

.....  
(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to establish nonvisual accessibility standards for certain devices with digital interfaces, and for other purposes.

\_\_\_\_\_  
**IN THE HOUSE OF REPRESENTATIVES**

Ms. SCHAKOWSKY introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to establish nonvisual accessibility standards for certain devices with digital interfaces, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Medical Device Non-  
5       visual Accessibility Act of 2025”.

6       **SEC. 2. FINDINGS.**

7       Congress finds the following:

1           (1) Rapid advances in digital technology have  
2           led to increasingly complex user interfaces for every-  
3           day products, such as life-sustaining medical devices  
4           and technologies.

5           (2) Many of these new devices utilize displays  
6           that can only be operated visually and require user  
7           interaction with on-screen menus and other inter-  
8           faces that are inaccessible to consumers who are  
9           blind or have low-vision.

10          (3) Medical devices designed for use in the  
11          home are being increasingly utilized to lessen the  
12          cost of inpatient care for consumers.

13          (4) Devices such as blood pressure monitors,  
14          sleep apnea machines, in-home chemotherapy treat-  
15          ments, and many others generally lack nonvisual ac-  
16          cessibility.

17          (5) If a medical device is not accessible in a  
18          nonvisual manner, a blind or low-vision individual is  
19          unable to use it privately, independently, and safely.

20          (6) Many technology companies have incor-  
21          porated screen access technology functions, such as  
22          text to speech software, into products developed and  
23          sold by such companies.

1           (7) Screen access technology is not the only  
2           mechanism by which medical devices can be made  
3           accessible to blind or low-vision consumers.

4           (8) Devices that utilize these mechanisms will  
5           be more user-friendly in general by including mul-  
6           tiple methods to confirm readings and other data,  
7           leading to less waste and fewer mistakes.

8           (9) Devices can be designed to work with non-  
9           visual access technology used by individuals who are  
10          blind or have low-vision at little or no extra cost as  
11          long as such compatibility is taken into consider-  
12          ation at the beginning of the design process.

13          (10) Consumers who are blind or have low-vi-  
14          sion must be able to operate medical devices in an  
15          equally effective and equally integrated manner and  
16          with equivalent ease of use as consumers without  
17          disabilities.

18   **SEC. 3. NONVISUAL ACCESSIBILITY STANDARDS FOR CER-**  
19                   **TAIN DEVICES.**

20          (a) IN GENERAL.—The Federal Food, Drug, and  
21          Cosmetic Act is amended by inserting after section 515C  
22          (as added by Public Law 117–328) the following:

1   **“SEC. 515D. NONVISUAL ACCESSIBILITY STANDARDS FOR**  
2                           **CERTAIN DEVICES.**

3           “(a) STANDARD.—The nonvisual accessibility stand-  
4   ard specified in this section is, with respect to a user inter-  
5   face of a device described in section 501(k), that the user  
6   interface is as effective in allowing blind or low-vision indi-  
7   viduals to access information, engage in interactions, and  
8   enjoy services with comparable privacy, independence, and  
9   ease of use as the user interface of the device enables indi-  
10   viduals who do not have low-vision or are not blind.

11          “(b) WAIVER.—The Secretary may waive the applica-  
12   tion of section 501(k) with respect to a covered device if,  
13   based on clear and convincing evidence (as determined by  
14   the Secretary) provided by the manufacturer involved, the  
15   Secretary determines that the application of such section  
16   to the device would result in a fundamental alteration to  
17   the nature of the product or an undue hardship for the  
18   manufacturer.

19          “(c) TRAINING.—The Secretary shall conduct train-  
20   ing to educate manufacturers of a user interface of a de-  
21   vice described in section 501(k) or of a device described  
22   in such section on the standards developed under sub-  
23   section (a) and how to comply with such standard.

24          “(d) STAKEHOLDERS.—In developing the standard  
25   under subsection (a) and the training to be conducted  
26   under subsection (c), the Secretary shall consult with—

1 “(1) the Architectural and Transportation Bar-  
2 riers Compliance Board established under section  
3 504 of the Rehabilitation Act of 1973; and

4 “(2) individuals who are blind or who have low-  
5 vision.

6 “(e) REGULATIONS.—

7 “(1) IN GENERAL.—The Secretary shall, in con-  
8 sultation with the Architectural and Transportation  
9 Barriers Compliance Board referred to in subsection  
10 (d)—

11 “(A) not later than 1 year after the date  
12 of the enactment of this section, issue proposed  
13 regulations to implement the standard specified  
14 under subsection (a); and

15 “(B) not later than 2 years after the date  
16 of the enactment of this section, publish a final  
17 rule with respect to such proposed regulations.

18 “(2) EFFECTIVE DATE.—The final rule pub-  
19 lished under paragraph (1)(B) shall take effect on  
20 the date that is 1 year after the date on which such  
21 rule is published.

22 “(f) DEFINITIONS.—In this section:

23 “(1) The term ‘covered device’ means a device  
24 that—

1           “(A) is classified under section 513 into  
2           class II or III;

3           “(B) is cleared under section 510(k),  
4           granted marketing authorization under section  
5           513(f)(2), or approved under section 515 after  
6           the effective date specified in subsection (e);

7           “(C) has a user interface; and

8           “(D) is not intended solely for use by a  
9           health care provider or in a setting outside the  
10          home.

11          “(2) The term ‘fundamental alteration’ means  
12          an alteration to the nature of a covered device that  
13          would render it unusable or incapable of performing  
14          an essential function.

15          “(3)(A) The term ‘undue hardship’ means an  
16          action requiring significant difficulty or expense,  
17          when considered in light of the factors specified in  
18          subparagraph (B).

19          “(B) In determining whether application of this  
20          section would impose an undue hardship on a manu-  
21          facturer of a covered device, factors to be considered  
22          may include

23                 “(C) the nature and cost of compliance  
24                 with the standard under this section; and

1                   “(D) the overall financial resources of the  
2                   manufacturer of a covered device.

3                   “(4) The term ‘user interface’ means a screen  
4                   or mobile application through which a human user  
5                   interacts or communicates with the device by  
6                   inputting or receiving information.”.

7                   (b) ADULTERATION.—Section 501 of the Federal  
8                   Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-  
9                   ed by inserting after paragraph (j) the following:

10                  “(k) Beginning on the effective date specified in sub-  
11                  section (e) of section 515D, if it is a covered device (as  
12                  defined in such section), unless the device meets the non-  
13                  visual accessibility standard specified under such section  
14                  or the Secretary issues a waiver with respect to the device  
15                  under such section.”.