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Responding to the Threat of Smallpox Bioterrorism

An Ounce of Prevention Is Best Approach

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Executive Summary

The threat of direct terrorist attack against the United States proved to be real. And the subsequent anthrax cases point to the possibility of a future bioterrorist attack, including use of the deadly smallpox virus. The nature of terrorism is such that it is impossible to accurately predict the probability of such an attack, but the potential consequences are catastrophic. Therefore, it is a serious threat that deserves serious attention.

The current ring containment strategy (administering smallpox vaccinations only after an outbreak in the hope of containing the spread of the virus) favored by the federal government may be appropriate for dealing with a natural outbreak of smallpox, but it is likely to be woefully inadequate for countering a direct attack by a thinking enemy intent on inflicting infection, death, and panic.

A better approach than leaving the entire population at risk and responding to a smallpox attack after the fact would be to take preventive measures. The current stockpile of smallpox vaccine can be effectively diluted to create a more abundant supply, which—along with a newly discovered stockpile and additional vaccine already ordered and scheduled to be delivered by the end of 2002—should be made available to the public. Even if only a small fraction of the population were vaccinated, a community immunity effect, which would lower the rate of transmission of a disease as well as significantly increase the chances of success of a ring containment strategy, would be produced. As a result, the chances of a successful attack would be lowered, and that could have a deterrent effect and might even prevent such an attack.

If the paramount obligation of the federal government is to protect the United States and its population, then an ounce of prevention in the form of a population partially vaccinated against smallpox will be more effective—both in deterring and in responding to a potential attack—than leaving the American public unprotected and completely at risk, hoping that a pound of cure will work after the fact.

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The nature of bioterrorism is very different from that of nuclear or chemical attacks.

Introduction

In the wake of September 11, the potential use of weapons of mass destruction (WMD) by terrorists cannot be dismissed or ignored. Osama bin Laden has claimed that his al-Qaeda terrorist organization has nuclear and chemical weapons and is not afraid to use them.[1] Such statements might be considered more boastful bluff and bluster than real threats, but there should be no doubting bin Laden's desire for WMD. In May 1998 he issued a statement titled "The Nuclear Bomb of Islam," which stated that "it is the duty of Muslims to prepare as much force as possible to terrorize the enemies of God."[2] In an interview with *Time* magazine in December 1998, bin Laden said, "If I have indeed acquired these weapons, then I thank God for enabling me to do so."[3]

There is evidence that al-Qaeda members have been trying to acquire nuclear materials since at least 1994 and have experimented with using chemical weapons (cyanide).[4] Intelligence sources have pointed to an al-Qaeda training camp (called abu-Khabab after the Egyptian chemical-biological weapons expert who directed it) outside Jalalabad, Afghanistan, as a chemical and biological weapons training facility.[5] And a manual ("Encyclopedia of Afghan Resistance") distributed on CD-ROM includes a section on how to make chemical and biological weapons.[6] Finally, there is evidence that the September 11 terrorists were interested in crop-dusters, which could be used to distribute a chemical or biological agent.[7]

Terrorism and WMD

Although the use of any WMD by a terrorist group would be an event of devastating proportions, there are differences worth noting and understanding between potential nuclear, chemical, and biological terrorist attacks. A low-yield nuclear weapon would cause immediate damage to a circumscribed area by explosive blast, overpressure, extreme heat, and radiation. If such a weapon were detonated in a major metropolitan area, the casualties would likely be in excess of 100,000 dead, injured, and subjected to lethal doses of radiation.[8]

The Aum Shinrikyo cult used a chemical weapon, Sarin (a nerve agent so deadly that a single drop on the skin can be fatal) in the 1995 Tokyo subway attack. The attack was not a complete success because of ineffective dissemination, but 12 people died and nearly 3,800 were injured.[9] Aum Shinrikyo also used VX (10 to 1,000 times stronger than Sarin) in four other attacks. Those attacks were targeted against specific individuals or groups of people rather than aimed at inflicting massive casualties. In one instance, there was 1 fatality and in another 20 deaths, but the other attacks failed because of ineffective release of the VX agent.[10] It is estimated that, under ideal conditions, a quart of VX properly distributed in a major metropolitan area could kill about 12 million people in 60 minutes.[11]

As catastrophic as either a nuclear or a chemical terrorist attack would be, the effects of the attack would be immediate and limited to people in the vicinity of the attack. Although the damage and casualties would likely be an order of magnitude or more greater than those of the World Trade Center attacks, it would be possible to know that an attack had taken place and respond accordingly. According to D. A. Henderson at Johns Hopkins University, "After an explosion or a chemical attack, the worst effects are quickly over, the dimensions of the catastrophe can be defined, the toll of injuries and deaths can be ascertained, and efforts can be directed to stabilization and recovery."[12]

Bioterrorism Is Different from Nuclear or Chemical Attacks

The nature of bioterrorism, however, is very different from that of nuclear or chemical attacks. Biological agents are disease-causing organisms. If the organisms used are contagious pathogens, their effects can be

passed on unknowingly, thereby spreading the damage well beyond the people who are initially infected. If successful, a smallpox attack could be more devastating than even a nuclear weapon. Unlike a nuclear or chemical attack, a biological attack would not be detected immediately; there is usually an incubation period of several days to a few weeks before the first symptoms appear in infected persons. Furthermore, it would be difficult to know immediately whether infection was the result of a *natural outbreak* of a disease or of a premeditated release of the pathogen. And even if there is an antidote for the disease, detection of the attack may occur too late for the antidote to be effective.

The devastation that could be caused by a biological attack can be demonstrated by the natural outbreak of influenza in the United States during the winter of 1918–19. The first signs of the influenza virus (the symptoms being no different than those of a common cold, which further highlights the difficulties associated with detecting and diagnosing biological infection) occurred in the spring of 1918 in military camps throughout the United States. American soldiers carried the flu to Europe where it mutated into a killer virus. Returning troops brought the disease back to the United States where it spread to the civilian population. By the fall of 1918 the United States was in the grips of an influenza epidemic that killed an estimated 675,000 Americans.[13] But, unlike a natural outbreak of a disease such as influenza, a bioterrorist attack would be an intentional release of a deadly disease by a thinking enemy intent on inflicting mass casualties. In all likelihood, an effective bioterrorist attack would ultimately exact a similar or greater toll.

