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Smallpox Vaccine Injury Compensation

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Susan Thaul
Specialist in Social Legislation
Domestic Social Policy Division

Smallpox Vaccine Injury Compensation

Summary

Four and a half months after announcing his decision to vaccinate military personnel and front-line civilian health workers against smallpox, President George W. Bush, on April 30, 2003, signed the Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20). Under the new law, the federal government will provide — to eligible individuals (or their survivors), for covered injuries — payment for related medical care, lost employment income, and death benefits.

Compensation had emerged as a major obstacle to the successful implementation of the Administration's smallpox vaccination program. Worker groups, public health experts, and others cited the lack of a clear and comprehensive compensation program as a primary reason for the lower than expected volunteer vaccination rate among health care workers.

The enacted legislation is modeled after the Public Safety Officers' Benefits Program. It provides for compensation of individuals injured by vaccinations given as part of a countermeasure plan declared by the Secretary of Health and Human Services in preparation for potential hostile activities involving the smallpox virus.

This report will be updated as warranted.

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Smallpox Vaccine Injury Compensation

Introduction

Four and a half months after announcing his decision to vaccinate military personnel and front-line civilian health workers against smallpox, 3 months after the vaccination program officially began, and 7 weeks after Senator Gregg introduced the administration smallpox vaccine injury compensation proposal, President George W. Bush, on April 30, 2003, signed the Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20).

Compensation had emerged as a major obstacle to the implementation of the Administration's smallpox vaccination program soon after it began. The number of workers volunteering for vaccination was far smaller than the White House had anticipated. One frequently cited reason was the concern of health workers that they would not be compensated if they experienced adverse reactions to the vaccine. Under the Administration's original plan, vaccinees who suffered adverse consequences and sought redress had two options: apply to their state's workers' compensation program or sue the federal government for negligence.

Some Members from across the political spectrum favored responding with legislation. While they differed on what should be in that legislation, there was bipartisan agreement that, given the President's request that health and safety workers volunteer for vaccination, the federal government should guarantee to protect them against the possible adverse effects of smallpox vaccination. Some legislators articulated a two-fold rationale: it is right to protect volunteers and, to recruit those volunteers, it is necessary.

This report first presents the reasons some Members of Congress, health care worker organizations, and others felt legislation was necessary; summarizes the range of approaches that Congress considered; and describes the smallpox vaccine injury compensation provisions Congress actually passed. Finally, it presents issues that Congress might consider if it revisits the new legislation.

Need for Legislation

On December 13, 2002, President Bush announced his decision to vaccinate military personnel and front-line civilian health workers against smallpox. The Department of Defense began the process in early January 2003 and, as of March 31,

2003, has vaccinated over 350,000 military personnel.¹ The civilian program, which is voluntary in contrast to the military program, did not begin until January 24, 2003, to coincide with the start of liability protections provided by Congress in the Homeland Security Act of 2002 (P.L. 107-296) to smallpox vaccine manufacturers and the institutions and individuals who administer the vaccine. The President had hoped to vaccinate 500,000 civilians, but, by June 6, 2003, only 37,478 civilians had been immunized.²

To explain the reluctance of many health workers to volunteer to be vaccinated, many, including Senator Gregg,³ pointed to the absence of a compensation program for people who are injured by the vaccine. Until the mid-1970s when the World Health Organization announced the eradication of naturally occurring smallpox, it was accepted that, in the face of endemic infection, the side effects of the smallpox vaccine⁴ are dwarfed by the benefits of immunization. It is difficult for some, however, to accept the risks of vaccine-associated illness and death when the risk of infection is perceived as theoretical. The President, backed by many health and defense experts, sought an immunized core of first-responder and public-health personnel as a public good, allowing treatment and vaccination of larger groups should smallpox infections appear. At the same time, many public health officials, infectious disease experts, lawyers, and health care personnel unions noted the need for a compensation mechanism.

The Administration has said that it expected workers' compensation programs to cover claims for the rare but anticipated side effects of the smallpox vaccinations.⁵ Soon, however, people noticed gaps in this approach. Other than the program that covers federal workers, workers' compensation in the United States is handled at the state level. Scope-of-employment and line-of-duty definitions differ, as do rules of eligibility, coverage, and benefits. In general, courts have found that workers' compensation is available for injuries resulting from employment-related vaccination.⁶ However, not all employees are covered by workers' compensation

¹ Assistant Secretary of Defense, DOD Smallpox Vaccination Program as of Mar. 31, 2003, link at CDC website [<http://www.cdc.gov/od/oc/media/smpxrprt.htm>], visited May 12, 2003.

² Centers for Disease Control and Prevention, Smallpox Vaccination Report: Status and Adverse Events [<http://www.cdc.gov/od/oc/media/smpxrprt.htm>], visited June 13, 2003.

