

119TH CONGRESS
1ST SESSION

S. 3323

To amend the Public Health Service Act to codify the Advisory Committee on Immunization Practices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 3, 2025

Mr. HICKENLOOPER (for himself, Mr. MARKEY, Ms. BLUNT ROCHESTER, Mr. BLUMENTHAL, Ms. ALSOBROOKS, Mr. KIM, Mr. SCHIFF, Mr. HEINRICH, and Mr. VAN HOLLEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to codify the Advisory Committee on Immunization Practices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Family Vaccine Protec-
5 tion Act”.

1 **SEC. 2. CODIFICATION OF ADVISORY COMMITTEE ON IM-**
 2 **MUNIZATION PRACTICES.**

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

6 **“SEC. 222A. ADVISORY COMMITTEE ON IMMUNIZATION**
 7 **PRACTICES.**

8 “(a) IN GENERAL.—The Advisory Committee on Im-
 9 munization Practices established pursuant to section 222
 10 (referred to in this section as the ‘Advisory Committee’)
 11 shall carry out the duties specified in this section.

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

16 “(c) ADVICE, GUIDANCE, AND RECOMMENDATIONS
 17 FROM ADVISORY COMMITTEE.—

18 “(1) IN GENERAL.—The Advisory Committee
 19 shall, based on a preponderance of the best avail-
 20 able, peer-reviewed scientific evidence, provide advice
 21 and guidance, and make recommendations, to the
 22 Director of the Centers for Disease Control and Pre-
 23 vention (referred to in this section as the ‘Director’)
 24 regarding the use of vaccines and related agents li-
 25 censed under section 351 for effective control of vac-

1 cine-preventable diseases in the civilian population of
2 the United States.

3 “(2) PROCEDURE FOR PUBLICATION.—

4 “(A) IN GENERAL.—The Director shall re-
5 view any recommendations received under para-
6 graph (1). The Director shall adopt any such
7 recommendation unless the Director determines
8 such recommendation is not supported by a pre-
9 ponderance of the best available, peer-reviewed
10 scientific evidence and publishes the results of
11 that review.

12 “(B) ADOPTED.—If the Director adopts
13 such a recommendation—

14 “(i) such recommendation shall be
15 considered as an official recommendation
16 of the Secretary, acting through the Direc-
17 tor, upon such adoption; and

18 “(ii) the Director shall—

19 “(I) publish such recommenda-
20 tion on the public website of the De-
21 partment of Health and Human Serv-
22 ices; and

23 “(II) inform the Secretary and
24 the Assistant Secretary for Health, in
25 writing, of such recommendation.

1 “(C) NOT ADOPTED.—If the Director does
2 not adopt such a recommendation, the Director
3 shall—

4 “(i) publish the basis for not adopting
5 such recommendation, including an expla-
6 nation on why the Director found that the
7 recommendation does not support the find-
8 ings of a preponderance of the best avail-
9 able, peer-reviewed scientific evidence; and

10 “(ii) not later than 48 hours after
11 such determination, submit a notification
12 to the Committee on Energy and Com-
13 merce of the House of Representatives and
14 the Committee on Health, Education,
15 Labor, and Pensions of the Senate con-
16 taining the information described in clause
17 (i).

18 “(3) CONSIDERATION OF NEW VACCINES.—
19 Upon the licensure of any vaccine or any new indica-
20 tion for a vaccine under section 351, the Advisory
21 Committee shall—

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

24 “(B) not later than 90 days after receiving
25 a notification in writing from the holder of the

1 license of the vaccine or new indication for a
2 vaccine under section 351, make a rec-
3 ommendation with respect to the use of such
4 vaccine under paragraph (1); and

5 “(C) submit to the Committee on Energy
6 and Commerce of the House of Representatives
7 and the Committee on Health, Education,
8 Labor, and Pensions of the Senate an update
9 on the status of the Advisory Committee’s con-
10 sideration of the use of the vaccine.

