(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the ''Comptroller General'') 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 on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)) that claim an active ingredient or formulation of a drug in combination with a device that is used for delivery of such drug, including an analysis of such patents and their claims.

(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

(A) data on—

(i) the number of patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)) that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, and that together claim the finished dosage form of the drug; and

(ii) the number of claims with respect to each patent included in the list published under such section 505(j)(7) that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

(B) an analysis of the listing of patents described in subparagraph (A)(ii), including the timing of listing such patents in relation to patents described in subparagraph (A)(i), and the effect listing the patents described in subparagraph (A)(ii) has on market entry of one or more drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act as compared to the effect of not listing the patents described in subparagraph (A)(ii); and

(C) recommendations about which kinds of patents relating to devices described in subparagraph (A)(i) should be submitted to the Secretary of Health and Human Services for inclusion on the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act and which patents should not be required to be so submitted in order to reduce barriers to approval and market entry.

(g) CONFORMING AMENDMENTS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (c)(3)(E), by striking ''clause (A) of subsection (b)(1)'' each place it appears and inserting ''subsection (b)(1)(A)(i)''; and

(2) in subsection (j)(2)(A)(vi), by striking ''clauses (B) through (F) of subsection (b)(1)'' and inserting ''clauses (ii) through (vi) of subsection (b)(1)(A)''.

Mrs. DINGELL (during the reading). Madam Speaker, I ask unanimous consent to dispense with the reading.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Michigan?

There was no objection.

The SPEAKER pro tempore. Is there objection to the original request of the gentlewoman from Michigan?

There was no objection.

A motion to reconsider was laid on the table.

SAFEGUARDING THERAPEUTICS ACT

Mrs. DINGELL. Madam Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 5663) to amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safeguarding Therapeutics Act''.

SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.

(a) IN GENERAL.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(1) in the fourth sentence, by inserting ''or counterfeit device'' after ''counterfeit drug''; and

(2) by striking ''The Secretary of the Treasury shall cause the destruction of'' and all that follows through ''liable for costs pursuant to subsection (c).'' and inserting the following: ''The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).''.

(b) DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) by redesignating subparagraphs (1), (2), and (3) as clauses (A), (B), and (C), respectively; and

(2) after making such redesignations—

(A) by striking ''(h) The term'' and inserting ''(h)(1) The term''; and

(B) by adding at the end the following:

''(2) The term 'counterfeit device' means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.''.

Mrs. DINGELL (during the reading). Madam Speaker, I ask unanimous consent to dispense with the reading of the amendment.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Michigan?

There was no objection.

The SPEAKER pro tempore. Is there objection to the original request of the gentlewoman from Michigan?

There was no objection.

A motion to reconsider was laid on the table.

LIFESPAN RESPITE CARE REAUTHORIZATION ACT OF 2020

Mrs. DINGELL. Madam Speaker, I ask unanimous consent that the Committee on Energy and Commerce be discharged from further consideration of the bill (H.R. 8906) to amend title XXIX of the Public Health Service Act to reauthorize the program under such title relating to lifespan respite care, 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 gentlewoman from Michigan?

There was no objection.

The text of the bill is as follows:

H.R. 8906

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 ''Lifespan Respite Care Reauthorization Act of 2020''.

SEC. 2. REAUTHORIZATION OF LIFESPAN RESPITE CARE PROGRAM.

(a) DATA COLLECTION AND REPORTING.—Section 2904 of the Public Health Service Act (42 U.S.C. 300ii–3) is amended to read as follows:

''SEC. 2904. DATA COLLECTION AND REPORTING.

''(a) IN GENERAL.—Each State agency awarded a grant or cooperative agreement under section 2902 shall report such data, information, and metrics as the Secretary may require for purposes of—

''(1) evaluating State programs and activities funded pursuant to such grant or cooperative agreement, including any results pursuant to section 2902(d)(2)(B)(xii); and

''(2) identifying effective programs and activities funded pursuant to section 2902.

''(b) REPORT.—Not later than October 1, 2023, 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 regarding the outcomes of the programs and activities funded pursuant to section 2902, including any effective programs and activities identified.''.

(b) FUNDING.—Section 2905 of the Public Health Service Act (42 U.S.C. 300ii–4) is amended by striking ''title'' and all that follows through the period and inserting ''title, $10,000,000 for each of fiscal years 2020 through fiscal year 2024.''.

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

SCARLETT'S SUNSHINE ON SUDDEN UNEXPECTED DEATH ACT

Mrs. DINGELL. Madam Speaker, I ask unanimous consent to take from the Speaker's table the bill (S. 1130) to amend the Public Health Service Act to improve the health of children and help better understand and enhance awareness about unexpected sudden death in early life, 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 gentlewoman from Michigan?

There was no objection.

The text of the bill is as follows:

S. 1130

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 ''Scarlett's Sunshine on Sudden Unexpected Death Act''.

SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part B of title XI of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended—

(1) in the part heading, by striking ''**SUDDEN INFANT DEATH SYNDROME**'' and inserting ''**SUDDEN UNEXPECTED INFANT DEATH, SUDDEN INFANT DEATH SYNDROME, AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD**''; and

(2) by inserting before section 1122 the following:

''SEC. 1121. ADDRESSING SUDDEN UNEXPECTED INFANT DEATH AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD.

