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Who Will Pay for the Adverse Events Resulting from Smallpox Vaccination? Liability and Compensation Issues

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OVERVIEW — *This paper summarizes liability and compensation concerns surrounding the smallpox vaccination program announced by President Bush on December 13, 2002. The paper examines the nature of adverse health events that are likely to occur in connection with the smallpox vaccine, assesses the liability protections that have been established for organizations and individuals participating in the vaccination program, and discusses the compensation mechanisms being considered to address the damages incurred by volunteers who may suffer from adverse vaccine reactions. Specifically, the implications of the Federal Tort Claims Act, workers' compensation programs, and the creation of a new no-fault compensation fund are explored.*

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Among the many significant changes that have evolved since the September 11 and anthrax attacks is the recognition that the United States is vulnerable to once-inconceivable threats, such as bioterrorism. These threats have created a new attitude about preparedness and have focused the attention of not only the public health community but also those involved with homeland security. Smallpox has become a focal point of this attention due to the enormous potential consequences of this disease and the nation's perceived vulnerability to this particular threat.

Concerns over a deliberate release of the smallpox virus were heightened immediately after the September 2001 attacks. One of the first acts of the federal government was to insure the availability of enough smallpox vaccine, should the worst case scenario unfold and the United States fall victim to a smallpox attack. Over time, the plans surrounding smallpox vaccine have been refined. Administration officials have delineated both a "pre-event" plan to vaccinate first responders who would be called on to address a smallpox outbreak and a "post-event" plan for mass vaccinations of the public in the actual event of a smallpox attack.

The president's pre-event plan calls for a three-phase approach. Phase one, already under way, calls for the voluntary inoculation of approximately 500,000 health care workers who would be called upon to vaccinate the public during a national emergency. Phase two calls for the inoculation of up to 10 million additional health care workers and first responders (police, firefighters, and paramedics). Phase three would establish a process that would allow members of the general public (adults without medical contraindications) to receive the vaccine if they insist, although the government does not recommend general vaccination at this time.

The policy and legislative challenges involved with this effort are particularly difficult. The majority of the public is uncomfortable thinking about the potential of smallpox release, and some in the health field are distressed with the political overtones that have entered in to the clinical debate. Still others in the public health field are concerned that the singular focus on smallpox has compromised their ability to provide essential daily services, such as childhood vaccines and screenings for sexually transmitted diseases, while at the same time detracting from broader preparedness-building efforts.

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Overlaying all of these concerns is the notion of perceived risk—how great is the smallpox risk to Americans? On balance, how much risk versus benefit does the vaccine provide? Are today's health providers sufficiently well informed to adequately assess and balance the risks of a smallpox attack against the risks inherent in the smallpox vaccination? What are the legal and ethical ramifications of pre-event vaccination?

While the risk-benefit calculation for all vaccines represents a departure from ordinary medical care in that healthy people are injected with something that may make them sick, the risk profile of the smallpox vaccine is particularly problematic. The smallpox vaccine has a higher percentage of known (and potentially dangerous, even life-threatening) side effects; it has not been given routinely in the United States for the past 30 years; it is administered differently than other vaccines; and, perhaps most confounding, the risks of contracting smallpox are almost impossible to quantify. Adding to the concerns of health providers is the fact that the president's smallpox vaccine plan is unfolding in today's litigious health care environment, one that is teetering on the brink of a liability and malpractice crisis.

In light of the various concerns and challenges, a number of the almost 3,600 hospitals deemed eligible by the Centers for Disease Control and Prevention (CDC) to form smallpox response teams have already declined to participate. By some accounts,¹ close to 350 hospitals across the country are forgoing the vaccinations. Although this reluctance to participate in the smallpox vaccination program stems from a variety of rationales, financial concerns regarding liability exposure and compensation for those who suffer from adverse vaccine reactions have been identified as important impediments to broader participation in the vaccination program.

