disease.

ASTHO strongly believes all healthcare personnel should be vaccinated annually against influenza illness, as a reasonable standard of care. Healthcare personnel are at high risk for acquiring influenza illness due to their close proximity to ill patients. Influenza vaccination protects healthcare personnel from developing illness and limits their ability to transmit illness to vulnerable patients at high risk for developing complications from the flu. The low influenza vaccination rates among healthcare personnel continue to be of concern for state public health officials as they work to reduce the transmission of illness in their jurisdictions.

ASTHO concurs with the tiered set of strategies set forth by the working group on Health Care Personnel Influenza Vaccination Subgroup (HCPiVS) to improve healthcare personnel immunization rates to reach the Healthy People 2020 annual goal of 90% influenza vaccine coverage. To accomplish this, ASTHO agrees that facilities need to establish a comprehensive influenza prevention program, if they have not done so already, and integrate vaccination programs into existing infection control measures, with strong emphasis and reliance on training and education. ASTHO supports the standardization of methodologies used to measure healthcare provider vaccination rates and the ongoing efforts to develop new and improved vaccine technology. Every opportunity to engage state health officials in

this multifaceted approach to increase influenza vaccine coverage among healthcare personnel is also strongly encouraged.

ASTHO applauds NVAC's efforts to increase coverage rates among healthcare personnel on the basis that influenza is a significant public health threat, the vaccine is safe and effective, and vaccination is the most effective mechanism to prevent influenza infection.

Sincerely,

James Blumenstock, MA
Chief Program Officer for Public Health Practice
Association of State and Territorial Health Officials

On behalf of the California Immunization Coalition (CIC) I would like to express support of the ***Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel*** proposed by the NVAC Adult Immunization Working Group Health Care Personnel Influenza Vaccination Subgroup. The CIC Emerging Issues Committee has discussed the issue of health care personnel influenza immunization at length and there is a consensus of this committee that mandatory health care influenza immunization will be required to achieve the Health People 2020 goal for health care personnel immunization. While we acknowledge that voluntary programs may be effective in some cases, the majority of such programs have not achieved sufficient results. Health care personnel have an imperative to protect patient safety by minimizing their chances of acquiring and transmitting influenza. In addition we need to lead by example for our patients and demonstrate our support of the CDC recommendations that all individuals greater than 6 months of age should receive an annual influenza vaccine.

Mark H. Sawyer, MD

President, California Immunization Coalition

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CALIFORNIA
NURSES
ASSOCIATION



NATIONAL NURSES
ORGANIZING COMMITTEE

January 13, 2012

A Voice for Nurses. A Vision for Healthcare.
www.calnurses.org / www.nnoc.net

National Vaccine Program Office
US Dept. of Health and Human Services
Att: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
200 Independence Avenue, SW
Room 733-G.3
Washington, CD 20201

Dear Sir or Madam:

On behalf of the National Nurses United (NNU), we thank you for this opportunity to offer our comments on the draft, "Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel", developed by the National Vaccine Advisory Committee (NVAC).

National Nurses United (NNU) represents 170,000 members in every state, the largest professional association and labor organization of direct care registered nurses (RNs) in the United States. Our members represent direct care RNS working in every state in the country including Advance Practiced Registered Nurses (APRN) in selected states. Nearly 95% of our membership works in hospitals and/or Critical Access Hospitals. Our mission is to provide safe, therapeutic and effective care in the exclusive interest of our patients and to expand the voice of the direct care RN and patients in the planning, development, implementation and evaluation of public policy as it relates to the health care needs of our patients.

NNU objects NVAC's Recommendation #4, "Healthy People 2020". We appreciate the concern of the Health and Human Services Department Secretary's over increasing influenza vaccination rates among health care providers, and as frontline caregivers, registered nurses (RN) care deeply about health policies regarding the transmission of the influenza virus in health care setting. Further, our organization maintains the position that every RN should be vaccinated against the flu. Despite this, we advise caution against placing an over-reliance upon vaccination as a means to fully stem transmission. Doing so may put RNs, other health care workers, and patients at an increased risk of infection. Issues such as vaccination supply and efficacy make it such that the vaccine cannot be relied upon to exclusively provide adequate protection from the flu virus. As recently as October 2011, the Center for Infectious Disease, Research and Policy, at the University of Minnesota published, "Efficacy effectiveness of influenza vaccines: a systematic review and meta-analysis¹". The study concludes that the efficacy rate for the influenza vaccine is 59% for working age adults, leaving a significant number of vaccinated individuals unprotected from the virus.

We believe that employer-sponsored voluntary vaccination programs can be effective if the program includes extensive education on the risks and benefits of vaccination, and if vaccines are conveniently accessible to employees. This is one reason we cannot support mandatory vaccination policies, because, rather than being educated on the importance of vaccination, employees are instead coerced into accepting the vaccine, or risk being punished, retaliated against, and, in some cases, fired by their

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employer. Mandatory flu vaccination programs engender distrust and resistance among employees; offer a disincentive to providing vaccination education to employees, and raise ethical and legal questions about the personal employment rights of employees. This is not the way to protect public health.

Additionally, we'd like to point out that requiring health care workers who decline vaccination to wear a mask will not properly stem the transmission of influenza, and will create a false sense of protection for employees and patients, particularly with regarding to the influenza virus which is know to be airborne transmissible. An abundance of research has shown that masks do not effectively protect health care workers from airborne transmission of disease. They are simply not designed to provide such protection. Mask are not a sufficient substitute for vaccination, and policies that require masks be worn by those who are not vaccinated do not appear to be borne out of science.

We remind NVAC the California Department of Industrial Relations, Division of Occupational Safety & Health, in Title 8, Section 5199, and Aerosol Transmissible Disease (ATD) provides for a declination statement that permits employees to decline the influenza vaccinationⁱⁱ. We believe this is a responsible policy. It states that education is mandatory, but allows for the civil right to decline the vaccination. NNU will vehemently oppose any erosion of this standard and civil right for health care workers.

Rather than imposing an employer requirement to vaccinate, we believe it is safer to require hospitals to offer accessible vaccinations to employees, with extensive education as one part of a comprehensive influenza transmission prevention program that also includes important protective measures such as the provision of safe and appropriate respiratory and personal protection equipment, hygienic improvements, and thoughtful isolation procedures. We hope NVAC will adopt our perspective and reject Recommendation #4 in the report.

Sincerely,



Bonnie Castillo
Director, Government Relations

ⁱ Osterholm, MT, Kelly NS, Sommer A and Belongia EA. Efficacy and effectiveness of influenza vaccines; a systematic review and meta-analysis. The Lancet Infectious disease. Published online October 26, 2011.

ⁱⁱ California Department of Industrial Relations, Division of Occupational Safety & Health:
<http://www.dir.ca.gov/Title8/5199.html>.

Since 1910



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January 13, 2012

National Vaccine Program Office

U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201

Dear Sir/Madam:

The Civil Service Employees Association (CSEA) is writing to comment on the National Vaccine Advisory Committee (NVAC) Health Care Personnel Influenza Vaccination Subgroup's (HCPiVS) draft report; Recommendation on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel.

Our first concern is the basis for the goal of the 90% vaccination rate for health care workers. Our understanding is that there is currently no scientific basis for this goal and that the needed rate of vaccination to obtain a "herd protection" is not generally agreed upon.

CSEA represents approximately 300,000 government employees across New York State many of whom are or directly assist healthcare workers. We strongly support the need for healthcare employers to develop and implement comprehensive infection control programs to prevent the spread of influenza and other infectious diseases among health care workers and their patients. While there is much that we support in the report, we feel that there is a serious element omitted in Recommendations #1 and #2 – the direct involvement of workers and their representatives (if unionized), in the development and implementation of these programs.

Frontline workers and their representatives are in a unique position to understand the scenarios that can lead to disease transmission in their workplace and to evaluate the efficacy, feasibility, and unintended consequences of infection control measures that are prescribed. This involvement, coupled with education and training about all aspects of the program, is critical. Only then will employees understand the role that vaccination plays in a comprehensive program. If the vaccine is then offered by the employer at no cost,



on-site, and during work time, the likelihood of high vaccination rates is great. Several studies have shown that the 90% goal can be easily achieved under these circumstances.

There will likely be scenarios where the vaccination rate is below the Healthy People 2020 goal of 90%. When this occurs, the employer should be encouraged to sit down again with the employees and their representatives to identify the barriers and to collectively address the shortcomings in the infection control and vaccination program.

Encouraging employers to mandate vaccination, as the HCPIVS report does in Recommendation #4, is misguided in a few ways. First, it would likely be unnecessary if the employer takes the cooperative approach offered in our previous recommendation. Second, mandating that individuals be vaccinated potentially violates individuals' rights, for those who are unwilling, for reasons of religious or conscious objection, to be vaccinated.

Our experience has been that some employers will rely on this mandatory vaccination program as a panacea, and will pay scant attention to other infection control measures. As the NVAC itself recognizes, the efficacy of the flu vaccine is sub-optimal, and varies annually. Thus, anything that leads to employers' diminished commitment to a comprehensive infection control program should be avoided.

For these reasons, CSEA requests that the U.S. Department of Health and Human Services modify the HCPIVS' recommendations in the manner outlined above, adding a requirement that employers directly involve their workers and their representatives, and eliminate Recommendation #4 of the report.

Thank you for considering CSEA's concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Foley", with a long, sweeping flourish extending to the right.

Janet Foley
Director, CSEA Occupational Safety and Health Department



January 16, 2012

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

Re: HCPIVS Draft Recommendations to the NVAC Adult Immunization Working Group on Influenza Vaccine Coverage for Health Care Personnel

Dear Sir or Madam:

The Coalition of Kaiser Permanente Unions is composed of 28 local unions representing 95,000 frontline employees of the Kaiser Permanente health system. Our members work primarily in hospitals, medical offices, and other supporting facilities, and have roles ranging from direct care providers such as nurses, therapists, and technicians, to support workers in environmental and food service, and reception and administration.

The HCPIVS report has progressed in the direction of more a balanced tone, through a clearer recognition that vaccination is just one component of a comprehensive infection prevention program, and by referring often to the importance of worker education and information about flu prevention. However the recommendations remain quite unbalanced, in particular recommendation 4 suggesting employers consider a requirement for healthcare worker vaccination as a condition of employment, and leaves open that this requirement could not allow workers to decline for personal or philosophical reasons. We are also disappointed the recommendations do not address the need for improved, consistent, appropriate education of health care workers about flu prevention.

We encourage NVAC to amend Recommendation #4 to call for an employer requirement to provide education, modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine.

The vaccine is not good enough to mandate

We agree with the broad consensus that it is a worthwhile goal to increase the flu vaccination rates of healthcare workers. We believe it is worth the effort to have more workers and their families vaccinated to reduce their risk of getting the flu. It is encouraging that rates are increasing in the past few years as more effort has been put

into education and outreach around vaccination, and to make vaccination more easily available.

However, we don't understand where the Healthy People 2020 goal of 90% vaccination rate for healthcare workers came from and what evidence it was based upon. The HCPIVS, and their allies in the health industry, are trying to turn this figure from a broad population-wide goal, into a mandatory standard of performance. Yet we are not told why such a high rate is needed. And we particularly question why we should push so hard for a vaccine that is now acknowledged to be only moderately effective, and in some years has little effectiveness at all.

The most recent review, from the fall of 2011, concludes flu the vaccine is only 59% effective in working age adults in a typical year.¹ CDC and others had prior to this been claiming the vaccine was 70 to 90% effective. The evidence has been mounting against this claim, and finally the CDC has, as of last fall, adjusted its claim to a lower range of 50-70%. Unfortunately, this has not led to a pause in the push by some individuals and institutions to make vaccination a condition of employment for healthcare workers.

The assumption that vaccinating health workers is necessary to protect patients seems logical, but this is not the same as having evidence that it is true to any significant degree. A 2007 review found the leading studies conducted in nursing homes showed no statistical evidence of increased infections among residents from transmission from healthcare workers to patients.² A more recent review published November last year in the research journal *Vaccine* concludes, "The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present."

3

Vaccinate-or-mask policies

The 'vaccinate or mask' option some hospitals and county health departments (including San Francisco, Sacramento and Yolo counties in California) are requiring is also not based on evidence of effectiveness. There is no scientific evidence that the routine wearing of surgical masks by unvaccinated healthcare workers protects either patients or the wear of the mask from getting the flu. We believe this practice is intended to coerce and intimidate workers into getting vaccinated, and is not grounded in thoughtful analysis of whether the practice of daily mask wearing protects anyone. Since the flu vaccine is typically only 59% effective in a given flu season (and can be substantially less effective in a bad-match year), and since there are many influenza-like illnesses (ILI) that cannot be prevented by the flu vaccine (about 15% of ILI are caused by influenza) then many workers who are vaccinated can and will get the flu

¹ Osterholm, M., et al., *Efficacy and effectiveness of influenza vaccines: a systematic and meta-analysis. Lancet Infect Dis, 2011.*

² Jefferson, T., et al., *Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev, 2007. 7: p. CD001269.*

³ Michiels, B., et al., *A systematic review of the evidence on the effectiveness and risks of inactivated influenza vaccines in different target groups. Vaccine, 2011. 29(49): p. 9159-9170.*

and they can also get another ILI. The logic of the situation tells us that it is not 'just' unvaccinated workers who are at risk of being a pre-symptomatic case of ILI (one of the justification we've been given for such policies). Both vaccinated and unvaccinated HCW could be a pre-symptomatic ILI case. By this logic every healthcare worker should be masked every day during flu season? We are not claiming this is a path that should be followed, but this is the direction logic leads us if we accept that the vaccinate-or-mask policy makes sense. However we do believe this situation makes it clearer still the need for beefing up infection prevention practices (standard, contact and aerosol precautions) as a key to preventing the spread of flu and other ILI.

We are also concerned that all-day mask wearing in the current environment (where masks are not consistently being replaced during the day) would increased exposure to flu virus (and other pathogens) by health workers and their patients due to the frequent mouth/nose/eyes contact that will happen when a worker uses their hands to don, duff and adjust a (possibly re-used) surgical mask throughout the day.

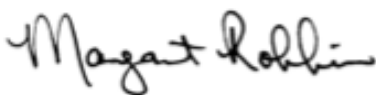
We wish the report and recommendations had reviewed and commented upon the safety and appropriateness of this type of requirement for vaccine refusal.

Workers should not be encouraged, not coerced

We recognize that public health departments have long used police powers to mandate aggressive policies to protect the public from major health threats. However, we don't believe the threat to patients of health workers who are unvaccinated for flu constitutes a major threat to the public health, compared to vaccinated workers. Is it an overall good idea to get more Americans vaccinated? Yes, it is. But that is not the same as saying the government should roll out the police powers to mandate vaccination, or by recommending employers do the same by making flu vaccination a condition of employment. We believe the government and employers should strive to be more effective when they educate and encourage health workers and the public to undertake health protective efforts, including flu vaccination. We can learn from our past, such as the Bloodborne Pathogens Standard, for ways to reach employees with vaccine and other infection prevention information. Employee relations and public health are not well served by the use of coercion to achieve flu vaccination ends. And it is not consistent with our national values openness, respect, and informed consent around medical treatments we receive.

Thanks you for the opportunity to comment on the draft document.

Sincerely,



Margaret Robbins, MPH
National Director, Occupational Safety and Health
Coalition of Kaiser Permanente Unions

1 Kaiser Plaza, 24L
Oakland, CA 94612
Maggie.Robbins@UnionCoalition.org

01/16/12

Re: <http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32308.pdf>

The Emergency Services Coalition on Medical Preparedness provides these comments on the National Vaccine Advisory Committee (NVAC) recommendations for achieving the Healthy People 2020 goal of 90% influenza vaccine coverage of healthcare personnel.

