AMENDMENT TO H.R. 5371

OFFERED BY M__. _____

At the end of division C, add the following:

TITLE VII—OTHER MATTERS

SEC. 7___. CODIFICATION OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

(a) IN GENERAL.—Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 222 (42 U.S.C. 217a) the following:

"SEC. 222A. ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

''(a) IN GENERAL.—The Advisory Committee on Immunization Practices established pursuant to section 222 (referred to in this section as the 'Advisory Committee') shall carry out the duties specified in this section.

''(b) APPLICATION OF CHAPTER 10 OF TITLE 5, UNITED STATES CODE.—The provisions of chapter 10 of title 5, United States Code (other than section 1013), shall apply with respect to the Advisory Committee.

''(c) ADVICE, GUIDANCE, AND RECOMMENDATIONS FROM ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Advisory Committee shall, based on a preponderance of the best avail-

able, peer-reviewed scientific evidence, provide advice and guidance, and make recommendations, to the Director regarding the use of vaccines and related agents licensed under section 351 for effective control of vaccine-preventable diseases in the civilian population of the United States.

''(2) PROCEDURE FOR PUBLICATION.—

''(A) IN GENERAL.—The Director shall review any recommendations received under paragraph (1). The Director shall adopt any such recommendation unless the Director determines such recommendation is not supported by a preponderance of the best available, peer-reviewed scientific evidence and publishes the results of that review.

''(B) ADOPTED.—If the Director adopts such a recommendation—

''(i) such recommendation shall be considered as an official recommendation of the Secretary, acting through the Director, upon such adoption; and

''(ii) the Director shall—

''(I) publish such recommendation on the public website of the De-

partment of Health and Human Services; and

''(II) inform the Secretary and the Assistant Secretary for Health, in writing, of such recommendation.

''(C) NOT ADOPTED.—If the Director does not adopt such a recommendation, the Director shall—

''(i) publish the basis for not adopting such recommendation, including an explanation on why the Director found that the recommendation does not support the findings of a preponderance of the best available, peer-reviewed scientific evidence; and

''(ii) not later than 48 hours after such determination, submit a notification to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate containing the information described in clause (i).

''(3) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indica-

tion for a vaccine under section 351, the Advisory Committee shall—

''(A) consider the use of the vaccine not later than its next regularly scheduled meeting;

''(B) not later than 90 days after receiving a notification in writing from the holder of the license of the vaccine or new indication for a vaccine under section 351, make a recommendation with respect to the use of such vaccine under paragraph (1); and

''(C) submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate an update on the status of the Advisory Committee's consideration of the use of the vaccine.

''(4) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations under paragraph (1) with respect to the use of vaccines that—

''(A) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act and licensed under section 351 of this Act; or

''(B) are intended to address a public health emergency as determined by the Secretary under section 319.

''(5) LIMITATION.—If the Secretary or the Director takes an action regarding the use of vaccines and related agents licensed under section 351 for effective control of vaccine-preventable diseases in the civilian population of the United States (including an action with respect to coverage under section 2713 or the listing of vaccines for purposes of the program under section 1928 of the Social Security Act) that is contrary to a recommendation of the Advisory Committee, the Secretary or the Director (as applicable) shall—

''(A) publish the basis for the action, including an explanation on why the Secretary or the Director (as applicable) found that the action supports the findings of a preponderance of the best available, peer-reviewed scientific evidence; and

''(B) not later than 48 hours after taking such action, the Secretary or the Director (as applicable) shall submit a notification to the Committee on Energy and Commerce of the House of Representatives and the Committee

on Health, Education, Labor, and Pensions of the Senate containing the information described in subparagraph (A).

"(d) DUTIES.—

"(1) IN GENERAL.—

"(A) IN GENERAL.—The Advisory Committee shall do the following:

"(i) Provide advice and guidance, and make recommendations, to the Director as specified in subsection (c)(1).

