

injury, we expect that the requester will be eligible for benefits associated with the ischemic heart disease.

Should sufficient scientific evidence be forthcoming that ischemic heart disease (absent these Table conditions) is caused by the vaccine, the Secretary would amend the Table (see discussion below), with retroactive effect, to include this condition too. Furthermore, even absent a Table injury for ischemic heart disease, requesters may provide sufficient evidence of causation in fact for this injury, which might also lead to Program benefits.

The Secretary will provide further information in the forthcoming companion regulation as to how he will determine whether an event was caused by, or was a health complication of, a covered injury.

In addition to specific injuries, the Table includes a category for any death resulting from an injury included on the Table in which the injury arose within the time interval set forth on the Table. No time interval is specified for the category of death. Therefore, so long as the Secretary determines that the death resulted from an injury meeting the Table requirements, the death can occur at any time subsequent to the injury and not necessarily in the time interval set forth on the Table.

Table Definitions and Requirements

The Table's Definitions and Requirements, set forth in 42 CFR 102.53(b), define and describe the scope of the terms included on the Table. As such, the listings included on the Table are to be read in conjunction with the Definitions and Requirements. For each Table injury, the Table Definitions and Requirements must be satisfied.

By law, requesters will be required to provide documentation showing that they meet other eligibility criteria, separate from the Table, in order to demonstrate eligibility to receive benefits and/or compensation under the Program. For example, each requester filing a contact request is required by law to demonstrate to the Secretary that the contact contracted vaccinia through accidental vaccinia inoculation during the effective dates of the Secretary's Declaration, or up to 30 days thereafter. This requirement applies to all contact requests filed, regardless of whether the injury in question is included on the Table. For this reason, the requirement that a requester with a contact request demonstrate that the contact contracted vaccinia within the time interval specified by law is not incorporated into the Table. The companion regulations that the Secretary will issue in the future will provide detailed information

concerning this requirement and other requirements that requesters must satisfy beyond those that pertain exclusively to injuries included on the Table.

Requests Based on Non-Table Injuries

A requester may be eligible to receive benefits and/or compensation available through the Program even if the underlying injury is not included on the Table, as defined through the Definitions and Requirements, or did not occur within the time-frame included on the Table. Because such requesters will not be afforded the presumption of causation given to requesters who establish Table injuries, requesters filing requests based on non-Table injuries must submit documentation that demonstrates to the Secretary that the injury underlying the request was actually caused by the administration of the covered countermeasure, or by vaccinia through accidental vaccinia inoculation in contact requests. The Secretary will give full and fair review of all such requests.

Medical evidence available concerning a possible causal link between the vaccinia virus and particular conditions may not be sufficient for the Secretary to add such conditions to the Table. However, such evidence together with medical documentation introduced by particular requesters may be sufficient for requesters with such conditions to persuade the Secretary that the vaccinia virus from vaccination or inoculation was a significant factor in causing the condition. For example, medical literature suggests that the vaccinia virus has caused acute vaccinia arthritis (VA) or vaccinia osteomyelitis (VO) in isolated instances. As a result, requesters with such conditions may be entitled to compensation even when such conditions are not included on the Table. In order to demonstrate that a particular person's condition was caused by the vaccinia virus through vaccination or inoculation, requesters must provide evidence demonstrating such a link, *e.g.*, evidence that the vaccinia virus was present in an infected joint in a case of alleged VA or in an osteomyelitis in a case of alleged VO. Such evidence may persuade the Secretary to determine that the person sustained a covered, albeit a non-Table, injury. Likewise, persons in whom a malignant melanoma (MM), basal cell carcinoma (BCC), or squamous cell carcinoma (SCC) originated with the first manifestation in a vaccination or inoculation scar may be able to demonstrate to the Secretary that the vaccinia virus caused the MM, BCC, or

SCC. This is consistent with the rare cases in the medical literature in which a causal link has been suggested between the vaccinia virus and such skin tumors, *e.g.*, persons who developed new tumors, *i.e.*, MM, BCC, or SCC (as the first manifestation of each tumor) in separate vaccinia scars from separate vaccinations given years apart.

To decide whether benefits and/or compensation under the Program are available in relation to a request that does not concern a Table injury, the Secretary will review the materials provided in each case. In reviewing these requests, the Secretary will employ a preponderance of the evidence standard, taking into consideration relevant medical and scientific evidence. The Secretary will provide further information concerning such requests when he publishes the companion final rule setting forth the administrative implementation of the Program.

No Table for Other Non-Vaccine Covered Countermeasures

The Secretary was statutorily directed to establish a Table identifying injuries presumed to result from the administration of or exposure to the smallpox vaccine. The SEPPA did not direct the Secretary to establish such a Table in relation to injuries presumed to result from the administration of other covered countermeasures. Nonetheless, certain requesters may still be entitled to benefits and/or compensation in relation to injuries that resulted from covered countermeasures other than the smallpox vaccine, *i.e.*, Vaccinia Immune Globulin, cidofovir and derivatives thereof. Requesters filing requests in relation to such injuries are not afforded the presumption of causation given to requesters who have sustained Table injuries. For this reason, a requester filing a request in relation to such non-vaccine covered countermeasures, as with any non-Table request, must demonstrate to the Secretary that the administration of the covered countermeasure actually caused an injury for which benefits and/or compensation may be available under the Program.

Amendments to Table

In accordance with Section 263(a)(2) of the Public Health Service Act (PHS Act), as established by SEPPA, the Secretary is authorized to amend by regulation the Table established in this interim final rule. The Secretary intends to monitor injuries in relation to covered countermeasures, including the smallpox vaccine. Based upon the best scientific evidence available, the