

Foreign Assistance Act of 1961 to modify treatment activities for assistance to combat HIV/AIDS.

S. 3130

At the request of Mr. McCORMICK, the name of the Senator from Ohio (Mr. MORENO) was added as a cosponsor of S. 3130, a bill to direct the Secretary of Veterans Affairs to carry out a program to award grants to eligible entities to develop, implement, and evaluate approaches and methodologies for prospective randomized control trials for neurorehabilitation treatments for the treatment of chronic mild traumatic brain injury in veterans, and for other purposes.

S. 3179

At the request of Mrs. MOODY, the name of the Senator from North Carolina (Mr. BUDD) was added as a cosponsor of S. 3179, a bill to amend title 18, United States Code, to establish a criminal penalty for obstructing immigration enforcement activities.

S. 3267

At the request of Ms. COLLINS, the name of the Senator from Indiana (Mr. BANKS) was added as a cosponsor of S. 3267, a bill to amend title XVIII of the Social Security Act to provide for Medicare coverage of blood-based dementia screening tests.

S. 3277

At the request of Mr. BLUMENTHAL, the name of the Senator from Maryland (Ms. ALSOBROOKS) was added as a cosponsor of S. 3277, a bill to amend the Higher Education Act of 1965 to provide for a percentage of student loan forgiveness for public service employment, and for other purposes.

S. 3302

At the request of Mr. MULLIN, the name of the Senator from Michigan (Ms. SLOTKIN) was added as a cosponsor of S. 3302, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes.

S. 3344

At the request of Mr. MERKLEY, the name of the Senator from New Jersey (Mr. KIM) was added as a cosponsor of S. 3344, a bill to prohibit the unauthorized use of United States Armed Forces in hostilities with respect to Venezuela.

S. 3366

At the request of Mr. CORNYN, the name of the Senator from Alaska (Mr. SULLIVAN) was added as a cosponsor of S. 3366, a bill to protect law enforcement officers, and for other purposes.

S. 3392

At the request of Mr. WYDEN, the names of the Senator from Illinois (Ms. DUCKWORTH) and the Senator from West Virginia (Mr. JUSTICE) were added as cosponsors of S. 3392, a bill to direct the Secretary of Agriculture to designate an Agritourism Advisor, and for other purposes.

## STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. DURBIN:

S. 3421. A bill to improve medical device recall notifications by amending the Federal Food, Drug, and Cosmetic Act to establish an electronic format for device recall notifications, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

S. 3421

*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 “Medical Device Recall Improvement Act of 2025”.

### SEC. 2. REGULATION OF MEDICAL DEVICE RECALLS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), is amended by inserting after section 518A of such Act the following:

#### “SEC. 518B. ELECTRONIC NOTIFICATION FORMAT FOR DEVICE RECALLS.

“(a) ELECTRONIC NOTIFICATION FORMAT FOR DEVICE RECALLS.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Medical Device Recall Improvement Act of 2025, the Secretary shall publish a form and manner for notifications of a recall.

“(2) CONTENT.—The form and manner prescribed by the Secretary under paragraph (1) shall—

“(A) be electronic;

“(B) include mandatory data elements, including—

“(i) the name of the manufacturer or importer;

“(ii) the contact information and address of the manufacturer or importer;

“(iii) the specific reason for the correction or removal from the market of the device;

“(iv) the specific device of the manufacturer or importer subject to such recall;

“(v) the unique device identifier of the device, including, as applicable, the device identifier and any production identifier;

“(vi) information for device user facilities and health professionals with regard to the device and such recall; and

“(vii) information for patients with regard to the device and such recall, including—

“(I) the risk presented by the device; and

“(II) any action that may be taken by, or on behalf of, such patients to eliminate or reduce such risk; and

“(C) include optional data elements as the Secretary determines to be appropriate.

“(b) NOTIFICATIONS.—

“(1) NOTIFICATIONS TO THE SECRETARY.—

“(A) IN GENERAL.—Beginning 180 days after the Secretary establishes the form and manner for recall notifications under subsection (a), a manufacturer or importer of a device shall submit notifications required under section 519(g) to the Secretary through the electronic notification format established under subsection (a).

“(B) REVIEW REQUIREMENT.—

“(i) INITIAL REVIEW.—Not later than 2 business days after receipt of a notification described in subparagraph (A), the Secretary shall conduct an initial review of such notification.

