116TH CONGRESS
1ST SESSION

S. _____

To establish a process by which reasonable drug prices may be determined, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. VAN HOLLEN (for himself and Mr. SCOTT of Florida) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To establish a process by which reasonable drug prices may be determined, and for other purposes.

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 ''We Protect American Investment in Drugs Act'' or the ''We PAID Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) In addition to spurring economic growth, the National Institutes of Health supports some of the most significant breakthroughs in biomedical in-

novation, including some that are commercialized into new pharmaceutical products.

(2) The National Institutes of Health funding contributed, either directly or indirectly, to the development of all 210 new molecular entities approved by the Food and Drug Administration between 2010 and 2016, according to an analysis published in the Proceedings of the National Academy of Sciences.

(3) In fiscal year 2019, Congress provided $39,100,000,000 in funding for the National Institutes of Health.

(4) According to a Kaiser Family Foundation health tracking poll in February 2019—

(A) nearly 80 percent of people in the United States say that the cost of prescription drugs is ''unreasonable'' and only 25 percent trust pharmaceutical companies to price their products fairly; and

(B) one-fourth of people in the United States say it is difficult to afford their prescription drugs, and 3 in 10 say they have not taken their medications as prescribed due to costs.

(5) According to a September 2018 report from the AARP—

(A) between 2016 and 2017, retail prices for 267 widely used brand name prescription drugs increased by 8.4 percent after 5 straight years of double-digit average annual price increases;

(B) brand name drug prices increased 4 times faster than general inflation in 2017; and

(C) retail prices increased in 2017 for 87 percent (231 of 267) of the widely used brand name prescription drugs reviewed, and all but 5 such increases exceeded the rate of inflation.

(6) In 2016, prescription drug spending in the United States was $477,000,000,000, according to an estimate from the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

(7) Prescription drugs account for nearly $1 out of every $5 in overall spending under the Medicare program, as well as 21 percent of Medicare beneficiaries' out-of-pocket health spending, not including premiums.

(8)(A) A drug's list price has a significant impact on what payors and patients pay to purchase prescription drugs.

(B) In prescription drug plans under Medicare part D, and a growing number of commercial health plans, seniors' and other beneficiaries' cost-sharing is based on a percentage of a drug's list price. As a result, higher drug list prices mean higher out-of-pocket costs for Medicare beneficiaries for their retail prescriptions.

(C) For prescription drugs covered under Medicare part B, beneficiaries are responsible for paying 20 percent of the Medicare-approved amount for the drug, and the part B deductible also applies. This can be a significant burden for high-cost part B drugs.

(D) A drug's list price is a factor in determining the amount of the rebate paid to State Medicaid plans by the drug's manufacturer under the Medicaid Drug Rebate Program, and an increase in the drug's list price may result in increased Medicaid costs.

(E) In the private health insurance market, pharmacy benefit manager and wholesaler fees are based on a percentage of the list price. Higher list prices increase costs in this part of the distribution chain.

(F) From 2007 through 2017, enrollment in high-deductible health plans with a health savings account (4.2 percent to 18.9 percent) and without a health savings account (10.6 percent to 24.5 percent) increased among adults between ages 18 and 64 with employment-based coverage, while enrollment in traditional plans decreased, according to the Centers for Disease Control and Prevention. Individuals with high-deductible health plans pay more out of pocket for medical expenses until their deductible is met, making high-cost drugs challenging to afford.

(G) A larger share of prescription drug plans under Medicare part D charged a deductible in 2019 than in 2018 (71 percent in 2019, and 63 percent in 2018), according to the Kaiser Family Foundation. Fifty-two percent of prescription drug plans will require enrollees to satisfy the standard deductible of $415 in 2019.

SEC. 3. DEFINITIONS.

