

112TH CONGRESS
1ST SESSION

H. R. 3214

To amend the Food and Drug Administration’s mission.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, Mrs. BLACKBURN, Mrs. MCMORRIS RODGERS, Mr. GUTHRIE, Mr. SHIMKUS, Mrs. BONO MACK, Mr. LATTA, and Mr. PAULSEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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—

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

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

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

5 (4) by inserting after paragraph (1) the fol-
6 lowing:

7 “(2) establish a regulatory system that—

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

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

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

21 “(D) allows for public participation and an
22 open exchange of ideas;

23 “(E) promotes predictability, allows flexi-
24 bility, and reduces uncertainty;

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

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

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

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

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