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(Original Signature of Member)

112TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Food and Drug Administration's mission.

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IN THE HOUSE OF REPRESENTATIVES

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, Mrs. BLACKBURN, and Mrs. McMORRIS RODGERS) introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_

**A BILL**

To amend the Food and Drug Administration's mission.

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 "Food and Drug Ad-  
5 ministration Mission Reform Act of 2011".

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

7 Section 1003(b) of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 393(b)) is amended—

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

4 (2) in paragraph (4), by striking “(1) through  
5 (3)” and inserting “(1) through (4)”;

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

8 (4) by inserting after paragraph (1) the fol-  
9 lowing:

10 “(2) establish a regulatory system that—

11 “(A) advances medical innovation by incor-  
12 porating modern scientific tools, standards, and  
13 approaches to ensure the predictable, con-  
14 sistent, efficient, and reasonable review, clear-  
15 ance, approval, and licensing (as appropriate)  
16 of innovative products, including drugs, devices,  
17 and biological products;

18 “(B) protects the public health and enables  
19 patients to access novel products while pro-  
20 moting economic growth, innovation, competi-  
21 tiveness, and job creation among the industries  
22 regulated by this Act;

23 “(C) is based on the best available science;

24 “(D) allows for public participation and an  
25 open exchange of ideas;

1           “(E) promotes predictability, allows flexi-  
2           bility, and reduces uncertainty;

3           “(F) identifies and uses the most innova-  
4           tive and least burdensome tools for achieving  
5           regulatory ends;

6           “(G) ensures that regulations are acces-  
7           sible, consistent, transparent, written in plain  
8           language, and easy to understand;

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

11          “(I) incorporates a patient-focused benefit-  
12          risk framework that accounts for varying de-  
13          grees of risk tolerance, including for people liv-  
14          ing with a life-impacting chronic disease or dis-  
15          ability;”.