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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 7192

To provide for the establishment of a panel on the real world impact of diagnostic medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. SCHRIER introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for the establishment of a panel on the real world impact of diagnostic medical devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Diagnostic Device Advisory Committee Act''.

SEC. 2. REAL WORLD IMPACT OF MEDICAL DEVICES PANEL.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Sec-

retary'') shall, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, amend the charter of the Medical Devices Advisory Committee (or successor advisory committee) to establish a panel of experts on diagnostic medical device products for the purpose of providing advice to the Secretary in connection with the real world impact of the clearance, classification, approval, and authorization of devices, including diagnostic devices, under sections 510(k), 513(f), 515, and 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f), 360e, and 360bbb–3) to be known as the Real World Impact of Medical Devices Panel (referred to in this section as the ''Panel'').

(b) APPLICATION OF FACA.—The Federal Advisory Committee Act shall apply to the Panel.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Panel shall consist of 15 members, including the Chair.

(2) REPRESENTATION.—11 members of the Panel shall be voting members. Of the remaining 4 members of the Panel—

(A) 1 shall be a representative of consumer interests;

(B) 1 shall be a representative of the interests of the device manufacturing industry; and

(C) 2 shall be public health or population health-specific representatives.

(3) TERM.—The members of the Panel specified in subparagraphs (A) through (C) of paragraph (2) shall be selected by the Secretary and shall be invited to serve for rotating terms of such duration as specified by the Secretary, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term.

(d) DUTIES.—The Panel shall provide to the Secretary—

(1) advice and recommendations on the real world impact of the clearance, classification, approval, and authorization of devices, including diagnostic devices, under sections 510(k), 513(f), 515, and 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f), 360e, and 360bbb–3), including the impact of such devices on rural, underserved, or minority populations; and

(2) register comments about the negative and positive impacts of such devices on the United

States population, the risk assessment posed by the use of such devices, and the need such devices would fill.

(e) CONSIDERATION OF RECOMMENDATIONS.—The Secretary, acting through the Commissioner of Food and Drugs, and any other applicable official shall, in making any final decisions, or amending existing decisions with respect to the clearance, classification, approval, and authorization of devices, including diagnostic devices, under sections 510(k), 513(f), 515, and 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f), 360e, and 360bbb–3), take comments received from the Panel under advisement.

(f) MEETINGS.—

(1) FREQUENCY.—The Panel shall hold at least 1 meeting each year, at the call of the Chair.

(2) RECORDINGS AVAILABLE.—Recordings of the meetings of the Panel shall be available on the public website of the Food and Drug Administration.