³ Senator Gregg's opening statement at the Senate Health, Education, Labor and Pensions (HELP) Committee hearing on the smallpox vaccination plan, Jan. 30, 2003.

⁴ See CRS Report RL31694, *Smallpox Vaccine Stockpile and Vaccination Policy*, by Judith Johnson, for a discussion of smallpox, U.S. vaccination policy, vaccine availability, and current research activities.

⁵ CDC Director Julie Gerberding, in response to questions, Senate HELP Committee, transcript of Jan. 30, 2003 committee hearing.

⁶ See *Lampkin v. Harzfeld's*, 407 S.W.2d 894 (Mo. 1966) (injuries sustained by a sales woman following an influenza inoculation were compensable); *Saintsing v. Steinbach Co.*, 64 A.2d 99 (N.J. 1949), *aff'd*, 66 A.2d 158 (N.J. 1949) (injuries resulting from smallpox vaccination were compensable because vaccination was mutually beneficial to employer and employees); *Monette v. Manatee Memorial Hospital*, 579 So.2d 195 (Fla. 1991) (injuries (continued...))

programs and not all first-response health care providers are employees. Workers' compensation programs, as their names indicate, cover the worker and not an individual whom the worker, because of the worker's injury, injures. This latter is a concern in planning for smallpox compensation because of the potential for secondary transmission of vaccine-related infection to contacts of those vaccinated. Furthermore, even for workers who do qualify for workers' compensation, the lost income benefit of most of these programs is two-thirds of income up to a yearly cap. Employers are the primary contributors to workers' compensation funds and would be acquiring a new burden if called upon to cover smallpox vaccine injuries.⁷

Some suggested that the Homeland Security Act of 2002 (P.L. 107-296) provided access to compensation through the Federal Tort Claims Act, but it addresses only injuries associated with negligence. Although necessary in certain circumstances, this coverage is not suitable for the injuries anticipated from the nonnegligent administration of vaccine.⁸

Components Suggested for Legislation

A month after the President announced the vaccination program and 1 week before the liability protection provisions from the Homeland Security Act were to begin, the Institute of Medicine of the National Academies issued a letter report⁹ in response to questions from the Centers for Disease Control and Prevention (CDC). The expert committee made two compensation-related recommendations:

... that CDC and its state and local public health partners immediately work to clarify each state's worker's compensation program's position on coverage for smallpox vaccine-related injuries and illnesses for workers covered under their programs.

... that CDC and the Department of Health and Human Services support all efforts, some of which might be administratively or legislatively bold and creative, to bring this issue of compensation for smallpox vaccine adverse reactions — including those reactions that occur despite non-negligent manufacture and administration of the vaccine — to speedy resolution. (p. 9)

⁶ (...continued)

resulting from influenza vaccination were compensable because vaccination flowed as a natural consequence of employment).

⁷ Bertram Cohen, *Workers' Compensation Management Programs* (Chapter 14), in *Occupational Health & Safety, 3rd Edition*, Marci Balge and Gary Krieger, editors, National Safety Council, 2000.

⁸ See CRS Report RL31649, *Homeland Security Act of 2002: Tort Liability Provisions*, by Henry Cohen.

⁹ Institute of Medicine, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation*, Letter Report #1 of the Committee on Smallpox Vaccination Program Implementation, Board on Health Promotion and Disease Prevention, Washington, D.C., Jan. 16, 2003.

Many other groups weighed in with other options. The Association of State and Territorial Health Officials, the American Public Health Association (APHA), and the National Association of County and City Health Officials issued a joint press release urging Congress to create a national program to protect individuals or their survivors from the costs of illness, disability, and death associated with vaccine injury.¹⁰ In a March 2003 press release, APHA specified the need for compensation of medical costs, lost wages, a no-fault system that could provide quick compensation, health insurance, and the more basic assurance that health care would be available to those without health insurance or with inadequate coverage.¹¹

In oral and written testimony to the Senate Health, Education, Labor and Pensions (HELP) Committee and in press releases, representatives of employee unions suggested numerous components for Congress to consider in creating a smallpox vaccine injury compensation program.¹² Some items appeared on many lists, some remained the focus of one speaker.

One set of points involved vaccine policy not explicitly related to injury compensation policy yet the recommendations fit within a discussion of compensation. These included free confidential pre-vaccination screening for contraindications; consistent pre-vaccination education; freedom to decline vaccine without employment discrimination; access to free medical treatment; availability of countermeasures — such as vaccinia immune globulin (often referred to as VIG) — to vaccine effects; safe needle use; liability protection of vaccinee for injury of patients; need for active and ongoing surveillance and reporting; and sufficient federal funding to states.

