[Roll No. 517]

YEAS—233

Aderholt	Graves (MO)	Pearce
Amash	Green, Gene	Peterson
Amodei	Griffin (AR)	Petri
Bachmann	Griffith (VA)	Pittenger
Bachus	Grimm	Pitts
Barr	Guthrie	Poe (TX)
Barton	Hanna	Pompeo
Benishek	Harper	Posey
Bentivolio	Harris	Price (GA)
Bilirakis	Hartzler	Rahall
Bishop (UT)	Hastings (WA)	Reed
Black	Heck (NV)	Reichert
Blackburn	Hensarling	Renacci
Boustany	Herrera Beutler	Ribble
Brady (TX)	Holding	Rice (SC)
Brat	Hudson	Rigell
Bridenstine	Huelskamp	Roby
Brooks (AL)	Huizenga (MI)	Roe (TN)
Brooks (IN)	Hultgren	Rogers (AL)
Broun (GA)	Hunter	Rogers (KY)
Buchanan	Hurt	Rogers (MI)
Bucshon	Jenkins	Rohrabacher
Burgess	Johnson (OH)	Rokita
Byrne	Johnson, Sam	Rooney
Calvert	Jolly	Ros-Lehtinen
Camp	Jones	Roskam
Capito	Jordan	Ross
Carter	Joyce	Rothfus
Cassidy	Kelly (PA)	Royce
Chabot	King (IA)	Ryan (WI)
Chaffetz	King (NY)	Salmon
Clawson (FL)	Kingston	Sanford
Coble	Kinzinger (IL)	Scalise
Coffman	Kline	Schock
Cole	Labrador	Schweikert
Collins (GA)	LaMalfa	Scott, Austin
Collins (NY)	Lamborn	Scott, David
Conaway	Lance	Sensenbrenner
Cook	Lankford	Sessions
Cotton	Latham	Shimkus
Cramer	Latta	Shuster
Crawford	LoBiondo	Simpson
Crenshaw	Long	Smith (MO)
Culberson	Lucas	Smith (NE)
Daines	Luetkemeyer	Smith (NJ)
Davis, Rodney	Lummis	Smith (TX)
Denham	Marchant	Southerland
Dent	Marino	Stewart
DeSantis	Massie	Stivers
DesJarlais	Matheson	Stockman
Diaz-Balart	McAllister	Stutzman
Duffy	McCarthy (CA)	Terry
Duncan (SC)	McCaul	Thompson (PA)
Duncan (TN)	McClintock	Thornberry
Ellmers	McHenry	Tiberi
Farenthold	McIntyre	Tipton
Fincher	McKinley	Turner
Fitzpatrick	McMorris Rodgers	Upton
Fleischmann	Meadows	Valadao
Fleming	Meehan	Wagner
Flores	Messer	Walberg
Forbes	Mica	Walden
Fortenberry	Miller (FL)	Walorski
Foxx	Miller (MI)	Weber (TX)
Franks (AZ)	Mullin	Webster (FL)
Frelinghuysen	Mulvaney	Wenstrup
Gardner	Murphy (FL)	Westmoreland
Garrett	Murphy (PA)	Whitfield
Gerlach	Neugebauer	Williams
Gibbs	Noem	Wilson (SC)
Gibson	Nugent	Wittman
Gingrey (GA)	Nunes	Wolf
Gohmert	Nunnelee	Womack
Goodlatte	Olson	Woodall
Gosar	Owens	Yoder
Gowdy	Palazzo	Yoho
Granger	Paulsen	Young (AK)
Graves (GA)		Young (IN)