“(ii) RESPONSE OF THE SECRETARY.—Not later than 3 business days after the completion of such review, the Secretary shall inform the manufacturer or importer of the information the Secretary determines, through the initial review under clause (i), should be shared with device user facilities and health professionals.

“(2) NOTIFICATIONS TO DEVICE USER FACILITIES AND HEALTH PROFESSIONALS.—

“(A) INITIAL NOTIFICATIONS.—A manufacturer or importer shall submit notifications to device user facilities and health professionals through the electronic notification format established under subsection (a) after an initial review by the Secretary is completed under paragraph (1)(B)(i).

“(B) SUBSEQUENT NOTIFICATIONS.—A manufacturer or importer shall provide notifications in addition to those described in subparagraph (A), as necessary, to device user facilities or health professionals through the electronic notification format established under subsection (a).

“(c) ELECTRONIC DATABASE.—The Secretary shall maintain an electronic database that is publicly accessible, downloadable, and populated with information regarding device notifications made under this section.

“(d) DEFINITIONS.—In this section and in section 518C—

“(1) the term ‘device user facility’ has the meaning given such term in section 519(b)(6); and

“(2) the term ‘recall’ has the meaning given such term in section 518A.

“(e) AUTHORIZATION OF APPROPRIATIONS.—

For purposes of conducting activities under this section and hiring personnel to conduct such activities, there is authorized to be appropriated \$6,700,000 for fiscal year 2026, \$1,700,000 for fiscal year 2027, and \$1,000,000 for each of fiscal years 2028 through 2030, to remain available until expended, without fiscal year limitation.

#### “SEC. 518C. PATIENT NOTIFICATION.

“(a) IN GENERAL.—The Secretary shall require that any recall strategy under section 519(g) provides for notice to patients whom device user facilities and health professionals treated with the device.

“(b) COMPLIANCE.—In accordance with subsection (a), the Secretary shall require recall notifications sent from the manufacturer or importer of the device to—

“(1) include information for device user facilities and health professionals about the risks presented by the device to patients whom device user facilities and health professionals treated with the device; and

“(2) instruct such device user facilities and health professionals to share information under paragraph (1) with patients whom device user facilities and health professionals treated with the device.

“(c) AFFECTED DEVICES.—Subsection (a) shall apply with respect to any class I or class II recall for a class II or class III device that is used outside of device user facilities and—

“(1) implanted in the human body;

“(2) life-sustaining;

“(3) life-supporting; or

“(4) used significantly in pediatric populations.

“(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require device user facilities or health professionals to provide patient information to the manufacturer or importer of the device.”.

#### SEC. 3. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following

“(jjj) The refusal or failure to submit notifications in accordance with paragraphs (1) and (2) of section 518B(b).

“(kkk) The refusal or failure to provide notice in accordance with section 518C.”.

By Mr. DURBIN (for himself and Mr. BLUMENTHAL):

S. 3422. A bill to establish the Federal Food Administration within the Department of Health and Human Services; to the Committee on Health, Education, Labor, and Pensions.

S. 3422

*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 “Federal Food Administration Act of 2025”.

#### SEC. 2. ESTABLISHMENT OF FEDERAL FOOD ADMINISTRATION.

(a) **ESTABLISHMENT.**—As soon as practicable, but not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall establish within the Department of Health and Human Services an agency to be known as the “Federal Food Administration”.

(b) **MISSION.**—The Federal Food Administration shall—

(1) promote the public health by promptly and efficiently reviewing food and nutrition research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled;

(3) participate through appropriate processes with representatives of other countries to protect public health and promote fair trade practices in food; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) **INTERAGENCY COLLABORATION.**—The Secretary shall implement programs and policies that will foster collaboration between the Federal Food Administration, the Department of Agriculture, the Centers for Disease Control and Prevention, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, investigation, evaluation, and postmarket monitoring of food.

(d) **COMMISSIONER OF FOODS.**—

(1) **IN GENERAL.**—The Federal Food Administration shall be headed by the Commissioner of Foods, who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) **GENERAL POWERS.**—The Secretary, acting through the Commissioner of Foods, shall be responsible for—

(A) providing overall direction to the Federal Food Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Federal Food Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Federal Food Administration;

(C) research relating to foods in carrying out the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(D) conducting educational and public information programs relating to the responsibilities of the Federal Food Administration; and

(E) performing such other functions as the Secretary may prescribe.