Other suggestions addressed the structure, administration, and content of a compensation program: a fair, easily accessible, no-fault compensation program; establishment of a vaccine injury table for presumptive causation; establishment of a mechanism to assert causation of other injuries; compensation of unreimbursable medical costs; compensation for pain and suffering; paid sick leave; lost earnings; permanent, total disability benefit; a death benefit; and attorney fees.

¹⁰ Association of State and Territorial Health Officials, National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers, Mar. 7, 2003 [http://www.astho.org/templates/display_pub.php?pub_id=618&admin=1], visited June 13, 2003.

¹¹ American Public Health Association, National Public Health Associations Urge Legislative Action to Protect Smallpox Vaccine Volunteers, Mar. 7, 2003 [<http://www.apha.org/news/press/2003/smallpoxvolunteers.htm>], visited June 13, 2003.

¹² Service Employees International Union, AFL-CIO (SEIU) [http://www.seiu.org/health/smallpox_response.cfm?printer=1] and [http://www.seiu.org/health/smallpox_concern.cfm?printer=1], visited June 13, 2003. See also testimony of Martha Baker, RN, on behalf of the Service Employees International Union, AFL-CIO, before the U.S. Senate Committee on Health, Education, Labor, and Pensions, On the Administration's Smallpox Vaccination Plan: Challenges and Next Steps, Thursday, Jan. 30, 2003; and attachment to testimony prepared by the AFL-CIO, American Federation of State and County Municipal Employees (AFSCME), the American Federation of Teachers (AFT) and the Service Employees International Union (SEIU), Jan. 8, 2003.

Beyond the testimony taken by the Senate HELP Committee, several existing compensation programs appear to have provided models for legislation.

Existing Federal Compensation Programs

In addition to relying on workers' compensation and traditional health insurance policies, Congress has devised several national programs to meet unique compensation needs in particular sets of circumstances, usually involving the concept of no-fault. These programs have defined benefits, funding structures, and eligibility rules. Two — the Public Safety Officers' Benefits (PSOB) program and the National Vaccine Injury Compensation (NVICP) Program — are particularly relevant because they appear as model structures for the smallpox vaccine compensation injury proposals.

Public Safety Officers' Benefits Program

Administered by the Bureau of Justice Assistance in the Department of Justice, the PSOB program provides one-time payments to survivors of public safety officers who are killed and to officers who are permanently and completely disabled in the line of duty.¹³ The Administration based its proposal on this structure.

The Public Safety Officers' Benefits Act (P.L. 94-430) initially covered state and local law enforcement officers and firefighters. Subsequently, Congress added federal law enforcement officers and firefighters; members of federal, state, and local public rescue squads and ambulance crews; Federal Emergency Management Agency personnel; and state, local and tribal emergency management and civil defense agency employees.¹⁴ At its 1976 inception, PSOB provided only a death benefit; in 1990, the program added the permanent, total disability benefit.¹⁵ The Act established the payment level at \$50,000 in 1976; in 1988, the benefit level was changed to \$100,000 pegged to increases in the Consumer Price Index (42 USC 3796). The total benefit payment — for either death or permanent, total disability — allowed in 2003 is \$262,100. Benefits are reduced for individuals receiving certain other death or disability benefits; certain benefit programs reduce benefits if PSOB payment is received. PSOB benefits are not subject to federal income or estate taxes.¹⁶

The PSOB death benefit program “was designed to offer peace of mind to men and women seeking careers in public safety and to make a strong statement about the value American society places on the contributions of those who serve their

¹³ The Public Safety Officers' Benefits (PSOB) program fact sheet is at [<http://www.ncjrs.org/pdffiles1/bja/fs000271.pdf>], visited June 13, 2003.

¹⁴ PSOB fact sheet.

¹⁵ PSOB fact sheet.

¹⁶ PSOB fact sheet.

communities in potentially dangerous circumstances.”¹⁷ Congress, in keeping with that intent, established the PSOB benefit as a supplement, rather than as an insurance or compensation program. PSOB manages claims administratively, rather than within a legal framework. Because the program does not include lost-income benefits or long-term survivor support, it need not debate questions such as projected earnings or other claims that might require review and appeal procedures. Although the smallpox vaccine compensation program in P.L. 108-20 is based on the PSOB structure, the smallpox vaccine injury compensation program does include longer term medical and lost income benefits and, therefore, will require a different structure to efficiently accommodate the complex determination of the possible range of claims following smallpox vaccine injuries.

National Vaccine Injury Compensation Program

In response to public concerns about vaccine safety and manufacturer concern about liability, Congress enacted the National Childhood Vaccine Injury Act (NCVIA) of 1986 (P.L. 99-660).¹⁸ A core piece of that Act is the National Vaccine Injury Compensation Program (VICP), begun in 1988, to handle vaccine injury claims in a no-fault, non-adversarial, and, consequently, more streamlined manner. VICP covers the vaccines that CDC, through the National Vaccine Program and the Advisory Committee on Immunization Practices, recommends for routine administration to all children in the United States. Although located in the Health Resources and Service Administration (HRSA) of the Department of Health and Human Services (HHS), VICP administration is actually shared among HHS, the U.S. Court of Federal Claims, and the U.S. Department of Justice.¹⁹ A proposal for smallpox vaccine injury compensation introduced as H.R. 865 by Representative Waxman based its plan on the VICP.

