CFR part 61 and 63 both part 70 and non-part 70 sources.

4. Other Implications

The scope of Chattanooga-Hamilton County's part 70 program that EPA proposes to approve, or interimly approve in the alternative, in this notice would apply to all part 70 sources (as defined in the approved program) within Hamilton County, except any sources of air pollution over which an Indian Tribe has jurisdiction. *See, e.g.,* 59 FR 55813, 55815–18 (Nov. 9, 1994). The term ''Indian Tribe'' is defined under the Act as ''any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village, which is Federally recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.'' *See* section 302(r) of the CAA; *see also* 59 FR 43956, 43962 (Aug. 24, 1994); 58 FR 54364 (Oct. 21, 1993).

III. Administrative Requirements

A. Request for Public Comments

EPA requests comments on all aspects of this proposed full/interim approval. Copies of CHCAPCB's submittal and other information relied upon for the proposed alternatives of full approval and interim approval are contained in docket number TN–CHAT–95–01, maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed full/interim approval. The principal purposes of the docket are:

(1) to allow interested parties a means to identify and locate documents so that they can effectively participate in the approval process; and

(2) to serve as the record in case of judicial review. EPA will consider any comments received by December 8, 1995.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permit programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act of 1995

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed action promulgated today does not include a Federal mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, and Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 31, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95–27698 Filed 11–7–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 100

RIN 0905–AE52

National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II

AGENCY: Health Resources and Services Administration, PHS, HHS.

ACTION: Notice of proposed rulemaking; findings.

SUMMARY: The Secretary has made findings as to certain illnesses and conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines. Based on these findings, the Secretary proposes to amend the Vaccine Injury Table (Table) by regulation under section 313 of the National Childhood Vaccine Injury Act of 1986 and section 2114 (c) and (e) of the Public Health Service Act (the Act).

These proposed regulations would have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the new regulations become effective.

DATES: Comments must be submitted on or before May 6, 1996. A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the Federal Register to provide the details of this hearing.

ADDRESSES: Written comments should be addressed to Fitzhugh Mullan, M.D., Director, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Office of Research and Planning, BHPr, Room 8–67, Parklawn Building, at the above address weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Chief Medical Officer, Division of Vaccine Injury Compensation, BHPr, (301) 443–4198 or David Benor, Senior Attorney, Office of the General Counsel, (301) 443–2006.

SUPPLEMENTARY INFORMATION: On August 14, 1992, the Secretary published in the Federal Register (57 FR 36878) findings as to the illnesses and conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines. Based on these findings, the Secretary proposed to amend the Vaccine Injury Table (Table) by regulation pursuant to section 312 of the National Childhood Vaccine Injury Act of 1986 and section 2114(c) of the Public Health Service Act (the Act). After consideration of comments on the proposed rule, the Secretary published a final rule in the Federal Register on February 8, 1995 (60 FR 7678). The Secretary indicated in the preamble to that rule that further modifications to

the Vaccine Injury Table would be made as new scientific evidence became available regarding the causal relationship between certain vaccines and various adverse events. Pursuant to section 313 of the National Childhood Vaccine Injury Act of 1986 and section 2114(c) of the Act, the Secretary arranged for a second study, again to be conducted by the Institute of Medicine (IOM) of the National Academy of Sciences. This study, entitled Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, covers those vaccines not addressed in the IOM's section 312 Report. (Institute of Medicine. Stratton KR, Howe CJ, Johnston RB, eds. Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington, D.C. National Academy Press; 1994) This Notice of Proposed Rulemaking (NPRM) addresses modifications to the Vaccine Injury Table as a result of this latest IOM report.

The National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99–660 (42 U.S.C. 300aa–10 et seq.), established a Federal compensation program for persons thought to be injured by vaccines. Petitions for compensation under this Program are filed with the United States Court of Federal Claims, with a copy served on the Secretary, who is denominated the ''Respondent.'' The Court, acting through Special Master, makes findings as to eligibility for, and amount of, compensation.

In order to gain an award under this program, the petitioner must establish a vaccine-related injury or death, either by showing an event which is presumed to be caused by a vaccine or by proving causation in fact. In some cases, the petitioner may simply demonstrate the occurrence of what has been referred to as a ''Table injury.'' That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in section 2114(a) of the Act (42 U.S.C. 300aa–14(a))—the ''Vaccine Injury Table''—corresponding to the vaccination in question, and that the *onset* of such injury took place within a time period from the vaccination also specified in the Table. If so, the Table injury was in effect presumed to have been caused by the vaccination, and the petitioner was automatically entitled to compensation (assuming that various jurisdictional requirements were satisfied), *unless* it was affirmatively shown that the injury was caused by some factor other than the vaccination (see secs. 2111(c)(1)(C)(i), 2113(a)(1)(B)), and 2114(a) of the Act). Congress recognized that the Table initially set forth in the statute inevitably would compensate some individuals whose injuries were not actually caused by the vaccine. Congress was willing to accept some such inaccuracy for simplicity's sake, and in order to ensure compensation of most persons actually injured by the enumerated vaccines.

The legislative history states:

> ''The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines * * * may propose to revise the Table, as provided below in Section 2114 [Initial Table]. Until such time, however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.'' [H.R. Rept. 99–908, Part 1, September 26, 1986, page 18 (or as found in 1986 U.S. Code Cong. and Admin. News, Vol. 6, page 6359)].

Since the enactment of the statute, there have been serious concerns about the degree to which the assumptions underlying the Vaccine Injury Table were founded in science, and concerns that substantial numbers of petitions were being compensated inappropriately because they are being compensated for non-vaccine-related injuries. Indeed, when it first enacted the statute creating this Program, Congress mandated reviews to be undertaken by the IOM with the express purpose of providing a better scientific rationale for any presumptions of vaccine causation. Under section 312 of Pub. L. 99–660, Congress mandated that the IOM review the scientific literature and other information on specific adverse consequences of pertussis and rubella vaccines. The 312 Report is discussed extensively in the Final Rule published on February 8, 1995 (60 FR 7678). Under section 313 of Pub. L. 99–660, Congress mandated that the IOM conduct a similar review regarding the risks associated with those pediatric vaccines not covered by the 312 Report.

Section 313 Report

The Institute of Medicine conducted this second review, and released its report in late 1993 (hereinafter ''313 Report''). The committee charged with undertaking this review consisted of fourteen members with expertise in the following fields: immunology, pediatrics, internal medicine, infectious diseases, neurology, virology, microbiology, epidemiology, and public health. The committee met six times over the course of 18 months, and reviewed more than 7,000 abstracts of scientific and medical studies. They read over 2,000 published books and articles, analyzed information from the U.S. Public Health Service Vaccine Adverse Events Reporting System, and considered additional material submitted by interested parties. The committee did not perform any original research. *See* 313 Report, Executive summary, pp. 3–4.