The Emergency Services Coalition for Medical Preparedness (Coalition) was formed to lead the development of a national strategy to protect providers in the event of a large-scale biological event. The Coalition has drawn support from the major emergency services associations, which represent more than three million providers. The three million providers additionally have at least eight million family and household contacts whose protection would be an essential component of any protective plan.

The Coalition fully supports the NVAC recommendations for comprehensive and specific strategies to improve influenza vaccination rates in healthcare personnel. The Coalition supports the NVAC goals to increase the level of healthcare personnel to 90% as part of the 2020 Healthy People goals.

The Coalition suggests that these immunization goals are appropriate for all emergency services personnel and their families/household contacts due to the public exposure and critical roles in maintaining continuity and community resilience. Corrections officers, ambulance personnel, and first responders of all kinds have equivalent institutional and public engagement roles as healthcare workers and require the same protections.

Further, we believe it is necessary to advocate for additional resources to be allocated for this important health goal. The document amply demonstrates the financial and health benefits of immunization.

Finally, we suggest the NVAC consider strengthening Recommendation 4 - facility employee requirements - using the word "enact" rather than "strongly consider." Comprehensive education programs have been in place for long enough, the 90% goal will remain unmet without higher institutional commitment.

Thank you again for the opportunity to comment.

Tim Stephens
Public Health Advisor
National Sheriffs Association on behalf of The Emergency Services Coalition on Medical Preparedness tstephens@sheriffs.org
202-297-6178

January 16, 2012

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

Dear Ms. Gordon, National Vaccine Program Office, and Members of the National Vaccine Advisory Committee:

I am submitting comments for the public record on behalf of my organization, Health Advocacy in the Public Interest, regarding "Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel" currently under consideration. Our specific concerns are with respect to recommendation number four:

"Recommendation 4: For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and cannot achieve and maintain the Healthy People 2020 goal of 90% influenza vaccination coverage of HCP in an efficient and timely manner, the HCPIVS recommends that HCE and facilities strongly consider an employer requirement for influenza immunization. HCPIVS also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff and Federally Qualified Health Centers) and urge all other HCE and facilities to do the same."

No American citizen should be required to undergo any medical procedure which carries risk, such as a flu vaccination, as a condition of employment, ever, period. If recommendation number four is to remain, at the very least, exemptions should be allowed for medical reasons, religious and personal beliefs. The flu vaccine carries risk and employees should have the right to opt out. Our organization has been contacted numerous times over this issue in the past couple of years. Many medical professionals are against mandatory flu vaccination as a condition of employment for many very good reasons.

It is also important that you consider the following from the U.S. Equal Employment Opportunity Commission:

http://www.eeoc.gov/facts/pandemic_flu.html#36

"May an employer covered by the ADA and Title VII of the Civil Rights Act of 1964 compel all of its employees to take the influenza vaccine regardless of their medical conditions or their religious beliefs during a pandemic?"

No. An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense). Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee's sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII ("more than de minimis cost" to the operation of the employer's business, which is a lower standard than under the ADA).

Generally, ADA-covered employers should consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it."

Not only does flu vaccination carry risk, it is also of very questionable efficacy. This is just one more reason why it should not be required as a condition of employment under any circumstance. The following statement comes from the Cochrane Collaboration:

Sept 8, 2010

"We conclude that there is no evidence that only vaccinating healthcare workers prevents laboratory-proven influenza, pneumonia, and death from pneumonia in elderly residents in long-term care facilities."

<http://summaries.cochrane.org/CD005187/influenza-vaccination-for-healthcare-workers-who-work-with-the-elderly>

Lastly, one member of the NVAC, Clement Lewin, has direct ties to Novartis. The last time I checked, Novartis manufactures flu vaccine. It is absurd that anyone who stands to benefit financially from such a policy or has such a blatant conflict of interest would be allowed to be part of the decision making. Mr. Lewin should be removed from any discussion on this proposed policy.

In conclusion, just because "Healthy People 2020" has a goal of a 90% flu vaccination rate for healthcare workers, the individual liberty and respect for health freedom for all American citizens should not be trampled on via employer mandated flu vaccines while pharmaceutical companies stand to profit and at the same time bear no liability and have no accountability for the damage caused by their product.

There has been less than one month of public comment period for this policy which will undoubtedly impact millions of healthcare workers in the United States of America. I would also like to request that you extend the comment period so that you may hear from the real stakeholders of this policy whom are only beginning to find out that this proposed policy exists.

In light of the fact that flu vaccine carries risk and is of questionable efficacy, either recommendation number four, regarding employer mandated flu vaccines, should be removed altogether or at the very minimum, broad and all encompassing exemption options should be added along with the requirement that each employer make said exemptions CLEAR to the employee and a requirement that employers are not allowed to punish or discriminate against employees who opt out of a flu vaccination.

Thank you for the opportunity to comment on this proposed policy. Please consider allowing more time for public comment.

In Health and Liberty,

Dawn Winkler
Executive Director
Health Advocacy in the Public Interest (HAPI)
PO Box 624
Quincy, CA 95971
hapi.vaxinfo@gmail.com
530-283-1018

My name is Dawn Winkler and I am the Executive Director of Health Advocacy in the Public Interest, a non-profit organization based in CA dedicated to promoting informed medical decisions and protecting the right and freedom to make informed medical decisions.

HAPI opposes Recommendation #4.

No employee, including healthcare workers, should have to choose between their livelihood and what they feel is best for themselves medically. HCW's are asked to respect patients' healthcare decisions.

This respect should be reciprocal. I myself, someone who has been a patient numerous times, would much rather prefer a healthcare worker taking care of me whose employer has respected their medical decisions than one who has been forced into compliance against their will.

No one mentioned today that OSHA is against Recommendation #4 without allowing all three types of exemptions. And I quote from OSHA's minutes: "The Occupational Safety and Health Administration (OSHA) is strongly supportive of efforts to increase influenza vaccination rates among healthcare workers in accordance with the Healthy People 2020 goals. However, at this time, OSHA believes there is insufficient scientific evidence for the federal government to promote mandatory influenza vaccination programs that do not have an option for the HCP to decline for medical, religious and/or personal philosophical reasons."

No one has mentioned EEOC violations under the Americans With Disabilities Act or Title VII of the Civil Rights Act of 1964 which requires exemptions. This is something that should be considered with respect to recommendation #4.

The true stakeholder's of this proposed policy have NOT been engaged. One month is NOT enough time for public comment on an issue which will impact literally millions of employees. If you advocate for a mandatory flu vaccine policy but leave the exemption policy up to individual healthcare providers, I guarantee that either none will be offered or in many cases, only a medical exemption will be offered. My organization has received numerous phone calls from healthcare professionals being placed in the position of having to choose between going against their wishes and getting a flu vaccine or keeping their job. Medical exemptions are simply not enough as they are nearly impossible to obtain and this type of limitation on exemptions equates to complete lack of respect for healthcare workers to make healthcare decisions that they believe best suit them.

Ineffectiveness of the flu vaccine has barely been touched on today but should be strongly considered. Efficacy rates vary from 35-60%, not even high enough for the CDC's "herd immunity" standards. Any medical procedure which carries risk should not be mandatory for any person for any reason. When you throw ineffectiveness on top of that, you are basically slapping healthcare workers across the face. Healthy People 2020 is not a mandate and 90% is just a target.

I would like to quote directly from the Cochrane Collaboration: Sept 8, 2010 "We conclude that there is no evidence that only vaccinating healthcare workers prevents laboratory-proven influenza, pneumonia, and death from pneumonia in elderly residents in long-term care facilities."

If a flu vaccine mandate for healthcare workers with no exemptions is being driven by a real 2% reduction in funding for healthcare facilities under the Affordable Healthcare Act, please provide the public with solid information backing up that claim. I won't thank the committee for their time since I didn't get to say anything. This is going on my website.

--

In Health and Liberty,

Dawn Winkler
Executive Director
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January 13, 2012

[By electronic submission to nvpo@hhs.gov]

Jennifer Gordon, Ph.D.
National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Ave. SW., Room 733G.3
Washington, DC 20201

ATTN: Healthcare Personnel Influenza Vaccination

To Whom It May Concern:

The Infectious Diseases Society of America (IDSA), the Pediatric Infectious Diseases Society (PIDS), and the Society for Healthcare Epidemiology of America (SHEA) are pleased to have the opportunity to comment on the National Vaccine Advisory Committee's (NVAC) Health Care Personnel Influenza Vaccination Subgroup's (HCPIVS) recommendations for improving Health Care Personnel (HCP) vaccination rates to reach the Healthy People 2020 annual goal of 90% influenza vaccine coverage.

IDSA, PIDS, and SHEA appreciate that the NVAC Adult Immunization Working Group established the HCPIVS to develop recommendations and strategies for addressing the gap between current HCP influenza immunization rates and the Healthy People 2020 goal of 90% vaccine coverage. The five recommendations from the HCPIVS encompass a tiered set of strategies for health care employers (HCE) and facilities, beginning with implementation of influenza infection prevention programs and vaccination programs, and progressing to consideration of employer mandates for HCP vaccination if the facility cannot achieve the targeted goal with other programs. While our Societies welcome recommendations that recognize the role of employer mandates, we regret that the draft NVAC recommendations do not provide much stronger support for employer requirements, as outlined in the 2010 SHEA position paper on influenza vaccination of HCP, endorsed by IDSA¹.

IDSA, PIDS, and SHEA urge the NVAC to strengthen its draft recommendations to strongly recommend policies for mandatory influenza vaccination of all health care personnel, unless valid medical contraindications exist, as the most efficient and reliable way of achieving targeted immunization rates. We maintain that it is difficult for health care facilities to achieve high HCP vaccination rates without employer mandate, and therefore the tiered recommendations will only result in delays in achieving higher vaccination rates and may result in failures if HCE and facilities merely "consider" an employer requirement and do not

¹ Talbot, TR et al., Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel, *Infect Control Hosp Epidemiol*, 2010; **31**(10): 987-995.

implement one. There are numerous examples, many cited in the draft report, that demonstrate that organizations with a mandatory vaccination policy in place have a much higher immunization rate than those who have a voluntary program or no program at all. Facilities such as Virginia Mason Medical Center² and the Hospital Corporation of America³ have demonstrated the effectiveness of these policies by achieving and maintaining vaccination rates of 98% and 96%, respectively, compared to rates of 54% and 58%, respectively, prior to implementation of requirements. The Centers for Disease Control and Prevention (CDC) found that during the 2010-11 influenza season, vaccination coverage was 98.1% among HCE that required vaccination as a condition of employment, compared to 58.3% among those without a requirement⁴. While data cited in the draft HCPIVS report suggest that 90% vaccination rates can be achieved through comprehensive programs without a mandate, both the St. Jude Children's Research Hospital and the Iowa Health care Collaborative examples contain important caveats (elements such as an especially vulnerable patient population and strong leadership dedicated to this issue) that do not exist in all health care facilities.

Some critics have argued that employer mandates will lead to a false sense of security and decreased adherence to infection prevention programs. There are no data to support this argument, and it is contradicted by observations that multiple infection prevention strategies (including mandate programs) often synergize to reduce healthcare-associated infections (HAIs) (e.g., requiring operating room attire along with adherence to sterile technique and Surgical Care Improvement Project (SCIP) measures). If a false sense of security is a concern, it could arise both from an employer mandate as well as voluntary achievement of high vaccination rates. Regardless, our Societies strongly support comprehensive influenza educational efforts for HCP and continuation of comprehensive infection prevention and control programs, in addition to employer mandates. Such programs would include identification and isolation of infected patients, adherence to hand hygiene and cough etiquette, the appropriate use of personal protective equipment, and restriction of ill healthcare workers and visitors in the facility.

While HCP vaccination rates have risen in the last couple of years since the 2009 H1N1 pandemic, they are still well below the targeted goal of 90%. As the CDC data referenced in the report shows, 61.9% of HCP were vaccinated in the 2009-10 influenza season and 63.5% in the 2010-11 season. Universal vaccination of HCP is the cornerstone to a comprehensive national effort to prevent the spread of influenza in health care facilities during a seasonal influenza outbreak or a pandemic. In addition to the arguments raised above, the rationale behind our position on mandatory influenza vaccination of HCP is as follows:

- Several studies demonstrate that immunizing HCP against influenza reduces the risk of patients acquiring the virus from HCP, reducing both morbidity and mortality^{5,6,7,8,9,10,11,12,13}. Thus, universal immunization of HCP against seasonal influenza

² Rakita, R, et al., Mandatory influenza vaccination of healthcare workers: A 5-year study. *Infect Control Hosp Epidemiol*, 2010; **31**(9): 881-889.

³ Septimus, E, et al., A multifaceted mandatory patient safety program and seasonal influenza vaccination of healthcare workers in community hospitals, *JAMA*, 2011; **305**(10):999-1000.

⁴ CDC, Influenza Vaccination Coverage Among Health-Care Personnel—United States, 2010–11 Influenza Season, *MMWR Morb Mortal Wkly Rep*, 2011; **60**(32):1073-1077.

⁵ Potter J et al., Influenza vaccination of health care workers in long-term care hospitals reduces the mortality of elderly patients, *J Infect Dis*, 1997; **175**:1-6.

is a critical patient safety issue.

- Immunizing HCP against influenza also protects the individual HCP (and his/her family) from falling ill, thus both protecting the HCP from potentially serious illness while maintaining an adequate workforce, which further protects patients.
- Decades of scientific data demonstrate U.S. Food and Drug Administration (FDA)-approved influenza vaccines to be safe, effective, and cost-saving.
- Educational programs, declination policies and easy access to influenza immunization have resulted in modest improvements in coverage in many health care systems in recent years, but generally have not achieved acceptable levels of coverage. Despite extensive and sophisticated efforts, most successful educational programs still average only 40 to 70 percent rates of influenza vaccine coverage.
- Other professional societies such as the American College of Physicians, Association of Professionals in Infection Control, National Patient Safety Foundation, the American Academy of Pediatrics, the American Public Health Association, the National Foundation for Infectious Diseases, the American Medical Directors Association, the American Hospital Association, as well as the Department of Defense, many large health care systems and individual hospitals have adopted policies supporting mandatory influenza immunization. Many of these policies have resulted in vaccination rates greater than 95 percent.
- Physicians and other health care providers should adhere to their ethical and moral obligation to prevent transmission of infectious diseases to their patients and must have these special objectives in mind when treating patients: "to do good or to do no harm" (Hippocratic Corpus in *Epidemics*: Bk. I, Sect. 5, trans. Adams).

Our primary goal continues to be the effective delivery of patient care while protecting both patients and HCP from acquiring infections, including influenza, in health care settings. The best preventive measure against influenza is the use of a safe and effective influenza vaccine. Our Societies believe that the NVAC is taking an important step with these draft recommendations, but we once again urge you to consider strongly recommending that an employer mandate be a part of every comprehensive influenza prevention program, instead of

⁶ Carman WF et al., Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial, *Lancet* 2000; **355**:93-7.

⁷ Salgado CD et al., Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians, *Infect Control Hosp Epidemiol*, 2004; **25**(11):923-8.

⁸ Hayward AC et al., Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial, *BMJ*, 2006; **333**(7581):1241-6.

⁹ Shugarman LR et al., The influence of staff and resident immunization rates on influenza-like illness outbreaks in nursing homes, *J Am Med Dir Assoc* 2006; **7**(9):562-7.

¹⁰ van den Dool C et al., The effects of influenza vaccination of health care workers in nursing homes: insights from a mathematical model, *PLoS Medicine*, 2008; **5**:1453-1460.