The basic tool of the VICP is its Table of Injuries. For each covered vaccine, the table lists each specific injury and the time period, relative to vaccination, during which that injury must have occurred in order to be considered for compensation. If a person presents a claim that corresponds to a listed vaccine — injury — time-period item, VICP is to assume that that person’s injury was caused by that vaccination. In theory, this streamlines the entire claims process. Claims involving other injuries from listed vaccines or any injury from other vaccines require proof that the vaccine aggravated or caused the condition.

For vaccine-related injury, VICP allows reasonable compensation for past and future unreimbursable medical, custodial care, and rehabilitation costs; actual and projected pain and suffering and emotional distress — capped at \$250,000; lost earnings; and reasonable attorneys’ fees and costs. For a vaccine-related death, VICP awards \$250,000 to the estate of the deceased, and reasonable attorneys’ fees and costs.

¹⁷ PSOB fact sheet.

¹⁸ Subtitle 2 of Title XXI of the Public Health Service Act.

¹⁹ VICP fact sheet [http://www.hrsa.gov/osp/vicp/fact_sheet.htm], visited June 13, 2003.

NCVIA authorized the use of federal tax dollars for compensation awarded for vaccination that occurred before the program began and authorized an excise tax on every dose of covered vaccine to cover compensation of future vaccine injuries. As of March 2003, “an excise tax of 75 cents on every dose of covered vaccine that is purchased” goes to the Vaccine Injury Compensation Fund.²⁰

According to the VICP Monthly Statistics Report dated May 31, 2003, 8,813 petitions were filed since the program began (4,262 for pre-1988 vaccinations and 4,551 for post-1988 vaccinations), resulting in 3,507 awards that total \$1,428,300,000. Awards for post-1988 vaccinations averaged \$772,675 (73 cases) in FY2002 and \$1,240,143 (48 cases) so far in FY2003.²¹

Although VICP was established as a no-fault system and is not structured as an adversarial process, the U.S. Court of Federal Claims handles its claims. The program’s extensive experience gained over its 15-year existence is concentrated on compensation for injuries incurred by children. How well it could adapt to the adjudication of adult-focused compensation issues, such as temporary lost income or dependent survivors, is not clear.

Others

Standard government programs of compensation include benefits to service-disabled veterans and workers injured on the job. Occasionally, Congress acts to ensure compensation for specific groups of people or their survivors in specific circumstances of death, injury, or medical condition. Examples include the programs instituted to compensate individuals seen as having been injured by the swine flu vaccinations in 1976;²² veterans of military service with illnesses presumed by law or regulation to be caused by certain radiation, chemical, or military service exposures;²³ people with presumed exposure to ionizing radiation by nature of being “downwind” of atomic test fallout, and adverse health effects of radiation;²⁴ Department of Energy employees and contractors with certain radiation-related

²⁰ Commonly Asked Questions About The National Vaccine Injury Compensation Program, updated Dec. 18, 2002 [<http://www.hrsa.gov/osp/vicp/qanda.htm#7>], visited June 13, 2003.

²¹ VICP Monthly Statistics Report [<http://www.hrsa.gov/osp/vicp/monthly.htm>], visited June 13, 2003.

²² The National Swine Flu Immunization Program of 1976 (P.L. 94-380); and David Brown, A Shot in the Dark: Swine Flu’s Vaccine Lessons, *Washington Post*, May 27, 2002.

²³ The 1984 Veterans’ Dioxin and Radiation Exposure Compensation Standards Act (P.L. 98-542) and the 1988 Radiation-Exposed Veterans’ Compensation Act (P.L. 100-321).

²⁴ The 1990 Radiation Exposure Compensation Act (P.L. 101-426), as amended by P.L. 106-245.

conditions;²⁵ miners with black lung disease;²⁶ and people with hemophilia infected with HIV through blood transfusions.²⁷

Legislative History of P.L. 108-20

Representative Waxman introduced H.R. 865, the Smallpox Vaccine Compensation and Safety Act of 2003, on February 13, 2003. Subsequently, Senator Gregg introduced the Administration's proposal, which went on to form the basis of the new legislation.

