112TH CONGRESS
1ST SESSION

# S. 1972

To amend the Food and Drug Administration's mission.

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IN THE SENATE OF THE UNITED STATES

DECEMBER 8, 2011

Mr. COATS (for himself and Ms. AYOTTE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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# A BILL

To amend the Food and Drug Administration's mission.

*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 ''Food and Drug Administration Mission Reform Act of 2011''.

**SEC. 2. FDA'S MISSION.**

Section 1003(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)) is amended—

(1) in paragraph (2), by striking ''with respect to such products'' and inserting ''with respect to regulated products'';

(2) in paragraph (4), by striking ''(1) through (3)'' and inserting ''(1) through (4)'';

(3) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5); and

(4) by inserting after paragraph (1) the following:

''(2) establish a regulatory system that—

''(A) advances medical innovation by incorporating modern scientific tools, standards, and approaches to ensure the predictable, consistent, and efficient review, clearance, approval, and licensing (as appropriate) of innovative products, including drugs, devices, and biological products;

''(B) protects the public health and enables patients to access novel products while promoting economic growth, innovation, competitiveness, and job creation among the industries regulated by this Act;

''(C) is based on the best available science;

''(D) allows for public participation and an open exchange of ideas;

''(E) promotes predictability, allows flexibility, and reduces uncertainty;

"(F) identifies and uses the most innovative and least burdensome tools for achieving regulatory ends;

"(G) ensures that regulations are accessible, consistent, transparent, written in plain language, and easy to understand;

"(H) measures, and seeks to improve, the actual results of regulatory requirements; and

"(I) incorporates a patient-focused benefit-risk framework that accounts for varying degrees of risk tolerance, including for people living with a life-impacting chronic disease or disability;".

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