11 “(4) CONSIDERATION FOR BREAKTHROUGH
12 THERAPIES AND FOR POTENTIAL USE DURING PUB-
13 LIC HEALTH EMERGENCY.—The Advisory Committee
14 shall make recommendations under paragraph (1)
15 with respect to the use of vaccines that—

16 “(A) are designated as a breakthrough
17 therapy under section 506 of the Federal Food,
18 Drug, and Cosmetic Act and licensed under sec-
19 tion 351 of this Act; or

20 “(B) are intended to address a public
21 health emergency as determined by the Sec-
22 retary under section 319.

23 “(5) LIMITATION.—If the Secretary or the Di-
24 rector takes an action regarding the use of vaccines
25 and related agents licensed under section 351 for ef-

1 fective control of vaccine-preventable diseases in the
2 civilian population of the United States (including
3 an action with respect to coverage under section
4 2713 or the listing of vaccines for purposes of the
5 program under section 1928 of the Social Security
6 Act) that is contrary to a recommendation of the
7 Advisory Committee, the Secretary or the Director
8 (as applicable) shall—

9 “(A) publish the basis for the action, in-
10 cluding an explanation on why the Secretary or
11 the Director (as applicable) found that the ac-
12 tion supports the findings of a preponderance of
13 the best available, peer-reviewed scientific evi-
14 dence; and

15 “(B) not later than 48 hours after taking
16 such action, the Secretary or the Director (as
17 applicable) shall submit a notification to the
18 Committee on Energy and Commerce of the
19 House of Representatives and the Committee
20 on Health, Education, Labor, and Pensions of
21 the Senate containing the information described
22 in subparagraph (A).

23 “(d) DUTIES.—

24 “(1) IN GENERAL.—

1 “(A) IN GENERAL.—The Advisory Com-
2 mittee shall do the following:

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

6 “(ii) Make immunization rec-
7 ommendations for purposes of the require-
8 ment under section 2713 for group health
9 plans and health insurance issuers offering
10 group or individual health insurance cov-
11 erage to provide coverage for immuniza-
12 tions that have in effect a recommendation
13 from the Advisory Committee.

14 “(iii) In accordance with section 1928
15 of the Social Security Act and this section,
16 establish and periodically review and, as
17 appropriate, revise the list of vaccines for
18 administration to children and adolescents
19 eligible to receive vaccines through the
20 Vaccines for Children Program, along with
21 schedules regarding the appropriate dose
22 and dosing interval, and contraindications
23 to administration of the pediatric vaccines.

24 “(B) USE OF LIST.—The Secretary, and
25 as delegated, the Director, shall use the list es-

1 tablished by the Advisory Committee for the
2 purpose of the purchase, delivery, and adminis-
3 tration of pediatric vaccines in the Vaccines for
4 Children Program under section 1928 of the
5 Social Security Act.

6 “(2) ADVICE AND GUIDANCE CONTENT.—Ad-
7 vice and guidance provided under paragraph (1)—

8 “(A) shall address—

9 “(i) the general use of vaccines and
10 immune globulin preparations as a class of
11 biologic agents;

12 “(ii) the use of specific antibody prod-
13 ucts for prevention of infectious diseases;
14 and

15 “(iii) special situations or populations
16 that may warrant modification of the rou-
17 tine recommendations for vaccine use;

18 “(B) may include recommendations for the
19 administration of immune globulin preparations
20 or antimicrobial therapy shown to be effective
21 in controlling a vaccine-preventable disease for
22 which a vaccine is available; and

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

1 “(i) population groups or cir-
2 cumstances in which a vaccine or related
3 agent is recommended;

4 “(ii) contraindications and pre-
5 cautions for use of the vaccine and related
6 agents; and

7 “(iii) information on recognized ad-
8 verse events associated with the use of
9 such vaccine.

10 “(3) EMERGENCY USE AUTHORIZATION.—Guid-
11 ance for use of vaccines and related agents author-
12 ized for emergency use under section 564 of the
13 Federal Food, Drug, and Cosmetic Act may be de-
14 veloped by the Advisory Committee if circumstances
15 warrant, including in the case of a public health
16 emergency, as determined by the Secretary under
17 section 319.