NAYS—185

Adams	Capps	Connolly
Barber	Capuano	Conyers
Barrow (GA)	Cárdenas	Cooper
Bass	Carney	Courtney
Beatty	Carson (IN)	Crowley
Becerra	Cartwright	Cuellar
Bera (CA)	Castor (FL)	Cummings
Bishop (GA)	Castro (TX)	Davis (CA)
Bishop (NY)	Chu	Davis, Danny
Bonamici	Cicilline	DeFazio
Brady (PA)	Clark (MA)	DeGette
Braley (IA)	Clarke (NY)	Delaney
Brown (FL)	Clay	DeLauro
Brownley (CA)	Cleaver	DelBene
Bustos	Clyburn	Deutch
Butterfield	Cohen	Dingell
Doggett	Lee (CA)	Richmond
Doyle	Levin	Roybal-Allard
Edwards	Lewis	Ruiz
Ellison	Lipinski	Ruppersberger
Engel	Loebsack	Rush
Eshoo	Lofgren	Ryan (OH)
Esty	Lowenthal	Sánchez, Linda T.
Farr	Lowey	Sanchez, Loretta
Fattah	Lujan Grisham (NM)	Sarbanes
Foster	Luján, Ben Ray (NM)	Schakowsky
Frankel (FL)	Lynch	Schiff
Fudge	Maffei	Schneider
Gabbard	Maloney, Carolyn	Schrader
Gallego	Maloney, Sean	Schwartz
Garamendi	Matsui	Scott (VA)
Garcia	McCarthy (NY)	Serrano
Grayson	McCollum	Sewell (AL)
Green, Al	McDermott	Shea-Porter
Grijalva	McGovern	Sherman
Gutiérrez	McNerney	Sinema
Hahn	Meeks	Sires
Hanabusa	Meng	Slaughter
Hastings (FL)	Michaud	Speier
Heck (WA)	Miller, George	Swalwell (CA)
Higgins	Moore	Takano
Himes	Nadler	Thompson (CA)
Holt	Napolitano	Thompson (MS)
Honda	Neal	Tierney
Horsford	Nolan	Titus
Hoyer	Norcross	Tonko
Huffman	O'Rourke	Tsongas
Israel	Pallone	Van Hollen
Jackson Lee	Pascrell	Vargas
Jeffries	Pastor (AZ)	Veasey
Johnson (GA)	Payne	Vela
Johnson, E. B.	Pelosi	Velázquez
Kaptur	Perlmutter	Visclosky
Keating	Peters (CA)	Walz
Kelly (IL)	Peters (MI)	Wasserman Schultz
Kennedy	Pingree (ME)	Waters
Kildee	Pocan	Waxman
Kilmer	Polis	Welch
Kind	Price (NC)	Wilson (FL)
Kirkpatrick	Quigley	Yarmuth
Kuster	Rangel	
Langevin		
Larsen (WA)		
Larson (CT)		

NOT VOTING—16

Barletta	Hall	Negrete McLeod
Blumenauer	Hinojosa	Perry
Campbell	Issa	Runyan
Costa	McKeon	Smith (WA)
Duckworth	Miller, Gary	
Enyart	Moran	

□ 1745

Ms. CASTOR of Florida changed her vote from ''yea'' to ''nay.''

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated against:

Mr. MORAN. Mr. Speaker, on rollcall No. 517, I was detained en route from National Airport. Had I been present, I would have voted "no."

SUNSCREEN INNOVATION ACT

Mr. LATTA. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (S. 2141) to amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

The text of the bill is as follows:

S. 2141

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Sunscreen Innovation Act''.

SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter I—Nonprescription Sunscreen and Other Active Ingredients

''SEC. 586. DEFINITIONS.

''In this subchapter—

''(1) the term 'Advisory Committee' means the Nonprescription Drug Advisory Committee of the Food and Drug Administration or any successor to such Committee;

''(2) the term 'final sunscreen order' means an order published by the Secretary in the Federal Register containing information stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

''(A) is GRASE and is not misbranded if marketed in accordance with such order; or

''(B) is not GRASE and is misbranded;

''(3) the term 'GRASE' means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of a drug as described in section 201(p);

''(4) the term 'GRASE determination' means, with respect to a nonprescription active ingredient or a combination of nonprescription active ingredients, a determination of whether such ingredient or combination of ingredients is GRASE;

''(5) the term 'nonprescription' means not subject to section 503(b)(1);

''(6) the term 'pending request' means each request with respect to a nonprescription sunscreen active ingredient submitted under section 330.14 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Sunscreen Innovation Act) for consideration for inclusion in the over-the-counter drug monograph system—

''(A) that was determined to be eligible for such review by publication of a notice of eligibility in the Federal Register prior to the date of enactment of such Act; and

''(B) for which safety and effectiveness data have been submitted to the Secretary prior to such date of enactment;

''(7) the term 'proposed sunscreen order' means an order containing a tentative determination published by the Secretary in the Federal Register containing information proposing that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

''(A) is GRASE and is not misbranded if marketed in accordance with such order;

''(B) is not GRASE and is misbranded; or

''(C) is not GRASE and is misbranded because the data are insufficient to classify such ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise;

''(8) the term 'sponsor' means the person that submitted—

''(A) a request under section 586A;

''(B) a pending request; or

''(C) any other application subject to this subchapter;

''(9) the term 'sunscreen' means a drug containing one or more sunscreen active ingredients; and

''(10) the term 'sunscreen active ingredient' means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

"SEC. 586A. SUBMISSION OF REQUESTS.

''Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen.

"SEC. 586B. ELIGIBILITY DETERMINATIONS; DATA SUBMISSION; FILING.

''(a) ELIGIBILITY DETERMINATIONS.—

''(1) IN GENERAL.—Not later than 60 calendar days after the date of receipt of a request under section 586A, the Secretary shall—

''(A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 586C;

''(B) notify the sponsor of the determination of the Secretary; and

''(C) make such determination publicly available in accordance with paragraph (3) and subsection (b)(1).

''(2) CRITERIA FOR ELIGIBILITY.—

''(A) IN GENERAL.—To be eligible for review under subsection (b) and section 586C, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

''(i) is not included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen; and

''(ii) has been used to a material extent and for a material time under such conditions, as described in section 201(p)(2).