The IOM Committee undertook the task of judging whether, based on available evidence, a causal relationship exists between each adverse event examined and exposure to vaccines against the following diseases: diphthteria, measles, mumps, poliomyelitis, tetanus, hepatitis B, and hemophilus influenzae type b (Hib). Vaccines for hepatitis B and hemophilus influenzae type b (Hib) were not mandated by Congress to be part of the section 313 study; however, because these vaccines are now mandated for inclusion in the Vaccine Injury Compensation Program, the Secretary asked the IOM to address these vaccines as well. See section 2114(e) of the Act, as added by section 13632(a)(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1993, Pub. L. 103–66, which is discussed fully below.)

As with the 312 Report, the IOM used a classification system to categorize their conclusions about the strength of a causal association. These categories are as follows:

1. No evidence bearing on a causal relation.
2. The evidence is inadequate to accept or reject a causal relation.
3. The evidence favors rejection of a causal relation.
4. The evidence favors acceptance of a causal relation.
5. The evidence establishes a causal relation.

After release of the IOM 313 Report in December 1993, the Advisory Commission on Childhood Vaccines (ACCV) recommended that the Secretary convene a task force of experts to review the conclusions of the IOM committee and to consider appropriate changes to the Vaccine Injury Table. Accordingly, on March 15, 1994, an ad hoc subcommittee of the National Vaccine Advisory Committee (NVAC) (see section 2105 of the Act) met to review the 313 Report. This subcommittee meeting included members of the NVAC, representatives from the

Advisory Committee on Immunization (ACIP), the ACCV, the Food and Drug Administration's Vaccine Related Biological Products Advisory Committee, the Academy of Pediatrics Committee on Infectious Diseases (the ''Redbook'' committee), and appropriate Public Health Services (PHS) staff. Where appropriate, the subcommittee also solicited the views of experts in the area of childhood vaccines. The subcommittee concurred with the IOM's conclusions in almost all cases. The subcommittee did not agree with the IOM's conclusions in six specific areas which will be discussed, as appropriate, in the individual vaccine sections below.

Following the NVAC Subcommittee's review, the ACCV, whose membership, by statutory directive, reflects a variety of views relating to childhood immunizations (section 2119 of the Act), considered the proposed changes to the Vaccine Injury Table at its September and December 1994 meetings. The ACCV deliberations included public policy considerations, whereas the NVAC charge was to consider only the scientific issues raised by the existing Table, the recent IOM report, and other scientific information.

The Secretary has examined the recommendations of the NVAC Subcommittee, and of the ACCV, and proposes that the Table set forth at 42 CFR 100.3 be revised as described below. As described above, the process for developing proposals for changing the Table in response to the 313 report is very similar to that undertaken with respect to the 312 Report. In both cases, the Department solicited the views of the two key advisory committees that are charged with making recommendations to the Department regarding vaccine safety and the vaccine compensation program. Making recommendations to change the Table involves the difficult task of balancing scientific concerns and public policy concerns. The Department's overall goal, consistent with Congress' intent in enacting the VICP, is to provide just and fair compensation to those individuals who experience adverse events that can reasonably be determined to have been caused by the covered vaccines. The Department views its role as requiring consideration of public policy concerns, as well as the purely scientific data, in translating these determinations into decisions to change the Table. Another important consideration in proposing changes to the Table is the need to make the Table as easy to understand and as clear as possible. With this goal in mind, the Department is proposing to revise the Qualifications and Aids to Interpretation which may be used by the Special Masters in understanding when a particular set of symptoms is consistent with a particular Table injury. The Department welcomes comments regarding the clarity of the proposed Qualifications and Aids to Interpretation. As provided in section 2114(c)(4), the new table will apply only to petitions filed under the Program after the effective date of the final regulation.

In addition, this NPRM includes changes to the Table based on the requirements of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66, which required, in part, that the Secretary amend the Table to include additional vaccines which have been recommended for routine administration to children. Specifically, this Act added a new section 2114(e) to the National Childhood Vaccine Injury Act of 1986. This section now reads as follows:

(e) ADDITIONAL VACCINES—

(1) VACCINES RECOMMENDED BEFORE AUGUST 1, 1993—

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention (CDC) before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) VACCINES RECOMMENDED AFTER AUGUST 1, 1993—When after August 1, 1993, the Centers for Disease Control and Prevention (CDC) recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

Based on the requirements of this section, the Department proposes to add to the Table hepatitis B and Hib vaccines. In addition, in order to create an efficient and streamlined method of adding additional vaccines to the Table, as required by section 2114(e)(2) above, the Department proposes to add to the Table now a general category for any new vaccine that in the future is recommended by CDC for routine administration to children, upon indication to the Secretary that a particular vaccine has been recommended. Accordingly, once Congress enacts an excise tax to cover that vaccine, the vaccine will be covered under the VICP. Until specified injuries are added to the Table through the rulemaking process, individuals who receive newly recommended vaccines will not receive a presumption of causation, but will instead be eligible to receive compensation upon proving causation in fact. Consistent with the general process for amending the Table, once the Department determines that specific adverse events have been associated with newly recommended vaccines, the Department will propose further changes to the Vaccine Injury Table in order to confer the appropriate presumption of causation.

Based on the requirements of the Administrative Procedure Act, the Department publishes a Notice of Proposed Rulemaking in the Federal Register before a regulation is promulgated. The public is invited to submit comments on this proposed rule. In addition, a public hearing will be held for this proposed rule. After the public comment period has expired, the Department will publish the final rule in the Federal Register. The Comments received on the proposed rule and the Department's responses to the comments will be addressed in the preamble to the final regulation.

Guidelines

Section 313 requires that the Secretary establish guidelines based on the results of the 313 Report ''respecting the administration'' of the vaccines that were reviewed, which guidelines shall include:

''(i) the circumstances under which any such vaccine should not be administered,

(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.''

The establishment of these guidelines will be undertaken as a separate activity from this rulemaking.

Findings

Section 313, unlike section 312, does not require that the Secretary make specific findings as to the ''illnesses or conditions * * * that can reasonably

be determined in some circumstances to be caused or significantly aggravated'' by the vaccines under review, or ''the circumstances under which such causation or aggravation can reasonably be determined to occur.'' Nevertheless, the Department has concluded that these determinations are the appropriate framework for making changes to the Table as a result of the 313 Report. Accordingly, the findings below and the proposed Table that follows are based on these determinations. For some Table changes, the ''circumstances under which * * * causation or aggravation can reasonably be determined to occur'' are reflected in the terms of the Table itself (e.g., vaccine strain polio infection in immunodeficient individuals); for others, the circumstances are reflected in the Qualifications and Aids to Interpretation that accompany the Table (e.g., thrombocytopenic purpura for vaccines to prevent measles).

The Secretary makes the following findings:

1. The scientific evidence favors acceptance of a causal relationship between vaccines containing tetanus toxoid and brachial neuritis.