RISKS ASSOCIATED WITH THE SMALLPOX VACCINE

The smallpox vaccine, called Dryvax, does not contain inactivated or attenuated smallpox virus. Rather it uses an organism called *vaccinia* (a live cowpox virus), which is grown from calf lymph,² resembles smallpox in many ways, and triggers an immune response that offers protection against smallpox. Because it is a live virus, *vaccinia* can cause severe reactions in those vaccinated, particularly for immune-compromised individuals, and can be transmitted from vaccinated persons to others until the injection site scabs over.

Smallpox vaccination poses a number of rare but significant health risks, both for persons who are vaccinated and for those who are exposed to *vaccinia* through secondary transmission. Non-life-threatening side effects of the smallpox vaccine can include local inflammation, rashes, fever, headaches, muscle pain, fatigue and weakness, and nausea. Life-threatening reactions can include encephalitis. Experts have estimated that, out of one million people vaccinated, approximately 1,000 will experience serious, though not life-threatening, reactions; between 14 and 52 out of

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one million vaccinated for the first time will experience potentially life-threatening reactions; and one to two people will die.³ Instances of secondary transmission, or inadvertent inoculation, may occur in 20 to 60 cases for every one million persons vaccinated. At high risk of adverse reactions are pregnant women, young children, immunocompromised patients (that is, those who are undergoing chemotherapy, are HIV-positive, or have received transplants), patients with autoimmune diseases such as lupus or rheumatoid arthritis, as well as those who have or have had eczema or other skin conditions.⁴

Information on the risks of smallpox vaccine is based on historical data gathered when smallpox was an immediate disease threat and vaccinations were routine. The United States stopped routine smallpox vaccination of Americans in 1972.⁵ The last natural case of smallpox was recorded in Somalia in 1977, and in 1980 the disease was declared officially eradicated by the World Health Organization. It has been a long time since the smallpox vaccine has been administered to large numbers of people. In fact, the smallpox vaccine currently available was manufactured in 1975, freeze-dried, and stored in vials.

While the nature of the U.S. population and the proportion of vulnerable persons has changed dramatically since the 1970s, experts believe that by carefully (and confidentially) screening out high-risk volunteer vaccinees, including those who are unaware they may be ill, the number of vaccinees experiencing serious side effects could be dramatically reduced. Similarly, experts have stressed that educating both the vaccinator and the vaccinee in the proper care of the injection site (keeping the site covered until it scabs over to avoid accidental exposure) will result in a decreased incidence level of secondary transmission.

Although a number of steps could be taken to minimize the risks associated with the vaccine, including volunteer education, thorough screening,⁶ and careful implementation, adverse reactions to the vaccine will occur. The establishment of financial protections related to these anticipated adverse events has yet to be completely resolved, leaving many health care workers uneasy. These financial concerns can be divided into the need for broader liability protection and the assurance that compensation for lost workdays and uncovered health costs will be guaranteed, given the potential health risks associated with the smallpox vaccine.

LIABILITY PROTECTION

Over the years, vaccine policy has become ensnared in a tangled legal web. While many herald vaccines as public health miracles that contribute to the public good, others question their safety and wonder about potential links to disease. Vaccine injury and the right to sue for vaccine-related injuries have been hotly debated issues recently, particularly in regard to some childhood vaccines.

With these liability concerns as a backdrop, the drafters of the Homeland Security Act of 2002 sought to address (through Section 304 of the act) the issue of liability protection as it pertains to the smallpox vaccine. While on the one hand, some consumer advocates are concerned that Section 304 has limited patients' rights to sue, on the other, health care providers, both individuals and organizations, are concerned whether the scope of protection for health care workers is sufficiently broad.

