II

117TH CONGRESS
1ST SESSION

S. 3357

To substantially restrict the use of animal testing for cosmetics.

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2021

Mr. BOOKER (for himself, Mr. PORTMAN, Mr. HICKENLOOPER, Ms. COLLINS, and Ms. ROSEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To substantially restrict the use of animal testing for cosmetics.

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 "Humane Cosmetics Act of 2021".

SEC. 2. ANIMAL TESTING.

(a) PROHIBITION ON ANIMAL TESTING.—Beginning on the date that is 1 year after the date of enactment of this Act, it shall be unlawful for any person, whether private or governmental, to knowingly conduct or contract

for cosmetic animal testing that occurs in the United States.

(b) PROHIBITION ON SALE OR TRANSPORT.—Beginning on the date that is 1 year after the date of enactment of this Act, it shall be unlawful to sell, offer for sale, or knowingly transport in interstate commerce in the United States any cosmetic product that was developed or manufactured using cosmetic animal testing that was conducted or contracted for by any person in the cosmetic product's supply chain after such date.

(c) DATA USE.—

(1) IN GENERAL.—No evidence derived from animal testing conducted after the effective date specified in subsection (a) may be relied upon to establish the safety of a cosmetic, cosmetic ingredient, or nonfunctional constituent under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), unless—

(A) in the case of such testing on an ingredient or nonfunctional constituent, there is no non-animal alternative method or strategy recognized by any Federal agency, the Interagency Coordinating Committee on the Validation of Alternative Methods, or the Organisation for Economic Co-operation and Development for

the relevant safety endpoints for such ingredient or nonfunctional constituent; and

(B)(i) such animal testing is subject to an exemption under paragraph (2) or (3) of subsection (d); or

(ii)(I) such animal testing is subject to an exemption under paragraph (4) of subsection (d);

(II) there is documented evidence of the non-cosmetic intent of the test; and

(III) there is a history of use of the ingredient outside of cosmetics at least 1 year prior to the reliance on such data.

(2) LIMITATION.—This section shall not be construed to prohibit any entity from reviewing, assessing, or retaining evidence generated from animal testing.

(d) EXEMPTIONS.—Subsections (a) and (b) shall not apply with respect to animal testing—

(1) conducted outside the United States in order to comply with a requirement from a foreign regulatory authority;

(2) requested, required, or conducted by the Secretary, following—

(A) a written finding by the Secretary that—

(i) there is no non-animal alternative method or strategy recognized by any Federal agency, the Interagency Coordinating Committee on the Validation of Alternative Methods, or the Organisation for Economic Co-operation and Development for the relevant safety endpoints for the cosmetic ingredient or nonfunctional constituent;

(ii) there is a reasonable probability that the ingredient or nonfunctional constituent poses a specific and serious adverse human health risk and the need to conduct an animal test is justified and supported by a detailed research protocol that is proposed for the basis for evaluation of the cosmetic ingredient or nonfunctional constituent; and

(iii) the cosmetic ingredient or nonfunctional constituent is in wide use and, in the case of a cosmetic ingredient, cannot be replaced by another cosmetic ingredient capable of performing a similar function;

(B) publication by the Secretary, on the website of the Food and Drug Administration, of the written finding under subparagraph (A) together with a notice that the Secretary intends to request, require, or conduct new animal testing, and providing a period of not less than 60 calendar days for public comment; and

(C) a written determination by the Secretary, after review of all public comments received pursuant to subparagraph (B), that no previously generated data that could be substituted for, or otherwise determined sufficient to replace, the data expected to be produced through new animal testing is available for review by the Secretary;

(3) conducted for any product or ingredient that is subject to regulation under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.); or

(4) conducted for non-cosmetic purposes pursuant to a requirement of a Federal, State, or foreign regulatory authority.

(e) RULE OF CONSTRUCTION.—With the exception of records or other information demonstrating compliance with subsection (c)(1)(B)(ii), nothing in this section shall

be construed to authorize the Secretary to impose any new recordkeeping requirements relating to cosmetic animal testing.

(f) CIVIL PENALTIES.—

(1) IN GENERAL.—In addition to any other penalties under applicable law, any person who violates this section may be subject to a civil penalty in an amount of not more than $10,000 for each such violation, as determined by the Secretary.

(2) MULTIPLE VIOLATIONS.—Each violation of this section with respect to a separate animal, and each day that a violation of this Act continues, constitutes a separate offense.

(g) RECORDS ACCESS.—

(1) IN GENERAL.—The Secretary may request any records or other information from a cosmetic manufacturer that such manufacturer relied upon to meet the criteria in subsection (c)(1)(B)(ii). Such manufacturer shall, upon such request of the Secretary in writing, provide to the Secretary such records or other information, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such manufacturer. The Secretary's request shall include a sufficient description

of the records requested and reference this subsection.

(2) CONFIRMATION OF RECEIPT.—Upon receipt of the records requested under paragraph (1), the Secretary shall provide to the manufacturer confirmation of receipt.

(3) INSPECTION AUTHORITY.—Nothing in this subsection supplants the authority of the Secretary to conduct inspections otherwise permitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(h) STATE AUTHORITY.—No State or political subdivision of a State may establish or continue in effect any prohibition relating to cosmetic animal testing, or to the regulation of data use, labeling, and packaging related to animal testing, that is not identical to the prohibitions set forth in subsections (a), (b), (c), and (j) and that does not include the exemptions contained in subsections (c), (d), and (j). No State or political subdivision of a State may require any entity to perform cosmetic animal testing that is not permitted by subsection (a).