2. The scientific evidence is insufficient to accept or reject a causal relationship between vaccines containing tetanus toxoid and Guillain Barre Syndrome (GBS). While there may be a causal relationship in extremely rare cases, the Secretary is unable to identify the circumstances in which the vaccine causes the condition.

3. The scientific evidence favors rejection of a causal relationship between vaccines containing tetanus toxoid and encephalopathy.

4. The scientific evidence is insufficient to accept or reject a causal relationship between vaccines containing tetanus toxoid and residual seizure disorder.

5. The scientific evidence indicates a causal relationship between vaccines to prevent measles and (a) thrombocytopenic purpura and (b) measles vaccine-strain viral infection in immunodeficient individuals.

6. The scientific evidence is insufficient to accept or reject a causal relationship between vaccines to prevent measles and residual seizure disorder.

7. The scientific evidence is insufficient to accept or reject a causal relationship between polio live virus (OPV) and Guillain-Barre Syndrome (GBS).

8. The scientific evidence indicates a causal relationship between OPV and vaccine-strain polio viral infection.

9. The scientific evidence indicates a causal relationship between hepatitis B vaccine and anaphylaxis.

10. The scientific evidence favors acceptance of a causal relationship between Hib vaccine (unconjugated, polyribosylribitol phosphate (PRP) vaccine only) and early-onset Hib disease.

Discussion of Proposed Table Changes

The following proposed revision of the Table and the related Qualifications and Aids to Interpretation takes into account the recommendations of the ACCV and the NVAC Subcommittee. These two outside reviewing bodies have based their recommendations primarily on the IOM Report as well as other relevant scientific information. Set forth below is a discussion of each proposed change to the Table, including an explanation of the rationale for the change. Where the Department proposes to amend the Table in a manner inconsistent with the recommendations of the ACCV, there is specific discussion of the basis for such proposal; for all other proposed changes, the ACCV concurred with the proposals.

The Department notes that the removal of a condition from the Table, or the inclusion of a revised definition thereof, will not necessarily result in compensation being denied where it would previously have been awarded. Rather, the result will be that a presumption of causation will no longer apply. Petitioners may still prevail by providing proof of causation in fact.

The Department is proposing to use different categories for the Table itself from those set forth in the initial statutory Table or in the revised Table set forth in the regulations at 42 CFR 100.3. Rather than combine different vaccines, such as DTP and DT in the same category, the Department is proposing to identify groups of vaccines by a primary antigen. Thus, one category will be vaccines to prevent pertussis, which would include P, DTP, DTaP, and other combination vaccines one of whose components is pertussis. Similarly, vaccines to prevent rubella would include MMR, MR, and R.

I. Tetanus Toxoid-Containing Vaccines

A. Guillain-Barre Syndrome

Guillain-Barre syndrome, or acute inflammatory demyelinating polyneuropathy, is a well-described neurologic disorder marked by an initially progressive motor paralysis. While the illness may be life-threatening, recovery is usually complete after weeks or months. Based on a great deal of data gathered since the entity was clearly delineated 75 years ago, it is thought that this disorder is immune-mediated and targets peripheral nerves.

Over half of all patients with GBS have a history of a preceding acute infectious illness, either respiratory or gastrointestinal, in the 1 to 4 weeks prior to the onset of neuropathic symptoms. Several infectious agents, including both bacterial (e.g., Campylobacter jejuni and Mycoplasma pneumoniae) and viral [e.g., Epstein-Barr virus, human immunodeficiency virus (HIV), and cytomegalovirus] ones, are associated with GBS.

Vaccinations in general are infrequent antecedent events in patients with GBS, probably occurring in less than 1 to 5 percent of all cases. GBS is known to occur following the administration of rabies vaccine produced from the nervous tissue of infected animals, and there were more than expected GBS cases in this country following the massive effort in 1976–77 to immunize the populace against a threatened pandemic of swine influenza. While the experience with rabies and swine influenza vaccines is well-documented, a causal relation, if one exists, between tetanus toxoid and GBS is not so self-evident. The Institute of Medicine did conclude that the evidence favors a causal relation between tetanus toxoid and GBS, and by extension that it favors a causal relation between vaccines containing tetanus toxoid, DT, Td, DTP and DTaP. A subcommittee of the National Vaccine Advisory Committee was divided on the question of causality, voting by only a 6 to 5 margin to concur with the IOM's conclusion as to causality between tetanus toxoid-containing vaccines and GBS; the subcommittee recommended unanimously that GBS not be added to the Vaccine Injury Table.

The IOM based its Category 4 conclusion (''The Evidence Favors Acceptance of a Causal Relation'') on an assessment of biologic plausibility and on case reports. One case in particular, that of a 42-year-old man who experienced three separate bouts of a GBS-like illness after tetanus immunizations and later had further relapses without antecedent immunizations of any sort, was relied on very heavily as evidence that there was more than a theoretical possibility of GBS brought on by tetanus immunizations (Pollard JD, Selby G. Relapsing neuropathy due to tetanus toxoid: report of a case. Journal of Neurological Science 1978;37:113–125). The significance of this case and other evidence was debated by the NVAC

Subcommittee before it made its recommendations.

CDC presented data to the NVAC Subcommittee from epidemiologic studies on this issue available since the IOM review. These large population studies showed that there was no increased risk of GBS after tetanus toxoid-containing vaccines in either adults or children. These findings suggest that while certain individuals may have a predilection for GBS after various triggers (including vaccination), such individuals are extremely rare.

The ACCV recommended by a 5 to 4 vote to add GBS to the Table as a recognized Table injury for tetanus toxoid-containing vaccines and that the Aids to Interpretation be designed to exclude from the presumption of causation cases which are not vaccine-related. There are no biologic markers or other means, however, to distinguish the very rare cases of vaccine-related GBS from the far more common cases of GBS due to other causes. As noted above, the one case primarily relied upon by the IOM was one which, due to the multiple occurrences of GBS following vaccination, could be found compensable under the causation in fact standard. Indeed, the VICP has compensated one individual for GBS following receipt of tetanus toxoid vaccine based on this causation in fact approach.

The Department has evaluated the comments of the NVAC Subcommittee and of the ACCV and has determined not to propose the addition of GBS to the Table. While the isolated cases of GBS following tetanus toxoid-containing vaccines do indicate biologic plausibility for causation, the results of CDC studies demonstrate that there is no measurable increase in risk of this condition following vaccination. (Chen R, Kent J, Rhodes P, Simon P, Schonberger L. Investigation of a possible association between influenza vaccination and Guillain-Barre syndrome in the United States, 1990–1991 (abstract); Post Marketing Surveillance 1992; 6:5–6.) Indeed, the IOM noted that ''no estimate of incidence or relative risk is available. It would seem to be low.'' (IOM Report, p. 89.) Thus, to add this condition to the Table would almost certainly result in compensating an inordinate number of non-vaccine-related cases for the extremely rate vaccine-related case. The Department has concluded that the condition should not be given a presumption of causation but should be addressed instead under the causation in fact standard.

