



July 12, 2013

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Tom Frieden, MD, MPH Director U.S. Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329 Francis Collins, MD, PhD Director National Institutes of Health 1 Center Drive Bethesda, MD 20892

Margaret Hamburg, MD Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear United States Government Leaders,

On behalf of the Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS), we write to urge broad government action to address the unprecedented incidence of pertussis observed across the country. Specifically, we recommend steps to ensure broad vaccination and continued research to improve vaccines.

IDSA and PIDS together represent more than 10,000 infectious diseases (ID) physicians and scientists devoted to patient care, prevention, public health, education and research. ID specialists play an important role in identifying and responding to public health challenges—both those existing today and those yet to emerge.

In 2012, the U.S. experienced the largest pertussis (or "whooping cough") outbreak in fifty years, with more than 42,000 cases reported nationwide. This included 18 deaths, with the majority of deaths occurring in infants less than three months of age who were too young to receive a complete series of pertussis vaccines. In addition to causing mortality in young children, pertussis is highly contagious and can cause prolonged and debilitating coughing illness in older children, adolescents, and adults. Outbreaks have been described worldwide, but variations in the epidemiology of the different outbreaks indicate that the issue is complex. The high incidence of pertussis among fully-vaccinated children and adolescents suggests rapid waning of immunity following vaccination with acellular pertussis vaccines, and recent studies have confirmed this suspicion. Although vaccination continues to be our best option for protection, we will likely continue to see more susceptible individuals in the population despite high vaccination coverage. Meanwhile, U.S. states and localities are expending substantial public health resources to investigate and contain outbreaks.

On March 6, 2013, IDSA and PIDS, along with the National Foundation for Infectious Diseases (NFID) and the National Vaccine Program Office (NVPO), co-sponsored a meeting of experts from government, industry, and academia to discuss the current state of knowledge about pertussis, including epidemiology, pathogenesis, protective immune responses, current vaccines and vaccines in development, and remaining critical gaps in scientific knowledge. The workshop included 64 in-person participants and 66 joining via webinar. The proceedings of this meeting will be published as a supplement to the *Journal of Infectious Diseases (JID)*.

Drawing upon insights and expertise presented at this meeting and from among our respective memberships, IDSA and PIDS present the following two recommendations for a coordinated federal government response to pertussis:

Recommendation: Promote Comprehensive Pertussis Vaccination, Education, and Other Prevention Policies For All Age Groups

Pertussis vaccines continue to be the best way to protect against pertussis and its complications. IDSA supports the recommendations of the Advisory Commission on Immunization Practices (ACIP), which promote the best practices available for preventing infant deaths from pertussis. Specifically, IDSA supports efforts to ensure that every child, adolescent, and adult receives a pertussis vaccine when eligible, pertussis vaccination of pregnant women during every pregnancy, and pertussis vaccination of all who will be in close contact with infants. The Centers for Disease Control and Prevention (CDC) should strengthen efforts to educate the public about the importance of vaccination against pertussis and take all necessary steps to promote vaccine uptake and other preventive measures.

Recommendation: Create a Multidisciplinary Pertussis Working Group that will Establish a National Research Agenda; Develop Pertussis Specimen Repository

We are concerned that today's vaccines and vaccination schedules leave too many individuals susceptible to pertussis, particularly due to the rapid waning of acellular pertussis vaccine-induced immunity after vaccination. In order to optimize vaccines and vaccine schedules and thereby minimize the pertussis burden, additional basic research on immune responses to pertussis and pertussis vaccines is needed.

To address concerns about the current vaccine's effectiveness and develop better prevention strategies, IDSA supports a national research agenda that includes investigation of the pathogenesis of pertussis and modes of protection against *B. pertussis* infection, informed by molecular microbiology, immunology, and epidemiology. A partnership between federal agencies, academic and industry scientists, and public health experts will spur progress toward this goal. The HHS Office of the Assistant Secretary of Health (ASH) should establish a multidisciplinary pertussis working group, composed of federal and academic experts, and charged with setting research priorities and a timeline for addressing the re-emergence of pertussis. Science has advanced since the early development of acellular pertussis vaccines several decades ago, and a twenty-first century approach is needed to control pertussis. In addition, the federal government should develop and oversee a pertussis specimen and data repository, as this would greatly aid pertussis research. In particular, this repository would aid in

the development of new diagnostics, studies of immune responses, and the identification of correlates of immune protection.

We look forward to a productive partnership between ID specialists and the federal government to address the significant public health burden posed by pertussis. We are eager to hear back from you about progress toward reducing the burden of pertussis disease, and we are ready and willing to provide consultation as needed.

Should you have any questions or comments, please do not hesitate to contact John Billington, JD, MPH, IDSA's Program Officer for Health Policy at jbillington@idsociety.org or 703.299.0015.

Sincerely,

David A. Relman President, IDSA

David W. Kimberlin President, PIDS

Ruth Lynfield

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Cc:

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