(e) **TECHNICAL AND SCIENTIFIC REVIEW GROUPS.**—The Secretary, acting through the Commissioner of Foods, may, without regard

to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Federal Food Administration, including functions under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) relating to food, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

#### SEC. 3. INSPECTION OF FOOD FACILITIES.

(a) **ESTABLISHMENT OF INSPECTION PROGRAM.**—

(1) **IN GENERAL.**—The Commissioner of Foods shall establish an inspection program, which shall include inspections of food facilities in accordance with subsection (b), subject to the facility category determined in accordance with the guidance issued under paragraph (2).

(2) **FACILITY CATEGORIES.**—As soon as practicable, but not later than 1 year after the date of enactment of this Act, the Commissioner of Foods shall issue formal guidance defining the criteria by which food facilities will be divided into “high-risk,” “intermediate risk,” and “low-risk” facilities.

(b) **INSPECTIONS OF FOOD FACILITIES.**—

(1) **FREQUENCY OF INSPECTIONS.**—

(A) **HIGH-RISK FACILITIES.**—The Commissioner of Foods shall inspect high-risk facilities not less frequently than annually.

(B) **INTERMEDIATE-RISK FACILITIES.**—The Commissioner of Foods shall inspect intermediate-risk facilities not less frequently than once every 2 years.

(C) **LOW-RISK FACILITIES.**—The Commissioner of Foods shall inspect low-risk facilities, which shall include warehouses or similar facilities that engage in packaging or distribution, and pose very minimal public health risk, not less frequently than once every 3 years.

(2) **INFANT FORMULA MANUFACTURING FACILITIES.**—The Commissioner of Foods shall inspect the facilities of each manufacturer of infant formula not less frequently than every 6 months.

(c) **FEDERAL AND STATE COOPERATION.**—The Commissioner of Foods shall contract with State officials to carry out not less than half of the inspections required under this section.

(d) **COMPLIANCE CHECKS.**—Not later than 30 days after issuing to a facility a form that is equivalent to FDA Form 483, pursuant to an inspection conducted under section 704 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), the Commissioner of Foods shall conduct a follow-up compliance check of the facility.

#### SEC. 4. TRANSFER OF AUTHORITY, FUNCTIONS AND AGENCIES.

(a) **TRANSFER OF AUTHORITY.**—The Federal Food Administration shall assume responsibility for carrying out the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as related to food, and shall assume and maintain all regulatory, administrative, and enforcement authorities with respect to food held by the Food and Drug Administration on the date of enactment of this Act.

(b) **TRANSFER OF FUNCTIONS.**—For each Federal agency, office, and center specified in subsection (c), there are transferred to the Federal Food Administration all functions that the head of the Federal agency exercised on the day before the date of enactment of this Act (including all related functions of any officer or employee of the Federal agency) that relate to the regulation of

food or the administration or enforcement of food law, as determined by the President.

(c) **TRANSFERRED AGENCIES.**—The Federal agencies referred to in subsection (b) are—

(1) the resources and facilities of the Human Foods Program of the Food and Drug Administration for purposes of administering the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) with respect to food;

(2) the resources and facilities of the Office of Inspections and Investigations of the Food and Drug Administration for purposes of administering the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) with respect to food;

(3) the resources and facilities of the Center for Veterinary Medicine of the Food and Drug Administration for purposes of administering the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) with respect to food; and

(4) such other offices, services, or agencies as the President designates by executive order to carry out this Act.

(d) **CONFORMING AMENDMENT.**—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

#### “SEC. 716. REGULATION OF FOOD.

“Notwithstanding any other provision of this Act, beginning as soon as practicable but not later than the date that is 1 year after the date of enactment of the Federal Food Administration Act of 2025—

“(1) any authority under this Act that relates to food shall be under the authority of the Federal Food Administration, and shall be carried out by the Commissioner of Foods described in section 2(d) of the Federal Food Administration Act of 2025; and

“(2) any reference in this Act to authorities related to food held by the Commissioner of Food and Drugs, including any reference in this Act to such authorities held by the Secretary, acting through the Commissioner of Food and Drugs, shall be deemed to be a reference to authorities held by the Commissioner of Foods, or by the Secretary, acting through the Commissioner of Foods, as appropriate.”.

