

117TH CONGRESS
2D SESSION

S. 4349

To amend the Federal Food, Drug, and Cosmetic Act with respect to notifications of emerging signals concerning devices.

IN THE SENATE OF THE UNITED STATES

JUNE 6, 2022

Mr. MARSHALL (for himself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to notifications of emerging signals concerning devices.

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. NOTIFICATION WITH RESPECT TO POTEN-**
4 **TIALLY HARMFUL DEVICES.**

5 Section 518(a) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 360h(a)) is amended by adding at
7 the end the following:

8 “(3)(A) This paragraph applies in the event that the
9 Secretary—

1 “(i) determines that a device meets the condi-
2 tions described in paragraph (1), but there are no
3 more practicable means available under the provi-
4 sions of this Act (other than this section) to elimi-
5 nate the risk described in paragraph (1), and the no-
6 tification described in paragraph (2) will not provide
7 a timely and practicable means to eliminate such
8 risk; or

9 “(ii) otherwise determines that it is necessary
10 to notify the public about an emerging signal con-
11 cerning a device in order to reduce or limit the num-
12 ber of patients exposed to a potential risk identified
13 based on an emerging signal.

14 “(B) For purposes of this paragraph, the term
15 ‘emerging signal’ mean new information about a marketed
16 device—

17 “(i) that supports a new causal association or
18 a new aspect of a known association between a de-
19 vice and an adverse event or set of adverse events;
20 and

21 “(ii) for which the Secretary has conducted an
22 initial evaluation and determined that the informa-
23 tion has the potential to impact patient management
24 decisions or the known benefit-risk profile of the de-
25 vice.

1 “(C) In considering and taking actions under this
2 section, the Secretary shall—

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

5 “(ii) in any event, base its actions on credible
6 scientific evidence, such that information that is
7 unconfirmed, unreliable, or lacks sufficient strength
8 of evidence shall not constitute an emerging signal
9 or otherwise provide a basis for notification.

10 “(D) In the circumstances described in subparagraph
11 (A), the Secretary may issue a public notification subject
12 to the following procedures:

13 “(i) Any public notification under this para-
14 graph shall include a description of the device or de-
15 vices to which the notification applies, and shall re-
16 flect a totality of the evidence on which the notifica-
17 tion is based and information about the known bene-
18 fits and risks of the device or devices, including in-
19 formation available from the manufacturer or manu-
20 facturers.

21 “(ii) To the extent credible scientific evidence is
22 presented to the Secretary that contradicts or modi-
23 fies the information that serves as a potential basis
24 for a notification, the Secretary shall include such
25 scientific evidence in the public notification in a

1 manner that provides the intended audience with a
2 complete understanding of the overall nature of in-
3 formation concerning the potential risk.

4 “(iii) Prior to issuance of the public notifica-
5 tion, the Secretary shall—

6 “(I) inform the manufacturer or manufac-
7 turers of the device or devices at issue, and pro-
8 vide the manufacturers the credible scientific
9 evidence that is the basis for considering a pub-
10 lic notification and the Secretary’s initial eval-
11 uation of such evidence as described in subpara-
12 graph (B)(ii);

13 “(II) to the extent the Secretary deter-
14 mines that any of the credible scientific evi-
15 dence described in subclause (I) cannot be pro-
16 vided to manufacturers because such evidence
17 constitutes confidential commercial information
18 or trade secret information, the Secretary shall
19 provide the manufacturers of the device or de-
20 vices at issue with a description of the withheld
21 evidence to the extent permissible by law and
22 also generally describe the basis for withholding
23 such evidence; and

24 “(III) provide the manufacturers of the de-
25 vice or devices at issue an adequate opportunity

1 to comment as to the nature of the potential
2 risk and the manner and content of an applica-
3 ble notification, to share information about the
4 potential risk, and to offer recommendations as
5 to the form and content of the proposed notifi-
6 cation, including consideration of alternative
7 forms of notification and risk mitigation, and
8 the Secretary shall consider such input from the
9 manufacturers before issuing a public notifica-
10 tion.

11 “(iv) Provide periodic and timely updates to the
12 notification based on new information or contrary
13 information, including affirmative notice in the event
14 that the emerging signal or other source of potential
15 risk has been determined not to apply or has other-
16 wise been resolved or mitigated, such that no addi-
17 tional actions are required. Information provided by
18 manufacturers subsequent to the initial public notifi-
19 cation should be considered by the Secretary for
20 purposes of providing updates.

21 “(v) With regard to information provided by
22 manufacturers, the Secretary shall inform such man-
23 ufacturers how such information affects or alters the
24 Secretary’s initial evaluation and whether the notifi-

1 cation will be updated or rescinded as a result of
2 such information.

3 “(vi) At least every 6 months after issuance,
4 the Secretary shall evaluate current credible sci-
5 entific evidence to determine if a public notification
6 should be rescinded, and if such determination is
7 made, promptly provide notice of the rescission to
8 the same audience and in the same manner as the
9 original notification.

10 “(E) Not later than September 30, 2023, the Sec-
11 retary shall revise the Food and Drug Administration
12 guidance titled ‘Public Notification of Emerging
13 Postmarket Medical Device Signals (“Emerging Sig-
14 nals”)', to conform with this subsection.

15 “(F) Not later than September 30, 2023, the Sec-
16 retary shall submit to the Committee on Health, Edu-
17 cation, Labor, and Pensions of the Senate and the Com-
18 mittee on Energy and Commerce of the House of Rep-
19 resentatives a report regarding how patients, providers,
20 and the public interpret and comprehend risk-related in-
21 formation provided or ordered by the Secretary relating
22 to devices, including reports under this section, notifica-
23 tions concerning recalls, and notifications concerning ad-
24 verse events, and whether the relative level of risk and ap-

1 appropriate mitigation for such risk are adequately under-
2 stood.

3 “(G) To the extent the Secretary seeks to rely on
4 data, analysis, or other information or findings provided
5 by third parties that has been funded in whole or in part
6 by, or otherwise performed under contract with, the Food
7 and Drug Administration in making significant decisions
8 concerning devices or considering issuance of orders under
9 this section or section 522, the Secretary shall—

10 “(i) obtain access to the raw datasets, inputs,
11 clinical or other assumptions, methods, analytical
12 code, results, and other components underlying or
13 comprising the analysis, conclusions or other find-
14 ings upon which the Secretary seeks to rely; and

15 “(ii) in the event a significant decision is made,
16 or an order under this section or section 522 is
17 under consideration, in reliance on such information
18 or findings, provide the manufacturer or manufac-
19 turers subject to such decision or order the informa-
20 tion or findings, including the underlying informa-
21 tion described in paragraph (1), except that any
22 such underlying information that the Secretary de-
23 termines to be confidential commercial information
24 or trade secret information may be withheld but

- 1 shall be described to the manufacturer or manufac-
- 2 turers to the extent permissible by law.”.

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