



January 31, 2012

Colorado Board of Health Committee Members
c/o Jamie Thornton, Colorado Board of Health Program Assistant
Colorado Department of Public Health and Environment
4300 Cherry Creek Dr. South
Denver, CO 80246-1530
Jamie.thornton@state.co.us
303-692-3464

Re: NVIC Written Public Comment on Rules Pertaining to the Standards for Hospitals and Health Facilities 6 CCR 1011-1 Chapter II, General Licensure Standards December 16, 2011

Dear Committee Members,

We write to you today in opposition to the December 16, 2011 proposed Rules Pertaining to the Standards for Hospitals and Health Facilities. The proposed rule changes would eliminate the right of healthcare workers to exercise voluntary, informed consent to vaccination, which is a violation of the ethical principle of informed consent to medical risk-taking.

As the oldest and largest non-profit consumer organization advocating for the institution of vaccine safety and informed consent protections in the U.S. public health system, the National Vaccine Information Center (NVIC) worked with Congress to pass the National Childhood Vaccine Injury Act of 1986 and was responsible for securing vaccine safety and informed consent provisions in that historic law. NVIC does not advocate for or against use of vaccines but defends the right for all Americans to make informed, voluntary decisions about vaccination for themselves and their children.¹ We maintain that every individual has the human right to be informed about the risks and complications associated with infectious diseases and vaccines, consult with one or more trusted health care professionals, and make a voluntary decision about the use of one or more vaccines.

The proposed rule change does not provide adequate exemptions to vaccination for health care workers for medical, religious or conscientious belief reasons. Comprehensive vaccine exemptions, which are already extended to schoolchildren by law in Colorado, should also be included in the proposed rule change currently under consideration by the Board of Health.

Colorado's legislators have a long history of respecting the informed consent rights of parents when making vaccination and other medical decisions on behalf of their minor children. By approving this proposed rule change, the Board of Health would be taking an opposite position with educated adult health care workers, whose informed consent rights would be violated because they would be subjected to coercion and the threat of being denied employment or losing their job if they do not comply with the mandatory influenza vaccination policy.

The current draft of the proposed rule change contains language too narrow with regard to the right of health care workers to follow religious or conscientiously held beliefs. In addition, the medical exemption is limited only to contraindications listed by the vaccine's manufacturer or those recommended by federal officials. This exemption, as currently written, severely restricts the ability of a licensed doctor to make a professional determination about what is best for the health of his or her patient.

The Board's one-size-fits-all requirement for health care workers also fails to recognize or respect increased individual susceptibility to influenza vaccine adverse responses for genetic and other biological reasons that don't fall within the narrowly prescribed contraindications listed by the Center's of Disease Control. Increased individual biological susceptibility to vaccine complications was acknowledged in the landmark 2011 Institute of Medicine (IOM) report *Adverse Effects of Vaccines: Evidence and Causality*.²

The IOM's report pointed out that medical science has not yet identified all of the pre-existing genetic and biological susceptibilities to vaccine complications and that more research is needed to identify additional risk factors that "contribute to vaccine susceptibility." The report also revealed gaps in the scientific understanding of influenza vaccine and stated that 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.³

With so much unknown about individual susceptibility to vaccine injury and death, respect for the ethical principle of informed consent to vaccination becomes even more important.

Additionally, the proposed rule change does not address the potential liability to the State of Colorado, Workers' Compensation and/or healthcare facilities, or the potential additional financial burden to Colorado taxpayers if a health care worker sustains a vaccine injury due to an employment prerequisite to receive influenza vaccine. If the proposed rule changes are approved, it is unknown if health care workers who are fired for non-compliance could draw unemployment benefits, or if injured if they would be eligible to receive Workers' Compensation benefits. Currently unemployment benefits have been paid to health care workers in Texas who were fired for noncompliance.

Vaccine injury is of great concern when considering statements made last year by the Chief Medical Officer (CMO) of the Federal Division of Vaccine Injury Compensation (DVIC). According to Dr. Rosemary Johann-Liang, DVIC's 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.⁴

While the proposed amendments to suspend informed consent rights for health care workers and force them to submit to annual influenza vaccination do cite recommendations of the Centers for Disease Control (CDC) and medical trade associations with financial ties to vaccine manufacturers, such as the American Academy of Pediatrics (AAP), we note that no scientific study references were cited in the amendments to provide an evidence-base for such action.