For purposes of this Act:

(1) APPLICABLE DRUG.—The term ''applicable drug'' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) that—

(A) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) is subject to section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(C) is covered by a qualifying patent on the drug, on a method of using such drug, or on a method or machine used to manufacture or administer such drug with respect to which the drug sponsor retained the title to any subject invention under section 202 of title 35, United State Code, or entered into a licensing agreement after the date of enactment of this Act.

(2) CONFLICT OF INTEREST.—The term ''conflict of interest'' means an association, including a financial or personal association, or past employment, that has the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Drug Affordability and Access Committee or the conduct of other activities under this Act.

(3) MANUFACTURER LIST PRICE.—The term ''manufacturer list price'' means the national price

for a prescription drug established by the manufacturer or licensee found in a catalogue or other public source that is the price from which market discounts and price concessions are calculated.

(4) PERIOD OF MARKET EXCLUSIVITY.—The term ''period of market exclusivity'' means any period of market exclusivity granted with respect to a prescription drug under clause (ii), (iii), or (iv) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)), clause (ii), (iii), or (iv) of section 505(j)(5)(F) of such Act, section 527 of such Act (21 U.S.C. 360cc), or section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)), and any extension of such period granted under section 505A or 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355f).

(5) QUALIFYING PATENT.—The term ''qualifying patent'' means any patent—

(A) held by the Federal Government; or

(B) which the applicant with respect to the patent was required to disclose under section 202(c)(6) of title 35, United States Code, in the application for the patent.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 4. NATIONAL ACADEMY OF MEDICINE STUDY ON DETERMINING A REASONABLE DRUG PRICE.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary shall seek to enter into a contract with the National Academy of Medicine (referred to in this section as the ''Academy'') under which the Academy agrees to study—

(1) how best to determine the reasonableness of a drug's manufacturer list price and retail price and develop at least 1 framework for determining the reasonableness of a drug's manufacturer list price and retail price taking into consideration—

(A) affordability of the drug to payers, purchasers, and patients across wide market segments in a manner that ensures equitable access;

(B) investment by the National Institutes of Health or any other Federal Government entity in the development of the drug;

(C) inclusion of research funded by the National Institutes of Health or other Federal Government entity in the development of the drug;

(D) manufacturer research and development costs as shown on the manufacturer's Federal tax filing under sections 41 and 174 of the Internal Revenue Code of 1986;

(E) investment and the rate of return needs for the drug manufacturer;

(F) market for the drug;

(G) the cost of production and distribution of the drug;

(H) the price of the drug in other similar, industrialized countries;

(I) estimated global and domestic sales of the drug;

(J) gross and net expenditures by public payers for coverage of the drug under Federal health programs, to the extent available; and

(K) any additional information the Academy determines appropriate;

(2) an appropriate timeline for the submission of information to the Drug Affordability and Access Committee required under section 6(a)(2) to determine the reasonableness of a drug's manufacturer list price and retail price; and

(3) an appropriate timeline for the Drug Affordability and Access Committee to determine the

reasonableness of a drug's manufacturer list price and retail price to be in effect the second year after coming to market.

(b) REPORT.—Any contract between the Secretary and the Academy under this section shall include a requirement that the Academy submit a report on the results of the study described in subsection (a) to the Secretary, the Drug Affordability and Access Committee, and Congress.

SEC. 5. DRUG AFFORDABILITY AND ACCESS COMMITTEE.

(a) ESTABLISHMENT.—There is hereby authorized to be established a nonprofit corporation to be known as the Drug Affordability and Access Committee (referred to in this section as the ''Committee''), which is neither an agency nor establishment of the United States Government. The Committee shall be headed by an Executive Director.

(b) PURPOSE.—The purpose of the Committee is to determine a reasonable manufacturer list price and retail price for each applicable drug.

(c) BOARD OF DIRECTORS.—

(1) IN GENERAL.—The Committee shall have a Board of Directors, which shall be composed of ex officio and appointed members in accordance with

this subsection. All appointed members of the Board shall be voting members.

