

119TH CONGRESS
2D SESSION

S. 4939

To require the Secretary of Health and Human Services to review certain medical devices manufactured in the People’s Republic of China for potential cybersecurity issues, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 24, 2026

Mr. COTTON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require the Secretary of Health and Human Services to review certain medical devices manufactured in the People’s Republic of China for potential cybersecurity issues, 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 “Countering Chinese
5 Cyberthreats for Patients Act” or the “Countering CCP
6 Act”.

1 **SEC. 2. REVIEW AND RECALL OF CERTAIN MEDICAL DE-**
2 **VICES MANUFACTURED IN THE PEOPLE’S RE-**
3 **PUBLIC OF CHINA.**

4 (a) REVIEW OF CERTAIN DEVICES.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services, acting through the Commissioner
7 of Food and Drugs (referred to in this section as the
8 “Secretary”), in consultation with the Director of
9 the Cybersecurity and Infrastructure Security Agen-
10 cy, shall review each covered device for potential cy-
11 bersecurity issues.

12 (2) REQUEST FOR INFORMATION.—

13 (A) IN GENERAL.—Not later than 180
14 days after the date of enactment of this Act,
15 the Secretary, in consultation with the Director
16 of the Cybersecurity and Infrastructure Secu-
17 rity Agency, shall request from each covered
18 manufacturer of a covered device such informa-
19 tion as is necessary to conduct the review under
20 paragraph (1), including—

21 (i) a software bill of materials for the
22 covered device, including commercial, open-
23 source, and off-the-shelf software compo-
24 nents, and data mapping and architecture
25 documentation;

1 (ii) locations of entities, information
2 systems, and servers holding patient data;
3 and

4 (iii) any other information the Sec-
5 retary determines necessary.

6 (B) REQUIREMENTS.—In determining the
7 form and scope of information to request under
8 subparagraph (A), the Secretary, in consulta-
9 tion with the Director of the Cybersecurity and
10 Infrastructure Security Agency, shall analyze
11 covered devices and seek information, including
12 information on any processes and procedures of
13 the covered manufacturer, that, as determined
14 by Secretary, in consultation with the Director
15 of the Cybersecurity and Infrastructure Secu-
16 rity Agency—

17 (i) would provide a reasonable assur-
18 ance that the covered device and related
19 systems are and will remain cybersecure;
20 and

21 (ii) would provide a reasonable assur-
22 ance that patient data would not be stored
23 or transferred through systems or servers
24 located in, owned, or controlled by entities

1 headquartered or subject to jurisdiction of
2 the People's Republic of China.

3 (b) RECALL AUTHORITY.—

4 (1) IN GENERAL.—Subject to paragraph (3),
5 not later than 18 months after the date of enact-
6 ment of this Act, the Secretary shall issue for all
7 covered devices that are determined pursuant to the
8 review under subsection (a) to pose a cybersecurity
9 risk an order requiring the appropriate person (in-
10 cluding the manufacturers, importers, distributors,
11 or retailers of the covered device)—

12 (A) to immediately cease distribution of
13 such covered device;

14 (B) to immediately notify health profes-
15 sionals and device user facilities of the order
16 and to instruct such professionals and facilities
17 to cease use of such covered device; and

18 (C) to notify all individuals subject to the
19 risks associated with the use of such covered
20 device.

21 (2) RECALL IN CASES OF FAILURE TO PROVIDE
22 INFORMATION.—Subject to paragraph (3), for any
23 covered device for which the covered manufacturer
24 fails to submit the information requested under sub-
25 section (a)(2)(A) by the date that is 180 days after

1 the date on which such covered manufacturer re-
2 ceived such request, the Secretary shall issue for
3 such covered device an order requiring the appro-
4 priate person (including the manufacturers, import-
5 ers, distributors, or retailers of the covered device)—

6 (A) to immediately cease distribution of
7 such covered device;

8 (B) to immediately notify health profes-
9 sionals and device user facilities of the order
10 and to instruct such professionals and facilities
11 to cease use of such covered device; and

12 (C) to notify all individuals subject to the
13 risks associated with the use of such covered
14 device.

15 (3) EXEMPTION.—The Secretary may exempt
16 from an order under paragraph (1) or (2) a covered
17 device for which a recall would, as determined by the
18 Secretary, create a shortage that would pose a dan-
19 ger to patient health.

20 (c) REPORT.—Not later than 2 years after the date
21 of enactment of this Act, the Secretary, in consultation
22 with the Director of the Cybersecurity and Infrastructure
23 Security Agency, shall submit to the Committee on
24 Health, Education, Labor, and Pensions and the Com-
25 mittee on Homeland Security and Governmental Affairs

1 of the Senate and the Committee on Energy and Com-
 2 merce and the Committee on Homeland Security of the
 3 House of Representatives a report that includes—

4 (1) a description of the cyber preparedness and
 5 data security of the device industry in the United
 6 States;

7 (2) an analysis of the market share of devices
 8 used in the United States of manufacturers
 9 headquartered in the People’s Republic of China;

10 (3) an analysis of data security requirements
 11 and protections of devices used in the United States
 12 of manufacturers headquartered in or subject to the
 13 jurisdiction of the People’s Republic of China; and

14 (4) recommendations for methods to bolster the
 15 cyber preparedness of the device industry in the
 16 United States.

17 (d) DEFINITIONS.—In this section:

18 (1) COVERED DEVICE.—The term “covered de-
 19 vice” means a networked device that was manufac-
 20 tured by a covered manufacturer and was cleared,
 21 authorized, approved, or exempted under section
 22 510(k), 513(f)(2), 515, or 520(m) of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 360(k),
 24 360c(f)(2), 360e, 360j(m)) on or before March 28,
 25 2023.

1 (2) COVERED MANUFACTURER.—

2 (A) IN GENERAL.—The term “covered
3 manufacturer” means a manufacturer—

4 (i) headquartered in the People’s Re-
5 public of China; or

6 (ii) that is owned or controlled by—

7 (I) the People’s Republic of
8 China; or

9 (II) 1 or more individuals or enti-
10 ties of the People’s Republic of China.

11 (B) EXCLUSION.—The term “covered man-
12 ufacturer” does not include a manufacturer
13 that has operations, subsidiaries, or publicly
14 traded securities in the People’s Republic of
15 China if such manufacturer is not otherwise a
16 manufacturer described in subparagraph (A).

17 (3) CYBERSECURITY RISK.—The term “cyberse-
18 curity risk” means threats to and vulnerabilities of
19 information or information systems and any related
20 consequences caused by or resulting from unauthor-
21 ized access, use, disclosure, degradation, disruption,
22 modification, or destruction of such information or
23 information systems, including such related con-
24 sequences caused by an act of terrorism.

1 (4) NETWORKED.—The term “networked”, with
2 respect to a device, means that the device includes
3 software that has the ability to connect to the inter-
4 net.