The threat of bioterrorism is especially worrisome because of the vulnerability of the U.S. population to such an attack. Indeed, according to the Chemical and Biological Arms Control Institute, "The vulnerabilities of the United States to bioterrorism attack are virtually infinite."[14] As a result, the problem of bioterrorism can paralyze policymakers and response planners. Frequently, such a large threat is downplayed, dismissed, or ignored. For example, Milton Leitenberg at the Center for International and Security Studies at the University of Maryland wrote (before September 11), "As regards bioterrorism, the current national discussion is characterized by gross exaggeration, hype, and abstract vulnerability assessments."[15] Leitenberg further asserted, "The greatest problem that the United States—and the world—face regarding biological weapons is their proliferation among nation states, and *not the potential of their use by non-state, or 'terrorist' actors.*"[16] In other words—at least before September 11—Leitenberg thought not only that the threat of bioterrorism was exaggerated but also that terrorists were not the problem the United States should focus on. September 11 demonstrated that the United States can ill afford such an attitude.

No one can predict a bioterrorist attack with high certainty and confidence. But a simple "back of the envelope" threat assessment using a model used by Col. Lani Kass (USAF, Ret.) at the National War College,[17]

Vulnerability x Intentions x Capabilities = Threat

provides insight about and understanding of the potential of a future bioterrorist attack. The vulnerability of the United States to such an attack is quite high. The attacks on the World Trade Center and the Pentagon demonstrate the seriousness of al-Qaeda's intentions. The big unknown is whether al-Qaeda possesses the capabilities to carry out an attack with biological weapons. But, as demonstrated by September 11, the United States can ill afford to ignore the possibility.

The Smallpox Threat

A bioterrorist attack could come in one (or more) of many forms (plague, smallpox, or anthrax, for example). Of those, smallpox is the threat most often discussed. Concerns about smallpox as a potential bioweapon were heightened when Ken Alibek, a former deputy director of the Soviet Union's civilian

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bioweapons program, alleged that the Soviet government produced the smallpox virus in large quantities and weaponized it. Alibek also contended that Russia continued the program after the disintegration of the USSR.[18] Given the deterioration of the Russian military and the supporting industrial complex, there are legitimate concerns that equipment, expertise, and possibly even the virus or weaponized smallpox[19] could have fallen into non-Russian hands.[20]

Smallpox is an especially serious threat because of its high case-fatality rate (30 percent or more of unvaccinated persons)[21] and transmissibility (it spreads easily via inhalation of droplets or direct contact with contaminated objects such as clothing or bed linens).[22] There is also no known effective treatment for smallpox.[23] Smallpox has long been feared as the most devastating of all infectious diseases (before its supposed eradication from the world in 1978, smallpox had killed more people than any other infectious disease in human history),[24] and its potential for devastation is far greater today since there has been no routine vaccination in the United States for more than 25 years.[25] Therefore, in a highly susceptible and mobile population, smallpox would be able to spread widely and rapidly.

The smallpox virus is also easy to disperse. It is one of the smallest living organisms and can be easily prepared as an aerosol and released into the air in a crowded place such as a shopping mall or a sports stadium. Or a suicide terrorist with the virus could infect passersby simply by coughing and sneezing, which can release millions of virus particles into the air.[26]

There is no known effective treatment for smallpox.

One example of the magnitude of the consequences of a potential bioterrorist attack with smallpox is the Dark Winter exercise conducted in June 2001.[27] Dark Winter was a fictional scenario depicting a terrorist attack using smallpox released via aerosol at three shopping malls in Oklahoma, Georgia, and Pennsylvania. On day 1 of the crisis (nine days after initial exposure), all that was known was that some two dozen people reported to hospitals in Oklahoma City (there were no similar signs of potential outbreak in Georgia and Pennsylvania where the dispersion was not as effective but nonetheless resulted in infected people) with flulike symptoms of a strange illness, which was later confirmed by the Centers for Disease Control as smallpox. Assuming that each case was expected to infect at least 10 other people,[28] on day 6 of the crisis there were 2,000 known cases of smallpox and 300 deaths. Due to limited amounts (12 million doses) on hand, the reserve of smallpox vaccine was effectively used up on day 6. By day 12 of the crisis, there were 3,000 cases and 1,000 dead in 25 states. With no vaccine, the smallpox virus was projected to explode as follows:

- After 3 weeks: 30,000 cases and 10,000 dead
- After 5 weeks: 300,000 cases and 100,000 dead
- After 7 weeks: 3 million cases and 1 million dead

It is important to emphasize that the purpose of the Dark Winter exercise was not to make the case that smallpox is the weapon most likely to be used in a bioterrorist attack (it is impossible to make such predictions). However, the Dark Winter exercise did demonstrate that the use of a contagious pathogen as a weapon of bioterrorism can have devastating and far-reaching effects. The consequences of an attack with smallpox are potentially catastrophic, and such an attack is the only external threat to the continued existence of the United States other than a massive nuclear attack from Russia. Therefore, even if likelihood cannot be established, the effects of smallpox as a weapon of bioterrorism warrant taking the threat seriously in order to understand the efficacy of potential response options. Also, preventive measures, which might act as a potential deterrent, reduce the risk, and mitigate the consequences of an attack, need to be examined and evaluated.

U.S. Government Response to Threat of Smallpox Bioterrorism

Since September 11 the federal government has been trying to prepare for a bioterrorist attack on the United States. Despite the lack of information about the probability of an attack, President Bush's $20 billion emergency relief budget request includes $1.5 billion for the Department of Health and Human Services, in addition to the department's regular fiscal year 2002 budget request of $345 million for bioterrorism preparedness.[29]

Also, in December 2001 Congress for the first time pumped up annual funding for bioterrorism research to roughly $1 billion, according to a press release from the Office of Management and Budget.[30] That funding was based on estimates of analysts at OMB and the American Association for the Advancement of Science. Finally, on February 4, 2002, the FY03 budget released by the White House requested nearly $38 billion for homeland defense; $5.9 billion of that amount is dedicated to bioterrorism preparedness.[31]

Some of that money will be used to improve public health agencies' capacities and ability to react in case of an attack. Before the Senate Committee on Health, Education, Labor and Pensions on October 9, 2001, D. A. Henderson, now in charge of HHS's preparedness effort, explained that the deficiencies of the public health system are so vast that any biological attack would be overwhelming.[32] For example, many of the nation's hospitals lack the equipment necessary—in some cases even fax machines—to receive or report information in an emergency. And, according to Mohammad Akhtar, executive director of the American Public Health Association, only 10 percent of local and state health departments have access to e-mail.[33] Therefore, effective transmission of news about a biological attack is a very real problem.