¹¹ Lemaitre M et al., Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial, *J Am Geriatr Soc* 2009; **57**(9):1580-6.

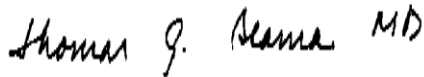
¹² van den Dool C et al., Modeling the effects of influenza vaccination of health care workers in hospital departments, *Vaccine*, 2009; **27**:6261-7.

¹³ Hayward AC and Watson J, Effectiveness of influenza vaccination of staff on morbidity, and mortality of residents of long term care facilities for the elderly, *Vaccine* 2011; **29**(13): 2357-8.

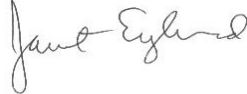
only being considered if other measures fail, as the best way to protect the health of both patients and HCP.

IDSA, PIDS and SHEA greatly appreciate the opportunity to comment on these draft recommendations. Should you have any questions, please do not hesitate to contact Audrey Jackson, PhD, IDSA's Senior Program Officer for Science and Research at ajackson@idsociety.org or 703.299.1216.

Sincerely,



Thomas G. Slama, MD, FIDSA
IDSA President



Janet A. Englund, MD
PIDS President



Jan E. Patterson, MD
SHEA President

About Our Organizations:

Infectious Diseases Society of America (IDSA)

IDSA represents nearly 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including influenza, meningitis, pneumonia, tuberculosis, surgical infections, other life-threatening infections caused by unusual or drug-resistant microorganisms, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

Pediatric Infectious Diseases Society (PIDS)

PIDS is a membership organization of over 1,000 specialists in pediatric infectious diseases, covering areas from basic and clinical research to patient care. PIDS' mission is to enhance the health of infants, children, and adolescents by promoting excellence in diagnosis, management, and prevention of infectious diseases through clinical care, education, research, and advocacy. PIDS represents the leading practitioners, policy-makers, and researchers who work with children's infectious diseases.

The Society for Healthcare Epidemiology of America (SHEA)

SHEA is a professional society representing more than 2,000 physicians and other healthcare professionals around the world with expertise in healthcare epidemiology and infection prevention and control. SHEA's mission is to prevent and control healthcare-associated infections and advance the field of healthcare epidemiology. The Society leads this field by promoting science and research and providing high-quality education and training in epidemiologic methods and prevention strategies. SHEA upholds the value and critical contributions of healthcare epidemiology to improving patient care and healthcare worker safety in all healthcare settings.



January 16, 2012

Dr. Jennifer Gordon, PhD
AAAS Science and Technology Policy Fellow

National Vaccine Program Office
U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination
Hubert H. Humphrey Building,
200 Independence Ave. SW.
Room 733G.3
Washington, DC 20201

Dear Dr. Gordon:

Since its founding in 1951, The Joint Commission has been acknowledged as the leader in developing the highest standards for quality and safety in the delivery of health care, and for evaluating organization performance based on these standards. Today, more than 19,000 health care organizations and programs use Joint Commission standards to guide how they administer care and continuously improve performance. The Joint Commission evaluates health care organizations across the continuum of care, including most of our Nation's hospitals, as well as laboratories, ambulatory care and office-based surgery facilities; behavioral healthcare; home care; hospice; and long term care organizations; as well as durable medical equipment suppliers. Although accreditation is voluntary, the federal government and most state regulatory bodies recognize and rely upon Joint Commission accreditation evaluations and decisions for their certification and licensure purposes.

The Joint Commission appreciates the opportunity to provide comments on the National Vaccine Advisory Committee's Adult Immunization Working Group's draft Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel. This proposed rule would require mandatory influenza vaccination for employees of health care facilities that cannot reach the 90 percent influenza vaccination rate. As a preeminent patient safety and quality improvement organization, the Joint Commission welcomes the chance to provide the following specific input the proposed recommendations that influence the delivery of high quality, safe health care.

HCP Transmission to Patients- Page Six, Line Seventeen

The workgroup states that HCP can acquire influenza infection and transmit it to patients.

However, The Joint Commission notes that patients seen in an ambulatory setting are not at a greater risk from providers than they are within their own communities. The Joint Commission would appreciate additional information and clarification on this point in future recommendations.

Offering Free and Readily Accessible Influenza Vaccination to HCP- Page Seven, Line Eleven

The group recommends that part of a health care facility's comprehensive influenza prevention plan include offering free and readily accessible influenza vaccination to HCP.

The Joint Commission believes that this recommendation should include ensuring that HCP are able to obtain influenza vaccinations across varying work shifts, locations, and days. Additionally, alternative funding sources should be encouraged to help providers with the costs of vaccinations. Alternative funding sources could include: using individual's private health insurance; having the health care facility or organization absorb the cost of providing the vaccinations; or exploring government subsidized vaccination programs.

Comprehensive Influenza Prevention Plan Requirements- Page Seven, Line Eighteen

The recommendations provided outline various components that should be included as part of a comprehensive influenza prevention plan, including hygiene etiquette, screening and isolation practices, use of standard and transmission-based precautions, and the management of ill HCP. The Joint Commission would also encourage the workgroup to provide recommendations related to those non-vaccinated HCP, such as the use of face masks to prevent influenza transmission, or being precluded from working within certain areas.

Again, The Joint Commission would like to offer its thanks for the opportunity to provide comment on this draft recommendations report. While we agree with the goals of the Healthy People 2020 Influenza Vaccine Coverage initiative, The Joint Commission would like to urge the workgroup to provide additional refinements to the recommendations, to provide the most clear and comprehensive counsel possible.

Thank you for considering The Joint Commission's comments. If you should have any questions, please feel free to contact me at (202) 783-6655 or via email at pkurtz@jointcommission.org.

Sincerely,



Patricia Kurtz, RN, MPA
Director, Federal Relations

Overall comments on the draft report of the Health Care Personnel Influenza Vaccination Subgroup of the National Vaccine Advisory Committee:

This was a very comprehensive recommendation; the suggested interventions and rationale are very compelling.

The Cochrane Review that is cited has been revised. This revision took place in 2010. The revised Cochrane Review reports a more limited conclusion on the efficacy of influenza vaccine. The 2007 version is no longer available on the Cochrane website. It is not appropriate to cite an outdated Cochrane Review without providing any rationale or explanation.

Below are the results of the most current Cochrane Review:

“Main results:

We included 50 reports. Forty (59 sub-studies) were clinical trials of over 70,000 people. Eight were comparative non-RCTs and assessed serious harms. Two were reports of harms which could not be introduced in the data analysis. In the relatively uncommon circumstance of vaccine matching the viral circulating strain and high circulation, 4% of unvaccinated people versus 1% of vaccinated people developed influenza symptoms (risk difference (RD) 3%, 95% confidence interval (CI) 2% to 5%). The corresponding figures for poor vaccine matching were 2% and 1% (RD 1, 95% CI 0% to 3%). These differences were not likely to be due to chance. Vaccination had a modest effect on time off work and had no effect on hospital admissions or complication rates. Inactivated vaccines caused local harms and an estimated 1.6 additional cases of Guillain-Barré Syndrome per million vaccinations. The harms evidence base is limited.

Authors' conclusions:

Influenza vaccines have a modest effect in reducing influenza symptoms and working days lost. There is no evidence that they affect complications, such as pneumonia, or transmission.”

Page2

Definitions

HCP refers to all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Thus, HCP includes a range of those directly, indirectly, and not involved in patient care who have the potential for transmitting influenza to patients, other HCP, and others.

Comment: The NQF has endorsed a more limited definition of HCP, dividing it into three groups for the denominator of their measure. NVAC suggests that the NQF measure be used as a standard to measure coverage. There should be clarification as to what NVAC considers HCP and what the NQF measures and rationale for why these are different.

HCE refers to a person or entity that has control over the wages, hours, and working conditions of HCP in health care settings. Health care settings include, but are not limited to, acute-care hospitals; adult day programs or facilities, ambulatory surgical facilities, long-term care facilities, such as nursing homes and skilled nursing facilities; outpatient clinics, physicians' offices; rehabilitation centers, residential health care facilities, home health care agencies, urgent-care centers, and outpatient clinics.

Comment: The NQF stated that measurements should be by „facility.“ It is not clear whether the NVAC’s definition of HCE is at the health facility level or the health system level. NVAC should clarify or explain how the term HCE applies to a health care system and rationalize the difference in language between their definition and the NQF measure.

Page 5, line 8

2. Immunization is the most effective way to protect patients and HCP from influenza infections. The Working Group’s recommendations are built on the principle that influenza is a significant public health threat, that the influenza vaccine is safe ~~and effective~~, and that vaccination is currently the most effective mechanism for preventing influenza infection.

Suggestion: Remove the words “and effective.” The vaccine is the most effective tool that is available; however, there is debate about whether it can be generally called effective.

Page 5, line17

Immunizing HCP has two potential benefits: 1) directly protecting HCP from influenza for their own health, allowing them to continue to work thus minimizing disruption of health care settings [18]; and 2) indirectly protecting other HCP and patients with whom they come in contact who may be at high risk for complications of influenza [11, 19-21].

Suggestion: 1) protecting other HCP and patients with whom they come in contact who may be at high risk for complications of influenza [11, 19-21] and 2) directly protecting HCP from influenza for their own health, allowing them to continue to work thus minimizing disruption of health care settings [18].

Page 12, line 29

Recommendation

The HCPIVS recommends that HCE and facilities integrate influenza vaccination programs into their existing infection prevention or occupational health programs. HCPIVS also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff, and Federally Qualified Health Centers) and strongly urge all HCE and facilities to do the same.

Comment: There was broad range of HCEs listed, considering this; some may not have occupational health or infection control programs. Would NVAC consider including a resource for HCEs who are newly implementing an influenza vaccination program for HCPs?

Page 13, line 20

Standardization of the methodology used to measure HCP influenza vaccination rates across health care settings will result in comparable data that can be used to improve HCP vaccination rates.

Work is underway to standardize the methodology to measure HCP influenza vaccination rates. In 2008, the CDC proposed a standardized measure for assessing influenza vaccination of HCP to the National Quality Forum (NQF). The measure was designed to ensure that reported HCP influenza vaccination rates were **comprehensive within a single health care facility and comparable across facilities**. A revised measure was approved by the NQF Population Health & Prevention Steering Committee in September, 2011. This measure includes acute care hospitals, ambulatory surgical centers, long-term care facilities, outpatient clinics, and renal dialysis centers.

Comment: Measuring by facility is the most transparent and comprehensive way to measure vaccination coverage, however it would be helpful for NVAC to clarify this point in the HCE definition.

Page 17, line 10

Employer requirement programs need leadership buy-in, education, and resource allocation in order to be successful.

Visible and vigorous leadership and accountability for vaccination are essential for programs requiring influenza vaccination as a condition for employment [35]. The key points to consider in implementing an employer required influenza vaccination policy include (1) having full support of health care leadership; (2) tailoring the policy to the geographic setting, educational resources, financial assets, local culture, and potential language barriers; (3) providing free vaccinations to all HCP; (4) publicizing the program to HCP at all levels; (5) offering convenient times and locations for education and immunization administration; (6) using a universal form with defined exemptions; and (7) developing a clear institutional policy for management of employees who are exempted from immunization or refuse immunization [40].

Comment: What kind of implications does a „universal“ form have on the autonomy of the vaccine provider? There may be situations where a provider does not feel comfortable with vaccinating a HCP and would refer that HCP to their own provider for vaccine (such as egg allergy or previous history of GBS). The requirement of a universal form may impinge on the rights of the vaccine provider.

Page 19, line 4

Religion – Some HCP may oppose influenza vaccination based on religious convictions, and many mandatory vaccination policies have allowed religious exemptions for HCP who decline vaccination in good faith because of strongly held beliefs [61].

Comment: Does NVAC or the CDC generally comment on religious exemptions?

Page 19, line 22

Several HCE have indicated that mandatory influenza vaccination policies are necessary to achieve the core purpose of their facilities, which is to promote patient health and safety. These HCE have argued that mandatory influenza vaccination policies are designed as patient protection measures, such that HCE should

not be obligated to negotiate these policies and the implementing procedures with Unions. However, union representatives have successfully argued that mandatory influenza vaccination policies are subject to the usual collective bargaining process because the requirements constitute a change in the terms and conditions of employment.

Comment: How do Unions view other types of requirements, like HepB or mantoux?

Page 22, line25

Influenza vaccine effectiveness is highest when the vaccine strains are well-matched to circulating virus. In years when the circulating virus strains vary from the vaccine strains, vaccinated HCP and their patients may still be at risk for contracting and spreading influenza infection.

Suggestion: Revised language: Influenza vaccine effectiveness is highest when the vaccine strains are well-matched to circulating virus. In years when the circulating virus strains vary from the vaccine strains, vaccinated HCP and their patients may have an increased risk for contracting and spreading influenza infection compared to years when the vaccine is well matched.

Comment: The above statement implies that flu vaccine efficacy is 100% in a well-matched year. Efficacy is better, but there is still some baseline risk of contracting influenza.

Vaccine efficacy can vary from year to year and from person to person, but usually some protection is provided against illness or severe illness. There is a great deal of debate regarding the effectiveness of the influenza vaccine. Several studies found that annual immunization with a vaccine antigenically well matched to circulating strains reduced serologically confirmed influenza cases by 70% to 90% among healthy adults under the age of 65 [23, 62-66]. However, recent studies estimate that vaccine effectiveness may be considerably lower. A report by Osterholm et al. reported a pooled efficacy of only 59% in adults 18-65 years old [67]. Others have also reported reduced vaccine effectiveness in the range of 45 to 75% [24]. The lower estimates in more recent studies may reflect new information regarding diagnostic testing; vaccine effectiveness is overestimated when serology is used as an endpoint. While current vaccines are a critical component of reducing influenza infection, an opportunity exists to provide improved vaccines with broader protection and increased duration of immunity. Additionally, novel approaches to improving influenza vaccines could result in vaccines that offer multi-year protection against numerous influenza strains, which will reduce the frequency of immunization [68-70].

Comment: We now know that there is little to no evidence to support the statement that flu vaccine is 70-90% effective. The studies cited here are generally older, representing an earlier era in laboratory testing, new standards like rtPCR are now in use. NVAC may consider more judicious use of early flu vaccine studies.

NVAC should elaborate on and explain the statement about “pooled efficacy,” especially because the next sentence reports a range, rather than a pooled statistic.

The lower estimates in more recent studies may reflect new information regarding diagnostic testing; vaccine effectiveness is overestimated when serology is used as an endpoint.

Suggestion: A citation is needed here, perhaps:

Petrie, J. G., Ohmit, S. E., Johnson, E., Cross, R. T., & Monto, A. S. (2011). Efficacy studies of influenza vaccines: Effect of end points used and characteristics of vaccine failures. *Journal of Infectious Diseases*, 203(9), 1309-1315. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=2010998664&site=ehost-live>

Page 23, line 31

Conclusion

Improved efficacy and reduction in the need for annual vaccinations will make it easier to achieve and sustain high vaccination coverage rates among HCP. Ensuring that adequate vaccine supplies are available will also help HCE and facilities to provide vaccine, free of charge, to HCP and, ultimately, achieve the Healthy People 2020 annual goal of vaccination of 90% of HCP or even higher coverage rates.

An influenza vaccine that confers multi-year protection against influenza with increased efficacy and comparable safety relative to the current annual vaccines could facilitate achieving and maintaining high coverage rates for influenza immunization in HCP and other populations. An ideal vaccine is a "universal" influenza vaccine that would not need to be updated each year depending on circulating influenza strains and could provide extended or life-time immunity. A longer lasting vaccine may contribute to higher coverage, reducing the need for employer requirements.

