MARCH 5, 2020

RULES COMMITTEE PRINT 116–52

TEXT OF HOUSE AMENDMENT TO THE SENATE AMENDMENT TO H.R. 2486

[Showing the text of H.R. 2214, NO BAN Act, as reported by the Committee on the Judiciary, with modifications]

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

TITLE I—NO BAN ACT

SEC. 101. SHORT TITLES.

This title may be cited as the ''National Origin-Based Antidiscrimination for Nonimmigrants Act'' or the ''NO BAN Act''.

SEC. 102. EXPANSION OF NONDISCRIMINATION PROVISION.

Section 202(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1152(a)(1)(A)) is amended—

(1) by inserting ''or a nonimmigrant visa, admission or other entry into the United States, or the approval or revocation of any immigration benefit'' after ''immigrant visa'';

(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.

SEC. 103. TRANSFER AND LIMITATIONS ON AUTHORITY TO SUSPEND OR RESTRICT THE ENTRY OF A CLASS OF ALIENS.

Section 212(f) of the Immigration and Nationality Act (8 U.S.C. 1182(f)) is amended to read as follows:

"(f) AUTHORITY TO SUSPEND OR 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 aliens or class of aliens as immigrants or nonimmigrants; or

''(B) impose any restrictions on the entry of such aliens that the President deems appropriate.

''(2) LIMITATIONS.—In carrying out paragraph (1), the President, the Secretary of State, 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);

''(B) narrowly tailor the suspension or restriction, using the least restrictive means, to achieve such compelling government interest;

''(C) specify the duration of the suspension or restriction; and

''(D) consider waivers to any class-based restriction or suspension and apply a rebuttable presumption in favor of granting family-based and humanitarian waivers.

''(3) CONGRESSIONAL NOTIFICATION.—

''(A) IN GENERAL.—Prior to the 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 sup-

porting the need for the suspension or restriction and its proposed duration.

''(B) BRIEFING AND 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 action;

''(ii) the estimated number of individuals who will be impacted by such action;

''(iii) the constitutional and legislative authority under which such action took place; and

''(iv) the circumstances necessitating such action, including how such action complies with paragraph (2), as well as any intelligence informing such actions.

''(C) TERMINATION.—If the briefing and report described in subparagraph (B) are not provided to Congress during the 48 hours that begin when the President exercises the authority under paragraph (1), the suspension or re-

striction shall immediately terminate absent intervening congressional action.

''(D) CONGRESSIONAL COMMITTEES.—The term 'Congress', as used in this paragraph, refers to the Select Committee on Intelligence of the Senate, the Committee on Foreign Relations of the 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.

''(4) PUBLICATION.—The Secretary of State and the Secretary of Homeland Security shall publicly announce and publish an unclassified version of the report described in paragraph (3)(B) in the Federal Register.

''(5) JUDICIAL REVIEW.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, an individual or entity who is present in the United States and has

been harmed by a violation of this subsection may file an action in an appropriate district court of the United States to seek declaratory or injunctive relief.

''(B) CLASS ACTION.—Nothing in this Act may be construed to preclude an action filed pursuant to subparagraph (A) from proceeding as a class action.

''(6) TREATMENT OF COMMERCIAL AIRLINES.—Whenever the Secretary of Homeland 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.

''(7) RULE OF CONSTRUCTION.—Nothing in this section may be construed as authorizing the President, the Secretary of State, or the Secretary of Homeland Security to act in a manner inconsistent with the policy decisions expressed in the immigration laws.

''(8) CLARIFICATION.—For purposes of paragraph (1), the term 'public safety of the United States' includes efforts necessary to contain a communicable disease of public health significance (as defined in section 34.2(b) of title 42, Code of Federal Regulations (or any successor regulation)).''.

SEC. 104. TERMINATION OF CERTAIN EXECUTIVE ACTIONS.

(a) TERMINATION.—Presidential Proclamations 9645, 9822, and 9983 and Executive Orders 13769, 13780, and 13815 shall be void beginning on the date of the enactment of this Act.

(b) EFFECT.—All actions taken pursuant to any proclamation or executive order terminated under subsection (a) shall cease on the date of the 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 de-

scribes 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:

"SEC. 27. PRODUCT HOPPING.

"(a) DEFINITIONS.—In this section:

"(1) ABBREVIATED NEW DRUG APPLICATION.—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. 355).

"(2) 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 subpara-

graph (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 30 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.

SEC. 203. TITLE 35 AMENDMENTS.

(a) IN GENERAL.—Section 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: ''With respect to a submission described in clause (ii), the act of infringement shall 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) by adding at the end 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 para-

graph 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 sub-

section (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.

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