B. Brachial Neuritis

Brachial neuritis, alternatively known as brachial plexus neuropathy and by other names, such as neuralgic amyotrophy, was first linked to vaccination or administration of antiserum a half century ago. It has also been reported after various infections and concurrent with other diseases, as well as after trauma, but in the majority of cases there is no history of antecedent illness or immunization. This acute onset peripheral nerve disorder usually begins with a deep, often severe aching pain in the shoulder and upper arm. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Recovery is complete in most cases, though it may require more than a year for full return of function. The IOM concluded that while the evidence is inadequate to accept or reject a causal relation between tetanus toxoid, DT, or Td and peripheral neuropathy (other than those caused by direct intraneural injection), there is biologic plausibility that vaccines could cause brachial neuritis. Taking into account biologic plausibility along with published case reports and uncontrolled observational studies (Tsairis P, Dyck PJ, Mulder DW. Natural history of brachial plexus neuropathy: report on 99 patients. Archives of Neurology 1972; 27:109–117) (Beghi E, Kurland LT, Mulder DW, Nicolosi A. Brachial plexus neuropathy in the population of Rochester, Minnesota, 1970–1981. Annals of Neurology 1985; 18:320–323) of brachial neuritis after receipt of tetanus toxoid, from which a relative risk on the order of 5 to 10 was estimated, the IOM viewed the evidence as favoring acceptance of a causal relation between all tetanus toxoid-containing vaccines and brachial neuritis.

A subcommittee of the National Vaccine Advisory Committee concurred with the IOM conclusion as to causality and recommended the addition of this condition to the Vaccine Injury Table. Citing the rarity of brachial neuritis in children, this panel left open the possibility of including an age-range qualifier to its recommendation that the condition be added to the Table.

The series reported in 1972 by Tsairis and colleagues included a case of brachial neuritis in a 3-month-old infant 3 days after a DTP immunization; and in 1973, Martin and Weintraub reported a case of brachial neuritis in a 5-month-old boy 2 days after he received in the thigh his first does of DTP, with resolution of the neuritis within 48 hours. (Martin GI, Weintraub MI. Brachial neuritis and seventh nerve palsy: a rare hazard of DPT vaccination. Clinical Pediatrics 1973; 12:506–507.) In view of these reported cases of brachial plexopathy in infants after receipt of tetanus toxoid-containing vaccines (DTP), and a paucity of data about incidence according to age, the Department has decided to add brachial plexopathy to the Vaccine Injury Table without any age-range qualifier.

Based on the published literature and case reports, the Department is proposing a time of onset between 2 and 28 days. The proposed Qualifications and Aids to Interpretation are designed to define this condition under new paragraph (b)(7) and to rule out other conditions for which there has been no finding of a causal relation to the vaccine.

C. Encephalopathy

The IOM concluded that the evidence favors rejection of a causal relation between DT, Td, or tetanus toxoid and either acute or chronic encephalopathy. A subcommittee of the National Vaccine Advisory Committee concurred with the IOM conclusion as to causality and recommended the removal of this condition from the Vaccine Injury Table. The ACCV concurred. Accordingly, the Department proposes to delete this condition from the Table.

D. Residual Seizure Disorder

The Department has already taken regulatory action, based on the section 312 review, to delete the condition of residual seizure disorder (RSD) from the Table for vaccines containing tetanus toxoid. See 42 CFR 100.3, as amended at 60 FR 7694. The additional findings from the section 313 Report provide further support for this action. Accordingly, the Department is setting forth a discussion of the additional findings from the IOM that are relevant to this decision.

The Institute of Medicine concluded that the evidence favors rejection of a causal relation between DT and infantile spasms, and is inadequate to accept or reject a causal relation between DT and residual seizure disorder other than infantile spasms. The IOM also viewed the evidence as inadequate to accept or reject a causal relation between tetanus toxoid or Td and residual seizure disorder. These conclusions paralleled its earlier conclusions about infantile spasms (''favors rejection of a causal relation'') and residual seizure disorder (''inadequate to accept or reject a causal relation'') for DTP.

While the IOM may not have felt that it had adequate evidence to reject a

causal relationship between tetanus toxoid, DT, or Td and residual seizure disorder, except in the special case of infantile spasms, it cited no evidence suggestive of a causal relationship. Indeed, the evidence adduced, which included data from three uncontrolled observational studies, could reasonably be interpreted as favoring rejection of a causal relationship. (Pollock TM, Morris J. A 7-year survey of disorders attributed to vaccination in North West Thames region. Lancet 1983; 1:753–757) (Pollock TM, Miller E, Mortimer, JY, Smith G. Symptoms after primary immunization with DTP and with DT vaccine. Lancet 1984; 2:146–149) (Pollock TM, Miller E, Mortimer JY, Smith G. Post-vaccination symptoms following DTP and DT vaccination. Developments in biological standardization. 1985; 61:407–410) (Hirtz DG, Nelson KB, Ellenberg JH. Seizures following childhood immunizations. Journal of Pediatrics 1983; 102:14–18)

All three studies reported on relatively large numbers of children (>200,000 in all) and did identify some who did experience seizures sometime after primary or booster DT immunizations. Of those who experienced seizures, almost all their seizures either: (1) Were isolated events (i.e., did not experience further seizures before observational period ended); (2) occurred in the face of fever or intercurrent illness and were without manifest neurologic residua; (3) occurred well after the receipt of vaccine (e.g., two individuals with convulsions at 22- and 24-days post-immunization, respectively); (4) happened in the face of a significant prior neurologic history (e.g., ''several months earlier he had sustained a skull fracture in a car accident and had been in a coma but had apparently recovered''); or (5) took place under some combination of these special circumstances. Of the Hertfordshire experience reported by Pollock et al. (1984 and 1985), the IOM said, ''That study did not show any evidence for residual seizure disorder de novo following receipt of DT.''

Clearly, whether the evidence is interpreted as inadequate to decide for or against a causal relation between these tetanus toxoid-containing vaccines (i.e., T, DT, and Td) and residual seizure disorders, or as sufficient to favor rejection, there is no support for a claim that there is a causal relationship, or that one is at all likely. The Department has therefore determined that residual seizure disorder cannot reasonably be determined in some circumstances to be caused or significantly aggravated by tetanus toxoid-containing vaccines.

II. Vaccines to Prevent Rubella

In the final rule recently issued after consideration of the section 312 IOM report, the Department added chronic arthritis as a Table injury for vaccines against rubella. (60 FR 7694–7695.) The Department also promulgated in the Qualifications and Aids to Interpretation criteria for determining when chronic arthritis would be given a presumption that the vaccine caused the condition.

Faced with petitions filed under the Program alleging that arthritis was caused in fact by the rubella vaccine, the Court of Federal Claims developed criteria for determining when to compensate such petitions. In an order dated January 11, 1993, a Special Master of the Court set forth criteria for such a determination. The Special Master did so after hearing expert testimony from witnesses representing the fields of rheumatology, virology and infectious disease.