More important, a portion of that budget will be used to purchase smallpox vaccine. Last November the federal government awarded a $428 million contract to a private joint venture between two pharmaceutical companies to produce 155 million doses of smallpox vaccine to be delivered by the end of 2002.[34] The new purchase will be added to the 15 million doses the government already has stockpiled and the 40 million doses ordered in 2000 by the Centers for Disease Control, as well as about 85 million doses discovered by vaccine maker Aventis Pasteur and donated to the federal government on March 29, 2002.[35]

Also, last October the National Institutes of Health launched a study to determine if a diluted vaccine combined with an alternative vaccination schedule would protect a greater number of people than do the standard dose and regimen. On March 29 the *New England Journal of Medicine* published the latest results of a study on dilution of the vaccine; the study concludes that a fivefold dilution does not reduce the stockpiled vaccine's effectiveness.[36] That means that, when the stockpile is diluted and added to the Aventis vaccine, the United States will have at least 150 million doses.

However, the various smallpox response plans released by the different public health branches as part of national efforts to prepare for potential terrorist attacks do not call for making the vaccine available to the American public until there is a confirmed smallpox outbreak.

According to HHS secretary Tommy G. Thompson, the administration will provide the vaccine only to high-risk groups and medical workers. The remainder of the vaccine will be stockpiled and used in the event of a terrorist attack. Only if an outbreak occurs will the government start vaccinating the population—a dubious strategy.

Ring Containment Strategy

In its updated plan and guidelines for a national response to a smallpox attack, the CDC explained that ring containment, not mass vaccination, should be the U.S. strategy for dealing with a terrorist attack with the deadly smallpox virus.[37] That strategy is

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modeled after the World Health Organization's method that successfully eradicated smallpox around the globe by 1980. The plan is to create mobile teams of eight people each to respond to potential smallpox outbreaks and to any reported smallpox cases. The response teams would include a physician leader, a senior public health adviser, two epidemiologists, a lab specialist, a communications specialist, a community liaison, and a technical support worker. The teams would cooperate with state and local officials. The procedure would be to isolate the patients, vaccinate everyone who had recent contact with the patients, and then vaccinate a second ring of people who were exposed to those who had had contact with the patients.

Risks Associated with Smallpox Vaccine

Injection of the smallpox vaccine causes the skin to redden at the vaccination site; that reaction lasts up to two weeks. More important, 1 of 150,000 recipients of smallpox vaccine experiences more severe reactions, including overwhelming infection (not smallpox), such as encephalitis or brain infection, due to the presence of the vaccine virus in individuals with abnormal immune systems. Another 1 of 500,000 individuals will die as a direct result of the vaccine.[38] Although the risk of either death or severe side effects may sound relatively minor, vaccination of the entire U.S. population would result in about 600 deaths and 2,000 individuals with serious brain infections.[39]

The risks of vaccination must, of course, be balanced against what is currently only a theoretical risk of smallpox being successfully introduced by terrorists. According to Paul Ewald, a professor of biology at Amherst College and the author of *Evolution of Infectious Disease and Plague Time,* "If fears of an attack using smallpox turn out to be much ado about nothing, this approach [stockpiling the vaccine and relying on ring containment] would have saved Americans from the vaccine's side effects."[40]

Given the risks and potential consequences, the question still remains: What if there is a successful bioterrorist attack using the smallpox virus?

Containment Strategy Not Appropriate for Bioterrorist Attack

A ring containment strategy is a valid approach for responding to a natural outbreak of smallpox in an unvaccinated population, because smallpox as a natural disease has been eradicated and a natural outbreak would likely be isolated. Public health authorities would have a very good idea about the potential point source of the outbreak and could thus implement a ring containment strategy to stop the spread of smallpox.

However, a ring containment strategy is much less likely to be successful against a threat of bioterrorist attack with smallpox. Unlike a natural outbreak, which is likely to be an isolated incident with an identifiable point source, a terrorist attack might have multiple sources, not all of which would be immediately and easily known. In fact, a terrorist attack may not be initially recognized as such.

The Dark Winter exercise demonstrated that the available information initially led public health officials to believe that they were dealing with an outbreak of smallpox in Oklahoma. The officials responded in the traditional manner: they focused on the point source of Oklahoma City as if they were dealing with an isolated incident and a natural outbreak. But the terrorists in this exercise had also dispersed the smallpox virus in two other cities (but less successfully, so that not as many people were initially infected), and by the time that was discovered, it was too late—the smallpox virus had spread past the point where a ring containment strategy could effectively control it. Moreover, because the first symptoms of smallpox resemble those of the flu, public health officials did not immediately diagnose the first cases as smallpox, and the virus had spread extensively before it was confirmed as smallpox.

Furthermore, a ring containment strategy assumes that the spread of the virus can be

stopped at its source. But a bioterrorist smallpox attack could have multiple sources and is not likely to be a single incident in time. There could be several attacks spread out over a period of time. A ring containment strategy would deal with each of those in sequence. But, in an unvaccinated population, the virus is likely to spread much faster than a ring containment strategy can respond. Indeed, the experience with the cases of anthrax after September 11 in the United States demonstrates the shortcomings of using an approach that might work well for a natural outbreak when a disease is being spread intentionally by a thinking enemy. The initial focus was on the Senate offices and buildings where the anthrax-infected mail was delivered. The Brentwood mail-handling facility was initially ignored and, as a result, anthrax spores infected workers at the facility and were also transferred to mail delivered to other locations.

U.S. health officials were thinking in terms of public health when that particular situation required thinking in terms of threats to national security. Public health authorities are likely to misidentify a problem and choose an inappropriate solution, thereby putting the population at great risk.

In the case of an outbreak in an unvaccinated population, people's fate will rest entirely in the hands of public health workers. Inevitably, there will be panic that spreads rapidly and possible riots and violence. It is assumed that public health workers will react calmly, quickly, and competently while the ring containment strategy is implemented.[41]

Using a ring containment strategy also means that, even if everything works according to plan, people who were infected at the onset of the attack will die whereas they might have lived had they been previously vaccinated. As was demonstrated by the anthrax-infected letters winding their way through the postal system, the first few victims of a bioterrorist attack are more likely to die than are those infected later, because by the time the initial victims become symptomatic and are diagnosed it is often too late to save them. Furthermore, if any step of the containment process fails, the number of casualties could rise dramatically.