(i) FDA STRATEGIC PLAN FOR NON-ANIMAL TEST METHODS.—

(1) SCIENTIFIC INNOVATION.—To promote the development of, and provide for expedited review and

acceptance of, new scientifically valid test methods and strategies that are not based on vertebrate animals, the Secretary shall—

(A) not later than 1 year after the date of enactment of this Act, develop and publish on the website of the Food and Drug Administration a strategic plan to promote the development and implementation of alternative test methods and strategies to replace vertebrate animal testing for assessing the safety of cosmetics;

(B) provide a period of not less than 60 calendar days for public comment regarding such strategic plan;

(C) include in the strategic plan developed under subparagraph (A) a list (which the Secretary shall update on a regular basis, and which shall be for informational purposes and shall not be deemed to constitute a list of the only acceptable non-animal test methods) of—

(i) scientifically reliable and relevant non-animal test methodology as alternatives to animal testing that have been recognized by any Federal agency or an international regulatory agency;

(ii) next generation risk assessment methods; and

(iii) examples of alternative methods and strategies that have been accepted by the Secretary; and

(D) to the maximum extent practicable given available resources, prioritize and carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that replace the use of vertebrate animals.

(2) PUBLIC MEETINGS.—

(A) INITIAL MEETING.—Not later than 90 days after the date of enactment of this Act, the Secretary shall convene a public meeting regarding the strategic plan described in paragraph (1)(A).

(B) SUBSEQUENT ANNUAL MEETINGS.—Not later than 1 year after the date of the public meeting under subparagraph (A), and annually thereafter, the Secretary shall convene a separate public meeting or add as an agenda item to an already existing meeting, in-person or virtually, to inform the Secretary's advance-

ment of alternative test methods and strategies to replace vertebrate animal testing for assessing the safety of cosmetics. The Secretary shall include in such meetings scientific and academic experts, animal and consumer advocacy groups, and the regulated industry.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary to address other tools to promote the development and implementation of alternative test methods and strategies to replace vertebrate animal testing for assessing the safety of cosmetics as part of the strategic plan described in paragraph (1)(A).

(j) CONSUMER INFORMATION RELATED TO ANIMAL TESTING.—

(1) IN GENERAL.—A cosmetic product manufacturer shall not include on the label of a cosmetic product or any of the product's containers or wrappers a claim that such cosmetic product was not tested on animals, including any claim or logo of ''cruelty free'' if—

(A) such cosmetic product or any ingredient or nonfunctional constituent contained in such cosmetic product was tested on an animal

after the effective date specified in subsection (a); and

(B)(i) the testing was conducted by or contracted for by the cosmetic product manufacturer or another person in the supply chain at the direction or request of the cosmetic product manufacturer; or

(ii) the cosmetic product manufacturer relied upon evidence from such testing, pursuant to subsection (c)(1)(B)(ii), to establish the safety of such product, ingredient, or nonfunctional constituent under chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.).

(2) EXCEPTIONS.—Notwithstanding paragraph (1), a cosmetic product manufacturer may include a claim described in such paragraph on the label of a cosmetic product described in such paragraph or any of the product's containers or wrappers if—

(A) such testing qualifies for the exemption under subsection (d)(4); and

(B)(i) in the case of animal testing conducted by or contracted for by the cosmetic product manufacturer or another person in the supply chain at the direction or request of the

cosmetic product manufacturer, the cosmetic manufacturer did not rely upon evidence from such testing for the purpose of establishing the safety of the product, ingredient, or nonfunctional constituent under chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.); or

(ii) in the case of animal testing conducted by or contracted for by a person that is not described in clause (i), evidence from which the cosmetic product manufacturer relied upon, pursuant to subsection (c)(1)(B)(ii), to establish the safety of such product, ingredient, or nonfunctional constituent under chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), the cosmetic product manufacturer includes on the label a disclosure describing the circumstances surrounding the use of the exemption under subsection (c)(1)(B)(ii) by such manufacturer that includes a reference to the specific Federal, State, or foreign requirement under which the animal testing was conducted or a reference to a publicly available internet website of such manufacturer that provides such disclosure.

(k) REPORT.—Beginning 2 years after the date of enactment of this Act, the Secretary shall biennially submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make available on the website of the Food and Drug Administration, a report that includes, with respect to the previous 2 fiscal years—

(1) updates on the Secretary's implementation of this section, including developments implementing the strategic plan under subsection (i)(1)(A);

(2) the number of times the Secretary requested animal test data under subsection (d)(2), the ingredients involved, and the animal tests performed; and

(3) based on the data reviewed by the Secretary under subsection (g)(1), the number of times manufacturers relied upon data pursuant to the exemption under subsection (d)(4) to establish the safety of a cosmetic under chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.).

(l) DEFINITIONS.—

(1) COSMETIC.—The term ''cosmetic'' has the meaning given such term in section 201(i) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(i)).

(2) COSMETIC ANIMAL TESTING.—The term ''cosmetic animal testing'' means the internal or external application or exposure of any cosmetic product, or any cosmetic ingredient or nonfunctional constituent, to the skin, eyes, or other body part (organ or extremity) of a live non-human vertebrate for the purpose of evaluating the safety or efficacy of a cosmetic product or a cosmetic ingredient or nonfunctional constituent for use in a cosmetic product.

(3) LABEL.—The term ''label'' has the meaning given such term in section 201(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)).

(4) NONFUNCTIONAL CONSTITUENT.—The term ''nonfunctional constituent'' means any incidental ingredient as defined in section 701.3(l) of title 21, Code of Federal Regulations, on the date of enactment of this section.

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

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