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118TH CONGRESS
1ST SESSION

H. R. 5399

To substantially restrict the use of animal testing for cosmetics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2023

Mr. BEYER (for himself, Mr. BUCHANAN, Mr. CÁRDENAS, Mr. CALVERT, and Mr. TONKO) 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, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Humane Cosmetics Act of 2023''.

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 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 knowingly sell, offer for sale, or 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 supply chain of the cosmetic product 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) such animal testing is subject to an exemption under subsection (d)(2); or

(B) in the case of such animal testing on an ingredient or nonfunctional constituent—

(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 such ingredient or nonfunctional constituent for use in cosmetics; and

(ii)(I) such animal testing is subject to an exemption under subsection (d)(3); or

(II)(aa) such animal testing is subject to an exemption under subsection (d)(4);

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

(cc) there is a history of use of the ingredient outside of cosmetics at least 1 year prior to the reliance on evidence described in the matter preceding subparagraph (A).

(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 for the relevant safety endpoints for the cosmetic ingredient or nonfunctional constituent;

(ii) there is information received by the Secretary of adverse health effects, other than minor and transient reactions or minor and transient skin irritations in some users, related to the cosmetic ingredient or nonfunctional constituent; and

(iii) the 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 ani-

mal 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) CIVIL PENALTIES.—

(1) IN GENERAL.—In addition to any other penalties under applicable law, the Secretary may impose on any person who violates this section 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.

(f) 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)(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.).

(g) 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 related to animal testing, that is not identical to the prohibitions set forth in subsections (a), (b), and (c), and that does not include the exemptions contained in subsections (c) and (d). No State or political subdivision of a State may require any entity to perform cosmetic animal testing that is not permitted by subsection (a).

(h) 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, 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 cos-

metic product or a cosmetic ingredient or nonfunctional constituent for use in a cosmetic product.

(3) 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.

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

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