It is important not to forget that the smallpox virus, on average, kills 30 percent or more of the people infected and leaves the others blind or terribly scarred for life. In fact, smallpox has killed substantially more people than warfare. In the 20th century, the bloodiest century for warfare, 111 million people died in war.[42] However, that staggering toll pales in comparison with the damage caused by the smallpox virus: best estimates indicate that from 300 million to 500 million people died from smallpox in the 20th century; that is several times the number of deaths from all wars combined.[43]

Also, its ability to spread in any climate and season makes smallpox one of the most devastating of all infectious diseases.[44] According to a study conducted by Raymond Gani and Steve Leach of the Center for Applied Microbiology and Research in the United Kingdom, a person who contracted smallpox could spread the disease to 4 to 12 other people.[45] By comparison, a study by the CDC estimates that a smallpox victim would infect about three other people before authorities administered vaccinations and undertook other countermeasures.[46] The CDC estimated that an outbreak in which 100 people in a city of 403,000 were initially exposed to the virus would lead to 4,200 smallpox cases and take a year to control. Authorities would have to quarantine at least one-quarter of the infected people and vaccinate more than 9 million people. Regardless of which estimates are used, the toll could be very large, and, according to Ewald, "A fully unvaccinated population could face dangers that would not be easy to control with [the ring containment] crisis approach."[47]

In fact, the ring containment-only strategy is not appropriate for all outbreaks, which may differ in degree of severity. Although a small outbreak in the middle of nowhere might be easily contained with the ring containment strategy, a large-scale outbreak carefully prepared by terrorists could overwhelm

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the system. Once again, the Dark Winter exercise is a very good example of that point. The simulation ended with projections of more than 3 million fictional victims and 1 million deaths—starting with 24 patients who first exhibited flulike symptoms of an undiagnosed illness in Oklahoma.[48]

For all those reasons, a ring containment strategy, which may be appropriate for a natural outbreak in an unvaccinated population, will not be effective in the case of a bioterrorist attack using the smallpox virus.

Civil Liberties Issues

At the same time that the federal government is adopting a ring containment strategy to respond to smallpox, HHS is encouraging the states to adopt the CDC's proposed Model State Emergency Health Powers Act,[49] developed with the National Governors Association and other groups. Among other things, that plan grants governors the authority to declare a state of emergency to deal with the threat of bioterrorism. Governors in many states already have limited quarantine powers, but the proposed act would broaden them, as well as governors' authority in other areas such as compulsory vaccinations. If an outbreak occurred, health authorities at the state level would be given the power to take strict measures against the population, including forced medical examination, forced vaccination, quarantine, and destruction of property. Finally, people who refused to comply with the emergency measures would be subject to criminal penalties, and state police could enforce the measures at gunpoint.

Clearly, the sweeping powers granted under the model act raise many civil rights questions. For example, the legislation suggests "the need to place public health over privacy issues," not only in the event an infectious disease outbreak, but before an outbreak as well. The measure calls for information exchange among doctors, pharmacists, and health organizations to keep the population under surveillance between outbreaks. It would require pharmacists to report increased prescription rates or "unusual trends" in pharmacy visits (ostensibly to alert public health officials to a potential epidemic). Those reports would include a patient's name, date of birth, sex, race, and address. The model act also requires doctors to report information about their patients, violating the doctor-patient privilege and one's right to privacy. Those requirements would place a huge burden on the shoulders of the medical profession but would not necessarily contribute to successfully containing an outbreak.

The justification for the attack on privacy in the Model State Emergency Powers Act is that "privacy laws thwart data-sharing between states, the Federal government, law enforcement, emergency teams, and the private sector."[50] Such reasoning ignores the Fourth Amendment of the Constitution that protects individuals against the power of abusive government.

Prior Vaccination Is Best Response to Bioterror Threat

The current government policy, which does not provide for vaccination before a bioterrorist attack with smallpox, is not an acceptable approach in a society that values individual life and liberty. A better way to prepare the country for a potential smallpox attack would be to make the smallpox vaccine available to the public. That solution would offer many advantages.

A public debate about the smallpox issue and the risks associated with the vaccine is very likely if the smallpox vaccine is made available to the public. Information would circulate and people would be better informed and then better prepared. By increasing public education and awareness, public health authorities may increase the rapidity with which an alert of an outbreak will be taken seriously and acted on. Education may also reduce the risk of panic.

Letting people decide whether to get vaccinated before an outbreak also allows doctors and patients to evaluate on a patient-by-

patient basis the risk posed by the smallpox vaccine. After being apprised of the risk of vaccination, people should be allowed to decide whether they want to be inoculated with the vaccine or want to take the risk associated with not being vaccinated. For citizens with certain physical or medical conditions, vaccination could pose the greater risk. Such persons might choose to be vaccinated later when the risk would be less.

For example, the immunization of a pregnant woman exposes the fetus to a serious risk of side effects and poses an increased risk for the mother. Therefore, a woman who knows she wants to become pregnant can choose to be vaccinated beforehand. In that case, in the event of an attack, she would not face the stark choice of risking her fetus or her own life.

Also, persons with compromised immune systems might decide not to be vaccinated but instead be ready to take all the necessary measures to protect themselves in case of an outbreak. For example, people with weakened immune systems could take all the precautions necessary to increase the chance of not being exposed to potentially infected people by being prepared to stay at home for an extended period of time and avoiding contact with others. They could also decide to be vaccinated after their doctor had controlled their condition and reduced the risk.

People could also make decisions about whether to be inoculated on the basis of their perceptions of vulnerability to the potential threat. For example, people who live in New York City, Washington, or other major metropolitan areas might feel that they were more likely to be the target of a terrorist attack than residents of Paducah, Kentucky.

Making the vaccine available to the public as soon as possible would allow time for Americans to decide what is best in each of their particular cases. Once a crisis erupts, health authorities will be administering vaccine without wondering who is likely to be killed by it or whether a woman is pregnant or not. Therefore, people would be placed in a position of having either to accept the risks associated with the vaccine or to be exposed to smallpox.

According to a November Associated Press poll, three-fifths of Americans said they would want a smallpox vaccination if it were available, despite health risks that include potential death. A majority, 53 percent, said they were worried that terrorists would use the smallpox virus in future attacks on the United States.[51]

Given the overwhelming number of people who would like to be vaccinated, and who have expressed their anxiety about a potential terrorist attack, it is hard to understand why the government does not make the vaccine available to the public but relies instead on a ring containment strategy. It does not make sense for the administration to spend so much taxpayer money to purchase the vaccine—sending a signal that there is a potential risk of being attacked—but not make the vaccine available to taxpayers despite a pressing demand.

