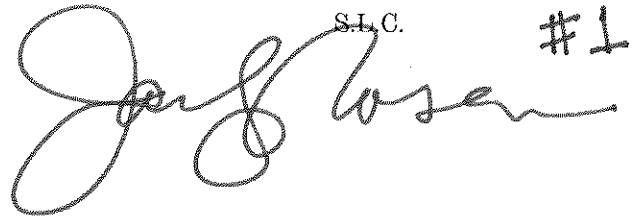


S.L.C. #1


AMENDMENT NO. _____ Calendar No. _____

Purpose: To require the Secretary of Health and Human Services to review and as appropriate update certain guidance and resources regarding medical device cybersecurity and to require the Comptroller General of the United States to issue a report identifying challenges in cybersecurity for medical devices.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

1 At the appropriate place in title IX, insert the fol-
2 lowing:

3 **SEC. 9 ____ . MEDICAL DEVICE CYBERSECURITY.**

4 (a) GUIDANCE FOR INDUSTRY AND FDA STAFF ON
5 MEDICAL DEVICE CYBERSECURITY.—Not later than 2
6 years after the date of enactment of this Act, and periodi-
7 cally thereafter as appropriate, the Secretary of Health
8 and Human Services (referred to in this section as the

1 “Secretary”), in consultation with the Director of the Cy-
2 bersecurity and Infrastructure Security Agency, shall re-
3 view and, as appropriate and after soliciting and receiving
4 feedback from medical device manufacturers, health care
5 providers, third party medical device servicers, patient ad-
6 vocates, and other appropriate stakeholders, update the
7 guidance entitled “Content of Premarket Submissions for
8 Management of Cybersecurity in Medical Devices” (or a
9 successor document).

10 (b) RESOURCES REGARDING CYBERSECURITY OF
11 MEDICAL DEVICES.—Not later than 180 days after the
12 date of enactment of this Act, and not less than annually
13 thereafter, the Secretary shall update public information
14 provided by the Food and Drug Administration, including
15 on the website of the Food and Drug Administration, with
16 information regarding improving cybersecurity of medical
17 devices. Such information shall include information on
18 identifying and addressing cyber vulnerabilities for health
19 care providers, health systems, and medical device manu-
20 facturers, and how such entities may access support
21 through the Cybersecurity and Infrastructure Security
22 Agency and other Federal entities, including the Depart-
23 ment of Health and Human Services, to improve cyberse-
24 curity of medical devices.

1 (c) GAO REPORT.—Not later than 1 year after the
2 date of enactment of this Act, the Comptroller General
3 of the United States shall publish a report identifying
4 challenges in cybersecurity for medical devices, including
5 legacy devices that may not support certain software secu-
6 rity updates. Through such report, the Comptroller Gen-
7 eral shall examine—

8 (1) challenges for medical device manufactur-
9 ers, health care providers, health systems, and pa-
10 tients in accessing Federal support to address
11 vulnerabilities across Federal agencies;

12 (2) how Federal agencies can strengthen coordi-
13 nation to better support cybersecurity for medical
14 devices; and

15 (3) statutory limitations and opportunities for
16 improving cybersecurity for medical devices.