Section 304 of the Homeland Security Act deems those entities and individuals involved in the manufacture, distribution, and administration of the smallpox vaccine as employees of the Public Health Service for tort liability purposes. Specifically, Section 304 defines covered persons or covered entities as the following:

- Manufacturers and distributors of a smallpox vaccine (referred to as a countermeasure).
- Health care entities (for example, hospitals and clinics) under whose auspices a smallpox vaccine is administered.
- Licensed health professionals or other individuals who are authorized to administer the vaccine under state law.

By deeming these covered persons or entities as employees of the federal government, the Homeland Security Act effectively transfers liability from these private-sector parties to the federal government under the auspices of the Federal Tort Claims Act (FTCA). Individuals seeking redress for harm caused by the smallpox vaccine are limited to the remedies available under the FTCA.

To place the smallpox liability issue in greater context, it is helpful to be familiar with the conceptual underpinnings of the FTCA.⁷ Historically, the notion that the U.S. government should be immune from suit was rooted in American law and is believed to have derived from English law and the theory that the king could do no wrong. "Sovereign immunity," as the theory is known, has come to rest on the rationale that the "sovereign is exempt from suit [on the] practical ground that there can be no legal right against the authority that makes the law on which the right depends."⁸ As the role of the U.S. government evolved and more uncompensated losses were seen, Congress enacted the Federal Tort Claims Act in 1946.

Though limited in nature, the FTCA provides a waiver of the federal government's sovereign immunity. The law allows individuals to recover from the U.S. government for property damage, personal injury, and wrongful death caused by the negligence of a federal employee acting within the scope of employment. Under the FTCA, the United States is liable for the acts of its employees "in the same manner and to the same extent as a private individual under similar circumstances."⁹ In essence, this means that if a private individual would be liable, the government is liable. The United States cannot be sued for acts that are strictly governmental and incapable of being performed by an individual.

The Homeland Security Act effectively transfers liability to the federal government.

Among many other limitations to the act, the government is not liable for most intentional acts of its employees, including assault and battery, and the FTCA bars courts from awarding punitive damages against the government. The law that governs FTCA cases is the law of the states in which the negligent acts occurred, including any limitations on damages. Defendants being sued under FTCA are represented in court by the Department of Justice, which bears the costs of these proceedings.

The concept of negligence is important as it relates to FTCA generally and the smallpox question specifically. For example, although individuals and organizations are generally shielded from liability related to the smallpox vaccine, Section 304 provides for the federal government to seek to recover any damages it pays to a third party injured by the smallpox vaccine if the covered entity engaged in any acts that constitute *gross negligence* (“recklessness or willful disregard for the safety of others”), recklessness, illegal conduct, or willful misconduct. Examples could include negligent manufacturing of the vaccine, negligent screening, negligent injection, and a failure to warn those being injected about the possible adverse effects of the vaccine. But, it is not yet clear what standard will be applied in determining whether someone has engaged in “grossly negligent, reckless, or illegal conduct or willful misconduct.”

Potential Liability Gaps under Section 304

While Section 304 provided important liability protections, gaps still remain. There appear to be classes of sponsoring organizations that may not qualify for liability protection under the Homeland Security Act. Critics generally point to two important omissions: (a) hospitals or other health care organizations that ask their employees to volunteer for the vaccine but are not directly responsible for administering the vaccine and (b) health care workers who are vaccinated and may inadvertently pass the *vaccinia* virus to an unvaccinated person.

The American College of Emergency Physicians, for example, is concerned that, even though its members will be on the front line of this effort, they may not be covered under the current Section 304 provision. Because many emergency physicians will be inoculated but may not have vaccinated others (that is, they have not administered the countermeasure), they do not fall within the liability protections stipulated under Section 304. They are not currently considered “covered entities” or agents of a covered entity. These providers, who could transmit the *vaccinia* virus to others who could experience serious complications, might be held liable for these injuries.

