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117TH CONGRESS
2D SESSION

H. R. 7646

To amend the Federal Food, Drug, and Cosmetic Act to notify the public about an emerging signal concerning a medical device in order to reduce or limit the number of patients exposed to a potential risk identified based on such emerging signal, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2022

Mr. GUTHRIE (for himself and Mr. MOULTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to notify the public about an emerging signal concerning a medical device in order to reduce or limit the number of patients exposed to a potential risk identified based on such emerging signal, 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 ''Emerging Signals Modernization Act of 2022''.

SEC. 2. PUBLIC NOTIFICATION OF AN EMERGING SIGNAL CONCERNING A MEDICAL DEVICE.

(a) TECHNICAL AMENDMENTS.—Section 518 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h) is amended—

(1) by striking the section designation and heading and that follows through ''If the Secretary determines that—'' and inserting the following:

''SEC. 518. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—

''(1) IN GENERAL.—If the Secretary determines that—''; and

(2) in subsection (a)—

(A) by striking ''(1) a device'' and inserting the following:

''(A) a device'';

(B) by striking ''(2) notification'' and inserting the following:

''(B) notification'';

(C) by moving the margin of the continuation text at the end of subsection (a) 2 ems to the right; and

(D) by striking ''this subsection'' each place it appears and inserting ''this paragraph''.

(b) EMERGING SIGNALS.—Section 518(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)), as amended by subsection (a), is further amended by adding at the end the following:

"(2) EMERGING SIGNALS AND OTHER NOTIFICATIONS.—

"(A) APPLICABILITY.—This paragraph applies if the Secretary—

"(i) determines that a device meets the conditions described in paragraph (1)(A), and no more practicable means is available under the provisions of this Act, including paragraph (1), to eliminate the risk described in paragraph (1)(A); or

"(ii) otherwise determines that it is necessary to notify the public about an emerging signal concerning a device in order to reduce or limit the number of patients exposed to a potential risk identified based on an emerging signal.

"(B) DEFINITION OF EMERGING SIGNAL.—In this paragraph, the term 'emerging signal' means new information about a marketed device—

''(i) that supports a new causal association or a new aspect of a known association between the device and an adverse event or set of adverse events; and

''(ii) for which the Secretary has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions or the known benefit-risk profile of the device.

''(C) RELIANCE ON SCIENTIFIC EVIDENCE.—In considering and taking actions under this section, the Secretary shall—

''(i) to the extent possible, rely solely on valid scientific evidence; and

''(ii) in any event, base such actions on credible scientific evidence, such that information that is unconfirmed, unreliable, or lacks sufficient strength of evidence shall not constitute an emerging signal or otherwise provide a basis for notification under this paragraph.

''(D) CONTENT OF PUBLIC NOTIFICATION.—Any public notification under this paragraph shall—

"(i) include a description of the device or devices to which the notification applies;

"(ii) reflect a totality of the evidence on which the notification is based; and

"(iii) incorporate information about the known benefits and risks of the device or devices, including information available from the manufacturer or manufacturers.

"(E) CONTRADICTORY EVIDENCE.—To the extent credible scientific evidence is presented to the Secretary that contradicts or modifies the information that serves as a potential basis for a public notification under this paragraph, the Secretary shall include such scientific evidence in the public notification in a manner that provides the intended audience with a complete understanding of the overall nature of information concerning the potential risk.

"(F) OPPORTUNITY FOR MANUFACTURERS TO COMMENT.—Prior to issuance of a public notification under this paragraph, the Secretary shall—

"(i) provide the manufacturer or manufacturers of the device or devices at issue the credible scientific evidence that is the

basis for considering the public notification and the Secretary's initial evaluation of such evidence as described in subparagraph (B)(ii);

"(ii) to the extent the Secretary determines that any of the credible scientific evidence described in clause (i) cannot be provided to manufacturers because such evidence constitutes confidential commercial information or trade secret information, provide the manufacturer or manufacturers of the device or devices at issue with a description of the withheld evidence to the extent permissible by law and generally describe the basis for withholding such evidence;

"(iii) provide the manufacturer or manufacturers of the device or devices at issue an adequate opportunity—

"(I) to comment as to the nature of the potential risk and the manner and content of the potential notification under this paragraph;

"(II) to share information about the potential risk; and

"(III) to offer recommendations as to the form and content of the potential notification, including consideration of alternative forms of notification and risk mitigation; and

"(iv) consider any input received under clause (iii).

"(G) UPDATES.—The Secretary shall provide periodic and timely updates to each notification under this paragraph based on new information or contrary information, including affirmative notice in the event that the emerging signal or other source of potential risk has been determined not to apply or has otherwise been resolved or mitigated, such that no additional actions are required. For purposes of providing updates under this subparagraph, the Secretary shall consider information provided to the Secretary by a manufacturer subsequent to the initial public notification.

"(H) RESPONSE TO INFORMATION PROVIDED BY MANUFACTURER.—With regard to information provided to the Secretary by a manufacturer relating to a notification under this

paragraph, the Secretary shall inform such manufacturer—

"(i) how such information affects or alters the Secretary's initial evaluation; and

"(ii) whether the notification will be updated or rescinded as a result of such information.

"(I) PERIODIC EVALUATION.—At least every six months after issuance of a notification under this paragraph, the Secretary shall—

"(i) evaluate current credible scientific evidence to determine if such notification should be rescinded; and

"(ii) if the Secretary determines such notification should be rescinded, promptly provide notice of the rescission to the same audience and in the same manner as the original notification.

"(J) REVISION OF GUIDANCE.—Not later than September 30, 2023, the Secretary shall revise the guidance of the Food and Drug Administration titled 'Public Notification of Emerging Postmarket Medical Device Signals

(''Emerging Signals'')', to conform with this paragraph.

''(K) REPORT TO CONGRESS.—Not later than September 30, 2023, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding—

''(i) how patients, health care providers, and the public interpret and comprehend risk-related information provided or ordered by the Secretary relating to devices, including reports under this section, notifications concerning recalls, and notifications concerning adverse events; and

''(ii) whether the relative level of risk and appropriate mitigations for such risk are adequately understood.

''(L) THIRD PARTY DATA TRANSPARENCY.—To the extent the Secretary seeks to rely on data, analysis, or other information or findings provided by third parties that has been funded in whole or in part by, or otherwise performed under contract with, the Food and Drug Administration, in making a significant

decision concerning one or more devices or considering issuance of an order under this section or section 522, the Secretary shall—

''(i) obtain access to the raw datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components underlying or comprising the data, analysis, or other information or findings upon which the Secretary seeks to rely; and

''(ii) if such a significant decision is made, or such an order under this section or section 522 is under consideration, in reliance on such data, analysis, or other information or findings, provide the manufacturer or manufacturers subject to such decision or order the data, analysis, or other information or findings, including the underlying raw datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components, except that any such raw datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components that the Secretary determines to be

confidential commercial information or trade secret information may be withheld but shall be described to the manufacturer or manufacturers to the extent permissible by law.''.

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