The Department concludes that it is appropriate to reconcile the Special Master's criteria with the criteria in the final rule, to the extent possible. Accordingly, the Department has undertaken to evaluate the Special Master's criteria for possible use in revised Qualifications and Aids to Interpretation, as well as in the time period for onset of the symptoms of arthritis set forth in the Table of Injuries.

The Special Master's criteria are quoted below:

''1. The petitioner in fact had a rubella vaccination, at a time when the petitioner was 18 years or older.

''2. The petitioner had a history, over a period of at least three years prior to the vaccination, of freedom from any sort of persistent or recurring polyarticular joint symptoms.

''3. The petitioner has developed an antibody response to the rubella virus.

''4. The petitioner experienced the *onset* of polyarticular arthropathic symptoms during the period between one and six weeks after the vaccination.

''5. Polyarticular arthropathic symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular arthropathic symptoms recurred within one year of such remission.

''6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of any of a number of other specified conditions.''

The Department has decided to propose incorporating into the Table and Aids to Interpretation elements of criteria 2, 3, and 4. That portion of criterion 2 that refers to a 3-year period without symptoms prior to vaccination is accepted and is proposed to be added in introductory paragraph (b)(6)(i); the portion of criteria 2 and 4 referring to polyarticular joint symptoms is not accepted, as the Department believes that objective signs of arthropathy (joint disease) are necessary. The Department does not agree with criterion 1, the age qualifier, as it would establish an arbitrary age of onset which is not supported by the current medical literature. Criterion 4 specifies a time of onset after vaccination from between 1 and 6 weeks. The final rule pursuant to the section 312 report specified a time of onset from 0–42 days. On review of the relevant medical literature and expert testimony, the Department believes that the evidence would not support a finding of causation with onset before the seventh day after rubella vaccination. Accordingly, the Department proposes to change the period for the first symptom or manifestation of onset of chronic arthritis in the Table itself to be between 7–42 days as reflected in revised paragraph (b)(6)(i)(A).

For the most part, criteria 5 and 6 are already part of the rule adopted pursuant to the section 312 report. No further changes are proposed in this regard.

The Department does not agree, however, with the Court's inclusion of arthralgia (joint pain) as evidence of arthropathic symptoms. Based on medical expert testimony and other related scientific information, the Department continues to believe that arthralgia alone, in the absence of objective signs of arthritis, should not be viewed as evidence of rubella vaccine-related chronic arthritis. Furthermore, the Department is proposing to add paragraph (b)(6)(i)(C) that ''medical documentation of an antibody response to the rubella virus'' is required.

Although criterion 6 does not list fibromyalgia as an alternative diagnosis for purposes of determining eligibility for compensation, a recent Court decision (Johnson v. Secretary, HHS, No. 92–478V), concluded that fibromyalgia is a condition unrelated to rubella vaccination. Accordingly, the Department proposes to add fibromyalgia in paragraph (b)(6)(ii) to the list of conditions which will not be given a presumption of vaccine causation.

III. Vaccines to Prevent Measles

A. Thrombocytopenic Purpura

In children, most cases of immune (idiopathic) thrombocytopenia purpura (ITP) are self-limited disorders that follow a viral infection, most commonly a nonspecific respiratory infection. Viral antigen is thought to trigger synthesis of antibody that reacts with virus antigen, and then the antibody-antigen complex is bound to receptors on the platelet surface. Immune thrombocytopenic purpura often produces petechiae, purpura, and mucosal bleeding. The associated symptoms of petechiae, purpura and mucosal bleeding are generally only seen when the platelet counts are less than 50,000/mm^3 (thrombocytopenia is defined as a platelet count less than 150,000/mm^3). Red and white blood cells are normal in ITP. Acute thrombocytopenia in children rarely becomes chronic, that is, lasting more than 6 months. Chronic thrombocytopenic purpura is thought to be related to an underlying autoimmune disorder and not to be the result of a viral vaccination or viral infection.

The Institute of Medicine (IOM) concluded that the evidence establishes a causal relation between MMR and immune thrombocytopenia and a causal relation between MMR and death from complications associated with severe thrombocytopenia. The conclusions of the IOM were based on biologic plausibility, case series, uncontrolled observational studies (e.g., Nieminen U, Peltola H, Syrjala MT, Makipernaa A, Kekomaki R. Acute thrombocytopenic purpura following measles, mumps and rubella vaccination: a report on 23 patients. Acta Paediatrica 1993; 82:267–270) and the controlled observational study by Oski and Naiman (Oski FA, Naiman JL. Effect of live measles vaccine on the platelet count. New England Journal of Medicine 1996; 275:352–356). The study by Oski and Naiman reported on the occurrence of immune thrombocytopenia after the administration of the Edmonston B measles vaccine, a vaccine which is no longer used in the United States. In this controlled observational study, the maximum depression of the platelet count was noted at 1 week post-immunization (although a decrease in platelet count could be seen by 3 days post-immunization), and platelet counts return to preimmunization levels generally by 3 weeks post-immunization. In the study by Nieminen and colleagues, 23 of approximately 700,000 children immunized over an 8-year period were found to have thrombocytopenia after immunization with MMR vaccine. The platelet count reached its nadir at 21 days (median) post-immunization, with purpura appearing at 17 days (median) post-immunization. The IOM thought that it was biologically plausible that the MMR vaccine could cause immune thrombocytopenia. The NVAC Subcommittee concurred with the IOM conclusion, but because the ITP that was observed after vaccination with MMR was relatively benign with complete recovery in less than 6 months, recommended against the addition of this disease to the Vaccine Injury Table. While cases with full recovery is less than 6 months will not be eligible for compensation (see section 2111(c)(1)(D)(i) of the Act), the rare case with continuing complications should be eligible for a presumption of causation. Thus, the Department proposes that thrombocytopenic purpura be added to the Vaccine Injury Table.

The Department's proposal is based on the IOM conclusion of biologic plausibility of immune thrombocytopenia occurring after MMR vaccination, the possible risk to injury from that thrombocytopenia, and the necessity to clarify the clinical aspects of thrombocytopenia that should be compensable. Conditions that can cause thrombocytopenia or are associated with thrombocytopenia, but are not related to immune thrombocytopenia associated with MMR vaccination, are listed in the Qualifications and Aids to Interpretation as noncompensable conditions. This list of conditions is not exhaustive. A 7- to 30-day timeframe of onset is proposed as the period for a Table injury. This timeframe is largely based on the 1993 uncontrolled study by Nieminen and colleagues.

The ACCV voted to concur with the proposal to add thrombocytopenic purpura to the Table but requested some clarification and changes to the proposed Qualifications and Aids to Interpretation. The reference to a bone marrow examination now includes the phrase ''if performed'' in response to concerns from ACCV members that this test may not have been used in rare cases. Some ACCV members were concerned about the reference to ''viral infections'' and suggested that examples of viruses that cause immune thrombocytopenia be listed. The Department has accepted this suggestion but notes that while some examples are listed, it would not be practical to list all viral etiologies of immune thrombocytopenia. Thrombocytopenic purpura is proposed to be added under paragraph (b)(8).