18 “(4) CONSIDERATIONS FOR RECOMMENDATION
19 DEVELOPMENT OR WITHDRAWAL OF RECOMMENDA-
20 TION.—The Advisory Committee, when making new
21 recommendations under subsection (c)(1), or revi-
22 sions or withdrawals of such recommendations under
23 paragraph (5), shall review evidence in the following
24 categories:

1 “(A) Identification of the specific interven-
2 tion, including dosage and schedule.

3 “(B) The strength of the design of the
4 study used to provide the evidence considered.

5 “(C) Randomized controlled trials or over-
6 whelming evidence from observational studies.

7 “(D) Comparison and outcome of the tar-
8 get population for the vaccine, including stand-
9 ard of care, existing vaccines, and other preven-
10 tion options.

11 “(E) Prevention outcome or scientifically
12 verified adverse effects associated with vaccina-
13 tion.

14 “(5) REVISION OR WITHDRAWAL OF REC-
15 OMMENDATION.—The Advisory Committee may re-
16 vise or withdraw any recommendation regarding a
17 particular vaccine under this subsection if and when
18 new information on disease epidemiology, vaccine ef-
19 fectiveness or safety, or other data become available,
20 and as supported by a preponderance of the best
21 available, peer-reviewed scientific evidence.

22 “(e) ADMINISTRATION.—

23 “(1) REPORTING STRUCTURE.—The Advisory
24 Committee shall report to the Director. The Director
25 shall inform the Secretary, the Assistant Secretary

1 for Health, and the Administrator of the Centers for
2 Medicare & Medicaid Services of immunization rec-
3 ommendations made by the Advisory Committee.

4 “(2) AGENCY SUPPORT.—For purposes of sup-
5 porting the Advisory Committee in carrying out this
6 section—

7 “(A) the Office of the Director of the Na-
8 tional Center for Immunization and Respiratory
9 Diseases of the Centers for Disease Control and
10 Prevention shall provide management and sup-
11 port services; and

12 “(B) the Advisory Committee may enter
13 into an agreement with the National Academies
14 of Sciences, Engineering, and Medicine to pro-
15 vide external support.

16 “(3) DESIGNATED FEDERAL OFFICER.—

17 “(A) SELECTION.—The Director shall se-
18 lect a full-time or permanent part-time Federal
19 employee to serve as the Designated Federal
20 Officer.

21 “(B) DUTIES.—The Designated Federal
22 Officer selected under subparagraph (A) shall—

23 “(i) attend each meeting of the Advi-
24 sory Committee (and any subcommittee

1 thereof) or select a designee to attend such
2 a meeting;

3 “(ii) ensure that all procedures of the
4 Advisory Committee for such a meeting are
5 within applicable statutory, regulatory, and
6 HHS General Administration Manual di-
7 rectives; and

8 “(iii) approve and prepare all policies
9 and agendas for each such meeting, call
10 any such meeting, adjourn any meeting
11 when the Designated Federal Officer
12 deems adjournment to be in the public in-
13 terest, and chair meetings when directed to
14 do so by the official to whom the Advisory
15 Committee reports.

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

23 “(f) MEETINGS.—

24 “(1) FREQUENCY.—Pursuant to the call of the
25 Designated Federal Officer, in consultation with the

1 Chair of the Advisory Committee, meetings shall be
2 held—

3 “(A) not less frequently than 3 times per
4 calendar year; and

5 “(B) upon the licensure of any vaccine, or
6 any new indication for a vaccine, under section
7 351(a), not later than 90 days after the date of
8 the first marketing of such vaccine.

9 “(2) OPEN TO THE PUBLIC.—Meetings of the
10 Advisory Committee shall be open to the public ex-
11 cept as determined otherwise by the Director, or
12 other official, to whom the authority has been dele-
13 gated, in accordance with sections 552b(c) and 1009
14 of title 5, United States Code. Notice of all such
15 meetings shall be given to the public.

16 “(g) MEMBERSHIP.—

17 “(1) IN GENERAL.—The Secretary shall appoint
18 at least 15 and not more than 19 individuals to
19 serve as members (including the chairperson) of the
20 Advisory Committee. Such individuals shall be ap-
21 pointed from among individuals recommended by the
22 Comptroller General of the United States. Such
23 members shall serve as Special Government Employ-
24 ees.