Comment: Is „universal“ the best descriptor of a new vaccine? It is possible that using this term could be confused with the „universal recommendation.“ The word also implies that this vaccine would protect against all strains and provide lifelong protection. Perhaps using a term like “broad strain” or “compound” would be more accurate.

Jennifer Heath, RN MPH
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01/17/12

Dear Ms. Gordon,

The National Association of School Nurses (NASN) reviewed the draft report of the Health Care Personnel Influenza Vaccination Subgroup. **NASN supports the draft report** and the tiered approach, which documents the typical barriers to influenza immunization. School nurses note:

1. Immunizations are part of our professional responsibility of taking care of our children;
2. When advocating for immunizations with parents, media, or legislators, credibility is increased when we can point to our profession's personal commitment; and
3. In economically challenged times, a recommendation like this assists the acquisition of vaccines for staff as a condition of employment.

Respectfully,

Donna Mazyck, MS, RN, NCSN
Executive Director
National Association of School Nurses
8484 Georgia Ave., Suite 420
Silver Spring, MD 20910
1-866-627-6767
301-585-1791 (fax)

Comment Submitted from the National Patient Safety Foundation:

The National Patient Safety Foundation recognizes vaccine-preventable diseases as a matter of patient safety and supports mandatory influenza vaccination of health care workers to protect the health of patients, health care workers, and the community. NPSF appreciates that where vaccination is not possible for any reason, due to unavailability or medical contraindications of potential vaccine recipients, hospitals and health care professionals must use all available alternatives to avoid transmission to patients and coworkers including masks and adjusting job responsibilities.

Diane C. Pinakiewicz, President, National Patient Safety Foundation.



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 vaccination⁷ 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 do 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 influenza²¹ 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 not 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 fired²⁶ 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

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January 13, 2012

nvpo@hhs.gov

RE: Comments on the Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel
[FR Doc No: 2011-32308]

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (NYC DOHMH) has reviewed the National Vaccine Program Office's request for comments regarding the Healthcare Personnel Influenza Vaccination Subgroup draft report and draft recommendations for increasing vaccination of healthcare personnel to meet the Healthy People 2020 goals.

Overall, NYC DOHMH believes that this document provided a comprehensive overview of the rationale and best practices for improving healthcare personnel (HCP) influenza vaccination coverage. Strengths of the document include the recommendation for use of the National Quality Forum (NQF) measure for HCP influenza vaccine coverage and for the recommendation for employer requirements for influenza vaccination in facilities. The following are our specific comments and recommendations:

1) Page 2 – Definition of healthcare personnel (HCP)

“HCP refers to all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Thus, HCP includes a range of those directly, indirectly, and not involved in patient care who have the potential for transmitting influenza to patients, other HCP, and others.”

Comment: Whereas we agree with the concept that HCP should be defined broadly and that influenza vaccination should be promoted and offered to all persons in as defined above – from a practical perspective, this is not feasible and HCP vaccine coverage would not be able to be reliably measured.

The document should reference the NQF definitions for healthcare personnel which include separate categories for employees, licensed independent practitioners, and students/trainees and volunteers as the standard for measurement. As mentioned in the document, CMS IQR program requirements reflect these definitions as well. Through pilot testing of the NQF measure, it was found that measurement of vaccination coverage in additional groups (specifically contract workers not employed by the facility) is extremely difficult and may deter facilities from tracking coverage rates.

2) Page 2 - Definition of a Health Care employer (HCE)

“HCE refers to a person or entity that has control over the wages, hours, and working conditions of HCP in health care settings. Health care settings include, but are not limited to, acute-care hospitals; adult day programs or facilities, ambulatory surgical facilities, long-term care facilities, such as nursing homes and skilled nursing facilities; outpatient clinics, physicians' offices; rehabilitation centers, residential health care facilities, home health care agencies, urgent-care centers, and outpatient clinics.”

Comment: The NQF stated that measurements should be by ‘facility.’ It is not clear whether the NVAC’s definition of HCE is at the health facility level or the health system level. NVAC should clarify or explain how the term HCE applies to a health care system and rationalize the difference in language between their definition and the NQF measure. The unit of measure for HCP influenza vaccine coverage should be endorsed as being at the facility level, to be consistent with the NQF measure.

3) Page 14: Recommendation

“HCPIVS recommends that the ASH encourage CDC and CMS to continue efforts to standardize the methodology used to measure HCP influenza vaccination rates across settings linking vaccine coverage levels and quality improvement activities. The ASH should also work with CMS to implement incentives, penalties or requirements that facilitate adoption of the recommendation.”

Comment: NYC DOHMH strongly supports that the NQF measure be adopted in outpatient and ambulatory care settings. We also strongly support the recommendation that CMS implement incentives, penalties or requirements to facilitate adoption and achievement of the 2020 goal of 90% influenza vaccine coverage for HCP. Interim coverage levels, or requirements to demonstrate increases in coverage levels (such as 80% by 2015), should be considered to ensure progress toward the 2020 goal.

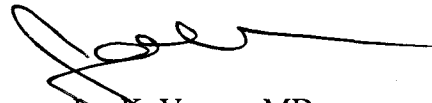
4) Page 19 – Religious exemptions

“Religion –Some HCP may oppose influenza vaccination based on religious convictions, and many mandatory vaccination policies have allowed religious exemptions for HCP who decline vaccination in good faith because of strongly held beliefs.”

Comment: The language used in this document should deter the allowance of religious exemptions to immunization. In New York State, religious exemptions for mandatory healthcare personnel immunizations, including MMR are not accepted insofar as they are not recognized in New York State law. Similar guidelines should be in place for influenza vaccination. At the very least, this should be a state specific decision in accordance with State legislation.

We appreciate the opportunity to provide our comments on the draft report and recommendations.

Sincerely,



Jay K. Varma, MD
Deputy Commissioner
Division of Disease Control



January 13, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
200 Independence Avenue SW
Room 733G.3
Washington, DC 20201
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Dear Sir / Madam;

The New York State Nurses Association, representing more than 37,000 nurses in New York State, fully recognizes the importance of a goal to protect their colleagues and the patients they care for from the effects the seasonal influenza. The creation and implementation of an integrated fully comprehensive infection control program is the best means to achieve that goal. Vaccination is but a single component of that program and to elevate a single component to a mandatory status, as is suggested in recommendation number 4 of the report, can serve to diminish the importance of the other, equally important components.

Furthermore, the flu begins in the community (200,00 infections) and is brought into the healthcare facility. The report fails to address the efforts healthcare facilities should be taking in the public health arena to stop the spread of the influenza at its source. Rather, after the fact, the report recommends taking healthcare providers away from direct patient care, even considering their termination, if they do not get the vaccine. It is counterintuitive to diminish an already understaffed healthcare work force unilaterally during the peak of the flu season. These tactics, while they may increase the uptake of vaccinations within the healthcare facility, do nothing to impact the root cause of the 200,000 pre-hospital infections.

In the report, NVAC admits that the efficacy of the flu vaccine is sub-optimal for particular populations and during those seasons when the vaccine is poorly matched with the circulating virus or when the strain shifts significantly during the season. Additionally, the vaccine efficacy varies annually. Mandating such a vaccine as the most effective means to stop the spread of the flu is misguided and NYSNA respectfully requests that the U.S. Department of Health and Human Services modify the HCPIVS' recommendations to eliminate the mandatory option for employees. A better alternative, patterned after the Hepatitis B vaccine, would be to mandate healthcare facilities to offer the flu vaccine free of charge and at a time and place convenient for all employees. The use of a standard declination form has also demonstrated positive results for increasing the uptake of the vaccine.



Additionally, NYSNA recommends that the employer be required to directly involve front line workers and their representatives in the development and implementation of a comprehensive infection prevention program.

If the goal is truly intended to reduce the spread of the influenza virus, then a recommendation should also include a mandate for the healthcare employer to participate in the development and offering of community outreach programs in cooperation with the local departments of health to educate the general population on prevention strategies.

Thank you for the opportunity to offer comments to help improve the efforts to stop the spread of influenza, not only in the hospital setting, but in the community on whole.

Respectfully,

Renee Gecsedi

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The New York State Nurses Association is the voice for nursing in the Empire State. With more than 37,000 members, it is New York's largest professional association and union for registered nurses. The association represents registered nurses, and some all-professional bargaining units, in New York and New Jersey. It supports nurses and nursing practice through education, research, legislative advocacy, and collective bargaining.



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National Vaccine Program Office
 U.S. Department of Health and Human Services
 Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon
 200 Independence Avenue SW
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 Washington, DC 20201

Dear Sir/Madam:

The New York State Public Employees Federation (PEF) is writing to comment on the National Vaccine Advisory Committee (NVAC) Health Care Personnel Influenza Vaccination Subgroup's (HCPIVS) draft report; Recommendation on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel.

PEF represents 56,000 state government employees in a myriad of New York agencies, including 15,000 healthcare workers. We strongly support the need for healthcare employers to develop and implement comprehensive programs to prevent the spread of influenza and other infectious diseases among employees and patients. While there is much that we support in the report, we feel that there is a serious element omitted in Recommendations #1 and #2 – the direct involvement of workers and their representatives (if unionized), in the development and implementation of the program.

Frontline workers and their representatives are in a unique position to understand the scenarios that can lead to disease transmission in their workplace and to evaluate the efficacy, feasibility, and unintended consequences of infection control measures that are prescribed. This involvement, coupled with education and training about all aspects of the program, is critical. Only then will employees understand the role that vaccination plays in a comprehensive program. If the vaccine is then offered by the employer at no cost, onsite, and during work time, the likelihood of high vaccination rates is great.

There will likely be scenarios where the vaccination rate is below the Healthy People 2020 goal of 90%. When this occurs, the employer should be encouraged to sit down again with the employees and their representatives to identify the barriers and to collectively address the shortcomings in the infection control and vaccination program.

Encouraging employers to *mandate* vaccination, as the HCPIVS report does in Recommendation #4, is misguided in a few ways. First, it will often be rendered moot if the employer complies with our recommendation above. Second, mandating that individuals be vaccinated potentially violates individuals' rights, for the small minority who are unable for medical or religious reasons to be vaccinated. Third, our experience has been that some employers will rely on this mandatory vaccination program as a panacea, and will pay scant attention to other infection control measures. As the NVAC itself recognizes, the efficacy of the flu vaccine is sub-optimal, and varies annually. Thus, anything that leads to employers' diminished commitment to a robust infection control program should be avoided.

For these reasons, PEF requests that the U.S. Department of Health and Human Services modify the HCPIVS' Recommendations in the manner outlined above, adding a requirement that employers directly involve their workers and their representatives, and eliminating Recommendation #4.

Thank you for considering PEF's comments.

Sincerely,

Kenneth Brynien
 Kenneth Brynien
 President



January 13, 2012

National Vaccine Program Office

Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

U.S. Department of Health and Human Services

200 Independence Avenue SW., Room 733G.3

Washington, DC 20201

Reference: Solicitation of written comments on the Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for consideration by the National Vaccine Advisory Committee on achieving Healthy People 2020 annual coverage goals for influenza vaccination in healthcare personnel. (FR Doc. 2011-323080)

SEIU Nurse Alliance of California offers these comments to the Health Care Personnel Influenza Vaccination Subgroup (HCPiVS) draft report. On behalf of our 35,000 Registered Nurses, we thank you for the opportunity to participate in your webinar and to present our comments on the draft document presented by the Healthcare Personnel Influenza Vaccination Subgroup (HCPiVS), of the National Vaccine Advisory Committee (NVAC).

As nurses, we recognize the importance of healthcare workers being offered free influenza vaccinations as part of a comprehensive infection control program. While we agree that there needs to be improvements in the effectiveness of the annual vaccine and education regarding flu vaccines in order to increase the number of employees who are actually vaccinated yearly; there remains some concerns and disagreement regarding mandatory or required vaccination programs and some of the goals listed in the draft recommendations.

Looking at the issue from the perspective of a bedside or practicing nurse, the goals are not necessarily realistic or viable. So far none of the draft goals have been met, the influenza vaccine is not particularly effective, at only 59% and the consequences imposed by an employer in their effort to reach those goals are punitive rather than constructive. Our nurses find that they have not really been informed or educated on why a flu vaccine is important or how safe the vaccine might be. We are simply told, you have get the vaccine, it's safe and if you don't there will be discipline or other consequences involved.

We haven't seen evidence that healthcare workers who may have the flu, have infected their patients, but we are told you can kill your patient if they contract the flu from you and could be liable if that happened. If we try to stay home with flu symptoms so that we don't infect our co-workers or patients, because even with a flu shot we can come down with the virus, and we are credited with an unexcused absence and subject to discipline. Or we are informed we have to get a doctor's release to return to work, even though we know many illnesses don't require an office visit and that could bog down an appointment book for patients that truly need to see the doctor.

There is no evidence that the requirement for healthy, unvaccinated care givers to wear a mask prevents the spread of influenza. But donning and removing a mask numerous times a day could increase the chances of contracting some kind of illness. Not to mention that many nurses who have received the vaccine are almost just as likely to come down with the flu as unvaccinated nurses, so everyone should be wearing a mask in that case. We also think that using vaccination rates as the marker for success gives a false sense of security, when hand hygiene and cough etiquette may do more for preventing the spread of illnesses. We consider those to be an even more important part of a comprehensive infection control policy, which not only would work for influenza but many infectious diseases.

Many nurses and healthcare staff work 12 hour shifts, being required to wear a surgical mask for that amount of time is not only punitive, it might be considered a form of torture. Patients who see hospital staff wearing a mask throughout the hospital or healthcare facility, for an entire shift, often wonder why, 'are they infected or am I'? As patient advocates, what happens when the public sees that nurses and other healthcare staff need a vaccine mandate? Is there something wrong or dangerous with the vaccine that even educated healthcare professionals don't want it? Wouldn't it be better if the employer could advertise they reached a high percentage of vaccinated employees through education and positive approaches?

Again, the Registered Nurses of SEIU Nurse Alliance of California sincerely thank the HCPIVS for the opportunity to submit comments for the draft report and recommendations for increasing influenza vaccination rates among healthcare workers.

Ingela Dahlgren, RN

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January 16, 2012

National Vaccine Program Office

U.S. Department of Health & Human Services

Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

200 Independence Avenue, SW

Room 733- G.3

Washington, DC 20201

Dear Sir or Madam

On behalf of the Nurse Alliance of Pennsylvania, a subsidiary of Service Employees International Union (SEIU) Healthcare Pennsylvania, thank you for the opportunity to present our comments on the draft, ‘Strategies to Achieve the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel.’

The Nurse Alliance of Pennsylvania is the voice of 10,000 registered nurses and licensed practical nurses in the Commonwealth of Pennsylvania. Our nurses can be found throughout healthcare facilities- working on the frontline in hospitals, long-term care facilities, clinics, and prisons.

As nurses we know the importance for a well-rounded infection control program to combat the influenza virus. We strongly support *employer-sponsored voluntary vaccination programs*.

Employers who provide a well-developed mandated educational program that provides support and answers to the individual concerns of personnel will be rewarded with a strong compliance. Vaccinations should be provided free of charge

and easily assessable on work units to further promote compliance. As such, we would like to declare our support for HCPIVS recommendations #1 and 2.

However, we do not and cannot support HCPIVS recommendation #4 that allows employers to mandate the influenza vaccine for healthcare personnel. We see this as a basic disregard of the civil liberties of individuals based on a supposition that has little or no scientific foundation.

We feel that such a change will promote a false sense of security within the healthcare environment and in the general public. Instead the recommendation should be to promote an increase in those environmental practices that prevent the spread and transmission of the virus within facilities. This would be of more benefit and would provide an effective protection against the spread of influenza.