"(ii) Make immunization recommendations for purposes of the requirement under section 2713 for group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for immunizations that have in effect a recommendation from the Advisory Committee.

"(iii) In accordance with section 1928 of the Social Security Act and this section, establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with

schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines.

''(B) USE OF LIST.—The Secretary, and as delegated, the Director, shall use the list established by the Advisory Committee for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program under section 1928 of the Social Security Act.

''(2) ADVICE AND GUIDANCE CONTENT.—Advice and guidance provided under paragraph (1)—

''(A) shall address—

''(i) the general use of vaccines and immune globulin preparations as a class of biologic agents;

''(ii) the use of specific antibody products for prevention of infectious diseases; and

''(iii) special situations or populations that may warrant modification of the routine recommendations for vaccine use;

''(B) may include recommendations for the administration of immune globulin preparations or antimicrobial therapy shown to be effective

in controlling a vaccine-preventable disease for which a vaccine is available; and

''(C) with respect to each vaccine described in such paragraph, shall include—

''(i) population groups or circumstances in which a vaccine or related agent is recommended;

''(ii) contraindications and precautions for use of the vaccine and related agents; and

''(iii) information on recognized adverse events associated with the use of such vaccine.

''(3) EMERGENCY USE AUTHORIZATION.—Guidance for use of vaccines and related agents authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act may be developed by the Advisory Committee if circumstances warrant, including in the case of a public health emergency, as determined by the Secretary under section 319.

''(4) CONSIDERATIONS FOR RECOMMENDATION DEVELOPMENT OR WITHDRAWAL OF RECOMMENDATION.—The Advisory Committee, when making new recommendations under subsection (c)(1), or revi-

sions or withdrawals of such recommendations under paragraph (5), shall review evidence in the following categories:

"(A) Identification of the specific intervention, including dosage and schedule.

"(B) The strength of the design of the study used to provide the evidence considered.

"(C) Randomized controlled trials or overwhelming evidence from observational studies.

"(D) Comparison and outcome of the target population for the vaccine, including standard of care, existing vaccines, and other prevention options.

"(E) Prevention outcome or scientifically verified adverse effects associated with vaccination.

"(5) REVISION OR WITHDRAWAL OF RECOMMENDATION.—The Advisory Committee may revise or withdraw any recommendation regarding a particular vaccine under this subsection if and when new information on disease epidemiology, vaccine effectiveness or safety, or other data become available, and as supported by a preponderance of the best available, peer-reviewed scientific evidence.

"(e) ADMINISTRATION.—

''(1) REPORTING STRUCTURE.—The Advisory Committee shall report to the Director. The Director shall inform the Secretary, the Assistant Secretary for Health, and the Administrator of the Centers for Medicare & Medicaid Services of immunization recommendations made by the Advisory Committee.

''(2) AGENCY SUPPORT.—For purposes of supporting the Advisory Committee in carrying out this section—

''(A) the Office of the Director, National Center for Immunization and Respiratory Diseases of the Centers for Disease Control and Prevention shall provide management and support services; and

''(B) the Advisory Committee may enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to provide external support.

''(3) DESIGNATED FEDERAL OFFICER.—

''(A) SELECTION.—The Director shall select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer.

''(B) DUTIES.—The Designated Federal Officer selected under subparagraph (A) shall—

''(i) attend each meeting of the Advisory Committee (and any subcommittee thereof) or select a designee to attend such a meeting;

''(ii) ensure that all procedures of the Advisory Committee for such a meeting are within applicable statutory, regulatory, and HHS General Administration Manual directives; and

''(iii) approve and prepare all policies and agendas for each such meeting, call any such meeting, adjourn any meeting when the Designated Federal Officer deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Advisory Committee reports.

''(C) ASSIGNMENT.—In the event that the Designated Federal Officer cannot fulfill the assigned duties of the Advisory Committee, one or more full-time or permanent part-time Federal employees shall be assigned as the Designated Federal Officer and carry out such duties on a temporary basis.