The presentation made by CDPHE's Immunization Section Chief during the January 18 meeting of the Board included systematic reviews, which have been acknowledged as necessary to correctly context new evidence and its relation to existing evidence and the totality of evidence.⁵ However, it appears that a 2009 systematic review published in *Public Health Reports* was not included, which found that asymptomatic individuals may shed influenza virus, but that asymptomatic and presymptomatic transmission of influenza has been inferred and studies have not conclusively determined if such people effectively transmit influenza.⁶ Also missing was the 2010 systematic review by the Cochrane Collaboration that concluded "there is no evidence that vaccinating HCWs prevents influenza in elderly residents in LTCFs." and recommended that higher quality research be conducted.⁷ These reviews are relevant to the Board's deliberations.

NVIC is not alone in its opposition to this proposed rule change for ethical and science-based reasons; the Association of American Physicians and Surgeons (AAPS)⁸ has also stated their opposition to these proposed changes, as has Occupational Safety and Health Administration (OSHA). OSHA's written position states, "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.”⁹

Threatening and forcing Americans to get vaccinated, including the firing of health care workers who refuse influenza vaccines,¹⁰ will further erode public trust in vaccines and public health policies.^{11 12 13} We take this opportunity to cite additional findings in scientific research regarding the influenza vaccine, which are also relevant to the board’s consideration of the proposed rule change:

- Systematic reviews of research conducted on the influenza vaccine has shown that most influenza studies are poorly designed and have failed to demonstrate that influenza vaccine is effective or safe;^{14 15}
- Studies reveal that 60 percent of health care professionals do not want to get influenza shots and are concerned about the vaccine’s ineffectiveness and side effects;¹⁶
- The influenza vaccine is **less than 70 percent effective** in preventing influenza,¹⁷ and like all pharmaceutical products, use of influenza vaccine is not without risk of vaccine injury;¹⁸
- Over 200 viruses cause influenza and influenza-like illness and can produce similar symptoms. It is estimated that 80% of flu-like illness reported during the “flu season” is not caused by influenza.¹⁹ Some researchers estimate that, at best, vaccines might be effective against only influenza A and B, which represent about 10% of all circulating viruses.²⁰
- Only 5 to 20 percent of Americans may experience type A or type B influenza in an average flu season²¹, with the majority having uncomplicated cases. Out of 308 million Americans, CDC estimates that about 12,000 deaths were associated with influenza in 2009, a pandemic year;²²
- Influenza transmission can be prevented or reduced in home and health care settings with hand washing, masking, and separating sick and healthy persons;^{23 24 25}

NVIC is requesting that healthcare workers be given access to full, accurate information on influenza and influenza vaccine and be allowed to exercise their right to voluntary, informed consent to use or refuse the vaccine, without being subjected to coercion, harassment and the threat of termination if they decline to use the vaccine. Further, we recommend that the Board of Health adopt a declination form similar to that of the [State of Illinois](#), which respects informed consent rights of healthcare workers and ensures access to information about influenza and the benefits and risks of the influenza vaccine.

Sincerely,

Theresa K. Wrangham

Theresa K. Wrangham
Executive Director

References

¹ Fisher BL – President and Co-Founder NVIC, [The Moral Right to Conscientious, Philosophical and Personal Belief Exemption to Vaccination](#), Presented to National Vaccine Advisory Committee - May 2, 1997

² Stratton K, Ford A, Rusch E, Clayton EW, editors. [Adverse Effects of Vaccines: Evidence and Causality](#). Committee to Review Adverse Effects of Vaccines. National Academies Press: 2011. Page 70: Increased Susceptibility.

³ Stratton K, Ford A, Rusch E, Clayton EW, editors. [Adverse Effects of Vaccines: Evidence and Causality](#). Committee to Review Adverse Effects of Vaccines. National Academies Press: 2011. Pages 351-353: Summary of Epidemiologic Assessments, Mechanistic Assessments, and Causality Conclusions for the Influenza Vaccine.