The annual vaccinations that have been developed provide a limited effectiveness against the influenza virus. When a vaccine can claim only an effectiveness of 38-59%, how can there be a justification that the vaccine is so relevant as to recommend mandating it?

In conclusion, the Nurse Alliance of Pennsylvania supports a *Mandatory-Offering of Vaccination by Employers* as well as a mandatory, well-developed educational program with the option for employee declination statements allowing for medical contraindication, or religious and/or personal objections. Instead, we believe that more progress would be made towards the *Healthy People 2020* goals by focusing efforts and resources on developing a more-effective, longer-lasting influenza vaccine as suggested in HVPICS recommendation #5.

Sincerely,

Deborah Bonn

Director, Pennsylvania Nurse Alliance

SEIU Healthcare Pennsylvania



JAN 13 2012

National Vaccine Program Office
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon
U.S. Department of Health and Human Services
200 Independence Avenue SW., Room 733G.3
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Reference: Solicitation of Written Comments on the Draft Report and Draft Recommendations of the Healthcare Personnel Influenza Vaccination Subgroup for Consideration by the National Vaccine Advisory Committee on Achieving the Healthy People 2020 Annual Coverage Goals for Influenza Vaccination in Healthcare Personnel (FR Doc. 2011-32308)

The Occupational Safety and Health Administration (OSHA) offers these comments on the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) draft report.

OSHA is strongly supportive of efforts to increase influenza vaccination rates among healthcare personnel in accordance with the Healthy People 2020 goals. However, OSHA believes that there must be a very high burden of proof that mandatory-taking programs are not just desirable, but also necessary to protect the public health before the government promotes such a controversial policy that may result in employment termination. At this time, OSHA believes there is insufficient evidence for the federal government to promote mandatory influenza vaccination programs that may result in employment termination.

While OSHA has serious policy concerns about promoting *mandatory-taking* influenza vaccination programs, and does not believe that there is sufficient evidence to support such programs, we nonetheless are convinced that influenza vaccination is generally beneficial for worker health and are supportive of efforts to promote vaccination. Accordingly, we support an approach of *mandatory-offering* of vaccination by employers, mandatory education of workers, and the option for employee declination statements.

OSHA is also concerned that minority comments describing insufficient evidence of a link between worker vaccination against influenza and patient safety have not been adequately addressed in the draft report. In order to prevent any allegations concerning the scientific integrity of this report, OSHA requests that the final report include appropriate minority comments.

The scientific literature clearly supports offering the influenza vaccine to workers for the protection of the workers themselves, however OSHA does not believe that at this time the scientific literature adequately supports the notion that vaccinating HCP also provides a significant measure of protection for the patients for whom they care. While we support the Healthy People 2020 goal of 90% HCP vaccination as an aspirational goal, we are troubled that some have tried to convert the goal into a mandate. High HCP influenza vaccination rates are generally desirable, but we are unaware of any evidence to support the notion that such a high influenza vaccination rate is also *essential* to protect patients, and should thus be *mandatory*.

We offer three recent and highly influential studies as support for our concerns:

- Jefferson et al. (Cochrane Database Syst Rev, 2010) states “There is no evidence that they [influenza vaccinations] affect complications, such as pneumonia, or transmission.” The evidence-based review also concluded that “At best, vaccines might be effective against only influenza A and B, which represent about 10% of all circulating viruses [that cause influenza or ILI symptoms].”
- Michiels et al. (Vaccine, 2011) concluded “There is a striking lack of sound evidence for the effect of vaccination on influenza complications such as pneumonia, hospitalization and mortality among individuals with co-morbidities.”
- Thomas et al. (Vaccine, 2010) determined that “there is no evidence that vaccinating HCPs prevents influenza in elderly residents in LTCFs.”

OSHA believes that these recent studies must be substantively addressed in the body of the final report. Furthermore, we are concerned that the subgroup has obscured the issue of insufficient evidence of a link between worker vaccination against influenza and patient safety, by addressing the issue at the end of the section on mandatory vaccination and just before the conclusion (Page 21, lines 4-12). The strength of association (or lack thereof) between worker vaccination and patient safety is a central and necessary element before contemplating whether mandatory influenza vaccination is an appropriate remedy. Additionally, the ethical and legal arguments associated with mandatory influenza vaccination also rely upon the integrity of the scientific evidence. OSHA asks the subgroup to reconsider the ethical and legal arguments in the context of an updated scientific analysis. Accordingly, OSHA believes that these important scientific concerns must be addressed in order to avoid any data quality concerns.

Furthermore, it is well-recognized that there is great variability in the effectiveness of the influenza vaccine in preventing infection, as well as preventing life-threatening illnesses. (Osterholm et al., Lancet Infect Dis., 2012) The vaccine also requires annual reformulation and revaccination. Every year there are numerous circulating strains of influenza that are not included in the vaccine. In years where the antigenic match is good, the vaccine only provides protection against the 3 strains in the formulation. In years when the antigenic match is poor, the vaccine may provide limited or no protection at all. The limits of current influenza vaccine technology are especially problematic in

the context of a mandatory influenza vaccination program that results in job loss. OSHA believes that the report should specifically address the implication of the limitations of current influenza vaccine technology on HCP mandatory vaccination [e.g., that, in some cases, a worker could be fired for refusing the influenza vaccine that provides little protection].

Given the current state of the science surrounding influenza vaccination, OSHA disagrees with HCPIVS' Recommendation #4 that states that if a healthcare employer (HCE) can not achieve Healthy People's 2020 goal of 90% HCP influenza vaccination rate, the HCE should "strongly consider an employer requirement for influenza immunization." OSHA believes the report should clearly state that HCP should not be terminated from employment for refusing the influenza vaccine. Consequently, we ask that the recommendation be deleted.

OSHA is a strong supporter of appropriate education, ready access and signed declination statements for HCP vaccinations. OSHA's bloodborne pathogen standard regarding Hepatitis B education and vaccination is a best-practice model. Influenza vaccination exemptions should be allowed for HCP with valid medical contraindications to vaccinations, or religious and/or personal objections. In addition, a signed declination statement should indicate that: the HCP has been educated regarding influenza; is aware of the risk and benefits of influenza vaccination; has been given the opportunity to be vaccinated at no charge; and can receive the influenza vaccine in the future, at no cost, should they change their mind. We believe declination statements are an appropriate way that healthcare settings can document employee refusal and employer actions to encourage vaccine acceptance.

OSHA is encouraged by and supportive of HCPIVS' DRAFT report recommendations 1, 2, 3, and 5 that state: healthcare employers (HCE) establish a comprehensive influenza infection prevention program (HCPIVS Recommendation 1), influenza vaccination programs be integrated with HCEs' existing infection prevention programs (HCPIVS Recommendation 2), the Centers for Medicare and Medicaid Services standardize the methodology used to measure HCP influenza vaccination rates (HCPIVS Recommendation 3), and improved and longer lasting influenza vaccines be developed (HCPIVS Recommendation 5).

We thank the subgroup for their work on improving the health and safety of healthcare personnel and will work with you and our colleagues at the Department of Health and Human Services to support efforts to increase influenza vaccination rates.

Sincerely,



Jordan Barab
Deputy Assistant Secretary for Occupational Safety and Health

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January 14, 2012

National Vaccine Program Office
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Room 733-G.3
Washington, DC 20201

Via Email: nvpo@hhs.gov

Dear HCPIVS staff and members:

We appreciate the opportunity to offer some brief comments on the draft document developed by the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS) of the National Vaccine Advisory Committee (NVAC), with the charge of recommending ways to increase influenza vaccination rates among healthcare workers.

That is a charge we support. We are strong proponents of flu vaccination. We get vaccinated annually, and urge family and friends to do likewise. (Dr. Lanard, who often works in the southern hemisphere, sometimes gets vaccinated twice.) We think the downsides of flu vaccination are negligible, while its upsides are substantial – even though the vaccine is only 50-70% effective in healthy adults under 65 in years with a good match. We think healthcare workers (HCWs), like everyone else, should choose to get vaccinated against the flu.

We are not experts in vaccination, influenza, or health policy. We are experts in risk communication, and will try to focus our comments on risk communication issues raised by your proposed recommendations.

We see two such issues: the dangers of overstating flu vaccination benefits, and the dangers of requiring reluctant HCWs to get vaccinated.

The dangers of overstating flu vaccination benefits

As you know, the evidence that vaccinating HCWs against the flu reduces patient mortality and morbidity comes almost entirely from studies conducted in nursing homes. There is little if any evidence demonstrating the same effect in a general hospital setting, far less an outpatient setting. Since patients in nursing homes have fewer close contacts with persons other than HCWs than patients elsewhere, extrapolating from one to the other without data is insupportable.

Yet many public health agencies and others have implied or explicitly claimed that there is strong scientific support for the contention that flu vaccination of HCWs benefits patients. Typically

they cite the nursing home studies without noting the questionable applicability of these studies to other healthcare settings.

In a [2010 editorial](#), for example, the Editor-in-Chief of *Vaccine*, the Mayo Clinic's Gregory Poland, wrote:

Further, studies have now demonstrated the relationship between levels of HCW influenza immunization and mortality among the patients they care for [3,4].

Dr. Poland's two footnotes in support of this statement lead to articles showing that HCW vaccination protected elderly patients in long-term care facilities. He cites no studies showing a similar protective effect in the general hospital population. The title of Dr. Poland's editorial is worth contemplating in the context of his own overstatement: "Mandating influenza vaccination for health care workers: Putting patients and professional ethics over personal preference."

Here is another typical passage, from the very first paragraph of a March 2012 article entitled "[Seasonal Influenza Vaccine Compliance among Hospital-Based and Nonhospital-Based Healthcare Workers](#)," [ahead-of-print link; search title if link does not work anymore] analyzing influenza vaccine compliance among HCWs, and also advocating mandatory HCW vaccination:

Influenza vaccination of HCWs has been shown to not only decrease employee sick leave(2) but also decrease morbidity and mortality among patients.(3-5)

We have no quarrel with the first part of this sentence. There appear to be ample data that increased HCW vaccination reduces staff absenteeism. (When there are more vaccinated HCWs around, there may be more staff with "failed vaccinations" who catch vaccine-tempered mild cases of the flu – and are not sick enough to stay home. But that is a problem for another day.)

Almost needless to say, footnotes 3-5 in the latter part of the sentence refer to the usual long-term care and nursing home studies. Later in the same article, footnote 5 (reabeled footnote 21) is used in support of the statement that "Research indicates that vaccinating HCWs in these [long-term care and nursing home] settings can decrease patient morbidity and mortality and is preferable to vaccinating the frail elderly." But nowhere does the article acknowledge that virtually no similar studies have been done in acute-care hospitals or outpatient settings.

Much more culpable, in terms of the misleading use of evidence, is this excerpt from the American College of Physicians' [position statement on mandatory HCP vaccination](#). We are going to examine two of the three "Evidence" paragraphs of this document in detail (we have bolded some words in the passage that follows):

THE EVIDENCE

Immunizing health care workers safely and effectively prevents a significant number of influenza infections, hospitalizations, and deaths among the patients they care for, as well as preventing workplace disruption and medical errors by workers absent from work due to illness, or present at work but ill.^{7,8,9}

Influenza vaccination of HCWs lowers mortality among patients. A study of **20 hospitals** found an overall 51% staff vaccination rate in **hospitals** where vaccine was offered vs. 5% staff vaccination rate in **hospitals** where influenza vaccine was not offered. Mortality among patients was 13.6% (102/749) in the **hospitals** providing HCW vaccination vs. 22.4% (154/688) ($P = 0.01$) in **hospitals** that did not.¹⁰ In another study of **12 hospitals**, HCWs and patients were randomized to receive influenza vaccine. There was no difference in patient mortality between **hospitals** with patients who received vaccine and patients who did not. However, the mortality rate among patients in **hospitals** where HCWs got vaccine was 10%, compared with 17% among **hospitals** that did not immunize HCWs.¹¹

Why is this so misleading? None of the five footnoted sources in these two paragraphs of “EVIDENCE” provides any evidence whatever that vaccinating HCWs protects patients in acute-care hospitals, outpatient clinics, physicians’ offices, or other non-long-term care healthcare settings.

The first paragraph cites three studies. “Effectiveness of Influenza Vaccine in Health Care Professionals” (footnote 7) showed that HCW vaccination “may reduce reported days of work absence and febrile respiratory illness,” but did not examine whether HCW vaccination reduces patient mortality or morbidity. “Effectiveness and Cost-Benefit of Influenza Vaccination of Healthy Working Adults” (footnote 8) showed reduced absenteeism among healthy adults in a manufacturing company. And “Prevention and Early Treatment of Influenza in Healthy Adults” (footnote 9) compares the effectiveness and cost-effectiveness of flu vaccines and antivirals.

None of the three citations in this first “EVIDENCE” paragraph substantiates the claim that HCW vaccination “prevents a significant number of influenza infections, hospitalizations, and deaths among the patients they care for.”

The second paragraph refers repeatedly to “hospitals” – citing one study of “20 hospitals” and another study of “12 hospitals” – but the two footnotes (10 and 11) refer to the usual long-term care hospital studies, not to hospitals in general (nor to other healthcare settings such as outpatient clinics).

The Immunization Action Coalition (supported by the U.S. CDC among others) lists an Honor Roll of organizations recommending mandatory HCW influenza vaccination. The American College of Physicians is on the Honor Roll. It would be enlightening to see how many of the other Honor Roll organizations’ position papers are similarly guilty of misleading evidentiary claims.

A crucial segment of the audience for these position papers is political leaders and institutional administrators trying to make decisions about mandatory HCW vaccination. These target audiences assume – and should be entitled to assume – that the evidentiary claims of these position papers are solid and meticulously honest. Many are not.

We are hopeful that you will avoid this type of misleading use of evidence. It would be enormously helpful if you would also document its frequency – we would be happy to provide as many examples as you require – and explicitly recommend against it.

Your current draft acknowledges that there are “significant gaps in understanding the impact of increasing vaccination rates on patient safety.” It stops short of conceding, as we believe it should, that there is virtually no evidence supporting the hoped-for benefits in settings other than nursing homes. The most relevant passage in the draft reads as follows:

Determining the overall effects of vaccination of HCP on patient outcomes is methodologically challenging and the outcomes measured often vary between studies. Findings specific to the effectiveness of HCP influenza vaccination in protecting patients vary by setting, year, and population studied and may lead to differing interpretations of the available data [21, 23-27]. Collectively, the impact of HCP vaccination on patient morbidity and mortality in the acute and long-term care settings requires continued investigation. While the working group discussed several scientific studies that evaluated the impact of HCP influenza vaccination on reducing health-care associated influenza infection among patients, evaluating the full merits of HCP vaccination was not included in the charge of the working group, and therefore is not directly addressed in this report.

This is far superior to the misleading evidentiary claims of many public health agencies and trade associations. But it seems to us that a recommendation on behalf of mandatory HCW vaccination would require you to explain why you believe that the recommendation would benefit patients, not just healthcare workers themselves. (The alternative is to explain why you believe healthcare workers should be coerced for their own benefit.)

Ethics aside, our concern here is for the credibility of public health as an institution. We have written at length elsewhere about the ways in which flu vaccination “hype” – partial truths misleadingly deployed – may undermine trust, not just trust in flu vaccination but trust in public health generally. See particularly our 2009 article on [“Convincing Health Care Workers to Get a Flu Shot ... Without the Hype.”](#)

Using such hype on behalf of coercion is in our judgment especially dangerous. HCWs who resent being coerced have reason to look closely at the rationales being offered for the coercion. Those rationales should be able to withstand close scrutiny.