''(B) ESTABLISHMENT OF TIME AND EXTENT.—A sponsor shall include in a request under section 586A the information required under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) to meet the standard described in subparagraph (A)(ii).

''(3) PUBLIC AVAILABILITY.—

''(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

''(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—At the time that a request is made under section 586A, the sponsor of such request shall identify any information that such sponsor considers to be confidential information described in subparagraph (A).

''(C) CONFIDENTIALITY DURING ELIGIBILITY REVIEW.—The information contained in a request under section 586A shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations (or any successor regulations).

''(b) DATA SUBMISSION AND FILING OF REQUESTS.—

''(1) IN GENERAL.—In the case of a request under section 586A that is determined to be eligible under subsection (a) for further review under this section and section 586C, the Secretary shall, in notifying the public under subsection (a)(1)(C) of such eligibility determination, post the eligibility determination on the Internet website of the Food and Drug Administration, invite the sponsor of such request and any other interested party to submit comments, and provide a period of not less than 45 calendar days for comments in support of or otherwise relating to a GRASE determination, including published and unpublished data and other information related to the safety and efficacy of such request.

''(2) FILING DETERMINATION.—Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, the Secretary shall determine whether the data and other information submitted by the sponsor under this section are sufficiently complete, including being formatted in a manner that enables the Secretary to determine the completeness of such data and information, to enable the Secretary to conduct a substantive review under section 586C with respect to such request. Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, if the Secretary determines—

''(A) that such data and other information are sufficiently complete, the Secretary shall—

''(i) issue a written notification to the sponsor of the determination to file such request, and make such notification publicly available; and

''(ii) file such request made under section 586A; or

''(B) that such data and other information are not sufficiently complete, the Secretary shall issue a written notification to the sponsor of the determination to refuse to file the request, which shall include the reasons for the refusal, including why such data and other information are not sufficiently complete, and make such notification publicly available.

''(3) REFUSAL TO FILE A REQUEST.—

''(A) REQUEST FOR MEETINGS; SUBMISSION OF ADDITIONAL DATA OR OTHER INFORMATION.—If the Secretary refuses to file a request made under section 586A, the sponsor may—

''(i) within 30 calendar days of receipt of written notification of such refusal, request, in writing, a meeting with the Secretary regarding the filing determination; and

''(ii) submit additional data or other information.

''(B) MEETINGS.—

''(i) IN GENERAL.—If a sponsor seeks a meeting under subparagraph (A)(i), the Secretary shall convene the meeting within 30 calendar days of the request for such meeting.

''(ii) ACTIONS AFTER MEETING.—Following any meeting held under clause (i)—

''(I) the Secretary may file the request within 60 calendar days;

''(II) the sponsor may submit additional data or other information; or

''(III) if the sponsor elects, within 120 calendar days, to have the Secretary file the request (with or without amendments to correct any purported deficiencies to the request)—

''(aa) the Secretary shall file the request over protest, not later than 30 calendar days after the sponsor makes such election;

''(bb) at the time of filing, the Secretary shall provide written notification of such filing to the sponsor; and

''(cc) the Secretary shall make such notification publicly available.

''(iii) REQUESTS FILED OVER PROTEST.—The Secretary shall not require the sponsor to resubmit a copy of the request for purposes of filing a request filed over protest, as described in clause (ii)(III).

''(C) SUBMISSIONS OF ADDITIONAL DATA OR OTHER INFORMATION.—Within 60 calendar days of any submission of additional data or other information under subparagraph (A)(ii) or (B)(ii)(II), the Secretary shall reconsider the previous determination made under paragraph (2) with respect to the applicable request and make a new determination in accordance with paragraph (2).

''(4) PUBLIC AVAILABILITY.—

''(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—After the period of confidentiality described in subsection (a)(3)(C), the Secretary shall make data and other information submitted in connection with a request under section 586A publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

''(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—A person submitting information under this section shall identify at the time of such submission the portions of such information that the person considers to be confidential information described in subparagraph (A).

"SEC. 586C. GRASE DETERMINATION.

''(a) REVIEW OF NEW REQUEST.—

''(1) PROPOSED SUNSCREEN ORDER.—In the case of a request under section 586A, not later than 300 calendar days after the date on which such request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 586B, the Secretary—

''(A) may convene a meeting of the Advisory Committee to review such request; and

''(B) shall complete the review of such request and issue a proposed sunscreen order with respect to such request.

''(2) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (1)(B) within such 300-day period, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. If such sponsor so notifies the Office of the Commissioner, the Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed sunscreen order with respect to such request.

''(3) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (1)(B) or (2) with respect to a request shall provide for a period of 45 calendar days for public comment.

''(4) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection and described in subparagraph (B) or (C) of section 586(7), not later than 30 calendar days after the Secretary issues such order. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after such request for a meeting.