1 “(2) REQUIRED EXPERTISE.—The Comptroller
2 General of the United States may recommend as a
3 member of the Advisory Committee only an indi-
4 vidual who has expertise or experience with respect
5 to one or more of the following:

6 “(A) A prevalence of peer-reviewed and
7 best available scientific research.

8 “(B) Expertise relating to epidemiology
9 and vaccine-preventable disease burden.

10 “(C) Expert experience to rigorously evalu-
11 ate the best available scientific evidence with
12 immunization recommendations and public
13 health.

14 “(D) Expertise in immunology as evi-
15 denced by publications on the topic of immu-
16 nology in peer-reviewed journals.

17 “(E) Expertise in the use of vaccines and
18 other immunobiologic agents in clinical practice
19 or preventive medicine.

20 “(F) Expertise in infectious diseases, par-
21 ticularly human immune responses to vaccines,
22 assessment of vaccine efficacy or effectiveness,
23 or vaccine safety, as evidenced by publications
24 on the topic in peer-reviewed journals.

1 “(G) Expertise with clinical or laboratory
2 vaccine research.

3 “(H) Expertise in assessment of vaccine
4 efficacy and safety.

5 “(I) Knowledge about consumer perspec-
6 tives or the social and community aspects of im-
7 munization programs, or both.

8 “(3) EX-OFFICIO MEMBERS.—In addition to the
9 individuals appointed under paragraph (1), the
10 membership of the Advisory Committee shall include
11 the following 6 non-voting ex-officio members (or
12 their designees):

13 “(A) The Administrator of the Health Re-
14 sources and Services Administration.

15 “(B) The Commissioner of Food and
16 Drugs.

17 “(C) The Administrator of the Centers for
18 Medicare & Medicaid Services.

19 “(D) The Director of the National Insti-
20 tutes of Health.

21 “(E) The Director of the Indian Health
22 Service.

23 “(F) The Director of the National Vaccine
24 Program Office.

1 “(4) QUORUM.—Two-thirds of the voting mem-
2 bers of the Advisory Committee shall constitute a
3 quorum for purposes of meetings of the Advisory
4 Committee.

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

13 “(6) NON-VOTING LIAISON REPRESENTA-
14 TIVES.—Meetings of the Advisory Committee may be
15 attended by non-voting liaison representatives who
16 shall be deemed representatives from a stakeholder
17 organization.

18 “(7) TERMS.—

19 “(A) IN GENERAL.—Except as specified in
20 subparagraph (B), individuals appointed under
21 paragraph (1) shall be invited to serve as mem-
22 bers of the Advisory Committee for overlapping
23 terms of 4 years, except that any member ap-
24 pointed to fill a vacancy for an unexpired term
25 shall be appointed for the remainder of that

1 term. A member of the Advisory Committee
 2 may continue to serve on the Advisory Com-
 3 mittee for a period not to exceed 180 days after
 4 the expiration of that member's term if a suc-
 5 cessor has not taken office.

6 “(B) CHAIRPERSON.—The term of the
 7 Chairperson of the Advisory Committee shall be
 8 7 years.

9 “(h) SUBCOMMITTEES.—

10 “(1) IN GENERAL.—The Advisory Committee
 11 may, subject to approval by the Secretary (or the
 12 Secretary's designee), establish subcommittees com-
 13 posed, in part, of members of the Advisory Com-
 14 mittee and other subject matter experts.

15 “(2) REPORTING.—The subcommittees shall re-
 16 port back to the parent committee and may not pro-
 17 vide advice or work products directly to the Depart-
 18 ment of Health and Human Services.

19 “(3) DEPARTMENT COMMITTEE MANAGEMENT
 20 OFFICER.—The Secretary shall—

21 “(A) notify the Committee Management
 22 Officer of the Department of Health and
 23 Human Services upon establishment of each
 24 subcommittee; and

1 “(B) provide to such Officer information
 2 on the name, membership, function, and esti-
 3 mated frequency of meetings of such sub-
 4 committee.