Senate — S. 719

Senator Gregg initially offered the smallpox compensation provisions as Title I of S. 15, a bill that also included the Administration's proposal for Project BioShield and changes to VICP. Faced with Senator Kennedy's intention to offer 75 amendments to the smallpox compensation title,²⁸ HELP Committee Chairman Gregg deleted Title I at the mark-up on March 11, 2003, and used it as the basis of S. 719.²⁹

S. 719 proposed a compensation program to cover people (health care and other workers who volunteered) with smallpox vaccine-related injury subsequent to vaccination or contact with a vaccinated person in response to the HHS Secretary's declaration of need. It included a timeframe for claims; assigned regulatory and administrative responsibility to the HHS Secretary; allowed no judicial review of the Secretary's decisions; excluded Medicare-eligible people from the medical care benefit; and made benefits secondary to most other coverage.

Benefits categories under S. 719 included medical; lost employment income; and death and permanent, total disability. The medical benefit covered "medical items and services as reasonable and necessary to treat a covered injury." Compensation for lost employment income would be two-thirds of lost income for a person with no dependents and 75% otherwise. The proposed total lifetime benefit for lost employment income was \$50,000. The coverage would not cover the first five lost work days. Following the amount specified by the PSOB legislation on which it was modeled, S. 719 proposed compensation for either death or permanent, total disability as a one-time, lump-sum payment of \$262,100 (April 2003 amount) minus payments made for lost employment income.

²⁵ The Energy Employees Occupational Illness Compensation Program Act of 2000 (P.L. 106-398).

²⁶ The Federal Coal Mine Health and Safety Act (P.L. 91-173).

²⁷ The Ricky Ray Hemophilia Relief Fund Act of 1998 (P.L. 105-369).

²⁸ Kate Schuler, Senate Committee Drops Smallpox Vaccine Provision and Approves Measure, *CQ Today*, March 19, 2003 [<http://www.cq.com>], visited June 13, 2003.

²⁹ Senator Gregg first introduced the smallpox vaccine compensation provisions as Title I of S. 15 on Mar. 11, 2003. On Mar. 26, 2003, he reintroduced them as S. 719.

The Senate HELP Committee marked-up S. 719 on April 2, 2003. The version it ordered reported included an amendment offered by Senator Mikulski to authorize the Secretary of HHS to award grants to states to administer the smallpox vaccine and provide related education, screening, and medical surveillance of vaccinees.

The committee-approved bill did not include three amendments that Senator Kennedy offered. One covered elements of medical care, disability, and lost income benefits. The amendment (1) would have specified that covered *medical care* include such services as rehabilitation, special education, custodial care, and special equipment; and (2) would have struck the provision in S. 719 that excludes Medicare-eligible people from any smallpox vaccine compensation medical benefit. Senator Kennedy's amendment also introduced new categories that would qualify for *disability* benefits: permanent disfigurement and permanent, partial disability. For *lost employment income* compensation, Senator Kennedy would have (1) maintained the committee bill's two-third, or three-quarter, lost income benefit, but calculated the base income taking into account future earnings, especially significant to a child injured by the smallpox vaccine; (2) modified the restriction on receiving death benefits and lost income benefits by allowing the lost income benefit to continue for the life of the spouse or until minor children reach the age of 22; and (3) increased the lifetime cap from \$50,000 to \$75,000.

Senator Kennedy's second amendment would have allowed the Secretary flexibility in applying the 180-day window in which to receive the vaccine and be eligible for benefits in this program. His third amendment sought to change the authorizing language of the reported bill into authorizing and appropriating language, making the funding mandatory rather than discretionary.

The Senate HELP Committee-reported bill was not brought to the Senate for a vote.

House — H.R. 1770, H.R. 1463, and H.R. 865

Representative Burr, the vice-chair of the House Energy and Commerce Committee, introduced H.R. 1463 on March 27, 2003, replacing H.R. 1413 that he had introduced on March 25, 2003. Both versions closely followed the Administration proposal, which also formed the basis of S. 719. The House Republican leadership brought H.R. 1463, which had not been discussed in committee, directly to the House floor on March 31, 2003. It lost 184-206, 84 votes short of the two-thirds vote required under suspension of the rules. Its content, however, formed the basis of the bill that was enacted into law.

Some House Democrats had offered a significantly different proposal in H.R. 865, Representative Waxman's Smallpox Vaccine Compensation and Safety Act of 2003. That bill differed from the Administration proposal both in its treatment of elements common to it and in its inclusion of elements not mentioned. Both contain the basic provisions for compensation for the costs of medical care, permanent and total disability, and death, and cover both the vaccinee and individuals infected

following contact with a vaccinee.³⁰ The major differences involve the mechanism established for adjudication of claims, whether the authorized appropriation is mandatory or discretionary, and the level of benefits. This report includes details of H.R. 865 because its alternative approach serves to identify issues that may resurface as the new compensation program is implemented.