''(5) FINAL SUNSCREEN ORDER.—With respect to a proposed sunscreen order under paragraph (1)(B) or (2)—

''(A) the Secretary shall issue a final sunscreen order—

''(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 586(7), not later than 90 calendar days after the end of the public comment period under paragraph (3); or

''(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7), not later than 210 calendar days after the date on which the sponsor submits

the additional information requested pursuant to such proposed sunscreen order; or

''(B) if the Secretary does not issue such final sunscreen order within such 90- or 210-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner.

''(6) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (5)(B) not later than 60 calendar days after the date of notification under such paragraph.

''(b) REVIEW OF PENDING REQUESTS.—

''(1) IN GENERAL.—The review of a pending request shall be carried out by the Secretary in accordance with this subsection.

''(2) INAPPLICABILITY OF SECTIONS 586A AND 586B.—Sections 586A and 586B shall not apply with respect to any pending request.

''(3) FEEDBACK LETTERS AS PROPOSED SUNSCREEN ORDER.—Notwithstanding the requirements of section 586(7), a letter issued pursuant to section 330.14(g) of title 21, Code of Federal Regulations before the date of enactment of the Sunscreen Innovation Act, with respect to a pending request, shall be deemed to be a proposed sunscreen order and displayed on the Internet website of the Food and Drug Administration. Notification of the availability of such letter shall be published in the Federal Register not later than 45 calendar days after the date of enactment of such Act.

''(4) PROPOSED SUNSCREEN ORDER.—In the case of a pending request for which the Secretary has not issued a letter pursuant to section 330.14(g) of title 21, Code of Federal Regulations before the date of enactment of the Sunscreen Innovation Act, the Secretary shall complete review of such request and, not later than 90 calendar days after the date of enactment of such Act, issue a proposed sunscreen order with respect to such request.

''(5) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (4), or the Secretary does not publish a notification of the availability of a letter under paragraph (3), as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. The Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed order with respect to such request.

''(6) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (4) or (5), or a notification of the availability of a letter under paragraph (3), with respect to a pending request shall provide for a period of 45 calendar days for public comment.

''(7) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection, including a letter deemed to be a proposed sunscreen order under paragraph (3), not later than 30 calendar days after the Secretary issues such order or the date upon which such feedback letter is deemed to be a proposed sunscreen order, as applicable. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after the date of such request for a meeting.

''(8) ADVISORY COMMITTEE.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5), an Advisory Committee meeting may be convened for the purpose of reviewing and providing recommendations regarding the pending request.

''(9) FINAL SUNSCREEN ORDER.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5)—

''(A) the Secretary shall issue a final sunscreen order with respect to the request—

''(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 586(7), not later than 90 calendar days after the end of the public comment period under paragraph (6); or

''(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7)—

''(I) if the Advisory Committee is not convened under paragraph (8), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order, which shall include a rationale for not convening such Advisory Committee; or

''(II) if the Advisory Committee is convened under paragraph (8), not later than 270 calendar days after the date on which the sponsor submits such additional information; or

''(B) if the Secretary does not issue such final sunscreen order within such 90-, 210-, or 270-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner about such request and request review by the Office of the Commissioner.

''(10) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (9)(B) not later than 60 calendar days after the date of notification under such paragraph.

''(c) ADVISORY COMMITTEE.—The Secretary shall not be required to—

''(1) convene the Advisory Committee—

''(A) more than once with respect to any request under section 586A or any pending request; or

''(B) more than twice in any calendar year with respect to the review under this section; or

''(2) submit more than a total of 3 requests under section 586A or pending requests to the Advisory Committee per meeting.

''(d) NO DELEGATION.—Any responsibility vested in the Commissioner by subsection (a)(2), (a)(6), (b)(5), or (b)(10) shall not be delegated.

''(e) EFFECT OF FINAL SUNSCREEN ORDER.—

''(1) IN GENERAL.—

''(A) SUNSCREEN ACTIVE INGREDIENTS DETERMINED TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, a sunscreen containing such ingredient or combination of ingredients shall be permitted to be introduced or delivered into interstate commerce for use under the conditions described in such final sunscreen order, in accordance with all requirements applicable to drugs not subject to section 503(b)(1), for so long as such final sunscreen order remains in effect.

''(B) SUNSCREEN ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded, a sunscreen containing such ingredient or combination of ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions described in such final sunscreen order, unless an application is approved pursuant to section 505 with respect to a sunscreen containing such ingredient or combination of ingredients, or unless conditions are later established under which such ingredient or combination of ingredients is later determined to be GRASE and not misbranded under the over-the-counter drug monograph system.