We are aware of one impressive-sounding tertiary care hospital study, [“Preventing Nosocomial Influenza by Improving the Vaccine Acceptance Rate of Clinicians,”](#) which documented decreased nosocomial influenza transmission during a 12-year period as HCW flu vaccination rates increased from 4% to 67%. We have probably missed other relevant articles. But it remains true that the main evidence routinely cited to support mandatory influenza vaccination of HCWs continues to be evidence from long-term care facilities – and the evidence is typically cited without acknowledgment of this significant limitation (unless the reader scrutinizes the footnoted sources).

We would not object to your saying that you think it’s plausible that vaccinating HCWs will provide some protection to patients in various healthcare settings, even though there is little if any evidence. That’s the frame the World Health Organization used when supporting the efficacy of the conventional “cover your cough” recommendation despite the lack of influenza-related evidence with regard to that precaution. The World Health Organization Writing Group

report on “Nonpharmaceutical Interventions for Pandemic Influenza” makes the recommendation but concedes that it makes it “more on the basis of plausible effectiveness than controlled studies.”

We don’t know if plausibility is sufficient to justify coercion, but we are not ethicists and we will leave that question to others. But first, let us offer you this thought experiment. If a healthcare researcher were to propose a study in which HCWs in certain hospitals would be given influenza vaccinations against their will (or lose their jobs) in order to assess the health outcomes of patients, would this methodology pass human subjects review?

At least a claim to base the policy on plausibility would not lack integrity, as a claim to base it on “sound science” would.

Is it in fact plausible that mandatory HCW vaccination reduces patient morbidity and mortality in settings other than nursing homes? We realize that there have been complex modeling studies to address this question, such as a 2009 study by van den Dool *et al.* If the manifold assumptions in that study are valid, then it is highly plausible that mandatory HCP vaccination would reduce hospital patients’ influenza risk. (This assertion will nonetheless sound implausible to many HCWs. Your draft cites a CDC study indicating that “55.4% of unvaccinated HCP do not believe that vaccination better protects those around them from influenza infection.”)

The potential benefit of mandatory flu vaccination strikes us as thoroughly implausible in outpatient settings, where patients spend more time in close proximity to each other in the waiting room than in close proximity to any healthcare worker ... and are spending the rest of the week immersed in their lives (unless they are sick at home): riding the bus, hugging friends, and going out to lunch with coworkers.

Perhaps your position is that “if mandatory HCW flu vaccination saves even one patient life, it’s worth doing.” If so, then that is what we think you should say. For obvious reasons, this is not normally the position of public health, which prioritizes health interventions based on their comparative benefits and costs. There are many interventions that might save a life here and there that public health wisely decides aren’t worth the expense, the opportunity cost, or (in this case) the interference with other people’s autonomy.

We don’t know how much patient mortality and morbidity a mandatory HCW flu vaccination policy needs to prevent in order to justify the downside of annual coercion. As a start, we would suggest that it needs to prevent at least enough patient mortality and morbidity to achieve robust statistical significance in studies conducted in the sorts of venues in which the policy will be implemented.

But we understand that there continues to be contentious debate over the questions of whether HCW flu vaccination benefits patients; and, if so, whether the benefits are sufficient to justify forcing reluctant HCWs to get vaccinated. You need not share our skepticism on these points to accept our more urgent contention that overstating the benefits or the evidence of benefits would be both dishonorable and dangerous.

You have an opportunity not just to avoid making any such misleading claims, but to add a strong recommendation that HCW flu vaccination programs – whether mandatory or voluntary – should also be careful not to overstate the benefits or the evidence of benefits of HCW flu vaccination.

The dangers of requiring reluctant HCWs to get vaccinated

The impact of coercion on the attitudes of those who are coerced is a complicated issue. There are two possibilities, both of them plausible.

One plausible outcome is that resentment of the coercion will exacerbate people’s negative feelings about what they are coerced into doing. Every parent has experienced this firsthand. Thus a healthcare worker who was initially skeptical about flu vaccination might become much more hostile to flu vaccination as a result of being forced to get vaccinated.

More broadly, mandatory HCW flu vaccination could lead to:

- increased opposition to flu vaccination;
- increased hostility to the management that imposes the policy;
- increased mistrust of public health prescriptions generally;
- increased inclination to misinterpret coincidences as adverse events; and
- increased willingness to express anti-vaccination attitudes to patients. (“They made me get the shot, but thank God you have a choice.”)

The other plausible outcome is that coerced HCWs will gain experience with and confidence in the vaccine, forget that they accepted it only because they were forced to do so, and end up more pro-vaccination than they started. There is evidence that mandatory seat belt laws, for example, led to increased attitudinal support for the efficacy of seatbelts.

Cognitive dissonance theory and research has largely reconciled the two plausible predictions.

People who choose to do something they’re not confident is wise experience cognitive dissonance, and seek out information that will resolve the dissonance by validating the questionable behavior. This is the basis for many foot-in-the-door persuasion strategies: First convince people to (voluntarily) do something; then teach them why it was a smart thing to do.

Might this be the way mandatory HCW flu vaccination works? Might HCWs reluctantly comply, wonder why they did so, seek out information to resolve the dissonance, and end up vaccination supporters? “I got the shot, so I must think it’s a good thing.”

We doubt it. HCWs in a mandatory flu vaccination program already know why getting vaccinated is a smart thing to do: because they’ll get fired otherwise! The coercion is intense. So there is likely to be no cognitive dissonance, and therefore no reason to seek out (or even accept) pro-vaccination information.

Then why did mandatory seat belt laws lead to more public support for seat belts? Because the coercion was weak. The laws were on the books, but not aggressively enforced. And the penalties were mild. Seat belt coercion was strong enough to increase compliance, but not strong

enough to enable those who complied to tell themselves that “I did it because I had no choice.” So they experienced cognitive dissonance, which motivated them to seek out pro-seat belt information.

There will undoubtedly be some HCWs for whom mandatory flu vaccination will lead to increased vaccination support. We would expect that effect for HCWs who weren’t especially hostile to flu vaccination at the outset, and who didn’t find the coercion especially offensive either. HCWs who were busy or lazy rather than hostile or skeptical may well experience a mandatory policy as simply a useful goad. Once vaccinated, they would feel that much better about themselves ... and about vaccination. Other healthcare workers may notice over time that they are not having the adverse reactions to the vaccine that they had feared, leading them to become increasingly supportive of flu vaccination.

There will undoubtedly be other HCWs for whom mandatory flu vaccination will have a negative effect on their attitudes toward flu vaccination, vaccination generally, public health, and the institution that employs them. We would expect that effect for HCWs who started out critical of flu vaccination, of coercive management policies, or both.

Which effect will be larger? We don’t know. We do think the latter effect will be burdensome. A policy that turns neutrals into mild supporters while simultaneously turning mild critics into bitter opponents doesn’t sound to us like a wise policy.

Your draft recommendations took note of some concerns similar to ours expressed by Dr. George Annas. You reference in particular Dr. Annas’s warning of “negative impacts including building opposition that could result in an unenforceable mandate if a significant number of HCP refuse vaccination.” (We are quoting your words, not his.) You point out in response that “[h]ospitals that have implemented mandatory influenza vaccination programs have not reported the backlash by HCP predicted by Annas.” The Children’s Hospital of Philadelphia survey you mention does show that HCWs can end up approving of a vaccination policy they know to be coercive. But this is a long way from showing how mandatory policies affect the vaccination attitudes of HCWs who start out as critics or opponents.

Hypotheses about the attitudinal impacts of mandatory HCW flu vaccination can easily be tested. If the impact of mandatory HCW flu vaccination on patient health turns out to be small, the greatest impact of a mandatory vaccination policy may well be on the attitudes of the HCWs themselves. Before expanding the initiative, it would be helpful to know more than we know today about its likely attitudinal impacts. At a minimum, surveys to assess these impacts should be part of the ongoing stewardship obligation of institutions that implement mandatory HCW influenza vaccination – another recommendation we urge you to consider adding.

The attitudinal impacts that most worry us aren’t just the result of coercion; they are the result of coercion on behalf of a policy that has little scientific underpinning and is less-than-candidly advocated (consistently overstating what is known about the potential benefits to patients by implying that “studies” have been done in settings other than long-term care facilities).

Put yourselves in the place of a HCW who knows the following:

- that there is little evidence of patient impact of healthcare worker flu vaccination except in nursing homes;
- that the flu vaccine “takes” only 50-70% of the time even in healthy adults under 65;
- that his/her institution is making no effort to protect patients from asymptomatic vaccinated HCWs whose vaccine didn’t take (for example, by instructing them to wear masks during flu season regardless of vaccination status);
- that his/her institution is making no effort to screen out unvaccinated visitors or require (or even urge) them to wear masks – or to require all visitors to wear masks regardless of vaccination status, given the high failure rate of influenza vaccination; and
- that none of this has been acknowledged in the rationale his/her institution has offered in support of the mandatory flu vaccination policy.

It would be understandable for such a HCW to conclude that the policy was hypocritical and that something other than patient health must be at stake – an effort to reduce absenteeism, perhaps, or even just an effort to assert control over obstreperous employees.

Additional comments

Risk communication aspects of mandatory flu vaccination are addressed in three website Guestbook entries by one or both of us. You may find these prior articles of interest:

- [Mandatory vaccination for health care workers](#) (October 2009)
- [Making health care workers get vaccinated against the flu](#) (March 2010)
- [Mandatory flu vaccination for health care workers \(again\)](#) (November 2010)

The following excerpts from these articles make points we would especially like you to consider.

From [Mandatory vaccination for health care workers](#):

As risk communication consultants, we know that control is one of the most powerful of the [outrage components](#). Coercion arouses outrage even when the coerced behavior itself doesn’t. And when the coerced behavior is something as personally upsetting as a medical intervention you have decided you don’t want, the outrage is likely to be extremely high. The resulting stress on health care workers’ morale, on labor-management relations, and on patient-provider relations is an awfully high price to pay.

From [Making health care workers get vaccinated against the flu](#):

The bigger question for me is the rationale for requiring HCWs to get vaccinated against the flu.

If it’s for the HCW himself/herself, then it’s unconscionable coercion. Making employees do things for their own good is pretty obviously wrong. We don’t (yet) make other people get vaccinated against flu. Why coerce HCWs for their own good more than we coerce people in other jobs? When officials tell HCWs “this is for your own good,” I think they’re undermining their own case.

If it's for the hospital, aimed at reducing absenteeism and thus the cost of health care, then one wants to see the data. How much is actually saved? Are there bigger savings available with less collateral damage that the hospital isn't pursuing? Is the hospital including morale issues in its cost-benefit calculation? Does the benefit justify the coercion? Moreover, in a unionized setting battles between what's good for the employer and what's good for the employee are the classical venue of labor-management negotiation. It would save the hospital money to pay HCWs less, too, but that's not enough reason to countenance unilateral pay cuts. If vaccination is for the sake of the hospital, it ought to be a contract negotiation issue.

If it's for the patient, the rationale for mandatory vaccination is stronger. Hospitals are entitled to regulate employee behavior for the benefit of patients. But here we really need data. My impression is that there are pretty good data that HCW flu vaccination reduces hospital costs, but not very good data that HCW flu vaccination reduces hospital-acquired flu in patients. Patient health is the strongest rationale for coercing HCWs, but only if the evidence is strong. Is it? And as you pointed out, if HCWs really give lots of patients the flu, you'd expect different hospital mask policies too. So officials end up trying to argue that the impact on patients is enough to justify making HCWs get vaccinated, but not enough to justify masking them when there's no vaccine (or when the vaccine is a bad match). That's a pretty narrow window. Similarly, why aren't hospitals requiring visitors to prove that they have been vaccinated? Unvaccinated family hang around the patient all day with impunity ... but the orderly has to get vaccinated?

Sometimes my clients get into fights with their employees (or other stakeholders) that started out over a real substantive issue (usually a fairly small one) ... and morphed into something that's really more about power and ego. I wonder how much of that is playing out in the HCW vaccination battle. "Whose hospital is it anyway?" "How dare someone without an M.D. question my judgment that the vaccine is safe?" "If we let them win this fight, what other policies will they decide to flout?" Of course the same could be true on the other side of the battle lines. When HCWs insist on their right to go unvaccinated, they may be bringing to that fight animus that comes from other labor-management issues, from pay to parking.

From [Mandatory flu vaccination for health care workers \(again\)](#):

It's also worth examining how HCW flu vaccination programs address the problem of unsuccessfully vaccinated employees, as opposed to the problem of those who decline to be vaccinated. Since the CDC says flu vaccination is 70–90 percent effective in healthy young adults, let's generously assume 80% for HCWs. So if a particular program gets 98% of employees vaccinated, the vaccination worked for 78.4 percent of all employees (80 percent of 98 percent). Who's left to give patients the flu? The 2 percent who weren't vaccinated and the 19.6 percent whose vaccinations didn't take. In this hypothetical hospital, unsuccessfully vaccinated employees are more than nine times as dangerous to patients as unvaccinated employees. *[Added January 2012: This point is all the more potent now that the CDC estimates only 50-70% effectiveness.]*

Yet HCW flu vaccination programs typically ignore the former risk, while many such programs force employees who decline vaccination to wear masks or take antiviral prophylaxis during flu season. The discrepancy doesn't necessarily mean the programs are hypocritical or punitive. Unvaccinated employees are lower-hanging fruit than unsuccessfully vaccinated employees. Identifying the latter would be difficult; making *all* employees wear masks during flu season or flu outbreaks would be burdensome (and would undermine the case for vaccination), while feeding all employees antiviral drugs at such times would be bad public health policy. Still, a hospital administration focused rationally on patient health would have to think hard about the wisdom of inviting a bitter controversy over forced HCW vaccination and forced masking of the holdouts, while leaving the much larger problem of unsuccessful vaccination unaddressed – and unacknowledged....

I am reminded of the 2003 U.S. smallpox vaccination campaign. (See "[Public Health Outrage and Smallpox Vaccination: An Afterthought](#).”) Intelligence agencies pushed smallpox vaccination out of a concern that terrorists might acquire the ability to launch a smallpox epidemic. The public health establishment opposed the program, unconvinced about the risk of a smallpox attack and worried about the risk of the smallpox vaccine itself. The President compromised with a program of voluntary smallpox vaccination for health care workers and emergency responders. Forced to implement (and pretend to support) a program they had vigorously opposed, public health professionals found ways to undermine it, and achieved a much lower level of vaccination than proponents had sought. It's hard not to see the failure of the smallpox vaccination program as a success (perhaps unconscious; certainly unacknowledged) for its public health opponents.

In much the same way, HCWs forced to get vaccinated against their will can find ways to undermine patient vaccination....

Vaccination has had a tough decade – not just flu vaccination; all vaccination. Anti-vaccination activism is up. Public skepticism is up. Trust in officials (including health officials) is down. Easy, automatic compliance is down.

Nearly all public health professionals (and hospital administrators) consider vaccination an obvious good. For many, it follows that prospective vaccinees who don't think vaccination is an obvious good are obviously irrational, and so reasoning with them is obviously a waste of time. This isn't a reasoned conclusion. In their calmer moments nearly all vaccination proponents will concede that it's better (if you can) to win over the doubters than to coerce them. But in their more outraged moments, they don't want to talk (far less listen). And over many years, their persuasion efforts have mostly failed. No wonder they want to coerce.

Deep in their hearts, many vaccination proponents would dearly love to make all recommended vaccines required for everyone, so they wouldn't have to spend precious time and emotional energy trying to coax reluctant vaccinees. Their outrage makes them want to coerce everyone. But they can't get away with coercing everyone, at least not yet (thank goodness). HCWs are one of the few groups they *can* try to coerce. Add to that the contempt of too many public health leaders and medical administrators for working-class

HCWs, and the emotional appeal of making HCWs get their flu shots becomes even clearer.