To be sure, the current stockpile by itself (even if diluted) is probably not adequate to make the smallpox vaccine immediately available to the general public. After the stockpile is diluted to provide 75 million doses and added to the newly found 85 million doses and the 195 million ordered doses, the federal government will have more than 350 million doses on hand by the end of 2002, which is more than enough to make the option of voluntary vaccination available to the general public. According to William J. Bickness, M.D., a Boston University professor and former director of the Massachusetts Department of Public Health, "Widespread, voluntary vaccination before exposure will greatly reduce the number of victims if an attack occurs."[52]

A Partially Vaccinated Populace Is Better Than Ring Containment

It is unrealistic to suppose that current opinion polls accurately predict the number of people who would ultimately get vaccinated. In fact, many people will probably be deterred from getting vaccinated when the first cases of

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side effects or the first death occurs. Such cases will make the front page of every major newspaper in the country. As a consequence, some of the people who were committed to getting the vaccine will change their minds, and a much smaller percentage of the population will really be vaccinated. However, in case of an outbreak, even a partially vaccinated population would stand a better chance than an unvaccinated population.

When even a small fraction of the population is vaccinated it creates what biologists call "community immunity." That term refers to the indirect protection of a community from a disease because of the proportion of individuals fully immunized.[53] That immunity generally lowers the rate of person-to-person transmission of the disease—a benefit that is lost when coverage levels fall. Experience with vaccination for hepatitis A and B, diphtheria, acellular pertussis, *Haemophilus influenza* type B, inactivated polio, pneumococcal conjugate, measles, mumps, rubella, and varicella[54] indicates that immunization greatly reduces the risk of contracting and spreading disease to a larger portion of the population.[55] Moreover, community immunity significantly increases the chances of success of a ring containment strategy. For example, even if only 15 percent of the population were vaccinated, there would be 40 million fewer people to vaccinate during a crisis, and the number of people likely to panic would be reduced.

Finally, a well-vaccinated population is probably unattractive to would-be bioterrorists. A partially vaccinated population creates uncertainty about the prospects for an attack's achieving the desired results of widespread panic, infection, and death.

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Liability Issues

With the production and distribution of the smallpox vaccine, as with any other vaccine, liability issues emerge. In December 2001 the U.S. House of Representatives approved legislation to spend more than $2.5 billion to fight biological terrorism,[56] and during the debate many of the sensitive issues associated with the threat of bioterrorism were raised. Biotechnology industry firms and drug manufacturers once again asked the federal government to provide them with special liability protection, arguing that the threat of runaway lawsuits would otherwise discourage vaccine research and production.

However, the final version of the House bill does not include liability protection for vaccine producers. Instead, it allows the White House to negotiate liability protection with individual companies. The bill does include a waiver from antitrust laws for pharmaceutical companies that decide to work together to produce vaccines and medicine to counter potential bioterrorism agents.[57] The legislation raises several questions, not only about the current situation, but also about the future production of vaccines.

Current and Future Liability Issues

To face the potential threat of bioterrorist attack with smallpox and address the current shortage of vaccine, the government initially has decided to dilute the current stockpile to increase the number of available doses and to buy more vaccine. It then must determine how to distribute the vaccine.

If the federal government is the sole purchaser and dominant decisionmaker about distribution, it is probably safe to assume that federal authorities will be primarily liable for any problems that might occur with the vaccine (to the extent allowed by federal tort liability). However, it remains unclear how much legal responsibility the federal government will choose to assume in dealing with vaccine manufacturers. Will the government promise immunity to them? To what degree would such immunity prevent costly litigation against manufacturers? At the moment, there are no clear guarantees that the federal government is ready to take full responsibility in case of major problems, even with vaccines manufactured according to federal specification under sole-source procurement contracts.

The first question to ask before embarking on a tightly controlled federal procurement process for new vaccines is whether the government should be the only party to decide who is going to produce the vaccines. If the long-run demand for vaccines continues to grow, reliance on government monopoly control over the supply, production, and distribution of vaccines is likely to produce shortages, reduced quality, and higher prices.

The production and distribution of vaccines would be best left to the free market. However, like any drug, vaccines are capable of causing serious problems, even death. Moreover, in the case of the smallpox vaccine, manufacturers know that side effects are significant enough to entail substantial liability risks. Even a handful of harmful side effects could trigger lawsuits that could lead to millions of dollars in awards to plaintiffs. The specter of liability claims clearly dampens the incentives of manufacturers to produce new doses of the vaccine.

Vaccines are typically given to very large numbers of healthy people. When an otherwise healthy person develops a new medical problem after immunization, observers are likely to speculate that the vaccine, not a random distribution of illness, caused the problem. For example, a lot of attention has recently been devoted to side effects, safety, and the potential relationship between various diseases and several vaccines.[58] Even though the vast majority of reports linking vaccines with various diseases have never successfully established clear causality, potential litigation risks reduce the incentive for pharmaceutical companies to produce vaccines in general and the smallpox vaccine in particular.

Indeed, accelerated vaccine production in the context of threats of bioterrorism might in itself increase the risk of manufacturers being sued for later health problems claimed to be the result of the vaccine. People are more likely to assume that vaccines to deal with the effects of biological weapons will undergo a shortened testing regimen and be rushed to market and that the manufacturers will rely on animal rather than human tests for efficacy. As a consequence, those vaccines and their manufacturers might arouse greater suspicion about their role in any unusual or unfortunate incidents—even if the vaccines themselves are as safe as more traditional vaccines.

Furthermore, smallpox and other vaccines brought to market specifically in response to the threat of bioterrorism might be more likely to be dispensed through mass distribution than in physicians' offices in case of an outbreak. Such distribution would cut off a strong legal defense for vaccine manufacturers—that the vaccine was dispensed only after a full warning from a physician and the patient's informed consent. That would increase the risk that drug firms would be sued for side effects suspected to be associated with the vaccine, which could decrease those firms' incentive to produce vaccines needed to counter the effects of bioterrorism.

Particularly in the case of a claim for personal injury attributed to smallpox vaccination, a jury might take a different ex post view of acceptable risks. The smallpox vaccine used to be distributed when smallpox was a prevalent threat. But today's jury members live in a post-smallpox-eradication world. Their evaluation of the risk of getting smallpox and the need to be inoculated with the vaccine is different than it might have been decades ago. If smallpox vaccine is distributed as a precaution against the effects of potential, but perceived as unlikely, terrorist attacks and no actual smallpox threat appears, side effects and deaths could be viewed even more negatively.