''(2) AMENDMENTS TO FINAL SUNSCREEN ORDERS.—

''(A) AMENDMENTS AT INITIATIVE OF SECRETARY.—In the event that information relevant to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients becomes available to the Secretary after issuance of a final sunscreen order, the Secretary may amend such final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

''(B) PETITION TO AMEND FINAL ORDER.—Any interested person may petition the Secretary to amend a final sunscreen order under section 10.30, title 21 Code of Federal Regulations (or any successor regulations). If the Secretary grants any petition under such section, the Secretary shall initiate the process for amending a final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

''(C) APPLICABILITY OF FINAL ORDERS.—Once the Secretary issues a new proposed sunscreen order to amend a final sunscreen order under subparagraph (A) or (B), such final sunscreen order shall remain in effect and paragraph (3) shall not apply to such final sunscreen order until the Secretary has issued a new final sunscreen order or has determined not to amend the final sunscreen order.

''(3) INCLUSION OF INGREDIENTS THAT ARE SUBJECTS OF FINAL ORDERS IN THE SUNSCREEN MONOGRAPH.—

''(A) AMENDING REGULATIONS.—

''(i) REQUIREMENT.—At any time that the Secretary proposes to amend part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen, including pursuant to section 586E, except as provided in clause (iv), the Secretary shall include in such part 352 (or any successor regulations) any nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of an effective final sunscreen order of the type described in section 586(2)(A) and issued since the time that the Secretary last amended such regulations. Such regulation shall set forth conditions of use under which each such ingredient or combination of ingredients is GRASE and not misbranded. If these conditions differ from, or are in addition to, those previously set forth in the applicable final sunscreen order, the Secretary shall provide notice and opportunity for comment on such conditions in the rulemaking, and the applicable final sunscreen order shall continue in effect until the effective date of a final regulation, as set forth in clause (iii).

''(ii) INCLUSION OF ORDERS.—In proposing to amend the regulations as described in clause (i), the Secretary shall include in the proposed regulations a list of final sunscreen orders that shall cease to be effective on the effective date of a resulting final regulation. Such list shall include all final sunscreen orders of the type described in section 586(2)(A) that are in effect on the date that such regulations are proposed, with the exception that such list shall not include any final sunscreen orders that, on the date that the regulations are proposed, the Secretary is in the process of amending under paragraph (2).

''(iii) ORDERS NO LONGER EFFECTIVE.—Any final sunscreen order included by the Secretary in a list described in clause (ii) and in a list included in resulting final regulations shall cease to be effective on the date that such final regulations including such order in such list become effective.

''(iv) INGREDIENTS NOT GRASE.—If, notwithstanding a final sunscreen order stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded if marketed in accordance with such order, while amending the regulations as described in clause (i), the Secretary concludes that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen, the Secretary shall, at the discretion of the Secretary, either initiate the process for amending the final sunscreen order set forth in paragraph (2) of this subsection or include in a proposed regulation an explanation and information supporting the determination of the Secretary that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen.

''(B) PROCEDURE FOR UPDATING REGULATIONS.—After the Secretary amends and finalizes the regulations under part 352 of title 21, Code of Federal Regulations under section 586E and such regulations become effective, the Secretary may use direct final rulemaking to include in such regulations any nonprescription sunscreen active ingredients that are the subject of effective final sunscreen orders.

''SEC. 586D. GUIDANCE; OTHER PROVISIONS.

''(a) GUIDANCE.—

''(1) IN GENERAL.—

''(A) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue draft guidance on the implementation of, and compliance with, the requirements with respect to sunscreen under this subchapter, including guidance on—

''(i) the format and content of information submitted by a sponsor in support of a request under section 586A or a pending request;

''(ii) the data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

''(iii) the process by which a request under section 586A or a pending request is withdrawn; and

''(iv) the process by which the Secretary will carry out section 586C(c), including with respect to how the Secretary will address the total number of requests received under section 586A and pending requests.

''(B) FINAL GUIDANCE.—The Secretary shall finalize the guidance described in subparagraph (A) not later than 2 years after the date of enactment of the Sunscreen Innovation Act.

''(C) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code shall not apply to collections of information made for purposes of guidance under this subsection.

''(2) SUBMISSIONS PENDING ISSUANCE OF FINAL GUIDANCE.—Irrespective of whether final guidance under paragraph (1) has been issued—

''(A) persons may, beginning on the date of enactment of the Sunscreen Innovation Act, make submissions under this subchapter; and

''(B) the Secretary shall review and act upon such submissions in accordance with this subchapter.

''(b) RULES OF CONSTRUCTION.—

''(1) CURRENTLY MARKETED SUNSCREENS.—Nothing in this subchapter shall be construed to affect the marketing of sunscreens that are marketed in interstate commerce on or before the date of enactment of this subchapter, except as otherwise provided in this subchapter.

''(2) ENSURING SAFETY AND EFFECTIVENESS.—Nothing in this subchapter shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this subchapter, including section 586C(e).

''(3) OTHER DRUGS.—Except as otherwise provided in section 586F, nothing in this subchapter shall be construed to affect the authority of the Secretary under this Act or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

''(4) EFFECT ON DRUGS OTHERWISE APPROVED.—Nothing in this subchapter shall affect the marketing of a drug approved under section 505 of this Act or section 351 of the Public Health Service Act.