Again, we thank you for the opportunity to submit these comments. We hope they are helpful to you in your deliberations.

Sincerely,

Peter M. Sandman, Ph.D.
Jody Lanard, M.D.



January 16, 2012

National Vaccine Program Office
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Washington, DC 20201

"The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present." Vaccine, Nov 2011 (1)

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Dear Sir or Madam:

On behalf of the Service Employees International Union (SEIU), thank you for this opportunity to present our comments on the draft document developed by the Healthcare Personnel Influenza Vaccination Subgroup (HCPIVS), of the National Vaccine Advisory Committee (NVAC), charged with increasing influenza vaccination rates among healthcare workers. I have also appreciated representing SEIU on the HCPIVS.

Introduction

SEIU is the nation's largest organization of healthcare workers representing more than 1.1 million doctors, nurses and other allied health workers from a broad range of occupations employed in hospitals, nursing homes, home care and other healthcare settings.

We are proud of our track record in promoting immunization of healthcare workers against influenza and other vaccine preventable illnesses. In 1986, when healthcare employees were denied education about, and free access to the hepatitis B vaccine, SEIU appealed to HHS and petitioned OSHA, which led to the promulgation of the OSHA Bloodborne Pathogens Standard of 1991. As a result of this standard, which requires employers to provide annual comprehensive education about the benefits of receiving the hepatitis B vaccine without charge within the framework of a comprehensive bloodborne diseases infection control program, hepatitis B cases among healthcare workers have plummeted from 17,000 to less than 400 per year. (2)

Summary Conclusion/Alternative Recommendation

Based on a number of scientific reviews that have found a lack of statistically significant epidemiological evidence of healthcare worker to patient flu transmission (1,3,4), a relatively low rate of flu vaccine effectiveness compared to other vaccines (5), unresolved legal and civil rights issues (6, 7, 8) and ethical considerations (9,10,11) including financial conflicts with flu vaccine manufacturers (12), there is insufficient justification at this time for the HHS National Vaccine Advisory Committee to vote to adopt Recommendation #4 that will lead to discriminatory and disciplinary action against healthcare workers who refuse to be vaccinated against their will. Such a premature action would undermine the public's trust in federal vaccine policy. (17)

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In a straw poll of HCPIVS members conducted in August 2011, there was deep a division on this question of an employer requirement. Only a minority of HCPIVS members (12 of 27) voted for an employer requirement that lacked an exemption for personal and/or philosophic reasons. (13,14) Thus we urge NVAC to reject Recommendation #4 as currently written.

As an alternative, a more measured and appropriate response by NVAC based on the sentiment expressed by this vote of the HCPIVS members would be for NVAC to amend Recommendation #4 to instead incorporate an employer requirement to provide education about the benefits of the flu vaccine vs. forced vaccination. Modeled after the highly successful OSHA Bloodborne Pathogens Standard's education requirements for the Hepatitis B vaccine, this change would also address an apparent oversight. The HCPIVS members and the report itself frequently cites the importance of healthcare worker education in promoting vaccination, yet none of the Recommendations actually include the word "education."

The breath of organizations that strongly support flu vaccination, but are on record concurring with SEIU in opposing a flu vaccine employer requirement in the absence a basic philosophic or personal exemption for healthcare workers include: OSHA, CDC's NIOSH, the EEOC, the AFL-CIO, the AMA (15), the ANA, ACOEM (the largest organization of occupational health physicians), and the Association of Occupational Health Professionals in Healthcare (AOHP), the California Nurses Association (CNA), Leading Edge (the trade association for the non-profit long term care industry), National Nurses United (NNU), the New York State Public Employees Federation (PEF), and the New York State Chapter of the American Civil Liberties Union (ACLU). OSHA asked that their particularly thoughtful statement be included in this final draft HCPIVS report. It is now included as an attachment to this letter for the benefit of, and review by the NVAC membership.

The Science

Lack of Evidence to Essentially "Legislate" a 90% Goal

While there is broad consensus that increasing flu vaccination rates among healthcare workers is a worthy goal, the HCPIVS was asked to accept the annual Healthy People 2020 goal without reservation and without any supporting documentation to provide a scientific basis to support the imperative of reaching this 90% figure. As this goal was inserted in the Immunization chapter of Healthy People 2020 instead of the Occupational Health chapter, few if any individuals or organizations within the occupational health community or groups representing the interests of healthcare workers, or healthcare workers themselves, were aware of, or consulted about this goal and thus did not have an opportunity to comment. And while this figure has been described as "achievable," none of the eight adult immunization Healthy People 2010 goals have yet been achieved.

Finally while it is fine to aspire to achieve a 90% vaccination rate, it is an entirely different exercise for NVAC to now suggest that this should be an employer requirement. By adopting Recommendation #4, HHS through NVAC will essentially be giving "license" to healthcare employers to do whatever is necessary to achieve this goal with the result that many healthcare workers will be discriminated against and disciplined, forced to wear unproven surgical masks and/or fired if they refuse to get vaccinated.

Vaccine Lacks Sufficient Effectiveness to be Mandated

The most recent review this past fall, which also finally lead to CDC updating their outdated website information, is that the flu vaccine is at best only 59% effective in working age adults in a typical year.(5) It is hard to justify the imperative of achieving such a high vaccination rate with such a marginally effective vaccine. A greater emphasis on achieving Recommendation #5 (a better vaccine), perhaps with its own Healthy People 2020 goal, would automatically lead to increased vaccination rates voluntarily.

Lack of Evidence that Vaccinating Healthcare Workers Protects Patients

While it is reasonable to assume that vaccinating healthcare workers will protect patients, the three most comprehensive reviews of all available epidemiological studies has concluded that unfortunately such information is not available. Remarkably these studies have found no statistically significant evidence that higher rates of vaccination of healthcare workers result in fewer cases of influenza and its complications among their patients. (1,3,4) In the most recently published study in the November 2011 issue of the journal *Vaccine*, the authors concluded that: "The benefit of vaccinating healthcare workers to protect their patients remains highly questionable and should not be mandatory at present." (1) This of course does not mean that healthcare workers cannot transmit the flu to their patients. However more research is clearly needed to document the extent of this potential threat and the efficacy of the current flu formulations in stemming this threat before justifying an employer vaccine requirement. We suggest that strong consideration be given to including a new sixth Recommendation in the final HCPIVS report calling for such additional research.

Lack of Basis to Recommend Surgical Masks

While many employers require unvaccinated healthcare workers to wear surgical masks, it is important to acknowledge that there is no scientific evidence that the wearing of surgical masks by unvaccinated healthcare workers is protective for patients. Instead there is evidence that this practice has been used as a modern day "Scarlett Letter" to label, coerce and intimidate workers into getting vaccinated. Otherwise with a vaccine that is only 59% effective in a given flu season, why wouldn't employers logically require ALL healthcare workers to wear surgical masks, as 4 out of 10 *vaccinated* workers would also pose a risk? Research has also shown that the more frequent mouth/ nose/eyes contact necessitated when workers use their hands to don, duff and adjust their surgical mask can actually lead to more contamination and potential for infection; not less. (16) Finally as currently practiced, the requirement to wear a surgical mask by unvaccinated workers could rightly be considered a potential HIPAA violation that essentially "broadcasts" the health status of unvaccinated healthcare workers.

The Law

Legally there are a number of barriers to implementing mandatory influenza vaccination programs. While the HCPIVS report relies on a case from 1905 involving the smallpox vaccine, more recent legal actions involving influenza is likely more instructive. In 2009 when New York State became the first state to mandate flu vaccination for healthcare workers, a judge considered the available evidence – including ACLU arguments that such a mandate would violate well established principles of personal autonomy including the right of competent adults to refuse medical care –and issued a stay. (6,7) This is not to suggest that a state never can require vaccination, but this case illustrates that a balance must be struck between the rights of the individual and public health. Comparing influenza with smallpox - a significantly more virulent disease with a much more effective vaccine - obviously makes for a poor comparison. Perhaps this is why, contrary to statements by the New York Department of Health officials that a mandate would be back by 2010, it has never been reintroduced.

Regarding the application of labor law and the ability of an employer to unilaterally impose a workplace based mandate, a recent decision by the full National Labor Relations Board concluded that the employer could not require vaccination nor the wearing of surgical masks without first providing employees with denied requested information, and bargaining over this change in working conditions.

Finally the Equal Employment Opportunity Commission has stated that flu vaccination should be voluntary. (8) Requests to include the ACLU (7) and EEOC (8) information and citations in the final HCPIVS draft report to portray a more balanced legal perspective have repeatedly been denied.

The Ethics

From an ethical standpoint, bioethicists and others have looked at these questions. Professor George Annas, Chair, Health Law, Bioethics & Human Rights, of Boston University School of Public Health reminds us that the practice of medicine is a voluntary pursuit based on informed choice. Forcing nurses and other healthcare workers to become unconsenting patients - even for a flu shot - undermines the consensual nature of the health care relationship. Dr. Annas also believes that the requirement that healthcare workers be vaccinated as a condition of employment will predictably confuse the public who will ask that if healthcare workers won't voluntarily take the swine flu vaccine, why should I?(9) The NY Chapter of the ACLU believes that a mandate will undermine trust in the public health system.(7) On the issue of mandating a vaccine with such limited effectiveness, Peter Sandman, perhaps the leading authority on matters concerning risk communication, argues that overselling flu vaccine effectiveness risks undermining public health credibility; that you will not build public trust. (17)

Additional articles were provided to the HCPIVS leadership team to provide a more balanced viewpoint on this particularly controversial topic. The first article argues that we first need more experience in implementing and evaluating flu vaccine programs, that requirements are premature, counter-productive and foment an adversarial relationship that can weaken trust.(10) The second article suggests we focus our energies on maximizing current best practices and education prior to supporting a mandatory approach. The article argues that while the desire to fulfill national patient safety goals requires our attention, "the ethical justification is not solid." (11)

Requests to include this information and citations in the final HCPIVS draft report to portray a more balanced legal perspective have been denied.

Lack of Financial Disclosure

In recent years, the inspector general of HHS has raised concerns that advisors involved in federal vaccine policy have potential conflicts of interest that are not identified or left unresolved. (12) The issue of the disclosure of financial conflicts of HCPIVS members was raised within our group. It was suggested that such disclosure was important for transparency and could add to the credibility of the report's recommendations. It is known that some HCPIVS members either work directly for, or the organizations that they are affiliated with, or their associated foundations, receive funds from flu vaccine manufacturers. With such concerns in mind, HCPIVS members agreed to divulge such conflicts and include this information in the final HCPIVS report. However Dr. Grabowski, the government official staffing the HCPIVS, stated that after consulting with HHS counsel, a decision was made to not ask HCPIVS members to reveal this information.

In conclusion, SEIU stands ready to continue to work with the government, employers and other organizations to promote the vaccination of healthcare workers against influenza as part of a comprehensive infection control effort.

However based on the lack of a firm scientific basis to support a vaccination rate of 90% along with a lack of epidemiological evidence documenting statistically significant transmission from healthcare workers to patients (1,3,4), as well as significant unresolved legal (6,7,8) and ethical issues (7,9,10,11), it would be premature for NVAC to vote to adopt Recommendation #4.

The practical effect of voting to adopt Recommendation #4 would in essence be to make flu vaccination a mandate for millions of healthcare workers, without NVAC or HHS ever having to go through the typical rulemaking procedures as stipulated under the Administrative Procedures Act. However this divisive action is unnecessary as comprehensive voluntary efforts have been proven to achieve vaccination rates in excess of 90%.

Finally a sound evidentiary base must precede the promulgation any public health policy, especially one that will lead to discrimination and unwarranted disciplinary actions against our nation's healthcare workers. Issuing such policies without such evidence also threatens to jeopardize the public's trust and support for flu vaccination. (17)

Sincerely,



William K. Borwegen, MPH
Director, Occupational Health and Safety
Service Employees International Union, CTW, CLC

cc Dr. Howard Koh, Assistant Secretary for Health, Health and Human Services
Dr. David Michaels, Assistant Secretary of Labor for Occupational Safety and Health

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The Occupational Safety and Health Administration (OSHA) is strongly supportive of efforts to increase influenza vaccination rates among healthcare workers in accordance with the Healthy People 2020 goals. However, at this time, OSHA believes there is insufficient scientific evidence for the federal government to promote mandatory influenza vaccination programs that do not have an option for the HCP to decline for medical, religious and/or personal philosophical reasons.

While we are supportive of the Healthy People 2020 goal of a 90% vaccination rate, we have seen no evidence that demonstrates that such a high rate is in fact necessary. Furthermore, the current influenza vaccine is no magic bullet. The current state of influenza vaccine technology requires annual reformulation and revaccination and the efficacy is quite variable. Every year there are numerous circulating strains of influenza that are not included in the vaccine. In years where the antigenic match is good, the vaccine only provides protection against the 3 strains in the formulation. In years when the antigenic match is poor, the vaccine may provide no protection at all. The limits of current influenza vaccine technology are especially problematic in the context of a mandatory influenza vaccination program that results in job loss. Lastly, reliance on a mandatory influenza vaccination policy may provide healthcare workers, health care facility management and patients with an unwarranted sense of security and result in poor adherence to other infection control practices that prevent all types of infections, not just influenza. Influenza vaccination has always been just one part of a comprehensive multi-layered infection control program.

While OSHA does not believe that there is sufficient evidence to meet the bar necessary to support mandatory vaccination programs, we nonetheless are convinced that influenza vaccination is generally beneficial and are supportive of efforts to promote vaccination. Influenza vaccination exemptions should be for HCP with valid medical contraindications to vaccinations, or religious and/or personal objections and a signed declination statement that indicates the HCP has been educated regarding influenza, is aware of the risk and benefits of influenza vaccination, has been given the opportunity to be vaccinated with the influenza vaccine at no charge, and can receive the influenza vaccine in the future at no charge to the HCP.



January 9, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Ave. SW.; Room 733G3
Washington, DC 20201
Attn: Healthcare Personnel Influenza Vaccination, c/o Jennifer Gordon

To Whom It May Concern:

On behalf of Trust for America's Health (TFAH), a nonprofit, nonpartisan public health advocacy organization, thank you for the opportunity to provide our comments on the *Recommendations on Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel* (Recommendations). As noted in the draft, influenza immunization rates among health care personnel (HCP) remain far below the Healthy People 2020 goal of 90 percent coverage, despite significant efforts to educate the workforce about the dangers of influenza for themselves and their patients. We applaud the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) for the strong recommendations contained in the draft and strongly urge the Assistant Secretary for Health (ASH) to quickly adopt and begin to implement these recommendations.

TFAH believes these low rates pose a significant public health risk for the patient population, HCPs, and the general population for four main reasons. First, by bypassing flu vaccines, HCPs place themselves, their families, and their communities at risk for illness. Second, patients, many of whom may be immunocompromised and susceptible to severe effects from influenza, are vulnerable to infection from their healthcare providers, making influenza another preventable healthcare-associated infection (HAI). Third, having healthy employees is key to the financial viability and continuity of operations of healthcare facilities by reducing absenteeism, presenteeism, and the risk of infecting other employees. Finally, vaccine hesitancy remains an issue in some segments of the U.S. population. Healthcare workers must be role models in trusting this safe, effective public health tool. Particularly during an influenza pandemic, healthcare professionals must educate their patients and "walk the talk" by receiving vaccines.