Although the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ) have issued guidance documents which suggest that Section 304 would be interpreted to include vaccinated health workers, given that they would be acting within the scope of employment defined by covered entities identified in the act, many provider

groups remain uncertain. Among the questions that health providers are asking are the following:

- How long after health care workers are inoculated are they protected under Section 304?
- How is the “scope of employment” defined? In other words, if a newly inoculated health care worker finishes a shift at the health care facility and takes the subway home, during which time he or she inadvertently spreads infection to another rider, is he or she protected under Section 304?
- Because of staff shortages, many hospitals rely on “registries” to find temporary staff or have a variety of contractual relationships with groups of nurses and physicians. Will contracted or temporary employees be covered under Section 304?

These lingering unanswered questions, the moving target nature of the program, and the lack of the full force of legislation or regulatory change have left many on the front lines of health care jittery. These and other similar questions are breaking new ground and are open to interpretation in the courts. This ambiguity is unsettling for many health care workers who are calling for more definitive statutory language regarding broader liability protections.

COMPENSATION QUESTIONS

While Section 304 provides liability protection to institutions involved in the smallpox vaccine program, it does not establish a clear avenue of compensation for individuals who incur injuries caused by administration of a smallpox countermeasure (that is, the vaccine). The risks associated with the vaccine range from relatively minor events (for example, health care workers missing several days of work due to vaccine reactions) to severe disability or death. In addition to the small number of serious adverse reactions anticipated, the CDC predicts that about 30 percent of those receiving the smallpox vaccine will be unable to work for a period of time due to minor reactions. These risks, both minor and life-threatening, are present even when the vaccine is administered exactly according to prescribed protocols. Therefore in many (if not most) cases of adverse reaction to the vaccine, provider negligence will not be a factor and redress under the Federal Tort Claims Act will not be feasible.

Critics have argued that it is not fair to expect health care workers to assume the risks associated with the vaccine without providing some form of compensation to those who will suffer bad outcomes. Some observers have attributed providers’ unwillingness to participate in the program to the lack of adequate compensation mechanisms. Providers’ decisions about whether or not to participate in the vaccination program are clearly not limited to a simple financial calculation and involve a more complex assessment of perceived risks, benefits, and responsibilities. However, legitimate concerns regarding compensation are an important component

Section 304 does not establish a clear avenue of compensation.

of this decision making process, and the compensation mechanisms currently being considered are receiving close scrutiny.

Workers' Compensation

Workers' compensation programs are often cited as an expected source of compensation for health care providers who suffer adverse effects caused by the smallpox vaccine. Workers' compensation programs, the first form of social insurance in the United States, provide benefits to workers who are injured on the job or who contract a work-related illness. These benefits include cash payments designed to partially replace lost wages for time spent away from work, reimbursement for medical care associated with the work-related illness or injury, and survivor benefits (in cases of fatality) to partially restore the lost wages of a deceased wage earner.

Workers' compensation programs are designed and administered by the states and vary significantly across states in terms of eligibility, benefits, and other program design features. Although structured by state statute, workers' compensation programs are financed almost exclusively by employers. Every state, except Texas, mandates participation in workers' compensation insurance for most employers.

While the vast majority of U.S. workers have worker's compensation benefits through the state programs, not all workers are covered in this manner.¹⁰ Employees of some units of state and local governments, such as police and firefighters, are typically exempt from workers' compensation and receive benefits through separate programs. Civilian employees of the federal government receive workers' compensation benefits through the Federal Employees Compensation Act, and U.S. military personnel are covered by federal veterans compensation programs. A small proportion of workers, such as the self-employed, certain types of agricultural workers, and U.S. Merchant Marines, do not have workers' compensation benefits.

Private insurance carriers remain the primary provider of workers' compensation benefits. Exclusive state funds or self-insurance mechanisms are also used by some states. Employers' premiums are based on their industry classification and the occupational classifications of their workers. Most large employers are also experience-rated, which results in higher premiums for employers whose past experience demonstrates that their workers are at greater risk of occupational injuries or disease than other workers in the same industry.

