



(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

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

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

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.

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 “Emerging Signals
5 Modernization Act of 2022”.

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

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

6 (1) by striking the section designation and
7 heading and that follows through “If the Secretary
8 determines that—” and inserting the following:

9 **“SEC. 518. NOTIFICATION AND OTHER REMEDIES.**

10 **“(a) NOTIFICATION.—**

11 **“(1) IN GENERAL.—**If the Secretary determines
12 **that—”**; and

13 (2) in subsection (a)—

14 (A) by striking “(1) a device” and insert-
15 ing the following:

16 “(A) a device”;

17 (B) by striking “(2) notification” and in-
18 sserting the following:

19 “(B) notification”;

20 (C) by moving the margin of the continu-
21 ation text at the end of subsection (a) 2 ems to
22 the right; and

23 (D) by striking “this subsection” each
24 place it appears and inserting “this para-
25 graph”.

1 (b) EMERGING SIGNALS.—Section 518(a) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)),
3 as amended by subsection (a), is further amended by add-
4 ing at the end the following:

5 “(2) EMERGING SIGNALS AND OTHER NOTIFI-
6 CATIONS.—

7 “(A) APPLICABILITY.—This paragraph ap-
8 plies if the Secretary—

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

15 “(ii) otherwise determines that it is
16 necessary to notify the public about an
17 emerging signal concerning a device in
18 order to reduce or limit the number of pa-
19 tients exposed to a potential risk identified
20 based on an emerging signal.

21 “(B) DEFINITION OF EMERGING SIGNAL.—

22 In this paragraph, the term ‘emerging signal’
23 means new information about a marketed de-
24 vice—

1 “(i) that supports a new causal asso-
2 ciation or a new aspect of a known associa-
3 tion between the device and an adverse
4 event or set of adverse events; and

5 “(ii) for which the Secretary has con-
6 ducted an initial evaluation and deter-
7 mined that the information has the poten-
8 tial to impact patient management deci-
9 sions or the known benefit-risk profile of
10 the device.

11 “(C) RELIANCE ON SCIENTIFIC EVI-
12 DENCE.—In considering and taking actions
13 under this section, the Secretary shall—

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

16 “(ii) in any event, base such actions
17 on credible scientific evidence, such that
18 information that is unconfirmed, unreli-
19 able, or lacks sufficient strength of evi-
20 dence shall not constitute an emerging sig-
21 nal or otherwise provide a basis for notifi-
22 cation under this paragraph.

23 “(D) CONTENT OF PUBLIC NOTIFICA-
24 TION.—Any public notification under this para-
25 graph shall—

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

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

5 “(iii) incorporate information about
6 the known benefits and risks of the device
7 or devices, including information available
8 from the manufacturer or manufacturers.

9 “(E) CONTRADICTION EVIDENCE.—To the
10 extent credible scientific evidence is presented
11 to the Secretary that contradicts or modifies
12 the information that serves as a potential basis
13 for a public notification under this paragraph,
14 the Secretary shall include such scientific evi-
15 dence in the public notification in a manner
16 that provides the intended audience with a com-
17 plete understanding of the overall nature of in-
18 formation concerning the potential risk.

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

23 “(i) provide the manufacturer or man-
24 ufacturers of the device or devices at issue
25 the credible scientific evidence that is the

1 basis for considering the public notification
2 and the Secretary's initial evaluation of
3 such evidence as described in subpara-
4 graph (B)(ii);

5 “(ii) to the extent the Secretary deter-
6 mines that any of the credible scientific
7 evidence described in clause (i) cannot be
8 provided to manufacturers because such
9 evidence constitutes confidential commer-
10 cial information or trade secret informa-
11 tion, provide the manufacturer or manu-
12 facturers of the device or devices at issue
13 with a description of the withheld evidence
14 to the extent permissible by law and gen-
15 erally describe the basis for withholding
16 such evidence;

17 “(iii) provide the manufacturer or
18 manufacturers of the device or devices at
19 issue an adequate opportunity—

20 “(I) to comment as to the nature
21 of the potential risk and the manner
22 and content of the potential notifica-
23 tion under this paragraph;

24 “(II) to share information about
25 the potential risk; and

1 “(III) to offer recommendations
2 as to the form and content of the po-
3 tential notification, including consider-
4 ation of alternative forms of notifica-
5 tion and risk mitigation; and

6 “(iv) consider any input received
7 under clause (iii).

