

July 29, 2011

Dr. David Michaels
Assistant Secretary of Labor for Occupational Safety and Health
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Re: A Prospective Standard to Address Occupational Exposure to Infectious Diseases in Healthcare and Healthcare-Related Settings

Dear Dr. Michaels,

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on a prospective standard to mitigate the risk of occupational exposure to infectious agents in healthcare and healthcare-related settings. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO membership includes both current and future vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to vaccines for all individuals, including healthcare workers (HCWs).

BIO fully supports the creation of an infectious disease standard by the Occupational Safety and Health Administration (OSHA) to protect HCWs, and BIO believes that vaccinations should be an integral part of this standard. Due to their contact with patients and infectious materials, healthcare workers are at risk for exposure to and possible transmission of vaccine-preventable diseases.¹ For this reason, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) strongly recommends that HCWs receive vaccinations against the following diseases: hepatitis B, influenza, measles-mumps-rubella, varicella, and tetanus-diphtheria-pertussis.^{2,3} In certain circumstances, ACIP recommends HCW vaccination against tuberculosis, hepatitis A, meningococcal disease, typhoid fever, and vaccinia.⁴ Vaccination against pneumococcal disease is also recommended in all adults aged ≥ 65 years and those adults

¹ CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR Morb Mortal Wkly Rep.* 1997;46(RR-18).

² *Ibid.*

³ CDC. ACIP Provisional Recommendations for Health Care Personnel on Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Use of Postexposure Antimicrobial Prophylaxis. April 4, 2011. Available at: <http://www.cdc.gov/vaccines/recs/provisional/default.htm>.

⁴ CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR Morb Mortal Wkly Rep.* 1997;46(RR-18).

aged 19-64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection.⁵

Studies have shown that vaccination benefits HCWs and the facilities where they work.⁶ Influenza vaccination of HCWs reduces sick days, prevents transmission to patients and family members, promotes a safer work environment, and avoids the associated disruption in the delivery of healthcare services by acute illness.⁷ A study at the University of Virginia Health System showed that when HCW vaccination rates increased from 4% in 1987-1988 to 67% in 1999-2000, the proportion of nosocomial influenza cases declined significantly among employees (42% to 9%) and patients (32% to 3%).⁸ Based on results from a placebo-controlled clinical trial, influenza vaccination produces cost savings of \$46.85 per worker due to decreases in sick leave and visits to physicians for upper respiratory illness.⁹ Additionally, cost-effectiveness studies of adults aged <65 years indicate that influenza vaccination reduces both direct medical costs and indirect costs from work absenteeism: 13% to 44% fewer healthcare provider visits; 18% to 45% fewer lost workdays; 18% to 28% fewer days working with reduced effectiveness; and a 25% decrease in antibiotic use for influenza-like illness (ILI).¹⁰

Pertussis is highly contagious, and its transmission has been well documented in various healthcare settings, including hospitals and emergency departments serving pediatric and adult populations, outpatient clinics, nursing homes, and long-term care facilities.^{11,12} A study of HCWs in Quebec, Canada found that they had a 1.7 times higher risk of pertussis than that of the general adult population.¹³ In a survey of infection control practitioners from pediatric hospitals, 90% reported HCW exposures to pertussis in a five-year period.¹⁴ Serologic studies suggest pertussis infection among HCWs is more frequent than suggested by the attack rate of clinical disease, and it has been documented that one infected HCW exposed 191 other people including co-workers and patients in a post-anesthesia care unit.¹⁵ Vaccination is an effective method for reducing this risk. One study model predicted that vaccinating HCWs against pertussis would prevent more

⁵ CDC. Updated recommendations for prevention of invasive pneumococcal disease among adults using 23-valent pneumococcal polysaccharide vaccine (PPSV23). *MMWR Morb Mortal Wkly Rep.* 2010;59(34):1102-1106.

⁶ Tilburt J, Mueller P, Ottenberg A, Poland G, Koenig B. Facing the challenges of influenza in healthcare settings: the ethical rationale for mandatory seasonal influenza vaccination and its implications for future pandemics. *Vaccine.* 2008;26S:D27-D30.

⁷ Ibid.

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

⁹ Walker F, Singleton J, Lu P, Wooten K, Strikas R. Influenza vaccination of healthcare workers in the United States, 1989-2002. *Infect Control Hosp Epidemiol.* 2006;27(3):257-265.

¹⁰ CDC. Influenza vaccination of healthcare personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 2006;55(RR-2):1-16.

¹¹ CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR Morb Mortal Wkly Rep.* 1997;46(RR-18).

¹² CDC. Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis. *MMWR Morb Mortal Wkly Rep.* 2006;55(RR-17).

¹³ De Serres G, Shadmani R, Duval B, et al. Morbidity of pertussis in adolescents and adults. *J Infect Dis.* 2000;182:174-179.

¹⁴ Ibid.

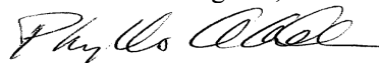
¹⁵ Ibid.

than 46% of exposures to pertussis per year and would provide net savings for the hospital of 2.38 times the dollar amount invested.¹⁶

Despite the benefits of vaccination, current vaccination rates among HCWs lag far behind desired targets. For instance, the *Healthy People 2020* goal for seasonal influenza vaccination among HCWs is 90% coverage; however, in the 2009-2010 season, only 62% of HCWs received the trivalent seasonal influenza vaccination.¹⁷ A mid-season influenza vaccine uptake survey among HCWs in November 2010 indicated that approximately 55% of HCWs had been vaccinated to-date.^{18,19} An OSHA standard that requires employers to make ACIP-recommended vaccines available to HCWs has the potential to impact worker safety significantly by increasing vaccination coverage, just as OSHA's bloodborne pathogen standard increased hepatitis B vaccination among HCWs.²⁰ The addition of routine vaccination complements the revised personal protective equipment (PPE) recommendations from the January 2011 NIOSH consensus report,²¹ and should supplement, not replace, the use of PPE and Universal Precautions annual training and certification.

BIO appreciates the opportunity to comment on OSHA's prospective infectious disease standard. We look forward to continuing to work with OSHA to address occupational exposure to vaccine-preventable diseases. Please do not hesitate to contact us for further information or clarification of our comments. Thank you for your attention to this very important matter.

With Sincerest Regards,



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¹⁶ Calugar A, Ortega-Sanchez I, Tiwari T, Oakes L, Jahre J, Murphy T. Nosocomial pertussis: costs of an outbreak and benefits of vaccinating health care workers. *Clin Infect Dis*. 2006;42:981-988.

¹⁷ CDC. Influenza Vaccination Coverage Estimates and Selected Related Results from a National Internet Panel Survey of Health Care Personnel, United States, November 2010. December 2010. Available at: www.cdc.gov/flu/pdf/vaccination/BlackNovemberHCPsurveyResults.pdf.

¹⁸ Ibid.

¹⁹ HHS. Healthy People 2020: IID-12.9 Health care personnel. Available at: <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>.

²⁰ Agerton T, Mahoney F, Polish L, Shapiro C. Impact of the bloodborne pathogen standard on vaccination of healthcare workers with hepatitis B vaccine. *Infect Control Hosp Epidemiol*. 1995;16(5):287-291.

²¹ Institute of Medicine. Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel Update 2010. January 27, 2011. Available at: <http://www.iom.edu/Reports/2011/Preventing-Transmission-of-Pandemic-Influenza-and-Other-Viral-Respiratory-Diseases.aspx>.