

The Smallpox Vaccination Plan: Challenges and Next Steps

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Witness:

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on behalf of the American Academy of Pediatrics
Washington, DC

Testimony:

Good morning, Mr. Chairman and members of the Committee, I am Jon Abramson, MD Chair, Wake Forest University Physicians, Physician-in-Chief, Brenner Children's Hospital and Weston M. Kelsey Professor and Chair of Pediatrics at Wake Forest. I am also the Chair of the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP). The AAP is an organization of 57,000 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. On behalf of the Academy, I would like to thank you for the opportunity to present this statement.

In December, the AAP applauded President Bush's announcement that the government did not recommend routine smallpox immunizations for the general public. At the same time, we urged the government to do all it could do to examine the needs of children.

This Committee has asked the AAP to respond to three very important questions about the President's smallpox vaccination plan. Everything that I say today in response to these questions is based on the information that the government has provided about the risk of a smallpox attack (i.e., the risk while not zero, is very small). Should the risk assessment change, then our answers to these questions might well be different.

What is the best approach for implementing the Administration's plan to make smallpox vaccine available to the general public?

The AAP has carefully analyzed this question and we believe that the general public, particularly children, should not be offered the smallpox vaccine at this time. This recommendation is based on weighing the relatively high rate of serious adverse events, including death, caused by the smallpox vaccine versus the low risk of a smallpox attack.

During any general public smallpox vaccination campaign infants and children would be particularly vulnerable to complications of vaccination for the following reasons:

- 1) High prevalence of atopic dermatitis.
- 2) Immune deficiencies that have not yet manifested or been diagnosed in the infant (e.g.,

primary immune deficiency) or child (e.g., HIV-infected children who have a delayed presentation).

3) Greater risk in infants of serious complications due to the smallpox vaccine.

4) Greater risk of unintended inoculation (e.g., self-inoculation of an eye, cross-inoculation between children in a child care center, some of whom will have contraindications to smallpox vaccination such as atopic dermatitis).

Currently, the AAP favors a ring-vaccination policy that includes a plan for rapid distribution of smallpox vaccine and development of strategies for urgent vaccination of large numbers of the population rather than a voluntary or mass vaccination program. However, if the risk of an attack was felt to be high or if an attack occurred, then a recommendation to vaccinate everyone, except those with high risk specific contraindications (e.g., a patient who recently received a bone marrow transplant), would make sense. Unfortunately, the concept of a pre-event voluntary vaccination program for the public, while appealing on the surface, makes the least sense from a scientific and public health standpoint.

Some have proposed that vaccination of the general public will decrease the spread of smallpox in the event of an attack. However, those of us in the public health community know that voluntary vaccination programs (without incentives) have not yielded vaccination rates at levels high enough to prevent outbreaks of disease. It is very unlikely that vaccination rates for smallpox will exceed the rates needed to prevent outbreaks and, therefore, this particular argument for vaccination of the general public is not based on sound, known public health principles. Ring vaccination is an effective method for containing this disease, if it occurs, while minimizing risks.

The words voluntary vaccination is a misnomer. Under a voluntary vaccination program scenario many infants, children and adults, who did not want to get the smallpox vaccine, would accidentally be inoculated by those who did receive the vaccine. It is important to point out that before 1972 when smallpox vaccine was routinely given to everyone who did not have a known contraindication, ~25% of those who developed serious side effects were those unintentionally inoculated with the vaccine. Moreover, although the use of semi-permeable dressings can reduce the risk of spread of the vaccine virus, these dressings are unlikely to be practical for large-scale vaccinations because they are expensive, cause allergic reactions in some people and compliance with their proper use will vary. Thus, many children whose parents did not wish for them to get the vaccine could end up with adverse consequences from the vaccine, some of which would be very serious - including death.

What more needs to be done to deal with liability and compensation concerns?

To answer this question I speak not only from the viewpoint of the AAP, but also as the Chair of the Wake Forest University School of Medicine physicians group. Over the past few months our medical center has struggled with trying to come up with a smallpox vaccination program that would allow us to implement President Bush's request that we immunize a group of healthcare workers at various hospitals to care for children or adults

who are exposed to or develop smallpox. There are a number of troublesome issues that arise from this request including concerns about liability and compensation.

Recent statements from the administration have clarified that the federal government's intent is to assume liability risk for physicians and hospitals that participate in this program. However, this does not provide injury compensation for patients or household contacts that are accidentally inoculated. This is very problematic. For example, if I as part of the healthcare team suffer a serious adverse event, I am covered by the workmen's compensation program. However, if I accidentally inoculate one of my children at home or a patient I am caring for in the hospital and they develop a serious side effect they are not covered. We urge Congress to correct this problem by enacting a "no fault" mechanism, similar to the successful National Childhood Vaccine Injury Compensation Program, to compensate those injured directly or indirectly by the smallpox vaccine. Furthermore, it is important that those receiving the smallpox vaccine be adequately informed about the risks associated with the vaccine including issues surrounding liability and compensation.

What needs to be done to ensure that children are eligible to receive the smallpox vaccine?

Recent studies have shown that the currently available licensed Dryvax vaccine can be safely and effectively administered to adults. However, no recent pertinent clinical trials have been or will be done using this 30-year-old frozen vaccine to ascertain whether this is true for children. Furthermore, the new tissue culture-derived vaccine that is currently being developed has never been tested in adults or children. We are aware of planned studies in adults for this new vaccine, but know of no such planned evaluation of the vaccine in children.

Surveillance studies done prior to 1970 when undiluted Dryvax vaccine was routinely used suggest that children have a higher incidence of adverse effects from the vaccine than adults do. Children are not 'little adults', and their distinct physiological responses must be studied before being exposed to the vaccine. Both the Committee on Infectious Diseases of the AAP and the Advisory Committee on Immunization Practices (ACIP) of the CDC have clearly stated that these studies need to be done in children similar to the testing that is done for other childhood vaccines.

In 1998, Congress passed the Food and Drug Administration Modernization Act (FDAMA) to make sure that children would no longer be subjected to receiving drugs that had not previously undergone testing to assure safety and effectiveness in children at various ages. Are we really willing to make and potentially use millions of doses of smallpox vaccine to prevent smallpox in children and not know if it will be safe and effective in preventing the disease? If a smallpox attack did occur are we really willing to let millions of children be part of an emergency experiment? The AAP and ACIP have clearly stated that these studies should be done and we hope that Congress will assure that they are. The AAP strongly recommends that Congress take immediate action to assure that they are.

The National Association of County and City Health Officials, have estimated that the total cost of the vaccination program, including purchase of the vaccine, training personnel, screening potential vaccine recipients, and data collection, could be as much as \$1 billion. Local health officials have indicated that the vaccination plan will divert public health funds from other health programs including childhood immunization clinics and control of tuberculosis and pertussis. The AAP strongly urges Congress to ensure that these other vital public health programs that are needed to protect against ongoing and preventable diseases are not sacrificed to protect the population against a potential, but currently non-existent disease (i.e., smallpox).

The American Academy of Pediatrics is eager to work with Congress and the Administration to assure that the appropriate research, therapeutic provisions and policies are in place to protect children against the threat of a biologic, chemical or nuclear attack, while continuing the programs needed to maintain the health of our children. Thank you for your consideration and I would be happy to engage in a dialogue and answer any questions that you have.