

States in the event of a smallpox virus attack.

In furtherance of the President's plan, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 24, 2003 (68 FR 4212). In this Declaration, the Secretary declared that "a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified * * * for prevention or treatment of smallpox [(virus infection)] or control or treatment of adverse events related to smallpox vaccination, to [specified] categories of individuals. * * *" The specific "covered countermeasures" described in the Declaration are smallpox vaccines, cidofovir and derivatives thereof, and Vaccinia Immune Globulin. The categories of persons to whom the Secretary recommended the administration of such covered countermeasures, on a voluntary basis, included certain health care workers, members of smallpox response teams identified by State or local government entities or the Department of Health and Human Services, certain public safety personnel, and certain personnel associated with certain Federal facilities abroad. The Secretary recommended that such persons volunteer to receive the smallpox vaccine in order to ensure that critical personnel would be able to mobilize immediately and provide critical services to the population of the United States in the event of a smallpox virus attack. The Secretary's Declaration became effective on January 24, 2003, and will remain effective until January 23, 2004, unless the Secretary extends or shortens the effective period of the Declaration by amendment.

The smallpox vaccine contains a live vaccinia virus that induces immunity to smallpox infection, but does not lead to variola infection or disease. Vaccinia virus is an orthopox type virus that is different from, but related to, the smallpox virus. Different strains of vaccinia have been used in the development of smallpox vaccines throughout the world, with some strains causing more injuries than other strains. The New York City Board of Health strain, "the NYCBH strain," is the only strain currently used in vaccines administered in the United States. The NYCBH strain was selected for use in such vaccines because it has shown itself to be both relatively safe and effective when compared to other vaccinia strains. Nevertheless, the routine use of smallpox vaccination in the United States and several other countries, irrespective of the strain used, was discontinued prior to the

certification of global eradication of smallpox. This was due to the relatively high complication rate observed with the smallpox vaccine, in addition to the lower risk of importation of smallpox with the increasing success of the global eradication program.

Because the vaccinia virus in the smallpox vaccine is live, it can be transmitted to other parts of the body of the vaccine recipient, *e.g.*, by touching a vaccination site before it has healed and then touching another part of the recipient's body (self-inoculation), or to another person, *e.g.*, by touching a vaccination site in a recipient before it has healed and then touching another person (accidental person-to-person inoculation). For purposes of this rule, the term "vaccination" refers to the administration and receipt of the smallpox vaccine and not through contact. Likewise, for purposes of this rule, the term "inoculation" is meant to refer to transmission of and subsequent infection with the vaccinia virus through a means other than smallpox vaccination, as described above.

Even though several studies documented the rate of serious complications after receipt of the smallpox vaccine during the 1960s and 1970s, these rates may be higher today as more individuals are immunocompromised, which has the same meaning for purposes of this regulation as immunosuppressed or immunodeficient. Furthermore, persons receiving primary smallpox vaccination under a smallpox emergency response plan will be doing so as adults. The earlier studies also primarily sought information only on what was known already to be caused by the smallpox vaccine. Unrecognized adverse reactions that may become more clearly evident with improved surveillance may not have been studied in the past.

The SEPPA authorized the Secretary to establish and implement the Smallpox Vaccine Injury Compensation Program. Under the Program, certain persons may receive benefits and/or compensation for covered injuries, described below, sustained as a result of such vaccination or accidental vaccinia inoculation. Specifically, SEPPA authorizes the Secretary to make available such benefits and/or compensation to two categories of persons who sustain covered injuries, provided they meet other legal requirements, *e.g.*, filing deadlines. The first category, described as "recipients," includes certain persons who volunteer for and are selected to be a member of a smallpox emergency response plan and are vaccinated with smallpox vaccine. In the event that recipients

sustain covered injuries as the result of the administration of the smallpox vaccine or other covered countermeasures listed in the Secretary's Declaration, they may be entitled to benefits and/or compensation under the Program. The second category, described as "contacts," includes certain persons who sustained covered injuries as the result of vaccinia contracted through accidental vaccinia inoculation through contact with categories of recipients described in the SEPPA or the contacts of such recipients. In addition, survivors of deceased recipients or contacts may be eligible for benefits and/or compensation under the Program in certain circumstances. Persons who do not meet the criteria for one of these categories (*e.g.*, individuals who receive the smallpox vaccine, but not as part of an approved smallpox emergency response plan) will not be entitled to benefits.

In order to obtain benefits and/or compensation under the Program, eligible individuals in these categories must file a request with the Program and demonstrate to the Secretary in their requests that applicable eligibility, benefits, and compensation criteria are satisfied. Persons filing such requests with the Program are described as requesters. The benefits and compensation available under the Program include compensation for medical care, lost employment income, and a death benefit for certain survivors of persons who died as the result of a covered injury. A requester's entitlement to such benefits and compensation will vary depending upon the nature of the requester's condition, the requester's particular personal circumstances, *e.g.*, whether the requester has insurance coverage, and the completeness of the request and accompanying documentation.

Among the criteria that must be satisfied in order for a person to be entitled to such benefits and/or compensation is the requirement that a person sustained a "covered injury" as the result of the administration of a covered countermeasure or as the result of an accidental vaccinia inoculation. A requester can demonstrate that such a covered injury, an injury either proven or presumed to be caused by the vaccinia virus contained in the smallpox vaccine or transmitted through accidental vaccinia inoculation and meeting all applicable requirements, occurred through two alternative mechanisms. First, in accordance with the SEPPA, a recipient or contact shall be presumed to have sustained a covered injury as the result of the