

Biodefense: Next Steps

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Testimony

Good morning, Mr. Chairman and members of the Committee, I am Jon Abramson, M.D. Chair, Wake Forest University Physicians, Physician-in-Chief, Brenner Children's Hospital and Weston M. Kelsey Professor and Chair of Pediatrics at Wake Forest University School of Medicine. I am a pediatric infectious disease specialist. I am the immediate past Chair of the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) and currently serve on the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC). I have served on the CDC anthrax working group and have coauthored AAP policy statements on the impact of bioterrorism on children and the use of smallpox vaccine in children. I have been asked by Senator Burr to speak to the Bioterrorism Subcommittee regarding the issue of liability and its impact on being able to effectively plan for and minimize the impact of a bioterrorist attack. The opinions I express today are my own and do not represent those of Wake Forest University School of Medicine, the AAP, CDC or any other organization.

Immunization is one of the greatest public health achievements of the 20th century and has saved millions of lives. Thanks to the widespread use of vaccines, millions of children and adults have avoided terrible diseases that can cause great suffering and even death. For example, before immunization, smallpox caused death in approximately 30% of those infected and serious morbidity in many other children and adults. This disease has now been eradicated from the planet, an unprecedented accomplishment made possible due to the introduction smallpox vaccination throughout the world. Polio, a disease that previously paralyzed approximately 350,000 people worldwide annually, will likely be eradicated during this decade. In the United States immunizations have reduced by more than 95 percent other vaccine-preventable infectious diseases including measles, whooping cough, tetanus, and Haemophilus influenzae, previously the most common cause of bacterial meningitis in children. These vaccines have proven to be a very cost-effective means for preventing these and other serious infectious diseases.

Despite the great reduction of disease due to the immunization program, the fragility of the vaccine supply has never been greater, as demonstrated by recent shortages of multiple vaccines including most recently those that prevent influenza and pneumococcal disease. The reasons for these shortages are multiple and include:

1) Many of the vaccine manufacturing plants are old, and considerable investment would be needed to update the plants to meet current FDA standards for good manufacturing practices

2) The price of older vaccines is relatively low and the profit potential is greater in other therapeutic areas. This relatively low profitability has led to a number of companies

discontinuing production of some or all of their vaccine products.

3) The risk of large liability suits recently has increased despite the protection afforded companies and health care providers by the national Vaccine Injury Compensation Program (VICP). For example, some attorneys are attempting to bypass the VICP and bring the allegation that vaccines can cause autism directly into court.

While each of these reasons contribute to the fragility of the vaccine supply, today I will focus my remarks on the impact that liability and compensation concerns have in allowing us to adequately prepare for a widespread public health emergency such as might occur due to emerging infections in nature (e.g., pandemic influenza) or a bioterrorist attack. Indeed, the recent experience with smallpox vaccine clearly demonstrated the effect that liability concerns had on implementing a preventive program designed to protect the American public from a smallpox bioterrorist attack. Some of the liability and compensations problems that arose are as follow:

1) Biotechnology companies were reluctant to produce a vaccine unless a national liability program was enacted that would hold manufacturers harmless against any lawsuits that arose from those who developed complications or died as a result of the vaccine.

2) Many medical centers struggled with developing a smallpox vaccination program that would allow them to fulfill President Bush's request to immunize a group of healthcare workers at various hospitals to care for people infected with smallpox. Even after the President and Congress assumed liability risk for physicians and hospitals, many did not participate in the smallpox immunization program due, at least in part, to liability and compensation issues. This was because the liability protection offered did not include injury compensation for healthcare workers' patients or household contacts who might be accidentally inoculated with the vaccine virus.

The current VICP was created in the 1980s and does not afford the liability and compensation protection necessary to implement a mass vaccination program, such as might occur from a bioterrorist attack or a pandemic. In the 108th Congress, Majority Leader Bill Frist (R-TN) introduced a bill, the Improved Vaccine Affordability and Availability Act (S.754) that, if passed, would have strengthened and made several important modifications to the VICP that would significantly help with liability and compensation issues that arise from the routine U. S. vaccination program. However, it was not the intent that this proposed legislation address a widespread public health emergency where vaccination of a very large percentage of the population would be needed to maximally protect both the individual as well the population as a whole.

So what needs to be done to minimize the impact of a bioterrorist attack? Congress needs to enact a "no fault" mechanism that could be modeled after the VICP. It should protect vaccine manufacturers and health care providers from lawsuits due to potential side effects of the vaccine and compensate children and adults injured directly or indirectly by vaccines that are recommended to prevent bioterrorism-inflicted disease. While the VICP does need to be modernized and strengthened, any program to address immunizations given in response to a bioterrorist attack should be a system separate from the VICP. The

program needs to have the following components:

- 1) Protection of the vaccine manufacturer against lawsuits should be absolute except in the case of gross negligence (e.g., failure to follow good manufacturing procedures during the production and distribution of the vaccine).
- 2) Health care workers and medical facilities participating in the immunization program need complete protection against lawsuits unless they violate standard medical procedures when administering the vaccine (e.g., failure to change needles when withdrawing vaccine from a multidose vial).
- 3) Those who develop a complication due to the vaccine should be reimbursed for their medical costs and lost earnings, but should not receive punitive damages.

While I have focused my remarks today on the use of vaccines in a bioterrorist attack, many of the same liability and compensation issues would arise during any widespread public health emergency due to an infectious disease such as will occur the next time there is a pandemic influenza season. Although the liability and compensation issues raised by a widespread public health emergency due to an infectious agent are multiple and complex, the overall goal is simple. The ability to make the necessary vaccines, administer them to a large number of people and have a public willing to be immunized are three events that must occur in consecutive order to minimize the impact of this type of event.

Similar liability and compensation issues will occur if experimental drugs are used to treat patients infected with microbial agent. For example, currently there is no FDA-approved drug to treat smallpox, although several antiviral agents are under development. In the event of a smallpox bioterrorist attack, one or more of these drugs might need to be used in an attempt to decrease mortality. The liability and compensation recommendations I have just discussed for vaccines would also apply for antimicrobial agents.

I urge Congress to thoughtfully, yet quickly, address the need to develop a compensation program to deal with the specific issues raised by a bioterrorist attack. It is critical to minimizing the impact of such an attack on the public health.