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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R.

To establish a working group of public and private entities led by the Food and Drug Administration to recommend voluntary frameworks and guidelines to increase the security and resilience of Internet of Medical Things devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To establish a working group of public and private entities led by the Food and Drug Administration to recommend voluntary frameworks and guidelines to increase the security and resilience of Internet of Medical Things devices, 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 “Internet of Medical
5 Things Resilience Partnership Act of 2017”.

1 **SEC. 2. STUDY ON THE SECURITY AND RESILIENCE OF CER-**
2 **TAIN MEDICAL DEVICES.**

3 (a) STUDY.—Not later than 5 months after the date
4 of enactment of this Act, the Commissioner of the Food
5 and Drug Administration, in consultation with the Na-
6 tional Institute of Standards and Technology, shall estab-
7 lish a working group of public and private entities to de-
8 velop recommendations for voluntary frameworks and
9 guidelines to increase the security and resilience of
10 networked medical devices sold in the United States that
11 store, receive, access, or transmit information to an exter-
12 nal recipient or system for which unauthorized access,
13 modification, misuse, or denial of use may result in patient
14 harm.

15 (b) WORKING GROUP.—

16 (1) IN GENERAL.—In developing the rec-
17 ommendations under subsection (a), the Commis-
18 sioner shall seek input from a working group rep-
19 resenting the Federal Government, industry, and
20 academia.

21 (2) CHAIRPERSON.—The Commissioner of the
22 Food and Drug Administration, or a designee of the
23 Commissioner, shall serve as the chairperson of the
24 working group established under paragraph (1).

1 (3) MEMBERSHIP.—Membership of the working
2 group shall include a representative from each of the
3 following:

4 (A) The Center for Devices and Radio-
5 logical Health of the Food and Drug Adminis-
6 tration.

7 (B) The Office of the National Coordinator
8 for Health Information Technology of the De-
9 partment of Health and Human Services.

10 (C) The Office of Technology Research
11 and Investigation of the Federal Trade Com-
12 mission.

13 (D) The Cybersecurity and Communica-
14 tions Reliability Division of the Federal Com-
15 munications Commission.

16 (E) The National Institute of Standards
17 and Technology of the Department of Com-
18 merce.

19 (F) The National Cyber Security Alliance.

20 (4) APPOINTED MEMBERS.—The chairperson
21 shall appoint to the working group a minimum of 3
22 qualified representatives from each of the following
23 private sector categories:

24 (A) Medical device manufacturers.

25 (B) Health care providers.

1 (C) Health insurance providers.

2 (D) Cloud computing.

3 (E) Wireless network providers.

4 (F) Enterprise security solutions systems.

5 (G) Health information technology.

6 (H) Web-based mobile application devel-
7 opers.

8 (I) Software developers.

9 (J) Hardware developers.

10 (c) REPORT.—Not later than 18 months after the
11 date of enactment of this Act, the Commissioner shall sub-
12 mit to Congress a report on the recommendations devel-
13 oped under subsection (a), including—

14 (1) an identification of existing cybersecurity
15 standards, guidelines, frameworks, and best prac-
16 tices that are applicable to mitigate vulnerabilities in
17 the devices described in subsection (a);

18 (2) an identification of existing and developing
19 international and domestic cybersecurity standards,
20 guidelines, frameworks, and best practices that miti-
21 gate vulnerabilities in such devices;

22 (3) a specification of high-priority gaps for
23 which new or revised standards are needed; and

24 (4) potential action plans by which such gaps
25 can be addressed.