Dealing with Liability: Possible Remedies

Federal assurances about liability risks for vaccines are neither foolproof nor airtight. During the outbreak of swine flu in 1976, for example, a flu vaccine was developed and used under government pressure. Even though the dangers of the vaccine were minimal, manufacturers developed the vaccine purely as a public service only after the federal government finally agreed to assume all responsibili-

Making the vaccine available to the public as soon as possible would allow time for Americans to decide what is best in each of their particular cases.

A partially vaccinated population creates uncertainty about the prospects for an attack's achieving the desired results of widespread panic, infection, and death.

ty.[59] A substantial round of litigation against the federal government itself followed, albeit with lower net claims payments than might have been the case in traditional litigation against a pharmaceutical manufacturer.

The swine flu experience led in part to a new legislative approach to vaccine liability concerns—setting up a federal compensation fund as the primary remedy for people claiming injuries related to vaccines. In 1986 Congress enacted the National Childhood Vaccine Injury Act, which established the National Vaccine Injury Compensation Program.[60] Its objective was to compensate individuals (or their families) who have been injured by childhood vaccines (whether administered in the private or public sector). The VICP represents the most likely type of model for a federal assumption of future smallpox vaccine liability risks.

From its inception, the VICP covered all vaccines recommended for childhood use (DPT, measles, mumps, rubella, polio, hepatitis B, rotavirus, varicella, *haemophilus influenza* type B, pneumococcal conjugate). All future vaccines recommended by the CDC for routine administration to children are automatically added to the list covered by the VICP. Other children's vaccines may be added, through federal rulemaking, on the basis of the recommendations of a private-sector pediatric advisory group.

The VICP handles all initial claims made for compensation due to any injury or death thought to be the result of a covered vaccine. Claims payments for vaccines administered after October 1, 1988, are funded from an excise tax on every dose of covered vaccine purchased (congressional appropriations were approved to cover claims for vaccines administered prior to that time).

A plaintiff must satisfy three conditions to qualify for compensation. First, the plaintiff must demonstrate that an injury on the Vaccine Injury Table[61] (which lists specific injuries or conditions and time frames) occurred. Second, a claimant must prove that the inoculation of the vaccine is what caused the condition. Third, a plaintiff with a preexisting condition must prove that the vaccine significantly aggravated it.

The National Childhood Vaccine Injury Act also placed caps on the amount that can be awarded to a plaintiff. The current award for death due to covered vaccines is limited to $250,000 plus attorney's fees and costs. Awards for injury, which are not capped and claims for which must meet certain standards of proof, have averaged $824,463.

Vaccine injury claims involving covered vaccines must be filed with the VICP before any civil tort litigation can be pursued. If the petitioner accepts a VICP award, no other tort claim may subsequently be brought in the legal system. Nevertheless, there are conditions under which a vaccine administrator or manufacturer can still be sued. For example, if the original VICP petition is judged noncompensable or dismissed, if the award granted by the VICP is otherwise rejected by the petitioner, or if the vaccine is not covered under the VICP, a party can bring a lawsuit in regular courts.

On balance, the VICP awards and litigation limits have curtailed lawsuits and damage payments. However, legal efforts continue to get around the VICP limits. Both the average size of injury awards and the scope of injuries listed in the Covered Injury Table remain subject to expansionary pressure.

Adapting the VICP model to cover everyone who receives smallpox vaccine would require new legislation, ideally with fewer loopholes and more sustainable damage caps. Whether an exclusive federal remedy can hold the line on damage costs over time remains to be seen. Perhaps an expedient and partial fix would be to add smallpox vaccination for children to the VICP list as an interim measure until a better way to provide vaccine makers sufficiently reasonable indemnification or other legal insulation from open-ended liability can be found.

Two other options might reduce the liability of pharmaceutical companies and provide an incentive to produce vaccines against the effects of biological weapons in general and smallpox in particular:

- A special liability regime for vaccines to counter the effects of bioterrorism could be created. That regime would include specific legal defenses (for example, federal regulatory approval as an absolute defense, findings of negligence instead of strict liability, strengthened enforcement of contractual waivers and assumptions of risk, and fixed damage caps or damages as multiples of economic losses and medical costs).[62] A prohibition on punitive damages would also reduce the open-ended liability risk otherwise faced by vaccine makers.
- A less attractive approach would be to have federal taxpayers assume the full liability costs of smallpox vaccine–related injuries. Although one might assert that protecting against threats of bioterrorism is part of the price tag for defending all Americans, this remedy (especially if it is a one-size-fits-all approach that provides a fixed award regardless of the severity of the injury) is likely to erode manufacturers' incentives to produce safer vaccines of consistent quality, stimulate interest group pressure to increase the funds available for federal damage awards, and ignore the important role of personal calculations of risk tradeoffs.

In the end—because of the potential catastrophic consequences of a bioterrorist attack (in particular, one using smallpox)—a more limited assumption of liability by taxpayers may be necessary for particular vaccines that must be pushed rapidly to market without undergoing more established testing regimes. But it should be understood that this is an extraordinary measure taken in response to a serious national security threat and that it is needed to ensure that an adequate supply of vaccine is produced in the shortest time possible. Politicians might resist setting reasonable limits on claims against private drug makers. However, if their own budget resources are placed at risk, they will be much more prone to place necessary ceilings on the scope and scale of vaccine-related litigation. A sunset provision for damage caps may also be appropriate.

Conclusion

Judging from the September 11 attacks, the threat of direct terrorist attack against the United States is real. And the subsequent anthrax cases point to the possibility of a future bioterrorist attack, possibly using the deadly smallpox virus. The nature of terrorism is such that it is impossible to accurately predict the probability of such an attack, but the potential consequences are catastrophic. Therefore, it is a serious threat that deserves serious attention.

The current ring containment strategy favored by the federal government means responding only after the fact if the smallpox virus is used by terrorists; ring containment does not provide any protection against the attack. That public health approach may be appropriate for dealing with a natural outbreak of smallpox, but it is likely to be woefully inadequate for countering a direct attack by a thinking enemy intent on inflicting infection, death, and panic. Furthermore, stockpiling the smallpox vaccine to be used only in the event of an attack means that the fate of the population will be totally in the hands of public health authorities who will decide who, where, and when individuals should be vaccinated. But as the Dark Winter exercise clearly demonstrated, if we wait for the government to respond after an attack, it may be too late.