B. Residual Seizure Disorder

The IOM placed Residual Seizure Disorder (RSD) in Category #2 (''insufficient evidence'') for monovalent measles, and multivalent measles and mumps vaccines, and Category #1 (''no evidence'') for mumps vaccine alone. Information from case reports, case series, and uncontrolled observational studies, seems to indicate that most seizures following measles immunization are ''febrile seizures'' and, therefore, are not expected to lead to recurrent seizures or epilepsy. There were no controlled studies identified by the IOM. Unlike encephalopathy following measles immunization, there is no apparent biologic plausibility for RSD. Furthermore, there is no apparent biologic plausibility for RSD. Furthermore, there is little evidence that seizures, in the absence of acute encephalopathy, can lead to chronic encephalopathy or any clinical manifestation such as RSD.

Both the 1991 and 1994 NVAC Ad Hoc Subcommittees commented on this issue. The former endorsed the removal of RSD, noting the lack of research or clinical data supporting this as a Table condition. Since its removal went significantly beyond the scope of the changes proposed by the PHS Task Force on the Vaccine Injury Compensation Program based on the section 312 IOM Report, the Secretary decided to defer removal awaiting publication of the section 313 IOM Report. Three years later, similar viewpoints were expressed by the NVAC Subcommittee. The Subcommittee unanimously recommended removal of any condition now present on the Table that was placed in Category #2 by the section 313 IOM. Residual Seizure Disorder fits this criterion, and therefore, the legal presumption of causation is proposed to be removed from the Table.

The ACCV voted 5 to 4 to retain RSD as a Table injury for MMR (and components thereof) vaccines. Some members felt that the IOM did not cite evidence strong enough to delete from the Table an injury that Congress had placed thereon. Some felt that there would be potential disruption of the Program if new data emerge showing that there is a causal relation for this condition. One member raised a concern about the number of cases now pending under the Program citing this Table injury. Furthermore, a member expressed concern that the U.S. Court of Federal Claims would make it more difficult for a petitioner to prove causation in fact for this condition if it is removed from the Table. Another

member felt it would be unwise to remove the condition prior to publication of the final Qualifications and Aids to Interpretation for ''encephalopathy'' under the section 312 rule.

The Department has given careful consideration to the issues raised by the ACCV. As indicated above, the evidence is insufficient for the Secretary to conclude that the condition can reasonably be determined in some cases to be caused or aggravated by the MMR vaccine. This is true regardless of the inclusion of the condition on the initial statutory Table of Injuries and regardless of the number of cases filed under the initial Table.

As to the possibility of having to include this condition again on the Table should new scientific data support such an action, the Department would of course be willing to consider such action should there be reliable data for doing so. Under section 2116(b) of the Act, should the condition be reintroduced to the Table, petitioners would have 2 years to file a petition based on injuries occurring at any time during the 8-year period prior to such reintroduction.

As to the increased difficulty of proving causation in fact, it is of course the case that this burden was not imposed on petitioners while there was a Table injury of this sort. The Court of Federal Claims will be faced with determining causation in fact under the statutory preponderance of the evidence standard. The IOM's conclusions and the data underlying it will be, in the Department's opinion, relevant to that inquiry.

Finally, with regard to the definition of ''encephalopathy'' in the section 312 rule, the Department notes that seizures alone are not defined as constituting an encephalopathy, but that certain serious seizure events with demonstrated sequelae can do so. (See 42 CFR § 100.3(b)(2), as added at 60 FR 7694).

For the foregoing reasons, the Department is proposing the removal of the condition RSD for MMR (or components thereof) vaccines from the Table.

C. Vaccine Strain Measles Viral Infection in an Immunodeficient Recipient

The Institute of Medicine study concluded that the evidence establishes a causal relation between vaccine-strain measles virus infection in immunocompromised individuals and death. This conclusion is based on a few case reports of death following the administration of live attenuated measles virus vaccine in children with severe combined immunodeficiency syndrome, leukemia, or dysgammaglobulinemia (Monafo WJ, Haslam DB, Roberts RL, Zaki SR, Bellini WJ, and Coffin CM. Disseminated measles infection after vaccination in a child with a congenital immunodeficiency. J of Pediatrics 1994; 124(2):273–276) (Hong R, Gilbert EF, Opitz JM. Omenn disease: termination in lymphoma. Pediatric Pathology 1985; 3:143–154) (Mihartsch MJ, Ohnacker H, Just M, Nars PW. Lethal measles giant cell pneumonia after live measles vaccination in a case of thymic alymphophasia Gitlin. Helvetica Paediatrica Acta 1972; 27(2):143–146) (Mawhinney H, Allen IV, Beare JM, Bridges JM, Connolly HH, Haire, et al. Dysgammaglobulinaemia complicated by disseminated measles. British Medical Journal 1971; 2:380–381) (Mitus A, Holloway A, Evans AE, Enders JF. Attenuated measles vaccine in children with acute leukemia. American Journal of Disease of Children 1962; 103:243–248). Measles and, to a much lesser extent, measles vaccine infection in severely immunocompromised individuals may result in an overwhelming infection and death. The NVAC Subcommittee concurred with the IOM conclusion, but recommended that compensation for this condition be provided under the causation in fact standard of the statute, rather than through the presumption given by the Vaccine Injury Table.

The Department has decided to propose adding disseminated vaccine-strain measles virus infection in immunocompromised recipients to the Table. This decision is based on the recently published report by Monafo et al. of a 15-month-old immunodeficient male who received measles vaccine and died 3 months later of a molecularly-confirmed vaccine-strain measles virus infection (Monafo WJ, Haslam DB, Roberts RL, Zaki SR, Bellini WJ, and Coffin CM. Disseminated measles infection after vaccination in a child with a congenital immunodeficiency. Journal of Pediatrics 1994; 124(2):273–276). The time for onset is proposed to be 6 months, as is the case in the statutory Table for immunocompromised individuals and polio vaccines. Death as a sequela to this condition would also be covered by the Table. The Qualifications and Aids to Interpretation, under proposed paragraph (b)(9), provides that the measles virus should be determined to be the vaccine-strain by vaccine-specific monoclonal antibody or polymerase chain reaction sequencing, in order to eliminate cases of injury based on endemic measles.