''(f) MEETINGS.—

''(1) FREQUENCY.—Pursuant to the call of the Designated Federal Officer, in consultation with the Chair of the Advisory Committee, meetings shall be held—

''(A) not less than three times per calendar year; and

''(B) upon the licensure of any vaccine, or any new indication for a vaccine, under section 351(a), not later than 90 days after the date of the first marketing of such vaccine.

''(2) OPEN TO THE PUBLIC.—Meetings of the Advisory Committee shall be open to the public except as determined otherwise by the Director, or other official, to whom the authority has been delegated, in accordance with sections 552b(c) and 1009 of title 5, United States Code. Notice of all such meetings shall be given to the public.

''(g) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary shall appoint at least 15 and not more than 19 individuals to serve as members (including the chairperson) of the Advisory Committee. Such individuals shall be appointed from among individuals recommended by the Comptroller General of the United States. Such

members shall serve as Special Government Employees.

''(2) REQUIRED EXPERTISE.—The Comptroller General of the United States may only recommend as a member of the Advisory Committee an individual who has expertise or experience with respect to one or more of the following:

''(A) A prevalence of peer-reviewed and best available scientific research.

''(B) Expertise relating to epidemiology and vaccine-preventable disease burden.

''(C) Expert experience to rigorously evaluate the best available scientific evidence with immunization recommendations and public health.

''(D) Expertise in immunology as evidenced by publications on the topic of immunology in peer-reviewed journals.

''(E) Expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine.

''(F) Expertise in infectious diseases, particularly human immune responses to vaccines, assessment of vaccine efficacy or effectiveness,

or vaccine safety, as evidenced by publications on the topic in peer-reviewed journals.

''(G) Expertise with clinical or laboratory vaccine research.

''(H) Expertise in assessment of vaccine efficacy and safety.

''(I) Knowledge about consumer perspectives or the social and community aspects of immunization programs, or both.

''(3) EX-OFFICIO MEMBERS.—In addition to the individuals appointed under paragraph (1), the membership of the Advisory Committee shall also consist of the following 6 non-voting ex-officio members (or their designees):

''(A) The Administrator of the Health Resources and Services Administration.

''(B) The Commissioner of Food and Drugs.

''(C) The Administrator of the Centers for Medicare & Medicaid Services.

''(D) The Director of the National Institutes of Health.

''(E) The Director of the Indian Health Service.

"(F) The Director of the National Vaccine Program Office.

"(4) QUORUM.—Two-thirds of the voting members of the Advisory Committee shall constitute a quorum for purposes of meetings of the Advisory Committee.

"(5) VOTING IF LESS THAN QUORUM PRESENT.—If fewer than a quorum of members of the Advisory Committee are eligible to vote due to absence or a financial or other conflict of interest at any meeting of the Advisory Committee, the Designated Federal Officer, or their designee, shall have the authority to temporarily designate the ex-officio members under paragraph (3) as voting members.

"(6) NON-VOTING LIAISON REPRESENTATIVES.—Meetings of the Advisory Committee may also be attended by non-voting liaison representatives who shall be deemed representatives from a stakeholder organization.

"(7) TERMS.—

"(A) IN GENERAL.—Except as specified in subparagraph (B), individuals appointed under paragraph (1) shall be invited to serve as members of the Advisory Committee for overlapping terms of 4 years, except that any member ap-

pointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member of the Advisory Committee may continue to serve on the Advisory Committee for a period not to exceed 180 days after the expiration of that member's term if a successor has not taken office.

''(B) CHAIRPERSON.—The term of the Chairperson of the Advisory Committee shall be 7 years.

''(h) SUBCOMMITTEES.—

''(1) IN GENERAL.—The Advisory Committee may, subject to approval by the Secretary (or the Secretary's designee), establish subcommittees composed, in part, of members of the Advisory Committee and other subject matter experts.