Questions have been raised by health care workers' unions and others regarding the adequacy of workers' compensation programs for the purposes of compensating individuals injured as a result of participation in the smallpox vaccine program. A joint workgroup of the Association of State and Territorial Health Officials and National Association of

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City and County Health Officials examined this concern and identified the following issues:¹¹

■ ***Persons infected with vaccinia through secondary transmission from vaccinated persons are not likely to be protected under workers' compensation programs.*** Experts believe that most cases of secondary transmission will occur in individuals who have very close personal contact with vaccinated persons, such as family members and, potentially, patients. If such individuals were to contract *vaccinia* from a vaccinated person, it is highly unlikely that the victims of secondary transmission would be exposed in a context related to their work. Therefore, workers' compensation would likely provide little, if any, financial protection to victims of secondary transmission.

■ ***The "voluntary" nature of the smallpox vaccine may preclude compensation under workers' compensation programs.*** Each state program has its own rules for determining if an illness can be considered work-related and thus compensable under its workers' compensation program. Given the voluntary nature of the smallpox vaccine, some observers have questioned if adverse events resulting from the vaccine would be covered. If not *required* for employment, would the vaccine be considered outside the scope of employment responsibilities and thus not work-related? Because there is no contemporary experience with the smallpox vaccination program, it is difficult to conclusively ascertain how each state would determine eligibility under these circumstances.

■ ***Not all providers participating in the vaccine program will be eligible for workers' compensation protection.*** States generally exempt from workers' compensation programs certain categories of workers, such as those employed in very small firms (for example, firms with fewer than four employees). Neither are self-employed persons covered by workers' compensation programs. A significant proportion of the workers who might be candidates for vaccination (for example, emergency room physicians and nurses) may not be employees of the hospitals in which they work but may be working as contracted labor. If these employees are independent contractors, they will not likely be eligible for workers' compensation benefits.

■ ***Most states impose waiting periods for wage replacement payments that make workers' compensation programs unsuitable coverage for very short-term, temporary disability.*** All states have imposed waiting periods during which disabled workers are ineligible for cash benefits to replace lost wages. These waiting periods range from three to seven days. Given that the vast majority of vaccine-related adverse events are likely to be minor, resulting in only a few days of missed work, workers' compensation programs will not compensate for the lost wages associated with these absences. Health care providers would typically need to use their annual or sick leave benefits, if available, to cover this time off the job.

■ *Wage replacement levels are limited, particularly for high-wage earners.* In instances of more severe disability or death resulting from the vaccine, compensation levels are limited, particularly for high-wage earners. Workers' compensation benefits only cover a fraction of the worker's pre-injury wage (for example, two-thirds of weekly salary) and states have generally instituted weekly benefit limits or caps. While it is difficult to determine "average" benefits in light of the diversity of state programs and specific benefit rules, an illustrative example helps to clarify the coverage limits.¹² In the District of Columbia, the family (a spouse and two children) of a deceased health care worker earning \$90,000 annually would be eligible for survivor benefits of \$49,296 each year under workers' compensation, only 55 percent of the deceased workers' annual salary. Many other states, including both Maryland and Virginia, would offer even less generous benefits, 39 percent and 35 percent of pre-injury salary, respectively. Furthermore, most states do not adjust benefit amounts annually to keep pace with inflation. While cases of severe disability or death are projected to be extremely rare, concerns over these risks, compounded by the financial insecurity that could ensue, may dampen volunteerism.