''(c) TIMELINES.—The timelines for the processes and procedures under paragraphs (1), (2), (5), and (6) of section 586C(a) shall not apply to any requests submitted to the Secretary under section 586A after the date that is 6 years after the date of enactment of the Sunscreen Innovation Act.

''SEC. 586E. SUNSCREEN MONOGRAPH.

''(a) IN GENERAL.—Not later than 5 years after the date of enactment of the Sunscreen Innovation Act, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after such date of enactment. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

''(b) REPORTS.—If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval under section 505, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for such provisions not being included in such regulations, and a plan and timeline to compile any information necessary to address such provisions through final regulations.''.

(b) RULES OF CONSTRUCTION.—Nothing in the amendment made by this section shall be construed to—

(1) limit the right of a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) to request that the Secretary of Health and Human Services convene an advisory committee; or

(2) limit the authority of the Secretary of Health and Human Services to meet with a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)).

SEC. 3. NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.

Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2, is amended by adding at the end the following:

''SEC. 586F. NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.

''(a) PENDING TIME AND EXTENT APPLICATIONS.—

''(1) IN GENERAL.—

''(A) REQUEST FOR FRAMEWORK FOR REVIEW.—If, prior to the date of enactment of the Sunscreen Innovation Act, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations for a GRASE determination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and such drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of such application may request that the Secretary provide a framework under paragraph (2) for the review of such application.

''(B) REQUEST REQUIREMENTS.—A request for a framework for review of an application made under subparagraph (A) shall be made within 180 calendar days of the date of enactment of the Sunscreen Innovation Act and shall include the preference of such sponsor as to whether such application is reviewed by the Secretary in accordance with—

''(i) the processes and procedures set forth for pending requests under section 586C(b), except that specific timelines shall be determined in accordance with other applicable requirements under this section;

''(ii) the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations);

''(iii) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth for pending requests under section 586C(b), except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

''(iv) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations).

''(C) NO REQUEST.—If a sponsor described in subparagraph (A) does not make such request within 180 calendar days of the date of enactment of the Sunscreen Innovation Act, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

''(2) FRAMEWORK.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Secretary shall provide, in writing, a framework to each sponsor that submitted a request under paragraph (1). Such framework shall set forth the various timelines, in calendar days, with respect to the processes and procedures for review under clauses (i), (ii), (iii), and (iv) of paragraph (1)(B) and—

''(A) such timelines shall account for the considerations under paragraph (5); and

''(B) the timelines for the various processes and procedures shall not be shorter than the timelines set forth for pending requests under sections 586B(b) and 586C(b), as applicable.

''(3) GOVERNING PROCESSES AND PROCEDURES FOR REVIEW.—

''(A) ELECTION.—Not later than 60 calendar days after the Secretary provides a framework to a sponsor under paragraph (2), such sponsor may provide an election to the Secretary regarding the processes and procedures for review under clause (i), (ii), (iii), or (iv) of paragraph (1)(B). If such sponsor makes such election, the Secretary shall review the application that is the subject of such election pursuant to the processes and procedures elected by such sponsor and the applicable timelines in calendar days set forth under such framework, which the Secretary shall confirm in writing to the sponsor not later than the date upon which the Secretary provides a report under paragraph (4). If such sponsor does not make such election, such application shall be reviewed by

the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

''(B) DIFFERENT PROCESSES AND PROCEDURES.—At any time during review of an application, the Secretary may review such application under different processes and procedures under clause (i), (ii), (iii), or (iv) of paragraph (1)(B) than the processes and procedures the sponsor elected in accordance with subparagraph (A), so long as the Secretary proposes, in writing, the change and the sponsor agrees, in writing, to such change.

''(C) INCLUSION OF INGREDIENTS IN MONOGRAPHS.—If the sponsor elects to use the processes and procedures for review in accordance with clause (i) or (iii) of paragraph (1)(B), the Secretary may incorporate any resulting final order into a regulation addressing the conditions under which other drugs in the same therapeutic category are GRASE and not misbranded, including through direct final rulemaking, and the final order so incorporated shall cease to be effective on the effective date of the final regulation that addresses such drug.

''(4) LETTER REGARDING PENDING APPLICATIONS.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, in writing, regarding all pending applications subject to paragraph (1). In such letter, the Secretary shall provide a report on the review of such applications, including the timelines, in calendar days, for the review and GRASE determination for each application. Such timelines shall account for the considerations under paragraph (5).