(2) EX OFFICIO MEMBERS.—The non-voting ex officio members of the Committee shall be the following individuals or their designees:

(A) The Secretary of Health and Human Services.

(B) The Director of the National Institutes of Health.

(C) The Commissioner of Food and Drugs.

(D) The Director of the Agency for Healthcare Research and Quality.

(E) The Director of the Centers for Disease Control and Prevention.

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

(G) The Assistant Secretary for Planning and Evaluation.

(3) APPOINTED MEMBERS.—

(A) IN GENERAL.—Ten additional members shall be appointed to the Committee by the Comptroller General of the United States not later than 180 days after the date of enactment of this Act. Such members shall include—

(i) 2 patient and consumer representatives not affiliated with any organization that receives funding from pharmaceutical manufacturers;

(ii) 3 provider representatives, including 1 hospital representative and 1 pharmacist representative;

(iii) 1 health services researcher;

(iv) 1 health care economist;

(v) 1 representative of a sponsor of a health plan or health insurance coverage;

(vi) 1 pharmacy benefit management services representative; and

(vii) 1 drug manufacturer representative.

(B) DURATION OF TERMS.—Members appointed to the Committee under subparagraph (A) shall be appointed to serve 5- year terms, which shall be staggered for the members first appointed.

(C) TERM LIMITS.—Members appointed to the Committee under subparagraph (A) may not be so appointed for more than 2 terms.

(D) CONFLICTS OF INTEREST.—

(i) IN GENERAL.—In appointing members under subparagraph (A), the Comptroller General of the United States shall consider and disclose any potential conflicts of interest. Members of the Board shall recuse themselves or be recused from relevant Committee activities in the case where the member (or an immediate family member of such member) has a conflict of interest.

(ii) DISCLOSURE OF CONFLICTS OF INTEREST.—

(I) IN GENERAL.—A conflict of interest or potential conflict of interest shall be disclosed, as applicable—

(aa) by the Committee, in appointing members to an advisory committee and for employment as staff on the Committee; and

(bb) by the Comptroller General of the United States, in appointing members of the Committee.

(II) MANNER OF DISCLOSURE.—Conflicts of interests shall be disclosed as soon as practicable on the internet websites of the Committee and of the Government Accountability Office. The information so disclosed shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of activity in which the potential conflict exists.

(E) CONFIDENTIALITY.—The Committee shall maintain the confidentiality of any information provided to the Committee under this section that is a trade secret or confidential information.

(F) VACANCIES.—Vacancies on the Board shall be filled in the same manner as the original appointment was made. Any vacancy in the membership of the Board shall not affect the power of the remaining members to execute the duties of the Board.

(G) COMPENSATION.—While serving on the business of the Committee (including travel time), a member of the Committee shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Committee.

(H) NO FEDERAL EMPLOYEES.—No employee of the Federal Government shall be an appointed member of the Committee.

(d) EXECUTIVE DIRECTOR.—

(1) APPOINTMENT.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Committee and shall have such specific duties and responsibilities as the Board shall prescribe, including to identify, recruit, and hire staff.

(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board.

(3) CONFLICTS OF INTEREST AND CONFIDENTIALITY.—The Executive Director and all staff of the Committee shall be subject to the same conflict of interest and confidentiality requirements as the Board members, as described in subparagraphs (D) and (E) of subsection (c)(3).

(e) INITIAL MEETING.—The initial meeting of the Committee shall take place within 60 days of all members being appointed. In the initial meeting, the Committee shall—

(1) incorporate the Committee;

(2) designate a Chair; and

(3) appoint the Executive Director.