⁴ [Minutes](#) – Federal Advisory Commission on Childhood Vaccines (ACCV), March 3-4, 2011

⁵ S Clark, R Horton [Putting research into context—revisited](#), *The Lancet*, Volume 376, Issue 9734, Pages 10 - 11, 3 July 2010, doi:10.1016/S0140-6736(10)61001

⁶ Patrozou, Mermel: [Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?](#), *Public Health Rep.* 2009 Mar-Apr; 124(2): 193–196.

⁷ Thomas RE, Jefferson T, Lasserson TJ. [Influenza vaccination for healthcare workers who work with the elderly](#). *Cochrane Database of Systematic Reviews* 2010, Issue 2. Art. No.: CD005187. DOI: 10.1002/14651858.CD005187.pub3.

-
- ⁸ JD Orient, [AAPS Letter to Colorado Public Health Officials on Mandatory Influenza Vaccine for Health Care Workers](#), Dec 14, 2011
- ⁹ National Vaccine Advisory Committee (NVAC) [Certified Meeting Minutes](#), Appendix B – pg 25, September 13–14, 2011
- ¹⁰ Offit P. 2010. [Mandating Influenza Vaccine: One Hospital's Experience](#). *Medscape*.
- ¹¹ ACLU. 2009. [NYCLU Urges Public Education and Voluntary Vaccine for H1N1 Flu](#), Warns Vaccine Mandate Violates Privacy Rights. [Testimony](#) by Donna Lieberman.
- ¹² Sullivan PL. 2010. [Influenza Vaccination in Healthcare Workers: Should It Be Mandatory?](#) *Journal of Issues in Nursing*.
- ¹³ Schwartz J. 2008. [Unintended Consequences: The Primacy of Public Trust in Vaccination](#). *Michigan Law Review*.
- ¹⁴ Jefferson T. 2006. [Influenza vaccination: policy versus evidence](#). *British Medical Journal*.
- ¹⁵ Jefferson T., Debalini MG et al. 2009. [Relation of study quality, concordance, take home message, funding, and impact in studies of influenza vaccines: systematic review](#). *British Medical Journal*.
- ¹⁶ King WD, Woolhandler SJ et al. 2006. [Influenza Vaccination and Health Care Workers in the U.S.](#) *Journal of General Internal Medicine*.
- ¹⁷ Osterholm M, Kelley N, Sommer A, Belongia E, [Efficacy and Effectiveness of Influenza Vaccines: a Systematic Review and Meta-Analysis](#), *The Lancet Infectious Diseases*, Early Online Publication, 26 October 2011, doi:10.1016/S1473-3099(11)70295-X
- ¹⁸ Centers for Disease Control. [Possible Side Effects from Influenza Vaccine](#).
- ¹⁹ FDA. Feb. 20, 2003. [Vaccines & Related Biological Products Advisory Committee](#) Meeting Transcript.
- ²⁰ Jefferson T, Di Pietrantonj C, Rivetti A, Bawazeer GA, Al-Ansary LA, Ferroni E. [Vaccines for preventing influenza in healthy adults](#). *Cochrane Database of Systematic Reviews* 2010, Issue 7. Art. No.: CD001269. DOI: 10.1002/14651858.CD001269.pub4.
- ²¹ Centers for Disease Control. [Seasonal Influenza](#).
- ²² Centers for Disease Control. 2010. [Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations & Deaths in the U.S.](#)
- ²³ Enstone J. 2010. [Influenza transmission and related infection control issues](#). *Introduction to Pandemic Influenza* (pp. 57-72). *CABI*.
- ²⁴ Aledort TE, Lurie N et al. 2007. [Non-pharmaceutical public health interventions for pandemic influenza: an evaluation of the evidence base](#). *BMC Public Health*.
- ²⁵ Stebbins, Samuel; [Reduction in the Incidence of Influenza A But Not Influenza B Associated With Use of Hand Sanitizer and Cough Hygiene in Schools: A Randomized Controlled Trial](#), *Pediatric Infectious Disease Journal*. 30(11):921-926, November 2011. doi: 10.1097/INF.0b013e3182218656, [Press Release](#)