H.R. 865 is patterned after VICP, which is structured differently from PSOB on which the Administration program is modeled. While requiring the Secretary to issue implementation regulations, the proposed VICP-modeled program would rely on special masters appointed in the U.S. Court of Federal Claims to hear claims.

H.R. 865 would allow for actual (rather than a percentage of) lost wages and does not cap the benefit. It would provide paid leave for the first 4 days out of work to cover the period before the lost-income disability benefit begins. H.R. 865 would provide a permanent disability benefit of unreimbursed actual lost wages and unreimbursed medical costs not subject to any limitations, plus a one-time \$250,000 payment for non-economic damages. H.R. 865 would award a death benefit of \$850,000.

H.R. 865 would require the Secretary to make grants to state and local governments to help meet the costs of their smallpox vaccination activities. The bill text specifies that each state "... agrees to provide such medical assistance as may be medically necessary" This differs from the new law's making the Secretary responsible for not only the overall program but also all implementation decisions. Finally, H.R. 865 would mandate appropriations in addition to authorizing them.

In addition, H.R. 865 would go beyond establishing a mechanism to compensate people whom the smallpox vaccine injures. H.R. 865 addresses others concerns outlined by worker groups, such as needle safety requirements; access to free medical care; paid sick leave for up to four days, and reimbursement of those costs to non-federal employers; prohibition against discrimination against an employee who declines or is ineligible for vaccination; procedures for filing complaints and judicial review; funding to states to cover cost of mandatory state activities in pre-vaccination education and screening, and post vaccination surveillance and treatment; and establishment of a uniform national reporting system of adverse reactions to the vaccine and a report to Congress from the Secretary of Health and Human Services.

H.R. 876 was referred to the Energy and Commerce Committee with no further action.

Following negotiation, Members reached the compromise that Representative Burr introduced as H.R. 1770, the Smallpox Emergency Personnel Protection Act of 2003, on April 11, 2003; the full House and then the full Senate passed it that day. H.R. 1770 reflected revisions of H.R. 1463; S. 719, ordered reported from the Senate

³⁰ A bill introduced by Senator Daschle at the beginning of the 108th Congress, S. 6, includes a section titled "Smallpox Injury Compensation Program" and would authorize \$750 million in FY 2004 for compensation. It does not offer the program details that these others present.

HELP Committee; selected language that Senator Kennedy had offered in committee as amendments to S. 719; and items raised in negotiations by others. President Bush signed the Smallpox Emergency Personnel Protection Act of 2003 on April 30, 2003.

P.L. 108-20 — The Smallpox Emergency Personnel Protection Act of 2003

The new law addresses injuries incurred from activities of an immunization plan declared by the HHS Secretary as a national response to threat of biologic agent attack on the United States. It covers injuries that the Secretary finds to be vaccine-related that occur in people who volunteer for vaccination under that plan or people who are infected after contact with those volunteers.

The new law specifies compensation for three things: (1) medical expenses; (2) lost employment income due to temporary and permanent, partial and total disability; and (3) death.

Administrative Mechanisms

The new compensation program uses the PSOB program as its base and adapts the structure of that program to address concerns specifically related to smallpox vaccine injuries. The Secretary of Health and Human Services will establish regulations and will run the compensation program. The law permits no judicial review of the Secretary's actions. It also directs the Secretary to promulgate, and revise when desired, a vaccine injury table listing specific conditions of presumptive causality — meaning that if someone had one of those conditions and had received the vaccine in a certain time period, the law would presume a causal connection. In this respect, it uses the VICP model. The Secretary may also consider claims regarding other adverse effects. The law directs the Secretary to develop a process that an individual could use to request reconsideration of the Secretary's determination.

Responding to concerns raised by Senator Kennedy, the final version of the legislation gives the Secretary flexibility when requiring that claims to this compensation program be made within specific time periods relative to vaccination, symptom identification, and changes in eligibility.

This compensation program applies to injuries related to the Secretary's declared "response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States."³¹ Civilian participation in that plan must be voluntary. Screening for contraindications to vaccination must also be voluntary, but it must be offered. The enacted legislation does not include Senator Mikulski's amendment that was accepted by the HELP committee in the

³¹ 42 USC Section 239, amended by Section 2 of P.L. 108-20.

mark-up of S. 719, although it does direct the Secretary to ensure “appropriate post-inoculation medical surveillance.”

Benefit Levels

Medical Care. P.L. 108-20 directs the HHS Secretary to provide

... payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation. (Section 264)

The legislation includes a more detailed description of *medical items and services* than had H.R. 1463 and S. 719. It also does not include the Senate bill’s exclusion of Medicare-eligible individuals from the new program’s payment for medical care. It does, however, maintain the requirement that its benefits be secondary to other federal, other government, and private payors (e.g., private health insurers, state workers’ compensation programs, and Medicare).

