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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to establish special rules relating to the regulation of general wellness products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BALDERSON introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish special rules relating to the regulation of general wellness products, 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 ''Digital Health Screeners Act of 2026''.

SEC. 2. CLARIFICATION REGARDING CLINICAL DECISION SUPPORT SOFTWARE RECOMMENDATIONS.

(a) IN GENERAL.—Section 520(o)(1)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)(1)(E)(ii)) is amended by inserting ''a recommendation (where only one option is clinically appropriate) or'' before ''recommendations''.

(b) CONFORMING AMENDMENTS.—Section 520(o)(1)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)(1)(E)(iii)) is amended—

(1) by striking ''such recommendations'' and inserting ''such recommendation or recommendations''; and

(2) by striking ''any of such recommendations'' and inserting ''the recommendation or recommendations''.

SEC. 3. EXPANSION OF GENERAL WELLNESS EXCLUSION BEYOND SOFTWARE FUNCTIONS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

''(r) REGULATION OF GENERAL WELLNESS PRODUCTS.—

''(1) EXCLUSION FROM DEFINITION OF DEVICE.—The term device, as defined in section 201(h), shall not include a general wellness product.

''(2) GENERAL WELLNESS PRODUCT DEFINED.—

''(A) IN GENERAL.—In this subsection, the term 'general wellness product' means a product (including software, hardware, or both) that—

''(i) is intended for maintaining or encouraging a healthy lifestyle; and

''(ii) is unrelated to, and not intended for, the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

''(B) REQUIREMENT.—To meet the definition in subparagraph (A), a product shall be non-invasive and not-implanted.

''(C) LIMITATION.—Subject to paragraph (4), a product shall not be excluded from the definition in subparagraph (A) solely because the product—

''(i) measures, estimates, infers, or outputs one or more physiologic parameters and displays values, ranges, trends, baselines, or longitudinal summaries; or

"(ii) contextualizes such outputs in relation to sleep, activity, stress, recovery, or similar wellness domains.

"(3) LABELING.—

"(A) IN GENERAL.—A general wellness product shall have labeling that is consistent with, and does not exceed, the product's stated intended use.

"(B) CONTENTS.—For purposes of subparagraph (A), the labeling for a general wellness product includes instructions for use, user-facing claims, promotional materials, and marketing communications.

"(4) ESTABLISHMENT OF CRITERIA.—Not later than 180 days after the date of enactment of this subsection, the Secretary shall, through guidance or regulation, establish criteria for determining whether a product described in paragraph (2)(C) meets the definition in paragraph (2)(A). Such criteria may include assessment of risk, labeling, and general acceptance of claims related to health and wellness.

"(5) LIMITATION ON STATUTORY CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary to regulate a

product as a device under this Act when the product meets the definition in section 201(h).''.

(b) CONFORMING AMENDMENT.—Section 520(o)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)(1)(B)) is amended to read as follows:

''(B) for use in a general wellness product, as defined in subsection (r);''.