(f) DUTIES AND AUTHORITIES.—The duties and authorities of the Committee are as follows:

(1) ADMINISTRATIVE DUTIES.—The Committee shall establish administrative guidelines for the Committee, including—

(A) establishing bylaws for the Committee that are published in the Federal Register and made available for public comment;

(B) establishing policies for the selection of officers, employees, agents, and contractors of the Committee;

(C) establishing policies that would subject all employees, fellows, and trainees of the Committee to the conflict of interest standards under subsection (c)(3)(D);

(D) specifying a process for annual Board review of the operations of the Committee;

(E) establishing specific duties of the Executive Director;

(F) evaluating the performance of the Executive Director; and

(G) carrying out other necessary activities regarding the functioning of the Committee.

(2) PROCESS, METHODOLOGY, AND TIMELINE FOR DETERMINING REASONABLE PRICES.—

(A) IN GENERAL.—Not later than 2 years after receipt of the report of the National Academy of Medicine under section 4, the Committee shall—

(i) outline the process and methodology by which the Committee will determine, based on such report, whether the manufacturer list price and retail price is reasonable for each applicable drug;

(ii) outline the timeline under which the manufacturer, based on such report, is

required to submit the information required under section 6(a)(2) to the Committee;

(iii) outline the timeline under which the Committee is required to determine, based on such report, whether the manufacturer list price and retail price is reasonable for each applicable drug; and

(iv) publish such proposed process, methodology, and timeline on the internet website of the Committee.

(B) PUBLIC INPUT.—Not later than 60 days after publication of the proposed process, methodology, and timeline under subparagraph (A), the Committee shall hold a minimum of 2 public stakeholder meetings to solicit feedback on such proposed process, methodology, and timeline.

(C) PUBLICATION OF FINAL PROCESS, METHODOLOGY, AND TIMELINE.—Not later than 30 months after receipt of the report under section 4, the Committee shall publish a final process, methodology, and timeline on the Committee's internet website.

(D) UPDATES TO PROCESS, METHODOLOGY, AND TIMELINE.—The Committee may make changes and updates to the final process, methodology, and timeline as necessary. Any such changes or updates shall be published on the internet website of the Committee.

(3) ISSUANCE OF REASONABLE PRICING DETERMINATION.—

(A) DETERMINATIONS.—The Committee shall issue a reasonable pricing determination for each applicable drug that—

(i) is based on a review of the information submitted under section 6(a); and

(ii) uses the process, methodology, and timeline developed by the Committee under paragraph (2).

(B) TIMEFRAME.—The Committee shall issue a reasonable pricing determination under subparagraph (A) for a drug that, upon approval of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), will be an applicable drug, taking into consideration

the recommended timeframe under section 4(a)(2).

(C) REPORTS TO DRUG MANUFACTURERS.—For each reasonable pricing determination made under subparagraph (A), the Committee shall submit a report in writing to the applicable drug manufacturer outlining such determination. Each such report shall be made public, excluding any proprietary information.

(4) APPOINTMENT OF ADVISORY COMMITTEES.—The Committee may appoint permanent or ad hoc advisory committees as determined appropriate to assist in the work of the Committee. All members of any such advisory committee shall be subject to the same conflict of interest requirements as Committee members.

(g) ANNUAL REPORTS.—The Committee shall submit an annual report to Congress and to the Secretary, and shall make the annual report available to the public. Each such report shall include—

(1) a description of the activities conducted under this Act;

(2) the budget of the Committee for the following year; and

(3) any other relevant information, including information on the membership of the Board, advisory committees, and the executive staff of the Committee, any conflicts of interest with respect to such individuals, and any bylaws adopted by the Board during the preceding year.

SEC. 6. REQUIREMENTS FOR ENTERING INTO A LICENSING AGREEMENT.

