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119TH CONGRESS
1ST SESSION

H. R. 2300

To ensure national uniformity with respect to certain requirements relating to preterm infant formula, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 2025

Mrs. HARSHBARGER (for herself and Mr. SCHNEIDER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To ensure national uniformity with respect to certain requirements relating to preterm infant formula, 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. PRETERM INFANT FORMULA.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall study—

(A) the availability of preterm infant formula in the United States;

(B) Federal and State laws, regulations, orders, and requirements, including under State common law, that relate to preterm infant formula, including with respect to—

(i) the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, and use of preterm infant formula; or

(ii) any aspect of the safety of preterm infant formula;

(C) whether the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) should be amended to require a manufacturer of preterm infant formula to obtain premarket approval for such formula from the Food and Drug Administration; and

(D) if the Secretary recommends such premarket approval, a process and corresponding requirements for such premarket approval.

(2) RECOMMENDATIONS.—Not later than two years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall

submit to the Congress a report on the results of the study under paragraph (1).

(b) TEMPORARY PREEMPTION.—

(1) PERIOD OF APPLICABILITY.—This subsection applies only during the period—

(A) beginning on the date of enactment of this Act; and

(B) ending on the date that is two years after the date of enactment of this Act.

(2) PREEMPTION.—Except as provided in paragraph (3), no State or political subdivision of a State may establish, implement, or enforce with respect to preterm infant formula any requirement, including under any State statute, regulation, order, or common law—

(A) that is different from, or in addition to, any requirement applicable to preterm infant formula under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.); and

(B) that relates to preterm infant formula, including—

(i) the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, and use of preterm infant formula; and

(ii) any aspect of the safety of preterm infant formula.

(3) EXCEPTION FOR CIVIL AND CRIMINAL ACTIONS FOR WILLFUL MISCONDUCT.—

(A) EXCEPTION.—Paragraph (2) does not preempt civil or criminal actions based on a requirement described in paragraph (2) to the extent such actions are against a manufacturer for willful misconduct in the manufacturing or production of preterm infant formula that caused death or serious physical injury.

(B) REMOVAL.—In the case of a civil action brought in a State court against a manufacturer, if that manufacturer alleges that the law under which the action is brought is preempted by paragraph (2), such action may be removed by the manufacturer to the district court of the United States for the district and division embracing the place wherein the civil

action is pending. This subparagraph applies to any action pending before, on, or after the date of enactment of this Act, except to the extent that there is a final judgment from which no appeal may be taken and no further review may be sought from a court of last resort, including the Supreme Court of the United States.

(C) BURDEN OF PROOF.—In determining whether the exception in subparagraph (A) applies, the plaintiff shall have the burden of proving that the criteria described in subparagraph (A) are met by clear and convincing evidence.

(4) DISMISSAL OF PENDING ACTIONS.—A civil or criminal action that is pending as of the date of enactment of this Act shall be dismissed to the extent such action seeks to implement or enforce a requirement that is preempted by paragraph (2).

(c) DEFINITIONS.—In this section:

(1) The term ''infant formula'' has the meaning given to such term in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

(2) The term ''manufacturer''—

(A) means a person who—

(i) prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of a preterm infant formula; or

(ii) packages or labels a preterm infant formula in a container for distribution; and

(B) does not include a person taking actions described in subparagraph (A) exclusively for an infant under such person's direct care.

(3) The term ''preterm infant formula'' means any infant formula that is exempt under section 412(h)(1) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 350a(h)) and intended to be administered to—

(A) an infant born before 37 weeks of gestation; or

(B) a low-birth-weight infant.

(4) The term ''willful misconduct'' means, except as such term is further restricted pursuant to subparagraph (B), an act or omission that is taken—

(A) intentionally to achieve a wrongful purpose;

(B) knowingly without legal or factual justification; and

(C) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

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