#### SEC. 5. FUNDING.

(a) **TRANSFER OF FUNDS.**—The appropriations, allocations, and other funds that relate to the authorities, functions and agencies transferred under section 4 shall be transferred to the Federal Food Administration.

(b) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal year 2026 and each fiscal year thereafter.

#### SEC. 6. DEFINITIONS.

In this Act:

(1) **COMMISSIONER OF FOODS.**—The term “Commissioner of Foods” means the Commissioner described in section 2(d).

(2) **FACILITY.**—The term “facility” means any factory, warehouse, or establishment that is subject to the requirements of section 415 or 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d; 350h).

(3) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Human Services.

## SUBMITTED RESOLUTIONS

## SENATE RESOLUTION 540—RECOGNIZING HUMAN RIGHTS DAY ON DECEMBER 10, 2025, AND COMMEMORATING THE 77TH ANNIVERSARY OF THE UNIVERSAL DECLARATION OF HUMAN RIGHTS AND THE CELEBRATION OF “HUMAN RIGHTS DAY”

Mr. COONS (for himself and Mr. TILLIS) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 540

Whereas the Senate passed S. Res. 731 during the 115th Congress, which designated December 10, 2018, as “Human Rights Day”;

Whereas December 10, 2025, marks the 77th anniversary of the adoption of the Universal Declaration of Human Rights, which was adopted by the United Nations General Assembly on December 10, 1948;

Whereas the Universal Declaration of Human Rights is a landmark document that represents the first comprehensive agreement among countries regarding the inalienable rights and freedoms of all human beings;

Whereas the state of global human rights and civil liberties has declined during the past 2 decades, with Freedom House notably tracking 19 consecutive years of decline in rights and freedoms around the world;

Whereas Freedom House reports that political rights and civil liberties diminished in 2024 in 60 countries and improved in only 34 countries;

Whereas the Human Rights Funders Network reported that major cuts to foreign aid programs promoting human rights is projected to decline by up to \$1,900,000,000 annually by 2026;

Whereas conflict and suffering continues in Sudan, Yemen, the Central African Republic, Ukraine, the Middle East, Haiti, and other countries and territories;

Whereas the Department of State estimates that 1,000,000 individuals are unjustly behind bars as political prisoners for exercising human rights and fundamental freedoms because of their race, religion, or ethnicity, or due to their private relationships;

Whereas authoritarian regimes continue to imprison innocent civilians;

Whereas religious minorities, religious freedom advocates, and missionaries are unjustly targeted, detained, and repressed for exercising their freedom to believe or not to believe;

Whereas, in many countries, political opposition figures and civil society members continue to be unjustly detained for their role in demanding free and fair elections and leading peaceful democratic protests in opposition to illiberal regimes;

Whereas anti-corruption prosecutors and pro-democracy activists are arbitrarily imprisoned on baseless charges for their advocacy of greater judicial independence and transparency in countries where judicial systems are weaponized against human rights advocates;

Whereas authoritarian governments and non-state actors around the world enforce systems of impunity and discrimination to systematically dismantle women’s and girls’ access to their civil liberties and imprison female human rights defenders;

Whereas journalists face political imprisonment for fighting to report the truth, advocating for greater protections for the freedom of the press, and holding governments accountable to their citizens;

Whereas awareness of human rights—

(1) is essential to the realization of fundamental freedoms;

(2) promotes equality among all people;

(3) contributes to preventing conflict and human rights violations;

(4) leads to communities that are more stable, more secure, and safer; and

(5) enhances participation in, and resilience of, fellow democracies;

Whereas Congress has a proud and consistent bipartisan history of promoting internationally recognized human rights; and

Whereas December 10 of each year is celebrated globally as “Human Rights Day”: Now, therefore, be it

Resolved, That the Senate—

(1) designates December 10, 2025 as “Human Rights Day” and recognizes its global significance;

(2) recognizes the 77th anniversary of the Universal Declaration of Human Rights;

(3) reaffirms the Universal Declaration of Human Rights;

(4) supports the work of civil society leaders and human rights defenders globally;

(5) condemns the use of political imprisonment as a tool of repression to restrict civil liberties and human rights;

(6) calls upon governments around the world to immediately and unconditionally release political prisoners who are being unjustly detained for advocating for human rights and civil society;

(7) encourages the people of the United States—

(A) to observe “Human Rights Day”; and

(B) to continue their commitment to upholding freedom, democracy, and human rights around the world.