(a) IN GENERAL.—Upon retaining the title to any subject invention under section 202 of title 35, United States Code, or entering into a partial or exclusive licensing agreement relating to an applicable drug, the drug manufacturer shall agree to—

(1) beginning one year after an applicable drug first comes to market, limit the annual price increase on such drug to the percentage by which the medical care consumer price index detailed expenditure category for all urban consumers for that year exceed such index for the preceding calendar year;

(2) submit to the Drug Affordability and Access Committee, on a good faith timeline that is consistent with the recommendation under section 5(f)(2)(A)(ii)—

(A) the manufacturer list price for the drug;

(B) the retail price for the drug;

(C) information on expenditures, including—

(i) the total annual expenditures of the manufacturer on materials and manufacturing for the drug;

(ii) the total expenditures of the manufacturer on acquiring patents and licensing for the drug, including expected royalty payments;

(iii) the total expenditures of the manufacturer on research and development as shown on the manufacturer's Federal tax returns under sections 41 and 174 of the Internal Revenue Code of 1986;

(iv) the amount of the manufacturer's total expenditures derived from any Federal funding source, including tax deductions or credits claimed; and

(v) total expected expenditures for marketing and advertising for the drug in the first 3 years that the drug is on the market;

(D) the anticipated number of patients who will be treated with the drug;

(E) a copy of the application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a) and any subsequent information or data requested by, or submitted to, the Food and Drug Administration during the approval process;

(F) any additional information requested by the Drug Affordability and Access Committee; and

(G) any additional information the manufacturer chooses to provide related to drug pricing decisions;

(3) submit the manufacturer list price and retail price of an applicable drug to the Drug Affordability and Access Committee for a reasonable price determination; and

(4) beginning one year after an applicable drug first comes to market, not exceed the reasonable price, as determined by such Committee, for the drug's manufacturer list price.

(b) PENALTIES.—

(1) LOSS OF PERIOD OF MARKET EXCLUSIVITY.—In the case of a drug manufacturer subject

to this section who increases the price of an applicable drug to an amount that exceeds the amount under subsection (a)(1) or exceeds the reasonable price as required under subsection (a)(4), any period of market exclusivity with respect to the applicable drug shall be deemed expired, effective on the date of such price increase or launch price.

(2) PROHIBITION ON ENTERING INTO FUTURE LICENSING AGREEMENTS.—If a drug manufacturer fails to adhere to the limit on annual price increases under subsection (a)(1), such drug manufacturer, and its president, chief executive officer, chief operating officer, and general counsel employed at the time of the violation, shall be ineligible for future licensing agreements for qualifying patented technology.

(3) PROHIBITION ON ENTERING INTO FUTURE LICENSING AGREEMENTS.—If a drug manufacturer fails to adhere to the reasonable price as required under subsection (a)(4), the drug manufacturer, and its president, chief executive officer, chief operating officer, and general counsel, shall be ineligible for future licensing agreements for qualifying patented technology.

(4) FAILURE TO SUBMIT INFORMATION OR SUBMITTING FALSE INFORMATION TO THE DRUG AFFORDABILITY AND ACCESS COMMITTEE.—Any manufacturer that fails to submit information required under subsection (a)(2) to be submitted to the Drug Affordability and Access Committee, or who submits false information to such Committee shall be subject to a civil monetary penalty of $500,000 and if a violation is not corrected within 30 days following notification of such violation, $1,000,000 for each day that the violation continues after such period until the violation is corrected.

(5) EXCESSIVE PRICE IN THE FIRST YEAR OF LAUNCH.—If a drug manufacturer's launch price in the first year for an applicable drug is at least 50 percent higher than the reasonable price as required under subsection (a)(4) to be in effect for the second year, the drug manufacturer shall be subject to a civil monetary penalty of the cost of the drug in excess of 50 percent multiplied by the number of doses of the drug sold in the United States in the first year on the market.

(6) DISTRIBUTION OF PAYMENTS TO THE NATIONAL INSTITUTES OF HEALTH.—

(A) IN GENERAL.—Each fiscal year, there shall be transferred, out of funds in the Treasury not otherwise obligated, to the Director of the National Institutes of Health, an amount equal to the amount collected in civil penalties under this subsection during the previous fiscal year, unless the amount otherwise appropriated to the National Institutes of Health for the fiscal year in which such transfer would occur is less than the amount so appropriated for the previous fiscal year.