Lost Employment Income. For lost employment income resulting from the covered injuries of a covered person, the program would provide — subject to certain caps — two-thirds of the usual employment income, which includes income from self-employment. If the person injured had “one or more dependents,” that rate would increase to 75% of usual employment income. The law, but not the predecessor bills, specifies that employment income refers to “... income at the time of injury.”

As with the medical care benefits to be provided by this program, lost employment income benefits are to be secondary to other federal, governmental, and private programs to provide employment-based benefits. The program will pay lost employment income compensation in addition to payment for covered medical care, but survivors cannot receive both lost income and death benefits. The lost income compensation begins after 5 missed work days.

A person considered by the program to be permanently and totally disabled could receive up to \$50,000 per year in lost employment income compensation. For disabilities that are temporary or partial, the lifetime cap — accrued at up to \$50,000 per year — is the amount, \$262,100 in May 2003, set by the PSOB legislation. Payments, subject to the lifetime cap if appropriate, would continue until the injured person reaches age 65.

Death (Survivor’s Benefit). The Smallpox Emergency Personnel Protection Act of 2003, P.L. 108-20, provides a one-time, lump-sum death benefit in the amount specified by the PSOB program, now \$262,100. Any death benefit to survivors would be reduced by the amount that the smallpox vaccine injury compensation program had paid as lost employment income benefits to the deceased. Neither could this death benefit be in addition to a PSOB disability or death benefit. The death

benefit would, however, be made in addition to any payment or reimbursement for medical care it had made to that person.

When a survivor is a minor, the legal guardian can choose between receiving a lump sum death benefit (the amount in May 2003 is \$262,100) or the calculated amount of lost employment income compensation (75% of actual income at the time of the injury up to \$50,000 per year) until the youngest dependent survivor reaches age 18.

Appropriations

While Congress was considering smallpox vaccine injury compensation bills, both houses issued their FY 2003 emergency supplemental packages. P.L. 108-11, the Emergency Wartime Supplemental Appropriations Act, 2003, included \$42 million for HRSA to administer the smallpox vaccine injury compensation program, in addition to the \$100 million it provided through the Public Health and Social Services Emergency Fund to CDC for the smallpox vaccination program.³² P.L. 108-20 authorizes the appropriation of "such sums as may be necessary for each of the fiscal years 2003 through 2007" and does not include language appropriating funding in advance of appropriations acts.

Next Steps

Assess

In discussing the need for legislation, many Members and their constituents described the absence of a smallpox vaccine injury compensation package as a major obstacle to volunteering. Will the new law make people more likely to volunteer? Has the end of the war in Iraq lessened the sense of urgency that may have compelled the Congress to enact P.L. 108-20?

An announcement from CDC the week after the bill's passage might also influence volunteer recruitment. The agency now estimates the nation needs only 50,000 immunized public health and health care people to be prepared for a smallpox outbreak, not the 500,000 figure that had been made up by summing the estimates that each state had submitted to CDC in December.³³ This new target is closer to the 39,000 who have already volunteered for vaccination, but Congress does not know

³² The Senate Appropriations Committee version, passed Apr. 3, 2003, included \$35 million for smallpox vaccine administration; the House Appropriations Committee had earlier included in its war supplemental bill \$50 million that would go for smallpox vaccine injury compensation if and when a program were authorized.

³³ Alicia Ault, Smallpox Shot Refusers Say Compensation a Concern, Reuters Health, May 2, 2003 [http://www.nlm.nih.gov/medlineplus/news/fullstory_12617.html], visited May 5, 2003; and David McGlinchy, CDC Says It Never Aimed for 500,000 Smallpox Vaccinations, *Global Security Newswire*, Feb. 26, 2003, link at GovExec.com [<http://www.govexec.com/dailyfed/0203/022603gsn1.htm>], visited June 13, 2003.

yet whether those volunteers are appropriately distributed across states and professions to meet the program goals.

Clarify

Regardless of the size of the program, the HHS Secretary may need to clarify details that the law does not explicitly cover in order to implement the law. Examples include definitions, regulatory treatment of standards of medical evidence, and federal tax law.

The law describes a contact case as “... (iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.”³⁴ What evidence of contact will the Secretary require? How would an unvaccinated person who nevertheless appears with vaccinia infection demonstrate that, for example, a particular, anonymous subway rider was the source of infection? Because vaccinia infection would come only from a vaccinia vaccine source, it may not be necessary — for compensation determination — to show that the person had contact with someone who had received the vaccine. (Knowing the chain of contact would be important, however, for public health reasons.)

The law gives the HHS Secretary authority to create the Table of Injuries to list injuries presumed by law to be vaccine-related. Because the rules — and art — of causal inference that epidemiologists use do not easily line up with legislative needs to assign responsibility, drafters of legislation turn to phrases such as “preponderance of the evidence standard”; “taking into consideration of relevant medical and scientific evidence”;³⁵ or “credible evidence for the association is equal to or outweighs the credible evidence against the association.”³⁶ The scientist’s language includes an uncertainty that the law’s presumptions override. Whether the new legislation provides sufficient guidance to the Secretary remains to be seen. One could anticipate that individual claimants will question whatever list the HHS Secretary promulgates.

Questions are also likely to arise regarding the tax status of the various benefit categories for various groups of recipients. Whether clarification responsibility rests with the HHS Secretary or with the Internal Revenue Service, the issues may involve input from both or require Congressional clarification.

Learn and Proceed

Finally, some Members of Congress may want to consider what lessons they could learn from the nation’s unprecedented foray into civilians’ taking health risks to prepare to protect the U.S. homeland from risks of uncertain likelihood but certain (and terrible) potential consequence. The public may have somewhat relaxed its

³⁴ 42 USC Section 239, amended by Section 2 of P.L. 108-20.

³⁵ Section 2 of S. 719.

³⁶ 38 USC Section 1116(b)(3), amended by P.L. 102-4, the Agent Orange Act of 1991.

concern, but, for public health and intelligence experts, the risks to the public remain real.

P.L. 108-20 addresses compensation of health care and emergency workers who volunteer and receive smallpox vaccine-related injuries resulting from an HHS Secretary's declaration of the need to prepare for bioterrorist actions. It does not, however, cover members of the general public who choose vaccination and it applies only to vaccinia infections that occur before any smallpox case is reported. Should future events make the Secretary's precaution unfortunately predictive and post-attack vaccination be recommended to the general population, how might Congress view vaccine-injury compensation for that group? Congress may choose to discuss how it might modify this legislation to allow its use in as yet unknown circumstances.³⁷

The President's pursuit of Project BioShield legislation³⁸ to encourage private sector participation in the development of other medical countermeasures to the intentional use of biologic agents against the U.S. population is one indication of a widespread view that new products are necessary.³⁹ As health care workers face (or are asked to face) each new product — whether vaccine or antitoxin, whether to

³⁷ In response to a multi-state outbreak of monkeypox, CDC, on June 11, 2003, recommended smallpox vaccination for people who are investigating monkeypox cases and for those who are caring for or are in close contact with already infected people or animals. The smallpox vaccine would be administered “under FDA special procedures to allow such emergency use in association with individual patient informed consent and approval by an ... ethics committee....” A June 12, 2003 CDC Health Alert states that the “risk of monkeypox disease for persons intimately exposed to symptomatic monkeypox cases is believed to be greater than the risk of adverse events resulting from vaccinia exposure for most persons for whom smallpox vaccination would be otherwise contraindicated in the pre-event smallpox setting.” The alert continues that in this situation “...neither age, pregnancy nor a history of eczema are contraindications to receipt of smallpox vaccination” (CDC, *Interim Guidance for Use of Smallpox Vaccine, Cidofovir, and Vaccinia Immune Globulin [VIG] for Prevention and Treatment in the Setting of Outbreak of Monkeypox Infections*, June 12, 2003, at the CDC website [<http://www.cdc.gov/ncidod/monkeypox/vaccination.htm>], visited June 13, 2003). Although the CDC press release quotes HHS Secretary Thompson, the comment regards “the importance of preparedness” and neither a declaration or plan, which would trigger eligibility for compensation, nor an explicit reference to smallpox vaccine injury compensation [<http://www.cdc.gov/od/oc/media/pressrel/r030611.htm>], visited June 13, 2003.

³⁸ See CRS Report RS21507, *Project BioShield*, by Frank Gottron, for a discussion of S. 15, the Biodefense Improvement and Treatment for America Act; H.R. 2122, the Project BioShield Act of 2003; and related issues.

³⁹ Other expert-group reports attesting to the need for enhanced development include DOD, “Department of Defense Acquisition of Vaccine Production, Report to the Deputy Secretary of Defense by the Independent Panel of Experts,” F.H. Top Jr., panel chair, December 2000, distributed as Appendix B of the *Report on Biological Warfare Defense Vaccine Research and Development Programs*, July 2001 [<http://www.acq.osd.mil/cp/bwdvrdp-july01.pdf>], visited May 23, 2003; and Institute of Medicine, *Accelerating the Research, Development, and Acquisition of Medical Countermeasures Against Biological Warfare Agents: Interim Report*, National Academies Press, 2003 [<http://www.search.nap.edu/books/N1000499/html>], visited June 13, 2003.

protect against a viral hemorrhagic fever, tularemia, or glanders⁴⁰ — they will ask about compensation for potential injuries.

⁴⁰ NIAID Category A, B & C Priority Pathogens
[http://www.niaid.nih.gov/biodefense/bandc_priority.htm], visited June 13, 2003.