''(a) IN GENERAL.—The Secretary may develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood, including by—

''(1) continuing to support the Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry of the Centers for Disease Control and Prevention and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood, as appropriate, including such systems supported by the Health Resources and Services Administration, in order to—

''(A) increase the number of States and jurisdictions participating in such registries or systems; and

''(B) improve the utility of such registries or systems, which may include—

''(i) making summary data available to the public in a timely manner on the internet website of the Department of Health and Human Services, in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law; and

''(ii) making the data submitted to such registries or systems available to researchers, in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law; and

''(2) awarding grants or cooperative agreements to States, Indian Tribes, and Tribal organizations for purposes of—

''(A) supporting fetal and infant mortality and child death review programs for sudden unexpected infant death and sudden unexpected death in childhood, including by establishing such programs at the local level;

''(B) improving data collection related to sudden unexpected infant death and sudden unexpected death in childhood, including by—

''(i) improving the completion of death scene investigations and comprehensive autopsies that include a review of clinical history and circumstances of death with appropriate ancillary testing; and

''(ii) training medical examiners, coroners, death scene investigators, law enforcement personnel, emergency medical technicians, paramedics, emergency department personnel, and others who perform death scene investigations with respect to the deaths of infants and children, as appropriate;

''(C) identifying, developing, and implementing best practices to reduce or prevent sudden unexpected infant death and sudden unexpected death in childhood, including practices to reduce sleep-related infant deaths;

''(D) increasing the voluntary inclusion, in registries established for the purpose of conducting research on sudden unexpected infant death and sudden unexpected death in childhood, of samples of tissues or genetic materials from autopsies that have been collected pursuant to Federal or State law and for which the parent or guardian has provided informed consent for inclusion in such registries; or

''(E) disseminating information and materials to health care professionals and the public on risk factors that contribute to sudden unexpected infant death and sudden unexpected death in childhood, which may include information on risk factors that contribute to sleep-related sudden unexpected infant death or sudden unexpected death in childhood.

''(b) APPLICATION.—To be eligible to receive a grant or cooperative agreement under subsection (a)(2), a State, Indian Tribe, or Tribal organization shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including information on how such State will ensure activities conducted under this section are coordinated with other federally-funded programs to reduce infant mortality, as appropriate.

''(c) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States, Tribes, and Tribal organizations receiving a grant or cooperative agreement under subsection (a)(2) for purposes of carrying out the program in accordance with this section.

''(d) REPORTING FORMS.—

''(1) IN GENERAL.—The Secretary shall, as appropriate, encourage the use of sudden unexpected infant death and sudden unexpected death in childhood reporting forms developed in collaboration with the Centers for Disease Control and Prevention to improve the quality of data submitted to the Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry, and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood.

''(2) UPDATE OF FORMS.—The Secretary shall assess whether updates are needed to the sudden unexpected infant death investigation reporting form used by the Centers for Disease Control and Prevention in order to improve the use of such form with other fatality case reporting systems supported by the Department of Health and Human Services, and shall make such updates as appropriate.

''(e) DEFINITIONS.—In this section:

''(1) SUDDEN INFANT DEATH SYNDROME.—The term 'sudden infant death syndrome' means a sudden unexpected infant death that remains unexplained after a thorough case investigation.

''(2) SUDDEN UNEXPECTED INFANT DEATH.—The term 'sudden unexpected infant death' means the sudden death of an infant under 1 year of age that when first discovered did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden infant death syndrome).

''(3) SUDDEN UNEXPECTED DEATH IN CHILDHOOD.—The term 'sudden unexpected death in childhood' means the sudden death of a child who is at least 1 year of age but not more than 17 years of age that, when first discovered, did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden unexplained death in childhood).

''(4) SUDDEN UNEXPLAINED DEATH IN CHILDHOOD.—The term 'sudden unexplained death in childhood' means a sudden unexpected death in childhood that remains unexplained after a thorough case investigation.

''(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $12,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 3. REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act and biennially thereafter, the Secretary of Health and Human Services 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 that contains, with respect to the reporting period—

(1) information regarding the incidence and number of sudden unexpected infant death and sudden unexpected death in childhood (including the number of such infant and child deaths that remain unexplained after investigation), including, to the extent practicable—

(A) a summary of such information by racial and ethnic group, and by State;

(B) aggregate information obtained from death scene investigations and autopsies; and

(C) recommendations for reducing the incidence of sudden unexpected infant death and sudden unexpected death in childhood;

(2) an assessment of the extent to which various approaches of reducing and preventing sudden unexpected infant death and sudden unexpected death in childhood have been effective; and

(3) a description of the activities carried out under section 1121 of the Public Health Service Act (as added by section 2).

(b) DEFINITIONS.—In this section, the terms ''sudden unexpected infant death'' and ''sudden unexpected death in childhood'' have the meanings given such terms in section 1121 of the Public Health Service Act (as added by section 2).

AMENDMENT OFFERED BY MRS. DINGELL

Mrs. DINGELL. Madam Speaker, I have an amendment at the desk.

The SPEAKER pro tempore. The Clerk will report the amendment.

The Clerk read as follows:

Strike all after section 1 and insert the following:

SECTION 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part B of title XI of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended—

(1) in the part heading, by striking ''**SUDDEN INFANT DEATH SYNDROME**'' and inserting ''**SUDDEN UNEXPECTED INFANT DEATH, SUDDEN INFANT DEATH SYNDROME, AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD**''; and

(2) by inserting before section 1122 the following: