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118TH CONGRESS
1ST SESSION

H. R. 71

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 2023

Mr. BIGGS introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic 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 ''Medical Innovation Acceleration Act of 2023''.

SEC. 2. EXEMPTING NON-INVASIVE DIAGNOSTIC DEVICES FROM REGULATION AS DEVICES.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) by striking ''section 520(o)'' and inserting the following: ''section 520(o) or any non-invasive diagnostic device''; and

(2) by adding at the end the following: ''For purposes of the preceding sentence, the term 'non-invasive' means, with respect to a diagnostic device, that the device does not penetrate the skin or any other membrane of the body, is not inserted or implanted into the body, causes no more than ephemeral compression or temperature changes to in situ bodily tissues, and does not subject bodily tissues to ionizing radiation.''.

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