These draft Recommendations provide an excellent range of policy options and strategies to address this ongoing challenge. As the National Vaccine Advisory Committee (NVAC) finalizes its recommendations to the ASH, we ask that you consider the following revisions:

- **Recommendation 2 (p. 12):** We support facilities integrating vaccination programs into existing infection prevention or occupational health programs and are especially pleased that this recommendation is urged in all Health and Human Services (HHS) facilities and services. However, we urge the Committee to revise this recommendation to reflect that some infection prevention or occupational health programs may exclude employees who are not involved in direct patient care. Appropriately, the draft defines HCP as inclusive of all persons working in health care settings who may be vectors of infectious agents,

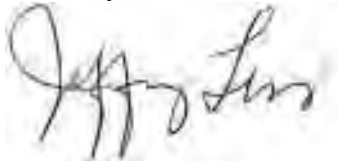


even if not providing direct care, such as housekeeping and security staff (p. 2, lines 24-28). We propose the following revision to Recommendation 2: “If necessary, infection control and occupational health programs should be revised to include outreach, education, and vaccination of personnel not providing direct patient care.”

- **Recommendation 3 (p. 13-14):** One way to ensure engagement of healthcare management is to build transparency around flu vaccination rates similar to the strong public reporting movement to increase awareness and prevention of HAIs. Public reporting of vaccination rates could build competition between facilities to significantly improve their vaccination rates and incentivize managers to strive for 100 percent vaccination coverage. We urge you to revise Recommendation 3 to include public reporting of vaccination rates in all facilities, in addition to standardization of measures. As the draft notes, acute care hospitals will soon be publicly reporting influenza vaccination rates through HospitalCompare.gov (p.13, line 27 – 30). In addition, CMS has proposed, but unfortunately has delayed until 2016, reporting of HCP vaccination rates as a measure for Hospital Outpatient Quality Reporting Program. We urge the ASH to implement these measures for all HHS facilities and services and to work with CMS to extend these measures and reporting to outpatient hospitals and non-hospital settings as expeditiously as possible.
- **Additional Recommendation: Communication** —TFAH believes that HHS must take a proactive approach to build a culture of influenza vaccine acceptance in the workplace. The ASH should encourage year-round, tailored, culturally sensitive communication with HCP about the importance of receiving the annual flu vaccine. CMS, CDC, associations representing each health profession, and health facilities must coordinate to develop appropriate communications strategies. Communicating the need, safety, and efficacy of the influenza vaccine is a key strategy in the effort to achieve full vaccine coverage. The ASH should spearhead an annual letter from HHS leadership, professional associations, unions, and senior management of healthcare institutions to all healthcare personnel at the beginning of flu season on the importance of immunizing against influenza.

Thank you for the opportunity to comment on these important draft recommendations. If you have any questions, please do not hesitate to contact Dara Lieberman, Government Relations Manager, at (202) 223-9870 ext. 20 or via e-mail at dlieberman@tfah.org.

Sincerely,



Jeffrey Levi, PhD
Executive Director



January 16, 2012

National Vaccine Program Office
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 733G.3
Washington, DC 20210
Attn: Healthcare Personnel Influenza Vaccination c/o Jennifer Gordon

Dear Sir or Madam:

On behalf of the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (hereafter United Steelworkers or USW), thank you for this opportunity to provide comments on the draft report and recommendations "Strategies to Achieve the Healthy People 2010 Annual Goal of 90% Influenza Vaccine Coverage for Health Care Personnel," developed by the National Vaccine Advisory Committee (NVAC) Adult Influenza Working Group's Health Care Personnel Influenza Vaccination Subgroup (HCPIV).

Among the first unions in the United States to organize health care workers, the United Steelworkers and our Health Care Workers Council represent 30,000 members throughout the health care sector. We care for our communities by working in hospitals, nursing homes, doctors' offices, rural clinics, dialysis centers, dental offices, pharmacies, and on ambulances. We utilize our collective voice to ensure that collective bargaining agreements and public policy remain patient focused and that they empower all health care workers to provide the highest quality patient care possible.

We strongly support policies and practices that promote safe and healthful environments for the benefit of patients, the workforce, visitors and others in health care settings. A multi-faceted and comprehensive infection control program that protects these personnel from exposure to agents including the influenza virus is important for patients and healthcare workers alike. Among the features of such a program are appropriate personal protective equipment (including respiratory protection that is protective for aerosolized viral transmission); procedures to identify and isolate infected patients; vaccination of healthcare workers; effective sick leave policies that support and in no way penalize workers for staying home themselves or with family members exhibiting symptoms of influenza-like-illness; housekeeping; information and education for all workers; and program evaluation. In order to achieve effective design and implementation of such a program, the involvement of healthcare workers in every aspect is critical.

The USW supports effective, voluntary programs for influenza vaccination of healthcare workers that include culturally sensitive information and education in the languages and literacy levels of

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union



the workforce, and vaccinations that are free and offered at accessible locations and times. Meaningful worker involvement in the design and elements of the vaccination program are essential to promote effective outreach to diverse populations including those who may have concerns about the influenza vaccine.

Studies have demonstrated that such comprehensive, voluntary vaccine programs can achieve over 90% coverage without a coercive component that threatens healthcare workers with disciplinary action including job loss if they choose to forgo influenza vaccination. (1)

Unfortunately, even though fourteen (14) of the twenty-four (24) voting members of the Health Care Personnel Influenza Vaccination Subgroup [HCPIVS] did not support a mandatory program with influenza vaccination as a condition of employment for all but those with a valid medical contraindication; mandatory, condition-of-employment vaccination policy appears to be codified in the subcommittee's Recommendation #4 ("For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and cannot achieve and maintain the Healthy People 2020 goal of 90% influenza vaccination coverage of HCP in an efficient and timely manner, the HCPIVS recommends that HCE and facilities strongly consider an employer requirement for influenza immunization. HCPIVS also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services [including the Public Health Service, HHS staff and Federally Qualified Health Centers] and urge all other HCE and facilities to do the same"). (2)

Our comments below will focus on three particular areas that speak against such a mandatory vaccination program for the healthcare workforce: concerns with influenza vaccine effectiveness; barriers that can discourage workers from being immunized; and U.S. labor law considerations.

Problems with the Effectiveness of Influenza Vaccinations and Reliance on Vaccination in Infection-control Strategies

Mandatory vaccination programs are not supported by an evidence-based review of the science. The HCPIVS draft report barely mentions the most recent review of medical studies with in-depth analyses of the effectiveness of the flu vaccine (3). The review and meta-analysis of these studies, undertaken by Osterholm et al, estimated the overall effectiveness of the seasonal influenza virus to be around 59%, much lower than other vaccines offered to healthcare workers. (4) Thus, over 40% of those who receive the vaccine can get no protection. This same study reported that some seasonal vaccine formulations barely offered any protection at all. It is heartening that the CDC revised and downgraded its vaccine effectiveness estimates on its website as a result of this study. It is essential that the most up-to-date evidence-based scientific information is communicated, so that public health agencies and officials maintain credibility with the public. It is equally essential that these findings are integrated into policy recommendations.

Another recent study that focused on influenza vaccination for healthcare workers who work with the elderly reported that there was no evidence that influenza vaccinations impact complications including pneumonia, or transmission; and concluded that at best influenza vaccines may be effective against 10% of all circulating viruses (influenza A and B) that cause influenza or influenza-like illnesses. (5) Most recently, a review published in the journal *Vaccine* in November, 2011 highlighted the lack of sound evidence for the effect of the influenza vaccination on influenza complications among those with co-morbidities, including pneumonia,

hospitalization and mortality. The authors concluded that influenza vaccines should not be mandatory at this time among healthcare workers, and the benefit of healthcare worker vaccinations on patient health remains “highly questionable”. (6) An earlier review by Jefferson et al offered the following explanation for a continued reliance on vaccine that was not evidence-based: “The optimistic and confident tone of some predictions of viral circulation and the impact of inactivated vaccines, which are at odds with the evidence, is striking. The reasons are probably complex and may involve ‘a messy blend of truth conflicts and conflicts of interest making it difficult to separate factual disputes from value disputes’ or a manifestation of optimism bias (an unwarranted belief in the efficacy of interventions).” (7)

Even with the vaccine efficacy problems noted above, we believe that healthcare workers should be encouraged to get vaccinated, and that employers should make vaccinations free and readily accessible to all. Further, problems with vaccine efficacy speak to the need for better vaccines. We support the subcommittee’s Recommendation #5, which encourages development of new and improved influenza vaccines and vaccine technologies. Given the problems with influenza vaccine effectiveness, it also makes sense for comprehensive infection control strategies to be implemented in healthcare settings that are not limited to nor focused solely upon a vaccination strategy. In light of these serious problems with vaccine efficacy, however, it makes no sense to mandate vaccination as a condition of employment.

The Need for Enhanced Outreach and Education Strategies

None of the five recommendations for increasing influenza vaccine coverage among healthcare workers includes the word “education”. While education is mentioned as an important element in a comprehensive program to reach the 90% coverage goal in the body of the subcommittee’s report, it was not emphasized in the text of any recommendation. This is an unfortunate oversight.

While there have been several studies reviewing healthcare worker decision-making about getting vaccinated, the majority have focused on physicians and registered nurses. The healthcare workforce includes LPN’s, nursing assistants, technicians and therapists, housekeeping, transport, unit secretaries, dietary, laundry, maintenance, and more. This workforce includes lower-wage workers, immigrants and workers from communities of color. There is a long history of suspicion and mistrust of medical and public health authorities in general, and of vaccines in particular, among some from communities who have suffered particular injustice. It is essential that those making public health policy understand barriers that can exist as a result of this history of injustice and develop policies accordingly.

Some have linked such distrust in the African-American community with the “Tuskegee Study of Untreated Syphilis in the Negro Male,” a 40-year government study from 1932 to 1972 under the aegis of the U.S. Public Health Service in which hundreds of African American men were recruited to participate in a study, and those found to have syphilis went untreated while they went blind and insane from the disease. (8) The Tuskegee Study was reported on in medical journals for almost 40 years without protest from those in the medical and public health communities. (9) However, the Tuskegee study was by no means the only government-aided medical assault on minority communities. (10) A public health and medical historian and researcher noted, “The powerful legacy of the Tuskegee Syphilis Study endures, in part, because the racism and disrespect for Black lives that it entailed mirror Black people’s contemporary experiences with the medical profession.” (11)

Revelations in the 1990's regarding a measles vaccine study financed by the U.S. Centers for Disease Control and Prevention (CDC) reflect this legacy. In 1989 during a measles epidemic in Los Angeles, the CDC, in cooperation with others, began a study to test whether an experimental vaccine could be used for children who were too young to use the standard vaccine. By 1991, approximately 900 infants, primarily African-American and Latino, received the experimental vaccination. The infants' parents were never informed that the vaccine was not licensed in the United States, nor were they told that this vaccine had been associated with increased death rates in Africa. The 1996 disclosure of this information prompted charges of medical racism and medical professionals' continued exploitation of minority communities. (12) In exploring the Tuskegee legacy into the 21st century, Professor Heintzelman concluded, "The most enduring legacy.... is its repercussions in the African American community....The study laid the foundation for African Americans' continued distrust of the medical establishment, especially public health programs and a fear of vaccinations. It reinforced views about the medical establishment and the federal government, as well as disregard for African American lives." (13)

Additional communities have experienced medical racism, with vaccination at its center. In 1900, when an autopsy performed on a deceased Chinese man in San Francisco found a bacteria suspected of causing Bubonic Plague, public health officials required people of Chinese ancestry in San Francisco to be vaccinated with a dangerous experimental vaccine before traveling out of their community. A federal court found this requirement unconstitutional, after which city officials quarantined the Chinatown area, "drawing a contorted map that included only the homes and businesses of Chinese Americans." (14)

According to a 2003 review of health disparities, the few studies that have focused on the Latino population identified mistrust of the medical community and biomedical research. (15)

In 2010 it was revealed that from 1946 to 1948, a U.S. Public Health Service physician ran a disease inoculation project in Guatemala, co-sponsored by the U.S. National Institutes of Health and others, during which over 1,000 prisoners, mental patients, soldiers and others were infected with sexually transmitted diseases without their permission or knowledge. (16) A Presidential Commission for the Study of Biomedical Issues was established in response to this revelation, and their report, "Moral Science: Protecting Participants in Human Subjects Research," was released last month (December, 2011). (17) Most recently (January 10, 2012), the United States government dismissed a lawsuit brought against it on behalf of victims of this Guatemala "experiment", saying that since the harm was suffered in a foreign country, the United States has sovereign immunity under the Federal Tort Claims Act. (18)

There are repercussions from this long, sordid and continuing history of medical injustice that must be understood by public health policy-makers, including those who currently favor making influenza vaccines a condition of employment for the healthcare workforce in this country.

A 2008 study and report on perceptions in certain communities that have the potential to threaten or even halt disease eradication programs noted that populations who develop mistrust and beliefs against government agencies and programs are often responding to injustices from the past or to inequalities in current experiences. In order to overcome such barriers, the report counsels that historical reasons for distrust must be addressed openly and people-centered approaches facilitated. The report concludes with the following advice:

“...[T]hough tensions between improving public health and respecting individual freedoms are not new, they continue to confront policy makers with difficult decisions. In light of the success of the smallpox eradication programme, which did resort to coercive methods in the final stages...there are some analysts who recommend similar tactics whenever non-compliance threatens a health initiative. Though each case must be judged separately, evidence suggests that coercion succeeds only in ensuring *coverage* of a programme, not *sustainability*. Populations that experience extremely coercive vaccination interventions may display increased resistance to future initiatives and an increased propensity to *exit*. Thus, when long-term community support is needed to perpetuate programmes year after year, a non-coercive pragmatism is preferable.” (19)

Resistance to taking the influenza vaccine can be related to concerns about its safety, to not understanding the importance of herd immunity in protecting others from disease, to distrust of vaccines in general, to distrust of public health vaccination programs or public health programs in general. It is imperative that information and education designed to encourage vaccination among healthcare workers include a focus on overcoming the range of obstacles, barriers and concerns resulting in workers choosing to not be vaccinated. In order to do this, meaningful involvement in the design of outreach, information and educational programs and materials of those from affected communities within the workforce must be welcomed, nurtured and supported.

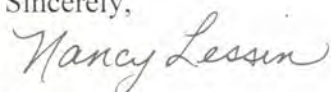
In light of decades and centuries of wrong-doing, exploitation and injustice in medical and public health arenas, we urge public health officials serving on the NVAC to reject mandating vaccinations as a condition of employment. An article on cultural perspectives on vaccination, part of the History of Vaccines Project of the College of Physicians of Philadelphia, concluded, “Divergent cultural perspectives and opinions toward vaccination, including libertarian and religious objections, as well as vaccine suspicions, signal the need for continued communication and collaboration between medical and public health officials and the public regarding acceptable and effective immunization policies.” (20) Robust efforts must be directed at understanding, naming and overcoming obstacles and barriers, and promoting rather than shutting down dialogue.

Public Policy Should Not Promote Employer Actions that Violate the National Labor Relations Act or other Labor Laws

Employers are prohibited by the National Labor Relations Act, and other labor laws with similar provisions, from making unilateral changes in conditions of employment including health and safety. A mandatory vaccination policy would certainly fall within this category. If an employer in a unionized setting wants to implement a new or changed vaccine policy that will require vaccination as a condition of employment, the employer must notify the union(s) of this proposed change, and provide an adequate opportunity to bargain. If the union(s) request bargaining, the matter must be negotiated. Those developing public health policy regarding influenza vaccination for healthcare workers must understand this tenet of labor law and assure that recommended policies are aligned.

In conclusion, we urge NVAC to drop the recommendation for mandatory vaccination as a condition of employment for healthcare workers, and instead focus on the kinds of information, education and dialogue that are necessary, in light of all that we have included in these comments, to encourage healthcare workers to voluntarily be vaccinated against influenza.

Sincerely,



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