IV. Oral Polio Vaccine

A. Guillain-Barre Syndrome (GBS)

The Institute of Medicine study concluded that the evidence favored the acceptance of a causal relation between oral poliovirus vaccine (OPV) and Guillain-Barre syndrome (GBS). The conclusion was based on an increased incidence of GBS in a 6-year surveillance study for GBS in a southern province of Finland (Uusimaa) reported by Kinnunen et al. in 1989 (Kinnunen E, Farkkila M, Hovi T, Juntunen J, Weckstrom P. Incidence of Guillain-Barre syndrome during a nationwide oral poliovirus vaccine campaign. Neurology 1989; 39:1034–1036). Ten cases of poliomyelitis due to wild poliovirus occurred between August 1984 and January 1985 at a time when inactivated polio vaccine (IPV) was generally used, and a mass immunization program with OPV immunized 94 percent of the Finnish population between 2/10/85 and 3/15/85. Ten cases of GBS occurred in OPV recipients within 10 weeks after immunization, and the relative risk calculated by the IOM committee among adult OPV recipients in a population previously immunized with IPV was statistically significant when calculated on calendar quarters. However, the discussion of the report by Kinnunen et al. states that ''if we add the 4 cases in the 4th quarter of 1985 (sic—data actually refer to 1984), there are 7 cases before OPV and 7 cases after OPV in this 6-month period.'' Thus, OPV in this population could not be the only explanation for the GBS cases, since the analysis by calendar quarters was inconsistent with the analysis of GBS cases based on the periods before and after the administration of OPV or if the quarters were constructed in another way.

Since the publication of the IOM report in 1993, Rantala et al. failed to show a temporal association between GBS and OPV after studying 93 cases of GBS identified in children less than 15 years of age from 22 hospitals over 6 years (Rantala H, Cherry JD, Shields WD, Uhari M. Journal of Pediatrics 1994; 124(2):220–3). On the basis of the available information, the presumption that OPV causes GBS within any time period should not be granted. Based on the most recent data, which had not been available to the IOM committee, the NVAC Subcommittee unanimously concurred with this proposal. The ACCV voted to concur with the proposal not to add GBS to the Table. Those not

voting in favor voiced reservations over their unfamiliarity with the Rantala study, and the fact that its conclusions differed from the IOM's findings.

The Department has evaluated the comments of the NVAC Subcommittee and of the ACCV and has decided not to propose the addition to GBS to the Table. While it is true that the IOM felt the evidence was sufficient to determine that GBS was casually related to OPV, new data published since the IOM study and the NVAC Subcommittee conclusions have persuaded the Department that a presumption of causation should not be provided. Petitioners, however, may use the IOM report to pursue a causation in fact theory before the U.S. Court of Federal Claims.

B. Vaccine-Strain Poliovirus Infection and Death

The Institute of Medicine study concluded that the evidence establishes a causal relation between oral poliovirus vaccine (OPV) and vaccine-strain infection and death, including infection that results in paralytic poliomyelitis. This conclusion is based on case reports of deaths with poliovirus infections among non-immunodeficient and immunodeficient vaccine recipients. (IOM Report, pages 296–299) Since September 1994, the eradication of indigenous wild type poliovirus in the United States has been certified.

Death and vaccine-associated paralytic poliomyelitis within 30 days in non-immunodeficient individuals, and within 6 months in immunodeficient individuals, are already covered in the Vaccine Injury Table, and poliovirus myocarditis and death in a 3-month-old non-immunodeficient male has been compensated by a preponderance of the medical evidence. Based on case reports, the Department has concluded that vaccine-strain poliovirus infection determined by the isolation of poliovirus from the affected tissue that occurs within 30 days after administration or contact in non-immunodeficient individuals, and within 6 months after administration or contact in immunodeficient individuals, should be added to the Table.

A subcommittee of the National Vaccine Advisory Committee concurred with the IOM conclusions and accepted the original Department proposal not to add it to the Table. Since the NVAC meeting, the Department has decided to provide a legal presumption of causation for vaccine-strain polioviral infection within 30 days in non-immunodeficient individuals, and within 6 months in immunodeficient individuals. The ACCV voted unanimously in favor of this proposal.

The Qualifications and Aids to Interpretation, under proposed paragraph (b)(10), contains standards for determining whether a case is due to the vaccine strain of the virus. The identification of poliovirus is necessary to eliminate an enterovirus other than vaccine-strain poliovirus that can cause similar overwhelming infection and death. Isolation of poliovirus from the stool is not sufficient to establish a specific tissue infection or disease caused by vaccine-strain poliovirus, because viral shedding from the gastrointestinal tract occurs in the absence of other tissue infection or disease. The poliovirus should be determined to be vaccine-strain by oligonucleotide or polymerase chain reaction tests.

V. Hepatitis B Vaccine

A. Anaphylaxis or Anaphylactic Shock

In 1981, a plasma-derived hepatitis B vaccine was licensed for the first time in the United States. In 1986, the first recombinant hepatitis B vaccine produced by genetic engineering was licensed and is the form currently used in the United States. In 1991, the Advisory Committee on Immunization Practices recommended that hepatitis B vaccine be administered to all infants in the United States.

The Institute of Medicine concluded that the evidence establishes a causal relation between hepatitis B vaccine and anaphylaxis (313 Report, p. 230). The conclusion was based on biologic plausibility, the temporal sequence of observed events following vaccination, and the observation of a spectrum of clinical reactions from mild hypersensitivity to anaphylaxis in the host after exposure to hepatitis B vaccine.

The Department proposes to add hepatitis B vaccine to the Table. Anaphylaxis and anaphylactic shock with onset within 4 hours following the administration of the vaccine is proposed as a Table injury. Both the NVAC Subcommittee and ACCV voted unanimously in favor of this proposal.

VI. Hemophilus influenzae type b (Hib) Vaccine [polyribosylribitol phosphate (PRP) only]

A. Early Onset Invasive Hib Disease

The unconjugated Hemophilus influenzae type b polysaccharide or PRP vaccine was first licensed in April 1985. Since December 1987, when the first polysaccaharide-protein conjugate vaccine was licensed, the PRP has not been routinely administered. It is no longer available for general use.

Surveillance, serologic, and experimental data have demonstrated a transient decrease in protective antibody levels following immunization with the unconjugated PRP vaccine. Analysis of the data suggests that children over 18 months of age who received their first Hib immunization with the unconjugated PRP vaccine had an increased risk of Hemophilus disease in the 7-day interval following the immunization. The Institute of Medicine found that the evidence favored acceptance of a causal relation between unconjugated PRP vaccine and early onset (i.e. onset within 7 days) invasive Hib disease in children over 18 months of age who received their first Hib immunization with the unconjugated PRP vaccine (IOM report, p. 260). However, ''the evidence favors rejection of a causal relation between immunization with Hib conjugate vaccines and early-onset Hib disease'' (IOM report, p. 261). The NVAC Subcommittee concurred with these conclusions. Thus, the statutory presumption of causation should be extended to cases of invasive Hib disease that meet the standards proposed in the Qualifications and Aids to Interpretation. Early-onset Hib disease is proposed to be added under paragraph (b)(11).