A better approach than leaving the entire population at risk and responding only in the event of an actual smallpox attack would be to take preventive measures. The current smallpox vaccine stockpile can be effectively diluted to create a more abundant supply. That supply, the newly discovered Aventis vaccine, and the additional vaccine ordered by the federal government and scheduled to be delivered by the end of 2002 should be made available to the public so that individu-

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als—preferably in consultation with their doctors—can make informed decisions about whether to vaccinate themselves or their family members. Even if only a small fraction of the population were vaccinated, there would be a community immunity effect that would lower the rate of transmission of the disease and significantly increase the chances of success of a ring containing strategy. As a result, the chances of a successful attack would be lowered; that could have a deterrent effect and might even prevent such an attack.

If the paramount obligation of the federal government is to protect the United States and its population, then an ounce of prevention in the form of a population partially vaccinated against smallpox will be more effective—both in deterring and in responding to an attack—than would be leaving the American public unprotected and completely at risk, in hopes that a pound of cure will work after the fact.

Notes

1. Hamid Mir, "Osama Claims He Has Nukes: If US Uses N-Arms It Will Get Same Response," *Dawn*, November 10, 2001, www.dawn.com/ 2001/11/10/ top1.htm.

2. U.S. Department of State, "Fact Sheet: The Charges against International Terrorist Osama bin Laden," December 15, 1999, www.usinfo. state.gov/topical/pol/terror/99129502.htm.

3. Quoted in "Inside the Hunt for Osama," *Time*, December 21, 1998.

4. Michael Dobbs and Peter Behr, "Analysts Debate Next Weapon in Al Qaeda Arsenal," *Washington Post*, November 16, 2001, p. A18.

5. "Evidence Suggests al Qaeda Pursuit of Chemical, Biological Weapons," CNN, November 14, 2001, www.cnn.com/2001/WORLD/asiapcf/central/11/ 14/ chemical.bio.

6. Ibid.

7. "U.S. extends Ban on Crop-Dusters," CNN, September 24, 2001, www.cnn.com/2001/US/09/ 24/inv.cropdusting.ban/index.html.

8. The atomic bomb dropped on Hiroshima, Japan, on August 6, 1945, was a 15-kiloton weapon. It is estimated that the bomb blast traveled about 3.2 kilometers, the thermal rays about 3.5 kilometers, and radiation about 2 kilometers from ground zero (hypocenter), resulting in 114,000 dead and 30,000 seriously injured. "Introduction: About the A-Bomb," A-Bomb WWW Museum, www.csi.ad.jp/ ABOMB/data. html.

9. Kyle B. Olson, "Aum Shinrikyo: Once and Future Threat?" *Emerging Infectious Diseases* 5, no. 4, (July–August 1999), www.cdc.gov/ncidod/EID/ vol5no4/olson.htm.

10. Tim Ballard et al., "Chronology of Aum Shinrikyo's CBW Activities," Monterey Institute of International Studies, Center for Nonproliferation Studies, March 13, 2001, www.cns.miis. edu/pubs/reports/pdfs/aum_chrn.pdf.

11. Barbara Slavin, "Biochemical Weapons: Poor Man's Nukes," *USA Today*, November 26, 1997, p. 4.

12. D. A. Henderson, "Bioterrorism as a Public Health Threat," *Emerging Infectious Diseases* 4, no. 3 (July–September 1998), www.cdc.gov/ncidod/ EID/vol4no3/hendrsn.htm.

13. "Influenza 1918: Program Description," Public Broadcasting System, www.pbs.org/wgbh/ amex/influenza/filmmore/description.html.

14. Chemical and Biological Arms Control Institute, *Bioterrorism in the United States: Threat, Preparedness, and Response*, November 2000, p. 5.

15. Milton Leitenberg, "An Assessment of the Biological Weapons Threat to the United States," White Paper prepared for Conference on the Emerging Threats Assessment: Biological Terrorism, Dartmouth College, Institute for Security Technology Studies, July 7–9, 2000, www.homelanddefense.org/journal/Articles/ Leitenberg.htm.

16. Ibid. Emphasis added.

17. Randall J. Larsen and Ruth A. David, "Homeland Defense: Assumptions First, Strategy Second," October 2000, www.homelanddefense. org/journal/Articles/article1.htm.

18. Ibid.

19. It would be more difficult for a terrorist group to weaponize the virus itself. Although acquisition of the smallpox virus by a terrorist group would certainly be a concern, even more dangerous would be procurement of weaponized smallpox.

20. This concern is further highlighted by the fact that the National Intelligence Council concluded

that "weapons-grade and weapons-usable nuclear materials have been stolen from some Russian institutes." Maxim Kniazkov, "US Certifies Theft of Russian Nuclear Material Has Occurred," *SpaceDaily*, February 23, 2002, www.spacer.com/news/nuclear-blackmarket-02a.html.

21. Donald A. Henderson et al., "Smallpox as a Biological Weapon," *Journal of the American Medical Association*, June 9, 1999, p. 2127.

22. "Bioterrorism Agent Fact Sheet: Smallpox/Variola Virus," St. Louis University School of Public Health, March 2001, www.bioterrorism.slu.edu.

23. Ibid.

24. Ibid.

25. Henderson et al.

26. "A Bioterror Nightmare: Smallpox Is a Terrifying Disease, But There Is a Vaccine," abcNEWS.com, October 19, 2001, www.abcnews.go./sections/primetime/DailyNews/smallpox_011018.html.

27. For more information (including background information, participant list, exercise briefing, and lessons learned) on Dark Winter, see Johns Hopkins University, Center for Civilian Biodefense Strategies, "Dark Winter: A Bioterrorism Exercise," www.hop kins-biodefense.org/darkwinter.html.

28. "Although transmission typically occurs in 3–4 susceptible contacts per case, 20 or more secondary cases may arise from each primary case." "Bioterrorism Agent Fact Sheet: Smallpox/Variola Virus." Henderson et al., p. 2128, note that "during the 1960s and 1970s in Europe, when smallpox was imported during the December to April period of high transmission, as many as 10 to 20 second-generation cases were often infected from a single case."

29. HHS News, www.hhs.gov/news/press/2001pres/20011017.html.

30. Office of Management and Budget, www.whitehouse.gov/news/releases/2002/02/20020205-4.html.

31. Office of Management and Budget, www.whitehouse. gov/omb/budget/fy2003/budget.html.

32. Donald A Henderson, "Effective Responses to the Threat of Bioterrorism," Testimony before the Senate Health, Education, Labor and Pensions Committee, October 9, 2001, labor.senate.gov/Hearings-2001/oct2001/100901wt/ 100901wt.htm.

