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November 15, 2002

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

I am writing to call your attention to a serious problem with the new smallpox vaccine provisions that were inserted into Section 304 of the Homeland Security Bill without careful consideration or debate. These provisions provide extensive liability protection for makers of the smallpox vaccine, for health care facilities where the vaccine may be administered, and for health care professionals who may administer the vaccine. Yet the provisions not only fail to provide appropriate compensation for children and adults who may be injured by the smallpox vaccine, but actually weaken the existing legal rights of these Americans.

The failure to provide for average Americans — including health care workers and first responders — while providing industry with clear protections is unacceptable.

According to the CDC, about one of every one million people vaccinated against smallpox will die, and several others will suffer serious medical complications, including brain damage, blindness, and significant scarring. Serious injury can occur even among people who have never been vaccinated but who catch the vaccine virus (called "vaccinia") from individuals who were recently vaccinated.

Under current law, individuals who are injured by the smallpox vaccine could bring actions in state court to recover damages under a variety of legal theories, such as product liability claims. The federal government, if it wants to provide protection to a vaccine manufacturer, can enter into an agreement to indemnify the manufacturer from liability. The indemnification approach protects the manufacturer by ensuring that the government will reimburse it for any losses, but does not take away any legal rights of victims.

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Under the new section 304 of the Homeland Security Bill, however, all of the rights that persons injured by the smallpox vaccine currently have to seek compensation are eliminated. In place of the ability to bring product liability and other claims against vaccine manufacturers, health care facilities, or health professionals in state court, injured individuals are allowed to bring claims only against the federal government in federal court under the Federal Tort Claims Act. These actions will be difficult to sustain because of the many restrictions on government liability under the Federal Tort Claims Act.

Section 304 even fails to assist persons who not take the smallpox vaccine themselves, but are injured as a result of exposure to someone who did take the vaccine. It is expected that many of those injured in this way will be small children.

A far better approach than section 304 would be a no-fault compensation program modeled on the successful program we currently have for childhood vaccines. This approach would facilitate — not block — compensation, while at the same time it would provide appropriate safeguards for vaccine manufacturers in order to assure a stable vaccine supply.

My staff has repeatedly contacted your Department over the past year to work together on a smallpox compensation program. We have even gained the support of vaccine manufacturers for such an initiative. Yet your staff has refused to discuss a compensation program. It now seems apparent that Administration's priority has been legislation that protects manufacturers but not injured people.

I request information on how this Administration position was put together. Please provide me with the following information:

- (1) a list of all outside groups or individuals consulted about Section 304 and potential compensation and care for those injured by the smallpox vaccine, including, but not limited to, members of Congress, public interest groups, lobbyists, private citizens, and vaccine manufacturers and their representatives;
- (2) with respect to each entity identified in response to question (1), a list identifying
 - (a) the date and nature — e.g., meeting, telephone call — of each contact between the entity and the Administration;
 - (b) the topics discussed during the contact; and
 - (c) all persons present or participating in the contact, including federal employees;

The Honorable Tommy G. Thompson

November 15, 2002

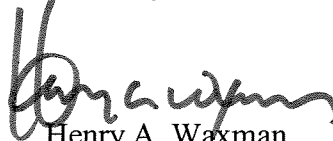
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- (3) copies of all documents and records — including, but not limited to, correspondence, notes, memoranda, and e-mail messages — created or received by the Administration regarding or relating to Section 304 and potential compensation and care for those injured by the smallpox vaccine.

Please also explain how the Administration intends to provide for persons injured by this vaccine and whether and how the Administration will work to support legislation providing compensation to them and their families. I would appreciate your providing the above information to me by December 9, 2002.

I urge you to work with the Congress to provide a compensation program for those Americans — including an estimated 500,000 health care workers in the near term — who risk their health to protect us all. I remain happy to work with you on developing such a program.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry A. Waxman". The signature is fluid and cursive, with a large initial "H" and "W".

Henry A. Waxman
Ranking Member