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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting a Rulemaking Proceeding

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa-14(c)(2)(B), notice is hereby given concerning the reasons for not conducting a rulemaking proceeding to add neurological disorders or conditions as injuries associated with seasonal influenza vaccines to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Narayan Nair, MD, Director, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, Health Resources and

Services Administration, 5600 Fishers Lane, Room 8N146B, Rockville, Maryland, 20857, or by telephone 301-443-6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, (Vaccine Act), Title III of Public Law 99-660, established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines.[1] Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. To gain entitlement to compensation under VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death in one of the following ways (unless another cause is found): 1) by proving that the first symptom of an injury or condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine; 2) by proving vaccine causation, if the injury or condition is not on the Table or did not occur within the time period specified on the Table; or 3) by proving that the vaccine significantly aggravated a pre-existing condition.

The statute authorizing VICP provides for the inclusion of additional vaccines in VICP when they are recommended by the Centers for Disease Control and Prevention for routine administration to children.[2] Consistent with section 13632(a)(3) of Public Law 103-66, the regulations governing VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to

[1] 42 U.S.C. 300 aa-10 et seq.
[2] Section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(e)(2).

such vaccines.[3] The statute authorizing VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table.[4] Finally, the Vaccine Act provides that:

> [a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] 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—
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> (A) Receipt of any recommendation of the Commission, or
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> (B) 180 days after the date of the referral to the Commission,
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> 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 or reasons for not conducting such proceeding.[5]

On January 28, 2016, a private citizen submitted a petition to the Department of Health and Human Services (HHS) requesting that: 1) any adverse neurological disorder or condition be added to the Table for the seasonal influenza vaccines; and 2) if any adverse neurological disorder or condition was too broad in scope, then at least anaphylaxis, Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barré Syndrome (GBS), transverse myelitis (TM), and myelitis be added to the Table for the seasonal influenza vaccine. The petitioner asserted that based on Vaccine Adverse Event Reporting System (VAERS) data and Department of Justice (DOJ) quarterly reports on vaccine settlements,

[3] 42 CFR 100.3(c)(8).
[4] Sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(c) and 300aa-14(e)(2).
[5] Section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa-14(c)(2).

which were presented at Commission meetings, there is sufficient evidence to add these conditions as injuries associated with the seasonal influenza vaccine to the Table. The petitioner did not provide any medical or scientific literature to accompany the request.

Pursuant to the Vaccine Act, the petition was referred to the Commission on June 3, 2016. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table to include "any adverse neurological disorder or condition," MS, TM, or myelitis as injuries associated with seasonal influenza vaccines as requested in the petition.

The petitioner requested the addition of any adverse neurological disorder or condition to the Table for the seasonal influenza vaccine. The petitioner alleged that the DOJ quarterly reports on vaccine settlement cases and VAERS data support the inclusion of all of these conditions to the Table. However, neither of these sources of data is sufficient to modify the Table. The DOJ quarterly report is the report that DOJ provides and discusses at the quarterly Commission meetings and is made available to the public at http://www.hrsa.gov/advisorycommittees/childhoodvaccines/meetings.html. The report includes a list of adjudicated settlements for the applicable quarter by vaccine and alleged injury, and time frame from petition filing to settlement filing. In negotiated settlements between the parties, HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury. These settlements are not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injury, and, in settled cases, the Court does not determine that the vaccine caused the injury. Therefore, a settlement cannot be characterized as a decision by HHS or by the Court that the vaccine caused

an injury. Thus, information from negotiated settlements cannot be used to establish that vaccines cause certain injuries.

The purposes of VAERS data are to: detect new, unusual, or rare vaccine adverse events; identify potential patient risk factors for particular types of adverse events; identify vaccine lots with increased numbers or types of reported adverse events; and assess the safety of newly licensed vaccines. The VAERS data are considered a useful tool in vaccine safety, but VAERS reports by themselves generally cannot demonstrate that vaccines cause injuries.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by VICP. The results of this review were published in the 2012 IOM Report, "*Adverse Effects of Vaccines: Evidence and Causality*." This report reviewed 8 of the 12 vaccines covered by the VICP and provided 158 causality conclusions. The 2012 IOM Report reviewed the medical and scientific literature regarding a causal relationship between seasonal influenza vaccines and the following conditions: encephalopathy, encephalitis, seizures, acute disseminated encephalomyelitis, TM, optic neuritis, neuromyelitis optica, MS, MS relapse, GBS, chronic inflammatory demyelinating polyneuropathy, Bell's palsy, brachial neuritis, and small fiber neuropathy. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and the above conditions. Therefore, "any adverse neurological disorder or condition," as suggested by the petitioner will not be added as injuries caused by the seasonal influenza vaccine to the Table since the medical and scientific literature is not sufficient to support this change.

The petitioner also requested that certain conditions be added to the Table if "any adverse neurological disorder or condition" could not be added to the Table. These conditions include: anaphylaxis**,** SIRVA, vasovagal syncope, MS, GBS, TM, and myelitis. The petitioner stated that VAERS and settlement data from quarterly reports support the inclusion of these conditions for seasonal influenza vaccines to the Table. However, as explained above, the VAERS data and the DOJ quarterly report do not demonstrate that vaccines cause injuries and do not establish causality. As stated previously, the 2012 IOM Report reviewed the medical and scientific literature regarding causal relationships between seasonal influenza vaccines and MS, TM, and myelitis. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and these conditions.

More recent studies support the lack of an association between the seasonal influenza vaccine and neurologic conditions, such as MS. The Williamson, et al. study found no substantiation to reports suggesting a link between MS and vaccines and that most of the studies that purported an increased risk of MS or relapse of MS after vaccination were small case series, which are methodologically less robust than other epidemiologic studies.[6] In addition, Langer-Gould, et al. conducted a nested case control study that found no long-term association between vaccines and MS or other central nervous system acquired demyelinating syndromes.[7] Therefore, MS, TM, and myelitis will not be added to the Table as injuries associated with the seasonal influenza vaccine since the medical and scientific literature is not sufficient to support those changes.

[6] Williamson et al. Vaccines in Multiple Sclerosis, Curr Neurol Neurosci Rep 2016 16:36.
[7] Langer-Gould et al., Vaccines and the risk of MS and other CNS Demyelinating Diseases, JAMA Neurol. 2014:71(12): 1506-13.

HHS proposed certain changes to the Vaccine Injury Table in a Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on July 29, 2015 (80 Fed. Reg. 45132 (July 29, 2015)). Among other proposed changes, anaphylaxis, SIRVA, GBS, and vasovagal syncope were proposed to be added as injuries for seasonal influenza vaccines. HHS is adding these injuries with the final rule, titled "National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table," concurrently publishing in the *Federal Register*.

In conclusion, there is no reliable evidence to support the addition of "any adverse neurological disorder or condition," MS, TM, or myelitis to the Table as injuries associated with the seasonal influenza vaccine. Therefore, the Table will not be amended at this time to include those injuries on the Table.

Dated: _ January 9, 2017 _____

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Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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