■ *Costs for adverse events are likely to be borne by employers.* Employers, such as hospitals and other health care entities, are concerned that the smallpox vaccine program will increase their workers' compensation expenses (that is, premiums). If their workers file claims due to injuries sustained from the smallpox vaccine, these costs will be reflected in the employers' experience-rated workers' compensation insurance premiums in the future. In addition to bearing the costs of workers' compensation payments, employers will also have to pay for replacement workers to cover the duties of those who may miss work due to adverse vaccine reactions. Although the magnitude of these costs are difficult to quantify until more people are vaccinated, some experts maintain that adverse events due to the vaccine are likely to be rare and should not have a significant impact on the cost of workers' compensation insurance or staffing expenses. While costs may not be high on average, the costs for any one employer relative to its current experience could be significant, particularly if that employer utilizes a high deductible policy. Others argue that *any* cost burden on employers will limit willingness to participate in this voluntary smallpox vaccination program.

■ *Uncertainty exists whether federal or state workers' compensation programs would be invoked.* Further complicating matters are questions related to *which* workers' compensation program would be responsible for payment. Section 304 of the Homeland Security Act deems covered entities as employees of the Public Health Service, and this "covered entities" language has been interpreted by DHHS to include those being vaccinated. Therefore, federal, rather than state, workers' compensation rules and benefits could apply.

Concerns over these risks and financial insecurity may dampen volunteerism.

These and other emerging issues raise questions regarding the sufficiency of workers' compensation programs for providing compensation to those injured from the smallpox vaccine, particularly if the goal is to encourage participation in the voluntary program.

Other Potential Sources of Compensation

In addition to workers' compensation, other potential immediate sources of financial assistance could come from private disability insurance policies, private health care policies (some have expressed concern over the 40 million uninsured Americans who do not have health insurance), and ultimately Social Security disability benefits, Medicare, and life insurance policies. All of these avenues of redress would be breaking new ground within the smallpox vaccine scenario and it is not clear how well these compensation mechanisms would work.

The American College of Emergency Physicians (ACEP) expressed concern over these various short-term financial assistance options in a January 8, 2003, letter to the secretary of DHHS:

ACEP believes that each of these potential sources of near-term financial support has serious shortcomings. For example, although financial support from private disability insurance policies ultimately will depend on how the particular policy is written, the fact that a health care professional underwent vaccination voluntarily and with notice of the potential for adverse consequences could undercut a claim for benefits under such a policy. Similar problems arise for their health care and life insurance policies. Finally, there are substantial delays in the Social Security disability determination process, and individuals who qualify for such benefits must wait two years before becoming eligible for Medicare.

These concerns echo some of the limitations cited with respect to workers' compensation and cast further doubt on the sufficiency of existing mechanisms to compensate those who suffer from adverse outcomes related to the smallpox vaccine.

Smallpox Vaccine Compensation Fund

Given the limitations of workers' compensation and other insurance options, many stakeholders, including some state officials, public health officers, physician groups (such as ACEP), and some of the largest health care worker unions, have called for the creation of a no-fault, federally financed smallpox vaccine injury compensation fund to insure adequate financial recompense. Rep. Henry Waxman (D-Calif.) has introduced a bill (H.R. 865) to establish such a fund, and the administration has issued its own compensation proposal modeled after the benefits provided to police and firefighters who die or are disabled in the line of duty. While congressional leaders from both parties have signaled their support to address the issue, the specific design of a smallpox compensation mechanism is currently being debated.

Proponents of a new vaccine injury compensation fund point to the current National Vaccine Injury Compensation Program (VICP),¹³ which Congress passed as part of the 1986 National Childhood Vaccine Injury Act, as a potential model for smallpox. The VICP represents a novel approach for compensating people who suffered a vaccine-related injury. Rather than suing the vaccine manufacturer and vaccine administrators, those who believe they were injured (or that their child or children were injured) file a claim under the program.

Individuals can qualify for compensation in one of three ways: (a) a petitioner must demonstrate that an injury listed on the VICP Vaccine Injury Table occurred, (b) a petitioner must prove that the vaccine significantly aggravated a pre-existing condition, or (c) the petitioner must prove the vaccine caused the condition. The table lists specific injuries or conditions and the time frames in which they must occur following the administration of vaccine. The table identifies those conditions that are *presumed* to be caused by the vaccine. Individuals with listed conditions must demonstrate only that they have the injury or condition identified to receive compensation. Individuals with conditions *not* listed in the table must prove a causative relationship between their condition and the vaccine, a much more difficult standard to meet.