## AMENDMENTS SUBMITTED AND PROPOSED

SA 3958. Mr. BARRASSO (for Mr. CORNYN) proposed an amendment to the bill S. 2584, to amend title 18, United States Code, regarding additional assessments on convicted persons, and for other persons.

SA 3959. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill S. 3385, to amend the Internal Revenue Code of 1986 to extend the enhancement of the health care premium tax credit; which was ordered to lie on the table.

SA 3960. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill S. 3385, supra; which was ordered to lie on the table.

## TEXT OF AMENDMENTS

SA 3958. Mr. BARRASSO (for Mr. CORNYN) proposed an amendment to the bill S. 2584, to amend title 18, United States Code, regarding additional assessments on convicted persons, and for other persons; as follows:

Strike all after the enacting clause and insert the following:

## SECTION 1. SHORT TITLE.

This Act may be cited as the “Enduring Justice for Victims of Trafficking Act”.

## SEC. 2. ADDITIONAL SPECIAL ASSESSMENTS.

Section 3014(a) of title 18, United States Code, is amended by striking “Beginning on the date” and all that follows through the em dash and inserting “In addition to the assessment imposed under section 3013, the court shall assess an amount of \$5,000 on any non-indigent person or entity convicted of an offense under—”.

SA 3959. Ms. COLLINS submitted an amendment intended to be proposed by

her to the bill S. 3385, to amend the Internal Revenue Code of 1986 to extend the enhancement of the health care premium tax credit; which was ordered to lie on the table; as follows:

Strike section 2 and insert the following:

## SEC. 2. EXTENSION OF ENHANCED PREMIUM TAX CREDIT.

(a) EXTENSION OF RULES TO INCREASE PREMIUM ASSISTANCE AMOUNTS.—Clause (iii) of section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended—

(1) by striking “January 1, 2026” and inserting “January 1, 2028”, and

(2) by striking “2025” in the heading and inserting “2027”.

(b) MODIFICATION OF INCOME ELIGIBILITY LIMIT.—

(1) IN GENERAL.—Section 36B(c)(1)(A) of the Internal Revenue Code 1986 is amended—

(A) by striking “a taxpayer whose household income” and inserting “a taxpayer whose—

“(i) household income”, and

(B) by striking the period at the end and inserting the following “, and

“(ii) whose modified adjusted gross income does not exceed—

“(I) \$200,000, in the case of a joint return,

“(II) \$150,000, in the case of a head of household, or

“(III) \$100,000, in any other case.”.

(2) CONFORMING AMENDMENT.—Section 36B(c)(1) is amended by striking subparagraph (E).

(c) MINIMUM MONTHLY PREMIUM CONTRIBUTION.—Section 36B(b)(2)(A) of the Internal Revenue Code of 1986 is amended by inserting “, reduced by \$5” after “1311 of the Patient Protection and Affordable Care Act”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2025.

SA 3960. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill S. 3385, to amend the Internal Revenue Code of 1986 to extend the enhancement of the health care premium tax credit; which was ordered to lie on the table; as follows:

At the end, add the following:

## TITLE IV—ENHANCED PREMIUM TAX CREDIT

## SEC. 401. EXTENSION OF ENHANCED PREMIUM TAX CREDIT.

(a) EXTENSION OF RULES TO INCREASE PREMIUM ASSISTANCE AMOUNTS.—Clause (iii) of section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended—

(1) by striking “January 1, 2026” and inserting “January 1, 2028”, and

(2) by striking “2025” in the heading and inserting “2027”.

(b) MODIFICATION OF INCOME ELIGIBILITY LIMIT.—

(1) IN GENERAL.—Section 36B(c)(1)(A) of the Internal Revenue Code 1986 is amended—

(A) by striking “a taxpayer whose household income” and inserting “a taxpayer whose—

“(i) household income”, and

(B) by striking the period at the end and inserting the following “, and

“(ii) whose modified adjusted gross income does not exceed—

“(I) \$200,000, in the case of a joint return,

“(II) \$150,000, in the case of a head of household, or

“(III) \$100,000, in any other case.”.

(2) CONFORMING AMENDMENT.—Section 36B(c)(1) is amended by striking subparagraph (E).

(c) MINIMUM MONTHLY PREMIUM CONTRIBUTION.—Section 36B(b)(2)(A) of the Internal