

disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. See sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 30aa–14(e)(2). Finally, section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2) provides that:

[a]ny person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission, whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish in the **Federal Register** a statement of reasons for not conducting such proceeding.

On September 9, 2010, a private person submitted a petition to amend the Table. This petition was submitted to the Chief Special Master, Sandra Lord, with a copy to Dr. Geoffrey Evans, Director, Division of Vaccine Injury Compensation. Pursuant to the VICP statute, Dr. Evans referred the petition to the Commission on October 28, 2010. The Commission discussed the petition at its meeting on March 3, 2011. At the conclusion of this discussion, the Commission voted unanimously to recommend that the Secretary not proceed with rule-making to amend the Table as requested in the petition.

The petition requests that the Secretary amend the Table to include Guillain-Barré Syndrome (GBS) as an injury following certain vaccines. The petition asserts that “[e]very drug company admits that GBS is linked to many different vaccines including influenza, meningitis, and cervical cancer [human papillomavirus].” The petitioner asserts that her mother received the seasonal influenza vaccine, and was subsequently diagnosed with GBS. Other than the assertion cited, the petition does not cite scientific support, nor indicate specifically for which vaccines GBS should be added as an injury, nor indicate any appropriate time-frame.

Nonetheless, the Secretary takes very seriously proposals to modify the Table. Prior to receipt of the petition, in 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP. The vaccines to be reviewed are:

- Varicella vaccines,
 - influenza vaccines,
 - hepatitis B vaccine,
 - human papillomavirus vaccines,
 - hepatitis A vaccines,
 - meningococcal vaccines,
 - measles-mumps rubella vaccines,
- and
- diphtheria, tetanus, pertussis vaccines.

The IOM committee will author a consensus report with conclusions on the evidence bearing on causality and the evidence regarding the biological mechanisms that underlie specific theories for how a specific vaccine is related to a specific adverse event. In particular, the report will contain updated findings on the possible causal relationship between certain VICP-covered vaccines and GBS, as well as other possible injuries/medical conditions. The Secretary expects to receive the IOM consensus report in early summer. After receipt of the consensus report, and a careful analysis of the important scientific and policy considerations raised by the findings in the report, the Secretary will consider whether to engage in a rule-making proceeding to modify the Table. As required by law, any such rule-making proceeding would include notice and opportunity for a public hearing and at least 180 days of public comment. See section 2114(c)(1) of the PHS Act, 42 U.S.C. 300aa–14(c)(1). Also as required by law, the Secretary would provide to the Commission a copy of the proposed regulation or revision, request recommendations and comments by the Commission, and afford the Commission at least 90 days to make such recommendations. See section 2114(d) of the PHS Act, 42 U.S.C. 300aa–14(d).

The Secretary intends to consider whether to engage in a rule-making process with the benefit of the important scientific information soon to be provided by the IOM; to begin the lengthy process without such additional information would not result in rule-making founded on the best and most recent scientific knowledge. For these reasons, it has been determined not to conduct a rule-making proceeding based on the petition received at this time.

Dated: April 1, 2011.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Center for Scientific Review Advisory Council (CSRAC), formerly National Institutes of Health Peer Review Committee, was renewed for an additional two-year period on March 31, 2011.

It is determined that the CSRAC is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or spaethj@od.nih.gov.

Dated: April 4, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases