

HR 2486 -- Redline

Engrossed Amendment to Engrossed Amendment -- FUTURE Act

Deletions ~~struck~~ · Insertions underlined

2486 Engrossed Amendment ~~SenateHouse~~ ~~(EAS)]~~ (EAH)] <DOC> In the ~~SenateHouse~~ of ~~the~~ Representatives, UnitedU. States, December 5, 2019.

~~Resolved, S., That July the 22, bill 2020, from the House of Representatives (H.R. 2486) Resolved, entitled That ``An the ActHouse agree to reauthorize the mandatory amendment funding of programs the for Senate historically to Black colleges and universities and other minority-serving institutions.'', do pass with the following bill AMENDMENT: (H.R.~~

~~Strike 2486) all entitled after ``An the Act enacting to clause reauthorize mandatory funding programs for historically Black colleges and insert universities and other minority-serving institutions.'', with the following: following HOUSE AMENDMENTS TO SENATE AMENDMENT:~~

~~SECTION (1) In 1, the matter proposed to be inserted by the amendment of the Senate, strike sections 1, 2, and 3 and insert the following:~~

~~SHORT TITLE TITLE; I--NO BAN ACT SEC.~~

~~REFERENCES 101.~~

~~(a) SHORT Short TITLES. Title. This Act may be cited as the ``Fostering Undergraduate Talent by Unlocking Resources for Education Act'' or the ``FUTURE Act''.~~

~~(b) This References. Except title as may otherwise be expressly cited provided, as whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference ``National shall Origin-Based be Antidiscrimination considered for to Nonimmigrants be Act'' made to a section or other provision of the Higher ``NO Education BAN Act Act'' of 1965 (20 U.S.C. 1001 et seq.).~~

~~2-102.~~

~~CONTINUED EXPANSION SUPPORT OF FOR NONDISCRIMINATION MINORITY-SERVING PROVISION. INSTITUTIONS.~~

~~Section 371(b)(1)(A) 202(a)(1)(A) (20 of the Immigration and Nationality Act (8 U.S.C.~~

~~1067q(b)(1)(A)) 1152(a)(1)(A)) is amended amended-- (1) by striking inserting ``for ``or each a of nonimmigrant the visa, fiscal admission years or 2008 other through entry 2019.'', into and the all United that States, follows or through the end approval of or the revocation subparagraph of and any inserting immigration ``for benefit'' fiscal after year ``immigrant 2020 visa''; and each fiscal year thereafter.'',~~

~~(2) by inserting ``religion,'' after ``sex,'';~~

~~and (3) by inserting `` , except if expressly required by statute, or if a statutorily authorized benefit takes into consideration such factors'' before the period at the end.~~

~~3-103.~~

~~SECURE TRANSFER DISCLOSURE AND OF LIMITATIONS TAX RETURN ON INFORMATION AUTHORITY TO CARRY SUSPEND OUT OR RESTRICT THE HIGHER ENTRY EDUCATION OF ACT A CLASS OF 1965 ALIENS.~~

~~(a) Section Amendments 212(f) to the Internal Revenue Code of 1986. (1) In general. Paragraph (13) of section 6103(l) of the Internal Immigration Revenue and Code Nationality of Act 1986 (8 is U.S.C. amended to read as follows:~~

~~``(13) 1182(f)) Disclosure is of amended return information to carry read out the higher education act of 1965. `` (A) Income-contingent or income-based repayment and total and permanent disability discharge. The Secretary shall, upon written request from the Secretary of Education, disclose to officers, employees, and contractors of the Department of Education, as specifically follows: authorized and designated by the Secretary of Education, only for the purpose of (and to the extent necessary in) establishing enrollment, renewing enrollment, administering, and conducting analyses and forecasts for estimating costs related to income-contingent or income-based repayment programs, and the discharge of loans based on a total and permanent disability (within the meaning of section 437(a) of the Higher Education Act of 1965), under title IV of the Higher Education Act of 1965, the following return information (as defined in subsection (b)(2)) with respect to taxpayers identified by the Secretary of Education as participating in the loan programs under title IV of such Act, for taxable years specified by such Secretary:~~

~~``(i) `` (f) Taxpayer Authority identity to information Suspend with or respect Restrict the Entry of a Class of Aliens. `` (1) In general. `` Subject to paragraph (2), if the Secretary of State, in consultation with the Secretary of Homeland Security, determines, based on specific and credible facts, that the entry of any aliens or any class of aliens into the United States would undermine the security or public safety of the United States or the preservation of human rights, democratic processes or institutions, or international stability, the President may temporarily-- `` (A) suspend the entry of such taxpayer, aliens or class of aliens as immigrants or nonimmigrants;~~

~~“(ii) or The (B) filing impose status any restrictions on the entry of such taxpayer, aliens that the President deems appropriate.~~

~~“(iii) (2) The Limitations.--In adjusted carrying gross out income paragraph (1), the President, the Secretary of such State, taxpayer, and the Secretary of Homeland Security shall-- (A) only issue a suspension or restriction when required to address specific acts implicating a compelling government interest in a factor identified in paragraph (1);~~

~~“(iv) (B) Total narrowly number tailor of the exemptions suspension claimed, or total restriction, number using of the individuals least and restrictive dependents means, claimed, to as achieve applicable, such on compelling the government return, interest;~~

~~“(v) (C) Number specify of the children duration with of respect the to suspension which or tax restriction; credits under section 24 are claimed on the return.~~

~~“(B) Federal student financial aid.--The Secretary shall, upon written request from the Secretary of Education, disclose to officers, employees, and contractors (D) of consider the waivers Department of Education, as specifically authorized and designated by the Secretary of Education, only for the purpose of (and to the any extent class-based necessary restriction in) or determining suspension eligibility for, and amount apply of, a Federal rebuttable student presumption financial aid under programs authorized by parts A, C, and D of title IV of the Higher Education Act of 1965 (as in effect favor on the date of the granting enactment family-based of the Fostering Undergraduate Talent by Unlocking Resources for Education Act) and conducting humanitarian analyses waivers, and forecasts for estimating costs related to such programs, the following return information (as defined in subsection (b)(2)) with respect to taxpayers identified by the Secretary of Education as applicants for Federal student financial aid under such parts of title IV of such Act, for taxable years specified by such Secretary:~~

~~“(i) (3) Taxpayer Congressional identity notification.-- information (A) with In respect general.--Prior to such the taxpayer, President exercising the authority under paragraph (1), the Secretary of State and the Secretary of Homeland Security shall consult Congress and provide Congress with specific evidence supporting the need for the suspension or restriction and its proposed duration.~~

~~“(ii) (B) The Briefing filing and status report.--Not later than 48 hours after the President exercises the authority under paragraph (1), the Secretary of State and the Secretary of Homeland Security shall provide a briefing and submit a written report to Congress that describes-- (i) the action taken pursuant to paragraph (1) and the specified objective of such taxpayer, action;~~

~~“(iii) (ii) The adjusted estimated gross number income of individuals who will be impacted by such taxpayer, action;~~

~~“(iv) (iii) The amount constitutional of any net earnings from self-employment (as defined in section 1402), wages (as defined in section 3121(a) or 3401(a)), taxable income from a farming business (as defined in section 236A(e)(4)), and investment legislative income authority for under the which periods such reported action on took the place; return.~~

~~“(v) and The (iv) total the income circumstances tax necessitating of such action, including how such taxpayer, action complies with paragraph (2), as well as any intelligence informing such actions.~~

~~“(vi) (C) Total Termination.--If number the of briefing exemptions and claimed, report or described total in number subparagraph of (B) individuals are and not dependents provided claimed, to as Congress applicable, during on the 48 hours that begin when the return, President exercises the authority under paragraph (1), the suspension or restriction shall immediately terminate absent intervening congressional action.~~

~~“(vii) (D) Number Congressional of committees.--The children term with Congress', respect as used in this paragraph, refers to which the tax Select credits Committee under on section Intelligence 24 of are the claimed Senate, the Committee on Foreign Relations of the return, Senate, the Committee on the Judiciary of the Senate, the Committee on Homeland Security and Governmental Affairs of the Senate, the Permanent Select Committee on Intelligence of the House of Representatives, the Committee on Foreign Affairs of the House of Representatives, the Committee on the Judiciary of the House of Representatives, and the Committee on Homeland Security of the House of Representatives.~~

~~“(viii) (4) Amount Publication.--The Secretary of any State credit and claimed the under Secretary section of 25A Homeland for Security shall publicly announce and publish an unclassified version of the taxable report year, described in paragraph (3)(B) in the Federal Register.~~

~~“(ix) (5) Amount Judicial review.-- (A) In general.--Notwithstanding any other provision of law, an individual retirement or account entity distributions who not is included present in adjusted the gross United income States for and has been harmed by a violation of this subsection may file an action in an appropriate district court of the taxable United year, States to seek declaratory or injunctive relief.~~

~~“(x) (B) Amount Class of action.--Nothing individual in retirement this account Act contributions may and be payments construed to self-preclude employed an SEP, action Keogh, filed and pursuant other to qualified subparagraph plans (A) which were deducted from income proceeding for as the taxable class year, action.~~

~~“(xi) (6) The Treatment amount of commercial airlines.--Whenever the Secretary of tax-exempt Homeland interest, Security finds that a commercial airline has failed to comply with regulations of the Secretary~~

of Homeland Security relating to requirements of airlines for the detection of fraudulent documents used by passengers traveling to the United States (including the training of personnel in such detection), the Secretary of Homeland Security may suspend the entry of some or all aliens transported to the United States by such airline.

~~“(xii)”(7) Amounts Rule from of retirement construction.--Nothing pensions in and this annuities section not may included be construed as authorizing the President, the Secretary of State, or the Secretary of Homeland Security to act in adjusted a gross manner income inconsistent for with the taxable policy year decisions expressed in the immigration laws.~~

~~“(xiii)”(8) If Clarification.--For applicable purposes of paragraph (1), the fact term that public any safety of the following United schedules States' (or includes equivalent efforts successor necessary schedules) to were contain filed a with communicable the disease return of public health significance (as defined in section 34.2(b) of title 42, Code of Federal Regulations (or any successor regulation)).”.~~

~~“(I) Schedule A.~~

~~“(II) Schedule B.~~

~~“(III) Schedule D.~~

~~“(IV) Schedule E.~~

~~“(V) Schedule F.~~

~~“(VI) Schedule H.~~

~~“(xiv) If applicable, the fact that Schedule C (or an equivalent successor schedule) was filed with the return showing a gain or loss greater than \$10,000.~~

~~“(xv) If applicable, the fact that there is no return filed for such taxpayer for the applicable year.~~

~~“(C) Restriction on use of disclosed information.--“(i) In general.--Return information disclosed under subparagraphs (A) and (B) may be used by officers, employees, and contractors of the Department of Education, as specifically authorized and designated by the Secretary of Education, only for the purposes and to the extent necessary described in such subparagraphs and for mitigating risks (as defined in clause (ii)) relating to the programs described in such subparagraphs.~~

~~“(ii) Mitigating risks.--For purposes of this subparagraph, the term “mitigating risks” means, with respect to the programs described in subparagraphs (A) and (B), “(I) oversight activities by the Office of Inspector General of the Department of Education as authorized by the Inspector General Act of 1978, as amended, and “(II) reducing the net cost of improper payments to Federal financial aid recipients. Such term does not include the conduct of criminal investigations or prosecutions.~~

~~“(iii) Redislosure to institutions of higher education, state higher education agencies, and designated scholarship organizations.--The Secretary of Education, and officers, employees, and contractors of the Department of Education, may disclose return information received under subparagraph (B), solely for the use in the application, award, and administration of student financial aid or aid awarded by such entities as the Secretary of Education may designate, to the following persons:~~

~~“(I) An institution of higher education with which the Secretary of Education has an agreement under subpart 1 of part A, part C, or part D of title IV of the Higher Education Act of 1965.~~

~~“(II) A State higher education agency.~~

~~“(III) A scholarship organization which is designated by the Secretary of Education as of the date of the enactment of the Fostering Undergraduate Talent by Unlocking Resources for Education Act as an organization eligible to receive the information provided under this clause.~~

~~The preceding sentence shall only apply to the extent that the taxpayer with respect to whom the return information relates provides consent for such disclosure to the Secretary of Education as part of the application for Federal student financial aid under title IV of the Higher Education Act of 1965.~~

~~“(D) Requirement of notification of request for tax return information.--Subparagraphs (A) and (B) shall apply to any disclosure of return information with respect to a taxpayer only if the Secretary of Education has provided to such taxpayer the notification required by section 494 of the Higher Education Act of 1965 prior to such disclosure.”.~~

~~(2) Confidentiality of return information.--Section 6103(a)(3) of such Code is amended by inserting “, (13)(A), (13)(B)” after “(12)”.~~

~~(3) Conforming amendments.--Section 6103(p)(4) of such Code is amended-- (A) by inserting “(A), (13)(B)” after “(13)” each place it occurs, and (B) by inserting “, (13)(A), (13)(B)” after “(1)(10)” each place it occurs.~~

~~(b) Effective Date.--The amendments made by this section shall apply to disclosures made under section 6103(l)(13) of the Internal Revenue Code of 1986 (as amended by this section) after the date of the enactment of this Act.~~

~~4-104.~~

~~NOTIFICATION TERMINATION OF REQUEST CERTAIN FOR EXECUTIVE TAX ACTIONS. RETURN INFORMATION.~~

~~(a) In Termination.--Presidential General.--Part Proclamations 9645, 9822, and 9983 and Executive Orders 13769, 13780, and 13815 shall be void beginning on the date of title the IV enactment (20 of U.S.C. this~~

Act.

~~1098(b) et seq.)~~ ~~Effect.--All actions is taken amended pursuant by to adding any at~~ proclamation or executive order terminated under subsection (a) shall cease on the end date of the following enactment of this Act.

SEC.

105.

VISA APPLICANTS REPORT.

(a) Initial Reports.-- (1) In general.--Not later than 90 days after the date of the enactment of this Act, the Secretary of State, in coordination with the Secretary of Homeland Security and the heads of other relevant Federal agencies, shall submit a report to the congressional committees referred to in section 212(f)(3)(D) of the Immigration and Nationality Act, as amended by section 103 of this title, that describes the implementation of each of the presidential proclamations and executive orders referred to in section 104.

(2) Presidential proclamation 9645 and 9983.--In addition to the content described in paragraph (1), the report submitted with respect to Presidential Proclamation 9645, issued on September 24, 2017, and Presidential Proclamation 9983, issued on January 31, 2020, shall include, for each country listed in such proclamation-- (A) the total number of individuals who applied for a visa during the time period the proclamation was in effect, disaggregated by country and visa category;

(B) the total number of visa applicants described in subparagraph (A) who were approved, disaggregated by country and visa category;

(C) the total number of visa applicants described in subparagraph (A) who were refused, disaggregated by country and visa category, and the reasons they were refused;

(D) the total number of visa applicants described in subparagraph (A) whose applications remain pending, disaggregated by country and visa category;

(E) the total number of visa applicants described in subparagraph (A) who were granted a waiver, disaggregated by country and visa category;

(F) the total number of visa applicants described in subparagraph (A) who were denied a waiver, disaggregated by country and visa category, and the reasons such waiver requests were denied;

(G) the total number of refugees admitted, disaggregated by country;

and (H) the complete reports that have been submitted to the President every 180 days in accordance with section 4 of Presidential Proclamation 9645 in its original form, and as amended by Presidential Proclamation 9983.

(b) Additional Reports.--Not later than 30 days after the date on which the President exercises the authority under section 212(f) of the Immigration and Nationality Act (8 U.S.C.

1182(f)), as amended by section 103 of this title, and every 30 days thereafter, the Secretary of State, in coordination with the Secretary of Homeland Security and heads of other relevant Federal agencies, shall submit a report to the congressional committees referred to in paragraph (3)(D) of such section 212(f) that identifies, with respect to countries affected by a suspension or restriction, the information described in subparagraphs (A) through (H) of subsection (a)(2) of this section and specific evidence supporting the need for the continued exercise of presidential authority under such section 212(f), including the information described in paragraph (3)(B) of such section 212(f).

If the report described in this subsection is not provided to Congress in the time specified, the suspension or restriction shall immediately terminate absent intervening congressional action.

A final report with such information shall be prepared and submitted to such congressional committees not later than 30 days after the suspension or restriction is lifted.

(c) Form;

Availability.--The reports required under subsections (a) and (b) shall be made publicly available online in unclassified form.

TITLE II--AFFORDABLE PRESCRIPTIONS FOR PATIENTS ACT OF 2020 SEC.

201.

SHORT TITLE.

This title may be cited as the ``Affordable Prescriptions for Patients Act of 2020''.

SEC.

202.

PRODUCT HOPPING.

(a) In General.--The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c-2) the following:

~~494-27.~~

~~NOTIFICATION PRODUCT OF HOPPING. REQUEST FOR TAX RETURN INFORMATION.~~

~~``The``(a) SecretaryDefinitions.--In shall advise students and borrowers who submit an application for Federal student financial aid under this titlesection: or for the discharge of a loan based on permanent and total disability, as described in section 437(a), or who request an income-contingent or income-based repayment plan on their loan (as well as parents and spouses who sign such an application or request or a Master Promissory Note on behalf of those students and borrowers) that the Secretary has the authority to request that the Internal Revenue Service disclose their tax return information (as well as that of parents and spouses who sign such an application or request or a Master Promissory Note on behalf of those students and borrowers) to officers, employees, and contractors of the Department of Education as authorized under section 6103(1)(13) of the Internal Revenue Code of 1986, to the extent necessary for the Secretary to carry out this title.''~~

(b)``(1) ConfirmingAbbreviated Amendment.--Sectionnew 484(q)drug (20application.--The term `abbreviated new drug application' means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1091(q))355).--is amended to read as follows:

``(q)``(2) ~~reserved~~'--Biosimilar biological product.--The term `biosimilar biological product' means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C.

262(k)).

``(3) Biosimilar biological product license application.-- The term `biosimilar biological product license application' means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C.

262(k)).

``(4) Follow-on product.--The term `follow-on product'-- ``(A) means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(b)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C.

262(a)) for a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that treats the same medical condition;

and ``(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355a, 355c).

``(5) Generic drug.--The term `generic drug' means a drug approved under an application submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355).

``(6) Listed drug.--The term `listed drug' means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)).

``(7) Manufacturer.--The term `manufacturer' means the holder, licensee, or assignee of-- ``(A) an approved application for a drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(c));

or ``(B) a biological product license under section 351(a) of the Public Health Service Act (42 U.S.C.

262(a)).

``(8) Reference product.--The term `reference product' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C.

262(i)).

``(9) Secretary.--The term `Secretary' means the Secretary of Health and Human Services.

``(10) Ultimate parent entity.--The term `ultimate parent entity' has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

``(b) Prohibition on Product Hopping.-- ``(1) Prima facie.--Except as provided in paragraph (2), a manufacturer of a reference product or listed drug shall be considered to have engaged in an unfair method of competition in or affecting commerce in violation of section 5(a) if the Commission demonstrates by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that, during the period beginning on the date on which the manufacturer of the reference product or listed drug first receives notice that an applicant has submitted to the Commissioner of Food and Drugs an abbreviated new drug application or biosimilar biological product license application and ending on the date that is 180 days after the date on which that generic drug or biosimilar biological product is first marketed, the manufacturer engaged in either of the following actions:

``(A) The manufacturer engaged in a hard switch, which shall be established by demonstrating that the

manufacturer engaged in either of the following actions:

“(i) Upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs withdrew the approval of the application for the listed drug or reference product or placed the listed drug or reference product on the discontinued products list and the manufacturer marketed or sold a follow-on product.

“(ii) The manufacturer of the listed drug or reference product-- “(I)(aa) announced withdrawal of, discontinuance of the manufacture of, or intent to withdraw the application with respect to the drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances;

or “(bb) destroyed the inventory of the listed drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, which may be established by objective circumstances;

and “(II) marketed or sold a follow-on product.

“(B) The manufacturer engaged in a soft switch, which shall be established by demonstrating that the manufacturer engaged in both of the following actions:

“(i) The manufacturer took actions with respect to the listed drug or reference product other than those described in subparagraph (A) that unfairly disadvantage the listed drug or reference product relative to the follow-on product described in clause (ii) in a manner that impedes competition from a generic drug or a biosimilar biological product that is highly similar to, and has no clinically meaningful difference with respect to safety, purity, and potency from, the reference product, which may be established by objective circumstances.

“(ii) The manufacturer marketed or sold a follow-on product.

“(2) Justification.-- “(A) In general.--Subject to paragraph (3), the actions described in paragraph (1) by a manufacturer of a listed drug or reference product shall not be considered to be an unfair method of competition in or affecting commerce if-- “(i) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that-- “(I) the manufacturer would have taken the actions regardless of whether a generic drug that references the listed drug or biosimilar biological product that references the reference product had already entered the market;

and “(II)(aa) with respect to a hard switch under paragraph (1)(A), the manufacturer took the action for reasons relating to the safety risk to patients of the listed drug or reference product;

“(bb) with respect to an action described in item (aa) or (bb) of paragraph (1)(A)(ii)(I), there is a supply disruption that-- “(AA) is outside of the control of the manufacturer;

“(BB) prevents the production or distribution of the applicable listed drug or reference product;

and “(CC) cannot be remedied by reasonable efforts;

or “(cc) with respect to a soft switch under paragraph (1)(B), the manufacturer had legitimate pro-competitive reasons, apart from the financial effects of reduced competition, to take the action.

“(B) Rule of construction.--Nothing in subparagraph (A) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

“(3) Response.--With respect to a justification offered by a manufacturer under paragraph (2), the Commission may-- “(A) rebut any evidence presented by a manufacturer during that justification;

or “(B) establish by a preponderance of the evidence that, on balance, the pro-competitive benefits from the conduct described in subparagraph (A) or (B) of paragraph (1), as applicable, do not outweigh any anticompetitive effects of the conduct, even in consideration of the justification so offered.

“(c) Enforcement.-- “(1) In general.--If the Commission has reason to believe that any manufacturer has violated, is violating, or is about to violate this section, the Commission may take any of the following actions:

“(A) Institute a proceeding-- “(i) that, except as provided in paragraph (2), complies with the requirements under section 5(b);

and “(ii) in which the Commission may impose on the manufacturer any penalty that the Commission may impose for a violation of section 5.

“(B) In the same manner and to the same extent as provided in section 13(b), bring suit in a district court of the United States to temporarily enjoin the action of the manufacturer.

“(C) Bring suit in a district court of the United States, in which the Commission may seek-- “(i) to permanently enjoin the action of the manufacturer;

“(ii) any of the remedies described in paragraph (3);

and “(iii) any other equitable remedy, including ancillary equitable relief.

“(2) Judicial review.-- “(A) In general.--Notwithstanding any provision of section 5, any manufacturer that is subject to a final order of the Commission that is issued in a proceeding instituted under

paragraph (1)(A) may, not later than days after the date on which the Commission issues the order, petition for review of the order in-- `` (i) the United States Court of Appeals for the District of Columbia Circuit;

or `` (ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

`` (B) Treatment of findings.--In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

`` (3) Equitable remedies.-- `` (A) Disgorgement.-- `` (i) In general.--In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit.

`` (ii) Calculation.--Any disgorgement that is ordered with respect to a person under clause (i) shall be offset by any amount of restitution ordered under subparagraph (B).

`` (iii) Limitations period.--The Commission may seek disgorgement under this subparagraph not later than 5 years after the latest date on which the person from which the disgorgement is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the disgorgement.

`` (B) Restitution.-- `` (i) In general.--In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, restitution with respect to the violation that gives rise to the suit.

`` (ii) Limitations period.--The Commission may seek restitution under this subparagraph not later than 5 years after the latest date on which the person from which the restitution is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the restitution.

`` (4) Rules of construction.--Nothing in this subsection may be construed as-- `` (A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C);

or `` (B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.''.

(b) Applicability.--Section 27 of the Federal Trade Commission Act, as added by subsection (a), shall apply with respect to any-- (1) conduct that occurs on or after the date of enactment of this Act; and (2) action or proceeding that is commenced on or after the date of enactment of this Act.

(c) Antitrust Laws.--Nothing in this section, or the amendments made by this section, shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C.

12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that it applies to unfair methods of competition.

(d) Rulemaking.--The Federal Trade Commission may issue rules under section 553 of title 5, United States Code, to carry out section 27 of the Federal Trade Commission Act, as added by subsection (a), including by defining any terms used in such section 27 (other than terms that are defined in subsection (a) of such section 27).

(e) Confirmation.--Upon the request of the Commission, the Secretary shall provide confirmation of-- (1) any request made by the Secretary to the manufacturer for an application or supplement to an application for a change, modification, or reformulation of a drug or biological product;

(2) any withdrawal by the manufacturer of an application for a drug or reference product;

or (3) any request made by a manufacturer to the Secretary for withdrawal of an approval of the application for a drug or reference product or a request for placement of a drug or reference product on the discontinued products list.

~~5--203.~~

~~INCREASED TITLE FUNDING³⁵ FOR AMENDMENTS. FEDERAL PELL GRANTS.~~

~~Section (a) 401(b)(7)(A)(iv) In (20) General.--Section U.S.C. 271(e) of title 35, United States Code, is amended-- (1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following:~~

~~1070a(b)(7)(A)(iv)) ``With is respect amended-- to (1) a submission described in subclause clause (X), (ii), by the striking act ``\$1,430,000,000'' of and infringement inserting shall ``\$1,455,000,000''; extend to any patent that claims the biological product, a method of using the biological product, or a method or product used to manufacture the biological product.'';~~

~~and (2) in subclause (XI), by striking adding ``\$1,145,000,000'' at and the insert end ``\$1,170,000,000'' the following:~~

~~`` (7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C.~~

~~262(i)) (referred to in this paragraph as the `reference product sponsor'), brings an action for~~

infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which shall have issued after the date specified in section 351(l)(7)(A) of such Act.

“(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

“(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C.

262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product.

“(ii) Patents that are included on the list of patents described in section 351(l)(3)(A) of the Public Health Service Act (42 U.S.C.

262(l)(3)(A)), including as provided under section 351(l)(7) of such Act.

“(iii) Patents that-- “(I) have an actual filing date of more than 4 years after the date on which the reference product is approved;

or “(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

“(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph-- “(i) if the request to increase that number is made without undue delay;

and “(ii)(I) if the interest of justice so requires;

or “(II) for good cause shown, which-- “(aa) shall be established if the subsection (k) applicant fails to provide information required under section 351(l)(2)(A) of the Public Health Service Act (42 U.S.C.

262(l)(2)(A)) that would enable the reference product sponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted;

and “(bb) may be established-- “(AA) if there is a material change to the biological product (or process with respect to the biological product) of the subsection (k) applicant that is the subject of the application;

“(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C.

262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b);

or “(CC) for another reason that shows good cause, as determined appropriate by the court.

“(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has provided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of infringement under this section could reasonably be asserted.

“(E) The limitation imposed under subparagraph (A)-- “(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C.

262(l));

and “(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.'’.

(b) Applicability.--The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C.

262(k)) on or after the date of enactment of this Act.

(2)In the matter proposed to be inserted by the amendment of the Senate, strike sections 4, 5, and 6 and insert the following:

TITLE III--ACCESS TO COUNSEL ACT OF 2020 SEC.

301.

SHORT TITLE.

This title may be cited as the ‘‘Access to Counsel Act of 2020’’.

~~6--~~302.

~~REPORTS~~ACCESS ~~ONTO~~ IMPLEMENTATION, COUNSEL AND OTHER ASSISTANCE AT PORTS OF ENTRY AND DEFERRED

INSPECTION.

~~(a) InAccess General. Notto laterCounsel than each specified date, the Secretary of Education and theOther SecretaryAssistance ofDuring theInspection.-- TreasurySection shall235 issue joint reports to the Committees on Health, Education, Labor, and Pensions and Finance of the SenateImmigration and theNationality CommitteesAct on(8 EducationU.S.C. and Labor and Ways and Means of the House of Representatives regarding the amendments made by this Act.~~

~~Each1225) suchis reportamended shall include, as applicable-- (1) an update on the status of implementation of the amendments made by thisadding Act, at (2) an evaluation of the processingend of applications for Federal student financial aid, and applications for income-based repayment and income-contingent repayment, under title IV of the Higherfollowing: Education Act of 1965 (20 U.S.C.~~

~~1070``(e) etAccess seq.), to inCounsel accordanceand withOther theAssistance amendmentsDuring madeInspection.-- by``(1) thisIn Act, general.--The andSecretary (3)of implementationHomeland issuesSecurity shall ensure that a covered individual has a meaningful opportunity to consult with counsel and suggestionsan forinterested potentialparty improvements. during the inspection process.~~

~~(b)``(2) SpecifiedScope Date. For purposes of subsectionassistance.--The (a), Secretary theof termHomeland ``specifiedSecurity date''shall-- means--``(A) (1)provide the datecovered thatindividual isa 90meaningful daysopportunity afterto theconsult datewith ofcounsel theand enactmentan ofinterested thisparty Act, not (2)later thethan dateone thathour is 120 days after the firstsecondary dayinspection that the disclosure process establishedcommences underand sectionsas 6103(1)(13)necessary ofthroughout the Internalinspection Revenueprocess, Codeincluding, of 1986, as amendedapplicable, byduring sectiondeferred 2(a)inspection; of this Act, is operational and accessible to officers, employees, and contractors of the Department of Education (as specifically authorized and designated by the Secretary of Education), and (3) the date that is 1 year after the report date described in paragraph (2).~~

~~``(B) allow counsel and an interested party to advocate on behalf of the covered individual, including by providing to the examining immigration officer information, documentation, and other evidence in support of the covered individual;~~

~~and ``(C) to the greatest extent practicable, accommodate a request by the covered individual for counsel or an interested party to appear in-person at the secondary or deferred inspection site.~~

~~``(3) Special rule for lawful permanent residents.-- ``(A) In general.--The Secretary of Homeland Security may not accept Form I-407 Record of Abandonment of Lawful Permanent Resident Status (or a successor form) from a lawful permanent resident subject to secondary or deferred inspection without providing such lawful permanent resident a reasonable opportunity to seek advice from counsel prior to the submission of the form.~~

~~``(B) Exception.--The Secretary of Homeland Security may accept Form I-407 Record of Abandonment of Lawful Permanent Resident Status (or a successor form) from a lawful permanent resident subject to secondary or deferred inspection if such lawful permanent resident knowingly, intelligently, and voluntarily waives, in writing, the opportunity to seek advice from counsel.~~

~~``(4) Definitions.--In this section:~~

~~``(A) Counsel.--The term 'counsel' means-- ``(i) an attorney who is a member in good standing of the bar of any State, the District of Columbia, or a territory or a possession of the United States and is not under an order suspending, enjoining, restraining, disbaring, or otherwise restricting the attorney in the practice of law;~~

~~or ``(ii) an individual accredited by the Attorney General, acting as a representative of an organization recognized by the Executive Office for Immigration Review, to represent a covered individual in immigration matters.~~

~~``(B) Covered individual.--The term 'covered individual' means an individual subject to secondary or deferred inspection who is-- ``(i) a national of the United States;~~

~~``(ii) an immigrant, lawfully admitted for permanent residence, who is returning from a temporary visit abroad;~~

~~``(iii) an alien seeking admission as an immigrant in possession of a valid unexpired immigrant visa;~~

~~``(iv) an alien seeking admission as a non-immigrant in possession of a valid unexpired non-immigrant visa;~~

~~``(v) a refugee;~~

~~``(vi) a returning asylee;~~

~~or ``(vii) an alien who has been approved for parole under section 212(d)(5)(A), including an alien who is returning to the United States in possession of a valid advance parole document.~~

~~``(C) Interested party.--The term 'interested party' means-- ``(i) a relative of the covered individual;~~

~~``(ii) in the case of a covered individual to whom an immigrant or non-immigrant visa has been issued, the petitioner or sponsor thereof (including an agent of such petitioner or sponsor);~~

~~or ``(iii) a person, organization, or entity in the United States with a bona fide connection to the covered individual.''.~~

(b) Effective Date.--The amendment made by subsection (a) shall take effect 180 days after the date of the enactment of this Act.

(c) Savings Provision.--Nothing in this title, or in any amendment made by this title, may be construed to limit a right to counsel or any right to appointed counsel under-- (1) section 240(b)(4)(A) (8 U.S.C. 1229a(b)(4)(A)), (2) section 292 of the Immigration and Nationality Act (8 U.S.C.

1362), or (3) any other provision of law, including any final court order securing such rights, as in effect on the day before the date of the enactment of this Act.

~~Secretary~~.Clerk.

116th CONGRESS ~~1st~~^{2d} Session H.R.

2486

HOUSE AMENDMENTS TO SENATE

AMENDMENT