5 “(i) RECORDKEEPING.—The records of the Advisory
 6 Committee, established subcommittees, or other subgroups
 7 of the committee, shall be managed in accordance with
 8 General Records Schedule 6.2, Federal Advisory Com-
 9 mittee Records, or other approved agency records disposi-
 10 tion schedule. Such records shall be available for public
 11 inspection and copying, subject to section 552 of title 5,
 12 United States Code.

13 “(j) DEFINITIONS.—In this section:

14 “(1) STAKEHOLDER ORGANIZATION.—The term
 15 ‘stakeholder organization’ means—

16 “(A) the American Academy of Family
 17 Physicians;

18 “(B) the American Academy of Pediatrics;

19 “(C) the American Academy of Physician
 20 Associates;

21 “(D) the American College Health Associa-
 22 tion;

23 “(E) the American College of Nurse Mid-
 24 wives;

- 1 “(F) the American College of Obstetricians
- 2 and Gynecologists;
- 3 “(G) the American College of Physicians;
- 4 “(H) the American Geriatrics Society;
- 5 “(I) the America’s Health Insurance
- 6 Plans;
- 7 “(J) the American Immunization Registry
- 8 Association;
- 9 “(K) the American Medical Association;
- 10 “(L) the American Nurses Association;
- 11 “(M) the American Osteopathic Associa-
- 12 tion;
- 13 “(N) the American Pharmacists Associa-
- 14 tion;
- 15 “(O) the Association of Immunization
- 16 Managers;
- 17 “(P) the Association for Prevention Teach-
- 18 ing and Research;
- 19 “(Q) the Association of State and Terri-
- 20 torial Health Officials;
- 21 “(R) the Biotechnology Innovation Organi-
- 22 zation;
- 23 “(S) the Council of State and Territorial
- 24 Epidemiologists;

1 “(T) the Canadian National Advisory
2 Committee on Immunization;

3 “(U) the Infectious Diseases Society of
4 America;

5 “(V) the International Society of Travel
6 Medicine;

7 “(W) the National Association of County
8 and City Health Officials;

9 “(X) the National Association of Pediatric
10 Nurse Practitioners;

11 “(Y) the National Foundation for Infec-
12 tious Diseases;

13 “(Z) the National Medical Association;

14 “(AA) the Pediatric Infectious Diseases
15 Society;

16 “(BB) the Pharmaceutical Research and
17 Manufacturers of America;

18 “(CC) the Society for Adolescent Health
19 and Medicine;

20 “(DD) the American Public Health Asso-
21 ciation;

22 “(EE) the Society for Healthcare Epidemi-
23 ology of America; and

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

1 carry out the functions of the Advisory Com-
2 mittee.

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

9 “(k) FUNDING.—There are authorized to be appro-
10 priated to carry out this section, including operating costs,
11 compensation and travel expenses for members, and staff
12 support of the Advisory Committee, \$2,800,000 for each
13 of fiscal years 2026 through 2029.”.

14 (b) RULE OF CONSTRUCTION.—Except as expressly
15 provided in the amendment made by subsection (a), noth-
16 ing in such amendment shall be construed as limiting the
17 authority of the Advisory Committee on Immunization
18 Practices, or the duties of such Advisory Committee, that
19 were in effect as of the day before the date of the enact-
20 ment of this Act, including with respect to subsections
21 (c)(2)(B)(i) and (e) of section 1928 of the Social Security
22 Act (42 U.S.C. 1396s) and section 2713(a)(2) of the Pub-
23 lic Health Service Act (42 U.S.C. 300gg–13(a)(2)) (as
24 such sections were in effect on the day before the date
25 of the enactment of this Act).

1 **SEC. 3. NATIONAL VACCINE INJURY COMPENSATION PRO-**
2 **GRAM.**

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

6 “(5) Any removal of a vaccine from the Vaccine
7 Injury Table, or any other modification under para-
8 graph (1), including any additions to the list of inju-
9 ries, disabilities, illnesses, conditions, and deaths for
10 which compensation may be provided, shall be sup-
11 ported by the preponderance of the best available
12 scientific evidence regarding the safety or efficacy of
13 the vaccine. Nothing in the preceding sentence shall
14 be construed to limit the authority of the Secretary
15 to amend the Vaccine Injury Table to include new
16 vaccines pursuant to subsection (e).”.

○