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(Original Signature of Member)

117TH 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.

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 ''Medical Device Nonvisual Accessibility Act of 2021''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

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

(4) Devices such as blood pressure monitors, sleep apnea machines, and in-home chemotherapy treatments generally lack nonvisual accessibility.

(5) If a medical device is not accessible in a nonvisual manner, a blind or low-vision individual cannot use it safely.

(6) Many technology companies have incorporated screen access technology functions into products developed and sold by such companies.

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

(8) Tactile markings, audible tones, or cost effective and widely available text-to-speech technology may be sufficient to make such devices fully accessible.

(9) Devices that utilize these mechanisms will be more user-friendly in general by increasing methods for confirmation of readings, which has the potential to lead to less waste and fewer mistakes.

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

(11) Consumers who are blind or have low-vision must be able to operate medical devices in an equally effective and equally integrated manner and with equivalent ease of use as consumers without disabilities.

SEC. 3. NONVISUAL ACCESSIBILITY STANDARDS FOR CERTAIN DEVICES.

(a) IN GENERAL.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after subsection (j) the following:

''(k) If it is a device classified under section 513 into class II or III, unless the device meets the nonvisual accessibility standards specified under section 515C.''.

(b) RECOGNITION OF STANDARD.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 515B (21 U.S.C. 360e–3) the following:

''SEC. 515C. NONVISUAL ACCESSIBILITY STANDARDS FOR CERTAIN DEVICES.

''(a) STANDARD.—The nonvisual accessibility standard specified in this section is, with respect to a digital interface of a device described in section 501(k), that the digital interface allows for blind or low-vision individuals to access the same information, engage in the same interactions, and to enjoy the same services with the same privacy, independence, and ease of use offered to individuals who do not have low-vision or are not blind.

''(b) TRAINING.—The Secretary shall, in consultation with the Architectural and Transportation Barriers Compliance Board (established under section 504 of the Rehabilitation Act of 1973), conduct training to educate manufacturers of a digital interface of a device described in section 501(k) or of a device described in such section on the standards developed under subsection (a).

''(c) REGULATIONS.—The Secretary shall, in consultation with the Architectural and Transportation Barriers Compliance Board—

''(1) not later than 1 year after the date of the enactment of this section, issue proposed regulations to implement the standard specified under subsection (a); and

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

''(d) EFFECTIVE DATE.—A final rule published under subsection (c)(2) shall take effect 1 year after the publication of such rule.

''(e) DIGITAL INTERFACE DEFINED.—In this section, the term 'digital interface' means a means by which human users interact or communicate with electronic devices, including computerized devices.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $1,500,000 fiscal years 2023 through 2024.''.