

117TH CONGRESS
2D SESSION

S. 3983

To amend the Federal Food, Drug, and Cosmetic Act to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 31, 2022

Mr. CASSIDY (for himself and Ms. BALDWIN) 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 to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, 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 “PATCH Act”.

1 **SEC. 2. ENSURING CYBERSECURITY OF MEDICAL DEVICES.**

2 (a) IN GENERAL.—Subchapter A of chapter V of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
4 et seq.) is amended by adding at the end the following:

5 **“SEC. 524B. ENSURING CYBERSECURITY OF DEVICES.**

6 “(a) IN GENERAL.—For purposes of ensuring cyber-
7 security throughout the lifecycle of a cyber device, any per-
8 son who submits a premarket submission for the cyber de-
9 vice shall include such information as the Secretary may
10 require to ensure that the cyber device meets such cyberse-
11 curity requirements as the Secretary determines to be ap-
12 propriate to demonstrate a reasonable assurance of safety
13 and effectiveness, including at a minimum the cybersecu-
14 rity requirements under subsection (b). The Secretary may
15 establish exemptions to the requirements under this sub-
16 section.

17 “(b) CYBERSECURITY REQUIREMENTS.—At a min-
18 imum, the manufacturer of a cyber device shall meet the
19 following cybersecurity requirements:

20 “(1) The manufacturer shall have a plan to ap-
21 propriately monitor, identify, and address in a rea-
22 sonable time postmarket cybersecurity vulnerabilities
23 and exploits.

24 “(2) The manufacturer shall—

25 “(A) have a plan and procedures for a Co-
26 ordinated Vulnerability Disclosure to be part of

1 submissions to the Food and Drug Administra-
2 tion; and

3 “(B) collect and maintain such other infor-
4 mation as the Secretary may (by order pub-
5 lished in the Federal Register or by other proc-
6 ess) require to demonstrate a reasonable assur-
7 ance of the safety and effectiveness of the cyber
8 device.

9 “(3) The manufacturer shall design, develop,
10 and maintain processes and procedures to make
11 available updates and patches to the cyber device
12 and related systems throughout the lifecycle of the
13 cyber device to address—

14 “(A) on a reasonably justified regular
15 cycle, known unacceptable vulnerabilities; and

16 “(B) as soon as possible out of cycle, crit-
17 ical vulnerabilities that could cause uncontrolled
18 risks.

19 “(4) The manufacturer shall furnish to the Sec-
20 retary a software bill of materials, including com-
21 mercial, open-sourced, and off-the-shelf software
22 components that will be provided to users.

23 “(c) SUBSTANTIAL EQUIVALENCE.—In making a de-
24 termination of substantial equivalence under section
25 513(i) for a cyber device, the Secretary may—

1 “(1) find that cybersecurity information for the
2 cyber device described in the relevant premarket
3 submission in the cyber device’s use environment is
4 inadequate; and

5 “(2) issue a nonsubstantial equivalence deter-
6 mination based on this finding.

7 “(d) DEFINITION.—In this section:

8 “(1) The term ‘cyber device’ means a device
9 that—

10 “(A) includes software; or

11 “(B) is intended to connect to the internet.

12 “(2) The term ‘lifecycle of the cyber device’ in-
13 cludes the postmarket lifecycle of the cyber device.

14 “(3) The term ‘premarket submission’ means
15 any submission under section 510(k), 513, 515(e),
16 515(f), or 520(m).”.

17 (b) PROHIBITED ACT.—Section 301(q) of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q))
19 is amended by adding at the end the following:

20 “(3) The failure to comply with any requirement
21 under section 524B (relating to ensuring the cybersecu-
22 rity).”.

23 (c) ADULTERATION.—Section 501 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
25 ed by adding at the end the following:

1 “(k) If it is a device with respect to which the sponsor
2 is in violation of section 524B (relating to ensuring cyber-
3 security).”.

4 (d) MISBRANDING.—Section 502(t) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is
6 amended—

7 (1) by striking “or (3)” and inserting “(3)”;

8 and

9 (2) by inserting before the period at the end the
10 following: “, or (4) to furnish a software bill of ma-
11 terials as required under section 524B (relating to
12 ensuring the cybersecurity)”.

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