VII. Hib Vaccine (Conjugate)

The Hib conjugate vaccines are proposed to be added to the Table with no condition specified. While the Hib conjugate vaccines appear to be capable of causing a transient decline in serum antibody levels following immunization, prospective observational studies have not demonstrated that immunization with the conjugate vaccines increases the risk of early-onset Hib disease. The Institute of Medicine found ''the evidence favors rejection of a causal relation between immunization with Hib conjugate vaccines and early-onset Hib disease'' (IOM report, p. 261). The NVAC Subcommittee concurred with this conclusion. One member of the ACCV expressed the view that the information upon which the IOM based its conclusion was unreliable. A motion to include early onset Hib disease as a Table injury for Hib conjugate vaccines did not pass. The ACCV voted to accept the Department's recommendation by an 8 to 1 vote.

VIII. New Vaccines Recommended for Routine Administration by CDC

The Department proposes to add to the Table any new vaccine that is

recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children, upon indication to the Secretary that the vaccine has been so recommended. Accordingly, once Congress enacts an excise tax to cover that vaccine, the vaccine will be covered under the VICP. Until specified injuries are added to the Table through the rulemaking process, individuals who receive newly recommended vaccines will not receive a presumption of causation, but will instead be required to prove causation in fact. Of course, consistent with the general process for amending the Table, once the Department determines that specific adverse events have been associated with newly recommended vaccines, the Department will propose further changes to the Vaccine Injury Table in order to confer the appropriate presumption of causation.

The Food and Drug Administration licensed hepatitis A virus vaccine on February 22, 1995, and licensed varicella virus vaccine on March 17, 1995. Vaccines licensed after August 10, 1993, and recommended by the CDC for ''routine administration'' to children are mandated by OBRA of 1993 to be included in the National Vaccine Injury Compensation Program. Recommendations on hepatitis A and varicella vaccine usage by CDC are pending. Furthermore, based on information from clinical trials, there are no specific injuries for either vaccine identified by the Secretary at this time that would warrant inclusion on the Vaccine Injury Table. Further guidance in these areas will be forthcoming during the NPRM's publication and public comment period.

Economic Impact

The Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small businesses, because it will have only small effects, and those primarily on individuals. The effects will be primarily on the ability of certain individuals to obtain compensation without having a burden of proving causation in fact. Attorneys who represent such individuals will be affected only to the extent that they may have a harder or easier burden of proof with respect to the petitions filed. However, under section 2115(e) of the Act, in almost all cases, attorneys' reasonable fees and costs are reimbursed from the Vaccine Injury Compensation Trust Fund.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

As stated above, this proposed rule would modify the Vaccine Injury Table based on legal authority, and under that authority the Court will award such fees and costs as appropriate under the law. As such, the regulation would have little direct effect on the economy or on Federal or State expenditures.

Effect of the New Rule

The proposed rule will have an effect for individuals who were not eligible to file petitions based on the earlier versions of the Vaccine Injury Table, but who may be eligible to file petitions based on the revised Table. The Act permits such individuals to file a petition for such compensation not later than 2 years after the effective date of the revision if the injury or death occurred no more than 8 years before the effective date of the revision of the Table. *See* 42 U.S.C. 300aa–16(b). As part of the Omnibus Budget Reconciliation Act of 1993, Congress amended this section to permit individuals to file claims within this 2-year period, even if they had already filed a claim involving a particular vaccine, but only if the Table revision will ''significantly increase the likelihood of obtaining compensation.'' *See* Pub. L. 103–66, sec. 13632(a)(1), August 10, 1993. For example, this amendment would permit an individual whose claim alleging MMR vaccine-related thrombocytopenic purpura had been dismissed by the Claims Court to file a new claim for the same vaccine-related injury, if the individual can show that the addition of thrombocytopenic purpura to the Table as a MMR vaccine-related condition has significantly increased the likelihood of obtaining compensation. This rule will also affect potential claims for individuals whose conditions are proposed to be removed from the Table. Although these individuals will be able to pursue their claims under the ''causation in fact'' standard, they will not be entitled to a presumption of causation that is granted by having a condition on the Vaccine Injury Table.

Possible Effect on Other Legislation

This rule will not have an effect on the Vaccines for Children program, implemented by the Centers for Disease Control and Prevention under section 1928 of the Social Security Act, as enacted by section 13631 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66, August 10, 1993). This section provides for the establishment of a program to distribute free vaccines to all vaccine-eligible children, as defined by this section. The proposed rule would modify the existing Vaccine Injury Table, a mechanism by which compensation is awarded to individuals who have been found to have suffered from vaccine-related injuries. Because the two authorities are not related, the publication of this rule should not have any impact on the Vaccines for Children Program.

Paperwork Reduction Act of 1980

This proposed rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Dated: June 2, 1995.

Philip R. Lee,

Assistant Secretary for Health.

Approved: August 22, 1995.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR Part 100 is proposed to be amended as set forth below.

PART 100—VACCINE INJURY COMPENSATION

1. The authority citation for part 100 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act, 100 Stat. 3767, as amended (42 U.S.C. 300aa–15); § 100.3, Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note) and sec. 2114 (c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14 (c) and (e)).

2. Section 100.3 is amended by revising the Vaccine Injury Table in paragraph (a); by setting out the introductory text in paragraph (b); by revising paragraph (b)(6); by adding paragraphs (b)(7), (b)(8), (b)(9), (b)(10), and (b)(11); and by revising paragraph (c) to read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT):	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Brachial Neuritis	2–28 days.
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib):	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Encephalopathy (or encephalitis)	72 hours.
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R):	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days).
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Vaccines containing rubella virus (e.g., MMR, MR, R):	
A. Chronic arthritis	7–42 days.
B. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M):	
A. Thrombocytopenic purpura	7–30 days.
B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months.
C. Any sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VI. Vaccines containing polio live virus (OPV):	
A. Paralytic Polio	
—in a non-immunodeficient recipient	30 days.
—in an immunodeficient recipient	6 months.
—in a vaccine associated community case	Not applicable.
B. Vaccine-Strain Polio Viral Infection	
—in a non-immunodeficient recipient	30 days.
—in an immunodeficient recipient	6 months.
—in a vaccine associated community case	Not applicable.
C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV):	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VIII. Hepatitis B. vaccines:	
A. Anaphylaxis or anaphylactic shock	4 hours.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines):	
A. Early-onset Hib disease	7 days.
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
X. Hemophilus influenzae type b polysaccharide conjugate vaccines:	
No Condition Specified	
XI. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage:	
No Condition Specified	

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

* * * * *

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile

rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reither's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(7) *Brachial neuritis.* (i) This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

(ii) Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) *Thrombocytopenic purpura.* This term is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) *Vaccine-strain measles viral infection.* This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(11) *Early-onset Hib disease.* This term is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.

(c) *Effective data provisions.* The revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after [the effective date of the Federal Register document which adopts these revisions as a final rule]. Petitions for compensation filed before [such effective date] shall be governed by section 2114 (a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.*, February 8, 1995) as applicable.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA–7161]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW., Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria