

Preparing for the Smallpox Vaccine

In the coming days, the President will launch a national smallpox vaccination program that will include, in its first wave, hundreds of thousands of healthcare workers and military personnel. The United States must be prepared for a bioterrorist attack, and vaccinating those on the front lines at home and abroad is part of that effort. My concern is that our nation is unprepared to take care of those injured by the vaccine itself.

The smallpox vaccine, while generally safe, causes rare but serious side effects. About one out of every million people who receive the vaccine will die, and several others will suffer severe medical complications, including brain damage, blindness, and significant scarring. Serious injury can occur even among people who have never been vaccinated, but who come into close contact with someone who has recently received the vaccine.

Given these medical facts, the health care workers who take the vaccine under the President's plan are knowingly placing themselves and their families at risk. And they are doing so not for any personal gain, but in order to be able to protect the rest of us in the event of a terrorist attack that unleashes smallpox.

In return, they deserve our help if something goes wrong. But will they get it?

Not if the homeland security bill Congress passed at the end of last year is the last word on the subject. A little-noticed section added at the eleventh hour protected drug companies, hospitals, and physicians from liability claims brought by those killed or injured by the smallpox vaccine. It did so by drastically reducing the legal rights of those injured or killed by the vaccine.

While taking care of the pharmaceutical industry and the medical profession, the homeland security bill gives vaccine victims just one chance in the court system: sue the United States government under the Federal Torts Claims Act, which requires a showing of negligence. Since it is well known that there are serious risks associated with the smallpox vaccine even in the absence of anyone's mistake, it is unlikely that anyone will receive compensation under this approach. Moreover, workers' compensation, which might be available in some circumstances, provides only limited assistance and shifts financial burdens to already strapped state and local governments.

Not only is this approach unfair, it is also counter-productive. The chance that a vaccine complication could devastate a family's finances will leave many reluctant to be vaccinated in the first place. Indeed, the Institute of Medicine recently concluded that the absence of a compensation program "could seriously impact the program's achievement of its overall goals of increasing United States terrorism preparedness."

The lack of compensation may also compound the severity of the medical complications. Several serious vaccine-related conditions, such as eczema vaccinatum, start slowly and build to a life-threatening stage. Without access to financial support, some families will forego the early treatment that can avert hospitalization, disability, and death.

Our nation faced a similar challenge in the 1980s, when makers of childhood vaccines were threatening to stop production because of the fear of litigation, and parents were avoiding vaccinations because of the fear of adverse reactions. Congress responded with bipartisan legislation, which I co-authored, that created a no-fault compensation program for childhood vaccines. Under this system, vaccine manufacturers received needed liability protections, while individuals who were injured by the vaccine were compensated quickly and fairly. In effect, both the manufacturer and the patient were protected, and confidence in the vaccine program was maintained.

This successful model should be applied to the smallpox vaccine. Those injured by the vaccine should not have to prove negligence if they suffer well-known side effects of the vaccine. Instead, a federal compensation program should quickly cover outstanding medical expenses and provide other benefits to those injured by the smallpox vaccine. This would assure uninsured Americans that they do not have to choose between seeking medical attention for a smallpox vaccine injury and paying the rent.

Establishing a no-fault compensation program will require an act of Congress, and if vaccinations are going to begin in January, it must be done quickly. The 108th Congress should make the creation of this program a top priority..