(B) DELAYED DISTRIBUTION.—If, in accordance with clause (i), the Secretary of the Treasury does not transfer amounts under such clause during any portion of a fiscal year, and, at a later date in such fiscal year, the appropriations to the National Institutes of Health becomes equal to or greater than the amount of appropriations for the previous fiscal year, such Secretary shall transfer such amount at any time in such fiscal year.

SEC. 7. PROPER DISCLOSURE OF GOVERNMENT SUPPORT.

(a) DEFINITIONS.—In this section—

(1) the term ''contractor''—

(A) has the meaning given the term in section 201 of title 35, United States Code; and

(B) includes an assignee of a contractor to the extent that the assignee is the entity that files an application described in section 202(c)(6);

(2) the term ''covered contractor'' means a contractor that—

(A) is a party to a funding agreement that contains an appropriate provision to effectuate the requirement under section 202(c)(6); and

(B) files a United States patent application with respect to a subject invention that the contractor conceived or first actually reduced to practice in the performance of work under the funding agreement described in subparagraph (A);

(3) the term ''covered patentee'' means the patentee with respect to a patent issuing from an application described in paragraph (2)(B);

(4) the term ''drug'' has the meaning given that term in section 201 of the Federal Food, Drug, and Cosmetic Act;

(5) the terms ''funding agreement'' and ''subject invention'' have the meanings given the terms in section 201 of title 35, United States Code;

(6) the term ''patentee'' has the meaning given the term in section 100 of title 35, United States Code; and

(7) the term ''section 202(c)(6)'' means section 202(c)(6) of title 35, United States Code.

(b) ACTIONS FOR FAILURE TO DISCLOSE GOVERNMENT SUPPORT.—

(1) PRIVATE RIGHT OF ACTION.—

(A) IN GENERAL.—A person (including a government entity) may bring a civil action in an appropriate district court of the United States against a covered patentee—

(i) on the ground that the application for the patent with respect to which the covered patentee holds title failed to comply with the requirement under section 202(c)(6); and

(ii) if the person is injured by the failure to comply described in clause (i).

(B) SCOPE.—In an action brought under subparagraph (A), if the court finds by a preponderance of the evidence that the application

described in that subparagraph failed to comply with the requirement under section 202(c)(6), the court shall cancel as unpatentable any claim of the patent issuing from that application.

(2) INTER PARTES REVIEW.—Section 311 of title 35, United States Code, is amended by striking subsection (b) and inserting the following:

''(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent—

''(1)(A) on a ground that could be raised under section 102 or 103; and

''(B) on the basis of prior art consisting of patents or printed publications; or

''(2) on the ground that the application with respect to the patent was subject to the requirement in section 202(c)(6) and failed to comply with that requirement.''.

(c) DISCLOSURE OF GRANTS.—Section 111(a)(2) of title 35, United States Code, is amended—

(1) in subparagraph (B), by striking ''and'' at the end;

(2) in subparagraph (C), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(D) with respect to a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) covered by a qualifying patent on the drug, on a method of using such drug, or on a method or machine used to manufacture or administer such drug, a disclosure of any Federal grant received in the 10-year period prior to submitting the application, in which the applicant is listed as the principal investigator or co-investigator with respect to the grant.''.

(d) GAO REPORT.—Not later than 5 years after the date of enactment of this Act, and once every 5 years thereafter, the Comptroller General of the United States shall—

(1) conduct a study that reviews—

(A) the compliance by covered contractors with the requirement under section 202(c)(6); and

(B) the effectiveness of the National Institutes of Health in conducting oversight of the extent to which covered contractors are complying with the requirement under section 202(c)(6); and

(2) submit to Congress the results of each study conducted under paragraph (1), which shall

include, in each case, recommendations for additional practices and policies to improve the effectiveness of the requirement under section 202(c)(6), including any mechanism to better enforce that requirement.