''(2) REPORTING.—The subcommittees shall report back to the parent committee and may not provide advice or work products directly to the Department of Health and Human Services.

''(3) DEPARTMENT COMMITTEE MANAGEMENT OFFICER.—The Secretary shall—

''(A) notify the Department Committee Management Officer upon establishment of each subcommittee; and

''(B) provide to such Officer information on the name, membership, function, and estimated frequency of meetings of such subcommittee.

''(i) RECORDKEEPING.—The records of the Advisory Committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. Such records shall be available for public inspection and copying, subject to section 552 of title 5, United States Code.

''(j) DEFINITIONS.—In this section:

''(1) STAKEHOLDER ORGANIZATION.—The term 'stakeholder organization' means—

''(A) the American Academy of Family Physicians;

''(B) the American Academy of Pediatrics;

''(C) the American Academy of Physician Associates;

''(D) the American College Health Association;

''(E) the American College of Nurse Midwives;

''(F) the American College of Obstetricians and Gynecologists;

''(G) the American College of Physicians;

''(H) the American Geriatrics Society;

''(I) the America's Health Insurance Plans;

''(J) the American Immunization Registry Association;

''(K) the American Medical Association;

''(L) the American Nurses Association;

''(M) the American Osteopathic Association;

''(N) the American Pharmacists Association;

''(O) the Association of Immunization Managers;

''(P) the Association for Prevention Teaching and Research;

''(Q) the Association of State and Territorial Health Officials;

''(R) the Biotechnology Innovation Organization;

''(S) the Council of State and Territorial Epidemiologists;

''(T) the Canadian National Advisory Committee on Immunization;

''(U) the Infectious Diseases Society of America;

''(V) the International Society of Travel Medicine;

''(W) the National Association of County and City Health Officials;

''(X) the National Association of Pediatric Nurse Practitioners;

''(Y) the National Foundation for Infectious Diseases;

''(Z) the National Medical Association;

''(AA) the Pediatric Infectious Diseases Society;

''(BB) the Pharmaceutical Research and Manufacturers of America;

''(CC) the Society for Adolescent Health and Medicine;

''(DD) the American Public Health Association;

''(EE) the Society for Healthcare Epidemiology of America; and

''(FF) such other non-voting liaison as the Secretary determines necessary to effectively

carry out the functions of the Advisory Committee.

''(2) VACCINE.—The term 'vaccine' means any substance (and any related agent) that is licensed under section 351 for the prevention of 1 or more diseases. Such term includes related agents that are administered prophylactically for active or passive antigen-specific immunity.

''(k) FUNDING.—There are authorized to be appropriated to carry out this section, including operating costs, compensation and travel expenses for members, and staff support of the Advisory Committee, $2,800,000 for each of fiscal years 2026 through 2029.''.

(b) RULE OF CONSTRUCTION.—Except as expressly provided in the amendment made by subsection (a), nothing in such amendment shall be construed as limiting the authority of the Advisory Committee on Immunization Practices, or the duties of such Advisory Committee, that were in effect as of the day before the date of the enactment of this Act, including with respect to subsections (c)(2)(B)(i) and (e) of section 1928 of the Social Security Act (42 U.S.C. 1396s) and section 2713(a)(2) of the Public Health Service Act (42 U.S.C. 300gg–13(a)(2)) (as such sections were in effect on the day before the date of the enactment of this Act).

SEC. 7___. NATIONAL VACCINE INJURY COMPENSATION PROGRAM.

Subsection (c) of section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14) is amended by adding at the end the following:

''(5) Any removal of a vaccine from the Vaccine Injury Table, or any other modification under paragraph (1), including any additions to the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided, shall be supported by the preponderance of the best available scientific evidence regarding the safety or efficacy of the vaccine. Nothing in the preceding sentence shall be construed to limit the authority of the Secretary to amend the Vaccine Injury Table to include new vaccines pursuant to subsection (e).''.

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