''(5) TIMELINES.—The timelines in calendar days established by the Secretary pursuant to this subsection—

''(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

''(B) shall—

''(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

''(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraphs (1)(B) and (2); and

''(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

''(b) NEW TIME AND EXTENT APPLICATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue proposed regulations establishing timelines for the review of applications for GRASE determinations for drugs other than nonprescription sunscreen active ingredients or combinations of nonprescription sunscreen active ingredients that are submitted to the Secretary after the date of enactment of the Sunscreen Innovation Act, under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations), and that are found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations (or any successor regulations), or that are subject to this subsection pursuant to paragraph (1) or (3) of subsection (a), as applicable, providing—

''(A) timely and efficient completion of evaluations of applications under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) for drugs other than sunscreens; and

''(B) timely and efficient completion of the review of the safety and effectiveness submissions pursuant to such applications, including establishing—

''(i) reasonable timelines, in calendar days, for the applicable proposed and final regulations for applications of various content, complexity, and format, and timelines for internal procedures related to such processes; and

''(ii) measurable metrics for tracking the extent to which the timelines set forth in the regulations are met.

''(2) TIMELINES.—The timelines in calendar days established in the regulations under paragraph (1)—

''(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

''(B) shall—

''(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

''(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraph (1); and

''(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

''(3) PROCEDURE.—In promulgating regulations under this subsection, the Secretary shall issue a notice of proposed rulemaking that includes a copy of the proposed regulation, provide a period of not less than 60 calendar days for comments on the proposed regulation, and publish the final regulation not less than 30 calendar days before the effective date of the regulation.

''(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraphs (1), (2), and (3).

''(5) FINAL REGULATIONS.—The Secretary shall finalize the regulations under this section not later than 27 months after the date of enactment of the Sunscreen Innovation Act.''.

SEC. 4. REPORTS.

(a) INITIAL GAO REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report reviewing the overall progress of the Secretary of Health and Human Services in carrying out subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (as added by section 2 and amended by section 3 and subsection (c)), including findings on and recommendations with respect to—

(1) the progress made in completing the review of requests under subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, including pending requests, and the feasibility of the timelines associated with such subchapter;

(2) the role of the Office of the Commissioner of Food and Drugs in issuing determinations with respect to requests reviewed under such subchapter, including the number of requests transferred to the Office of the Commissioner under section 586C of such Act;

(3) the extent to which advisory committees were convened by the Secretary regarding requests under subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, including pending requests; and

(4) the types of metrics that have been, or should be, established for the review of time and extent applications.

(b) SUBSEQUENT GAO REPORT.—Not later than 5½ years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report reviewing the overall progress of the Secretary of Health and Human Services in carrying out subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (as added by section 2 and amended by section 3 and subsection (c)) and the regulation of over-the-counter drug products, including findings on and recommendations with respect to—

(1) updates on the matters reported on by the Comptroller General under subsection (a);

(2) significant factors impacting the ability of the Food and Drug Administration to fulfill the mission of the agency with regard to the regulation of over-the-counter drug products, including finalizing outstanding monographs and responding to emerging and novel safety issues;

(3) the performance of the Secretary in carrying out section 586E of the Federal Food, Drug, and Cosmetic Act;

(4) the types of metrics that have been, or should be, established for the review and regulation of over-the-counter drug products; and

(5) timeliness, efficiency, and accountability in reviewing time and extent applications and safety and effectiveness reviews for over-the-counter drug products.

(c) FDA REPORT.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 3, is further amended by adding at the end the following:

''SEC. 586G. REPORT.

''(a) IN GENERAL.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, and on the dates that are 2 and 4 years thereafter, the Secretary shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives describing actions taken under this subchapter.

''(2) CONTENTS.—The reports under this subsection shall include—

''(A) a review of the progress made in issuing GRASE determinations for pending requests, including the number of pending requests—

''(i) reviewed and the decision times for each request, measured from the date of the original request for an eligibility determination submitted by the sponsor;

''(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

''(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded and the reasons for such determinations; and

''(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

''(B) a review of the progress made in issuing GRASE determinations for requests not included in the reporting under subparagraph (A), including the number of such requests—

''(i) reviewed and the decision times for each request;

''(ii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is GRASE and is not misbranded;

''(iii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is not GRASE and is misbranded and the reasons for such determinations; and

''(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

''(C) an annual accounting (including information from years prior to the date of enactment of the Sunscreen Innovation Act where such information is available) of the total number of requests submitted, pending, or completed under this subchapter, including whether such requests were the subject of an advisory committee convened by the Secretary;

''(D) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this subchapter;

''(E) a review of the progress made in meeting the deadlines with respect to processing requests under this subchapter; and

''(F) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of requests under this subchapter, including the advisory committee review process.

''(b) METHOD.—The Secretary shall publish the reports under subsection (a) in the manner the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.''.

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

TRAUMATIC BRAIN INJURY REAUTHORIZATION ACT OF 2014

Mr. LATTA. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (S. 2539) to amend the Public Health Service Act to reauthorize certain programs relating to traumatic brain injury and to trauma research, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

The text of the bill is as follows:

S. 2539

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Traumatic Brain Injury Reauthorization Act of 2014''.

SEC. 2. CDC PROGRAMS FOR PREVENTION AND SURVEILLANCE OF TRAUMATIC BRAIN INJURY.