The VICP, which is administered jointly by DHHS, DOJ, and the U.S. Court of Federal Claims, pays claims from a trust fund financed by an excise tax on vaccines.¹⁴ A DHHS physician reviews each claim to determine whether it meets the medical criteria for compensation. The DHHS position is presented by an attorney from DOJ in hearings before a “special master,” appointed by the federal claims court, who makes the decision for compensation under the VICP. Decisions may be appealed to the federal claims court and to higher courts.

If a case is found eligible for compensation, the amount of award is usually negotiated between DOJ and the petitioner’s attorneys. If these parties can not agree the case is heard by the special master to assess the amount of compensation. A petitioner may file a claim in civil court against the vaccine manufacturer or administrator only after first filing a claim under VICP and rejecting the decision of the federal claims court.

Although there has been some discussion as to whether smallpox should be added to the existing VICP, several arguments have been made that do not support this approach. Some argue, for example, that it would be difficult to add smallpox to the existing VICP because it was designed for children who generally are not awarded damages for lost wages. Additionally, supporters of the VICP are concerned that adding smallpox to the current fund would divert money away from the children. Another significant difference that could make merging smallpox into the VICP difficult lies in the financing—whereas the VICP is financed by an excise tax on each dose of vaccine covered by the program, that mechanism would not work for the smallpox vaccine because it is federally purchased.

An alternative suggested by various health-related groups is a federally financed smallpox vaccine injury compensation fund.

In designing a smallpox-specific vaccine injury compensation fund, policymakers may need to consider a variety of factors, including the following:

Eligibility — A key decision must be made regarding who will be eligible to receive compensation. Will compensation be limited to those who volunteer for vaccination, or will it be extended to include victims of secondary transmission? Will members of the general public who seek vaccination under “phase three” of the program, despite federal recommendations against mass vaccination, be excluded? In the rare cases of fatality, who will be eligible for survivor benefits? Will employers, insurers, or other third parties who incur costs due to vaccine injuries be permitted to seek compensation from the federal fund?

Relationship to Existing Compensation Mechanisms — Another important consideration will be determining how the federal compensation fund will function relative to other compensation mechanisms. To what extent will claimants be allowed, required, and/or precluded from seeking recompense from alternative payers, such as workers’ compensation programs and health insurers? The federal compensation fund could be reviewed as a “last resort” for individuals unable to receive compensation through other avenues, or it could be constructed as a sole remedy. To what extent will claimants be allowed to pursue civil action under the Federal Tort Claims Act, as provided for under Section 304 of the Homeland Security Act?

Generosity of Benefits — The level of compensation that will be forthcoming from the fund will be an important factor for providers as they make decisions about whether or not to volunteer for the vaccine. The existing VICP relies on negotiated settlements that are based in part on past awards under similar circumstances. Such historical conventions do not exist for the smallpox vaccine, making potential payment awards ambiguous. The existing VICP establishes a \$250,000 limit on pain and suffering awards, again based on assumptions regarding the types of injuries commonly sustained. Injuries resulting from the smallpox vaccine would likely differ in type and severity. Would the new fund utilize the existing limit, set an alternative cap, leave pain and suffering award determinations entirely to the federal claims court, or limit payment to “pure” compensation for lost wages? The existing VICP also sets a \$250,000 limit on awards to victim’s estates in the event of a vaccine-related death. Given that the existing program is designed primarily to compensate victims of injuries incurred from childhood vaccines, such limits may not be appropriate for the adults likely to be injured from the smallpox vaccine.