33. "Public Health Experts Urge Lawmakers to Act at Bioterrorism Hearing," *Daily Health Policy Report*, October 10, 2001.

34. The smallpox vaccine will be produced by a joint venture of Acambis and Baxter International.

35. Ceci Connolly, "Aventis to Donate Smallpox Vaccine," *Washington Post*, March 30, 2002, p. A2.

36. Sharon E. Frey et al., "Clinical Responses to Undiluted and Diluted Smallpox Vaccine," *New England Journal of Medicine* 346, no. 17 (April 25, 2002): 1265–74.

37. Centers for Diseases Control, "Interim Smallpox Outbreak Response Plan and Guidelines," January 23, 2002, www.bt.cdc.gov/DocumentsApp/Smallpox/RP6/index.asp.

38. Steve Black, "Vaccine Has Small but Significant Risks," Commentary, Special to ABCNEWS.com, December 4, 2001, www.vaccinationnews.com/DailyNews/December2001/SmallpoxSense.htm.

39. Ibid.

40. Paul E. Ewald, "A Risky Policy on Smallpox Vaccinations," AEI-Brookings Joint Center for Regulatory Studies, *Policy Matters*, January 2002, p. 2. See also Jonathan Rauch, "Countering the Smallpox Threat," *Atlantic Monthly*, December 2001, www.theatlantic.com/issues/2001/12/rauch.htm.

41. According to an Associated Press poll on November 19, 2001, half of the people polled said the way U.S. authorities handled the anthrax cases had not affected their confidence in the government's ability to protect citizens from terrorist attacks. Slightly more than a quarter said that the government's actions had increased their confidence, and about one-fifth said they were less confident. "Smallpox: Americans Want Vaccine," Global Security Newswire, November 19, 2001, www.nti.org/d_newswire/issues/2001/11/19/10s.html.

42. "Two Millenniums of Wars," *Washington Post*, March 13, 1999, p. A13.

43. H. R. Shepherd and Peter J. Hotez, "The First Great Terror of the 21st century," *Sabin Vaccine Report* 3, no. 2 (Winter 2001).

44. Center for Civilian Biodefense Strategies, www.hopkinsbiodefense.org/pages/agents/agentsmallpox.html.

45. R. Gani and S. Leach, "Transmission Potential of Smallpox in Contemporary Populations," *Nature* 414 (2001): 748–51.

46. M. I. Meltzer et al., "Modeling Potential Responses to Smallpox as a Bioterrorist Weapon," *Emerging Infectious Diseases* 7, no. 6 (November–December 2001), www.cdc.gov/ncidod/EID/vol7no6/ meltzer.htm.

47. Ewald, p. 1.

48. Institute for Homeland Security, Dark Winter exercise June 2001, www.homelandsecurity.org/ darkwinter/index.cfm.

49. Lawrence O. Gostin, "The Model State Emergency Health Powers Act," Prepared by the Center for Law and the Public's Health for the Centers for Disease Control and Prevention, in collaboration with National Governors Association, National Conference of State Legislatures, Association of State and Territorial Health Officials, National Association of City and County Health Officers, and National Association of Attorneys General, 2001, www.publichealthlaw.net/MSEHPA/MSEHPA.pdf.

50. Ibid.

51. "Smallpox: Americans Want Vaccine."

52. Quoted in Charles Ornstein and Megan Garvey, "Experts Urge Debate on Voluntary Smallpox Vaccinations," *Los Angeles Times,* March 29, 2002, p. A24.

53. D. R. Smith et al., "The Promise of Vaccines: The Science and the Controversy," American Council on Science and Health, September 2001, p. 7.

54. Centers for Disease Control, National Vaccine Program Office, "Definitions of Terms Related to Immunization," www.cdc.gov/od/nvpo/glossary1.htm.

55. A multiyear trial is currently under way to test the community immunity theory for the spread of influenza among school children. See National Institutes of Health, Institute of Allergy and Infectious Diseases, "NIAID Research Highlights: Vaccine Research," *Focus on the Flu,* updated October 30, 2001, www.niaid.nih.gov/newsroom/ focuson/flu00/vaccrsch.htm.

56. David Ruppe, "U.S. Response I: House Prepares Major Bioterrorism Bill," Global Security Newswire, December 11, 2001, www.nti. org/d_newswire/issues/ 2001/12/11/1s.html.

57. "U.S. Response I: House Approves Funds to Combat Bioterrorism," Global Security Newswire, December 13, 2001, www.nti.org/d_newswire/ issues/2001/ 12/13/1s.html.

58. Smith et al., p. 5.

59. Elissa A. Laitin, and Elise M. Pelletier, "The Influenza A/New Jersey (Swine Flu) Vaccine and Guillain-Barré Syndrome: The Arguments for a Causal Association," 1997, www.hsph.harvard. edu/Organizations/DDIL/swineflu.html.

60. The National Vaccine Injury Compensation Program was established in response to a Supreme Court ruling. "Since *Reyes v. Wyeth* was decided by the Supreme Court in favor of the plaintiff, a child who allegedly contracted poliomyelitis as a result of polio vaccine, more information about vaccines has been made available to parents. In that suit, the vaccine was administered in a public health clinic. The mother testified that she would not have consented to the child's vaccination if she had known that a polio infection might result. The Supreme Court held that in a situation in which no personal physician was present to transmit information, the manufacturer was responsible for directly warning parents about the adverse effects of a vaccine." Vaccine Adverse Event Reporting System, www.paaap.org/immunize/course/vaers.html.

61. National Vaccine Injury Compensation Program, Vaccine Injury Table, www.ccandh.com/ table.htm.

62. Such a federally imposed liability regime is an extraordinary remedy and should not normally be considered a proper solution to runaway litigation. However, in this case, where the national security needs are so pressing, it can probably be imposed without doing violence to the Constitution. Article I, sec. 8, of the Constitution grants the federal government the power to "provide for the common Defense" and to make "all Laws which shall be Necessary and Proper for carrying into Execution" that and other powers. The restrictions on recovery and proposed revisions to common law rights are not dramatic enough to infringe constitutional protections such as the right to trial by jury in federal court guaranteed by the Seventh Amendment and the right to due process of law guaranteed by the Fifth Amendment. See, for example, *Duke Power Co. v. Carolina Envtl. Study Group, Inc.,* 438 U.S. 59, 87–89 (1978).

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