(a) PREVENTION OF TRAUMATIC BRAIN INJURY.—Section 393B(b)(3) of the Public Health Service Act (42 U.S.C. 280b–1c(b)(3)) is amended by striking ''2010, commonly referred to as Healthy People 2010'' and inserting ''2020, commonly referred to as Healthy People 2020''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 394A of the Public Health Service Act (42 U.S.C. 280b–3) is amended—

(1) by striking the section heading and all that follows through ''For the purpose'' and inserting the following:

''SEC. 394A. AUTHORIZATION OF APPROPRIATIONS.

''(a) IN GENERAL.—For the purpose'';

(2) by striking the second period; and

(3) by adding at the end the following:

''(b) TRAUMATIC BRAIN INJURY.—To carry out sections 393B and 393C, there are authorized to be appropriated $6,564,000 for each of fiscal years 2015 through 2019.''.

SEC. 3. STATE GRANTS FOR PROJECTS REGARDING TRAUMATIC BRAIN INJURY.

Section 1252 of the Public Health Service Act (42 U.S.C. 300d–52) is amended—

(1) in subsection (a), by striking '', acting through the Administrator of the Health Resources and Services Administration,'';

(2) in paragraphs (1)(A)(i) and (3)(E) of subsection (f), by striking ''brain injury'' and inserting ''traumatic brain injury'';

(3) in subsection (h), by striking ''under this section, and section 1253 including'' and inserting ''under this section and section 1253, including''; and

(4) in subsection (j), by striking ''such sums as may be necessary for each of the fiscal years 2001 through 2005, and such sums as may be necessary for each of the fiscal years 2009 through 2012'' and inserting ''$5,500,000 for each of the fiscal years 2015 through 2019''.

SEC. 4. STATE GRANTS FOR PROTECTION AND ADVOCACY SERVICES.

Section 1253 of the Public Health Service Act (42 U.S.C. 300d–53) is amended—

(1) in subsection (a), by striking '', acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Administrator'),'';

(2) in subsections (c), (d)(1), (e)(1), (e)(4), (g), (h), and (j)(1), by striking ''Administrator'' each place it appears and inserting ''Secretary'';

(3) in subsection (h)—

(A) by striking the subsection heading and inserting ''**REPORTING**'';

(B) by striking ''Each protection and advocacy system'' and inserting the following:

''(1) REPORTS BY SYSTEMS.—Each protection and advocacy system''; and

(C) by adding at the end the following:

''(2) REPORT BY SECRETARY.—Not later than 1 year after the date of enactment of the Traumatic Brain Injury Reauthorization Act of 2014, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the services and activities carried out under this section during the period for which the report is being prepared.'';

(4) in subsection (i), by striking ''The Administrator of the Health Resources'' and all that follows through ''regarding'' and inserting ''The Secretary shall facilitate agreements to coordinate the collection of data by agencies within the Department of Health and Human Services regarding'';

(5) in subsection (k), by striking ''subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000'' and inserting ''subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)'';

(6) in subsection (l), by striking ''$5,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2009 through 2012'' and inserting ''$3,100,000 for each of the fiscal years 2015 through 2019''; and

(7) in subsection (m)—

(A) in paragraph (1), by striking ''part C of the Developmental Disabilities Assistance Bill of Rights Act (42 U.S.C. 6042 et seq.)'' and inserting ''subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)''; and

(B) in paragraph (2), by striking ''part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6042 et seq.)'' and inserting ''subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)''.

SEC. 5. TRAUMATIC BRAIN INJURY COORDINATION PLAN.

(a) DEVELOPMENT OF PLAN.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall develop a plan for improved coordination of Federal activities with respect to traumatic brain injury. Such plan shall—

(1) review existing interagency coordination efforts with respect to Federal activities related to traumatic brain injury, including services for individuals with traumatic brain injury;

(2) identify areas for improved coordination between relevant Federal agencies and programs, including agencies and programs with a focus on serving individuals with disabilities;

(3) identify each recommendation in the report required by section 393C(b) of the Public Health Service Act (42 U.S.C. 280b–1d(b)) that has been adopted and each such recommendation that has not been adopted, and describe any planned activities to address each such recommendation that has not been adopted; and

(4) incorporate, as appropriate, stakeholder feedback, including feedback from individuals with traumatic brain injury and their caregivers.

(b) SUBMISSION TO CONGRESS.—The Secretary of Health and Human Services shall submit the plan developed under subsection (a) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

SEC. 6. REVIEW OF BRAIN INJURY MANAGEMENT IN CHILDREN.

The Director of the Centers for Disease Control and Prevention, in consultation with the Director of the National Institutes of Health, shall conduct a review of the scientific evidence related to brain injury management in children, such as the restriction or prohibition of children from attending school or participating in athletic activities following a head injury, and identify ongoing and potential further opportunities for research. Not later than 2 years after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives the results of such review.

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.