Administrative Processes — The design of the compensation program will have to address a broad range of administrative processes dictating how claimants can request compensation and how the fund will

How will smallpox compensation function relative to other mechanisms?

operate. While many of these administrative details will be left to rule-making, some parameters of the programs will likely be addressed in statute. These program features are likely to include the conditions and onset time frames to be presented in the Vaccine Injury Table that will identify those injuries that will be presumed to be caused by the vaccine, as well as time limits for filing a claim. In determining which administrative details to include in authorizing legislation, policymakers will likely consider issues which have been raised in criticism of the existing VICP. Although the original vaccine injury fund was established to provide compensation "quickly, easily, with certainty and generosity,"¹⁵ there has been concern over how well the VICP program has met these goals. The U.S. General Accounting Office was asked by Sen. James M. Jeffords (I-Vt.), then chairman of the Committee on Health, Education, Labor and Pensions, to look at this question. The resulting December 1999 report, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily*, found that, while the program provided more expedient settlement than the traditional civil tort system, the claims process had not been as quick as expected, with only 14 percent of claims settled in one year or less.¹⁶ Some administrative procedures may be delineated in statute to ensure expedient processing of claims.

Efforts to ensure timely and fair compensation for all parties who incur damages due to the smallpox vaccine must be balanced against the government's legitimate needs to protect against fraud and minimize federal expenditures. Policymakers will need to balance these sometimes competing objectives while considering all of the issues discussed above. Furthermore, some forward-thinking debate may ensue regarding the possibility of expanding the scope of the compensation fund beyond smallpox vaccine to include other countermeasures that may be required for other bioterrorism threats.

As the federal government moves forward with the smallpox vaccination program, a variety of challenges are likely to emerge that will require modifications to the initial plan. Because the vaccination program is breaking new ground, unanticipated hurdles almost certainly will be encountered. In addition to the perceived needs for additional liability protections and compensation mechanisms addressed above, policymakers may consider other program changes and enhancements to shorten implementation delays and ensure program effectiveness. The Institute of Medicine Committee on Smallpox Vaccination Program Implementation has identified a number of issues for consideration and has issued recommendations related to the informed consent process, contraindications screening, adverse event monitoring, guidance for the treatment of vaccine complications, professional training, and additional funding for the vaccination program.¹⁷

In light of the perceived urgency of vaccinating emergency responders against smallpox to ensure preparedness against potential terrorist attacks, policymakers are under pressure to quickly adapt the vaccination

Compensation efforts will be balanced against the government's legitimate needs to protect against fraud and minimize expenditures.

program to address the implementation challenges that have, and will continue to, surface. Among these many challenges, concerns related to liability and compensation are currently producing calls for immediate legislative action.

ENDNOTES

1. Donald G. McNeil, Jr., "Many Balking at Vaccination for Smallpox," *New York Times*, February 7, 2003.
2. A new vaccine is being developed by Acambis of Cambridge, Massachusetts, under a government contract. This newer vaccine, which uses genetically uniform *vaccinia* virus, is being grown in tissue cell cultures under laboratory conditions and will be available in 2004.
3. Centers for Disease Control and Prevention (CDC), "Smallpox Fact Sheet: Vaccine Overview"; accessed March 11, 2003, at <http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp>.
4. CDC, "Smallpox Fact Sheet."
5. Committee on Smallpox Vaccination Program Implementation, "Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation: Letter Report #1," Board on Health Promotion and Disease Prevention, Institute of Medicine, Washington, D.C., January 2003, 2; accessed March 12, 2003, at <http://www.nap.edu/books/NI000489/html/>.
6. The flip side of the screening issue, which is of some, albeit lesser, concern, is that too many people will be screened out of the program, thereby weakening its overall success.
7. The author wishes to thank Dawn Gencarelli, J.D., Senior Research Associate with the National Health Policy Forum, for her assistance on the portions of this paper covering the Federal Tort Claims Act.
8. 205 U.S.C. 349, 353.
9. 28 U.S.C. 2674 (1994).
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