8 “(G) UPDATES.—The Secretary shall pro-
9 vide periodic and timely updates to each notifi-
10 cation under this paragraph based on new in-
11 formation or contrary information, including af-
12 firmative notice in the event that the emerging
13 signal or other source of potential risk has been
14 determined not to apply or has otherwise been
15 resolved or mitigated, such that no additional
16 actions are required. For purposes of providing
17 updates under this subparagraph, the Secretary
18 shall consider information provided to the Sec-
19 retary by a manufacturer subsequent to the ini-
20 tial public notification.

21 “(H) RESPONSE TO INFORMATION PRO-
22 VIDED BY MANUFACTURER.—With regard to in-
23 formation provided to the Secretary by a manu-
24 facturer relating to a notification under this

1 paragraph, the Secretary shall inform such
2 manufacturer—

3 “(i) how such information affects or
4 alters the Secretary’s initial evaluation;
5 and

6 “(ii) whether the notification will be
7 updated or rescinded as a result of such
8 information.

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

12 “(i) evaluate current credible scientific
13 evidence to determine if such notification
14 should be rescinded; and

15 “(ii) if the Secretary determines such
16 notification should be rescinded, promptly
17 provide notice of the rescission to the same
18 audience and in the same manner as the
19 original notification.

20 “(J) REVISION OF GUIDANCE.—Not later
21 than September 30, 2023, the Secretary shall
22 revise the guidance of the Food and Drug Ad-
23 ministration titled ‘Public Notification of
24 Emerging Postmarket Medical Device Signals

1 (“Emerging Signals”)', to conform with this
2 paragraph.

3 “(K) REPORT TO CONGRESS.—Not later
4 than September 30, 2023, the Secretary shall
5 submit to the Committee on Energy and Com-
6 merce of the House of Representatives and the
7 Committee on Health, Education, Labor, and
8 Pensions of the Senate a report regarding—

9 “(i) how patients, health care pro-
10 viders, and the public interpret and com-
11 prehend risk-related information provided
12 or ordered by the Secretary relating to de-
13 vices, including reports under this section,
14 notifications concerning recalls, and notifi-
15 cations concerning adverse events; and

16 “(ii) whether the relative level of risk
17 and appropriate mitigations for such risk
18 are adequately understood.

19 “(L) THIRD PARTY DATA TRANS-
20 PARENCY.—To the extent the Secretary seeks
21 to rely on data, analysis, or other information
22 or findings provided by third parties that has
23 been funded in whole or in part by, or otherwise
24 performed under contract with, the Food and
25 Drug Administration, in making a significant

1 decision concerning one or more devices or con-
2 sidering issuance of an order under this section
3 or section 522, the Secretary shall—

4 “(i) obtain access to the raw datasets,
5 inputs, clinical or other assumptions, meth-
6 ods, analytical code, results, and other
7 components underlying or comprising the
8 data, analysis, or other information or
9 findings upon which the Secretary seeks to
10 rely; and

11 “(ii) if such a significant decision is
12 made, or such an order under this section
13 or section 522 is under consideration, in
14 reliance on such data, analysis, or other in-
15 formation or findings, provide the manu-
16 facturer or manufacturers subject to such
17 decision or order the data, analysis, or
18 other information or findings, including
19 the underlying raw datasets, inputs, clin-
20 ical or other assumptions, methods, analyt-
21 ical code, results, and other components,
22 except that any such raw datasets, inputs,
23 clinical or other assumptions, methods, an-
24 alytical code, results, and other compo-
25 nents that the Secretary determines to be

1 confidential commercial information or
2 trade secret information may be withheld
3 but shall be described to the manufacturer
4 or manufacturers to the extent permissible
5 by law.”;