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116TH CONGRESS
1ST SESSION

H. R. 5141

To substantially restrict the use of animal testing for cosmetics.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2019

Mr. BEYER (for himself, Mr. BUCHANAN, Mr. CÁRDENAS, Mr. TONKO, and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 2019''.

SEC. 2. ANIMAL TESTING.

(a) PROHIBITION ON ANIMAL TESTING.—Beginning 1 year after the date of enactment of this Act, it shall be unlawful for any person, whether private or govern-

mental, to knowingly conduct or contract for cosmetic animal testing that occurs in the United States.

(b) PROHIBITION ON SALE OR TRANSPORT.—It shall be unlawful to sell, offer for sale, or knowingly transport in interstate commerce in the United States any cosmetic 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 the date that is 1 year after the date of enactment of this Act.

(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 non-functional 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 non-functional constituent, there is no non-animal alternative method or strategy recognized by any Federal agency or the Organisation for Economic Co-operation and Development for the relevant safety endpoints

for such ingredient or non-functional 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 or the Organisation for Economic Co-operation and Development for the relevant safety endpoints for the cosmetic ingredient or non-functional constituent;

(ii) the cosmetic ingredient or non-functional constituent poses a risk of causing serious adverse health consequences or death; and

(iii) the cosmetic ingredient or non-functional 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 of the written finding required by subparagraph (A) on the internet website of the Food and Drug Administration together with a notice that the Secretary intends to request, require, or conduct new animal testing, and provides 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 applicable under law, the Secretary shall assess whoever violates any provision of this section a civil penalty of not more than $10,000 for each such violation.

(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 (k) and that does not include the exemptions contained in subsections (c), (d), and (k). 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 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 internet 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, of 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, which also includes next generation risk assessment methods, and a list of examples of alternative methods and strategies that have been accepted by the Secretary (such lists shall be for information purposes and shall not be deemed to constitute a list of the only acceptable non-animal test methods); and

(D) to the maximum extent practicable with 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.—No 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.—No later than 1 year after the date of the public meeting under subparagraph (A), and annually thereafter, the Secretary shall convene a public meeting to inform the Secretary's advancement 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) 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 non-functional 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 non-functional 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) NON-FUNCTIONAL CONSTITUENT.—The term ''non-functional constituent'' means any incidental ingredient as defined in section 701.3(1) 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.

(k) 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 non-functional 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 manufac-

turer 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 nonfunc-

tional 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.

(l) 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 internet 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 as set forth in 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.).

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