114TH CONGRESS
2D SESSION

H. R. 6463

To direct the Secretary of Health and Human Services to issue guidance with respect to three-dimensional human tissue models, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 7, 2016

Mr. COLLINS of New York (for himself and Mr. LONG) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services to issue guidance with respect to three-dimensional human tissue models, and for other purposes.

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 "Patient Safety and

5   Toxicology Modernization Act of 2016".

6   **SEC. 2. FINDINGS.**

7   Congress finds the following:

1   (1) Preclinical testing serves a fundamental role

2   in characterizing the potential risks and benefits as-

3   sociated with regulated medicines and products.

4   (2) Critical gaps remain in the understanding

5   of the relationship between patient response and pre-

6   clinical findings.

7   (3) Serious, rare, and unexpected adverse

8   events may be observed in clinical trials or post-

9   approval, particularly toxicology effects not identi-

10   fied in animals that may harm human organs.

11   (4) Patient efficacy, safety, dosage information,

12   and speedier access to new medicines will benefit

13   from models that are more predictive than animals

14   and that mimic key elements of human organs.

15   (5) A 2011 report by the Food and Drug Ad-

16   ministration, entitled "Advancing Regulatory

17   Science at FDA", prioritized toxicology testing and

18   the development of models of human adverse re-

19   sponse as one of the areas of regulatory science

20   where new or enhanced engagement by the agency is

21   essential to the continued success of the public

22   health and regulatory mission of the Food and Drug

23   Administration.

24   (6) The Food and Drug Administration's 2016

25   draft commitment letter concerning the reauthoriza-

1 tion of fees relating to drugs under part 2 of sub-

2 chapter C of chapter VII of the Federal Food, Drug,

3 and Cosmetic Act (21 U.S.C. 379g et seq.) proposes

4 a process to add new preclinical models that will not

5 be finalized until at least 2021.

6 (7) Peer-reviewed data is readily available to il-

7 lustrate the benefits of commercially available

8 human tissue models to improve the drug discovery

9 process by replicating key elements of living human

10 tissue.

11 (8) The Food and Drug Administration should

12 take immediate steps to validate new models, includ-

13 ing three-dimensional human tissue models, that im-

14 prove regulatory decisionmaking in preclinical, clin-

15 ical, labeling, and postmarket safety and efficacy

16 testing, or other uses by product sponsors.

17 **SEC. 3. GUIDANCE WITH RESPECT TO THREE-DIMENSIONAL**

18 **HUMAN TISSUE MODELS.**

19 (a) IN GENERAL.—Not later than December 31,

20 2018, the Secretary of Health and Human Services, acting

21 through the Commissioner of Food and Drugs, shall issue

22 guidance addressing—

23 (1) the development and use of novel tools for

24 toxicology and efficacy testing, including three-di-

25 mensional human tissue models; and

1 (2) the use of three-dimensional human tissue

2 models for preclinical, clinical, and postmarket safe-

3 ty and efficacy testing, labeling, or other uses by

4 product sponsors.

5 (b) PERIODIC UPDATES.—The Secretary shall peri-

6 odically update the guidance issued under subsection (a).

7 **SEC. 4. RULE OF CONSTRUCTION.**

8 Nothing in this Act shall be construed to prohibit or

9 limit the use of three-dimensional human tissue models by

10 product sponsors with respect to—

11 (1) obtaining approval or licensure of a drug or

12 biological product, including a combination product,

13 under section 505 of the Federal Food, Drug, and

14 Cosmetic Act (21 U.S.C. 355) or section 351 of the

15 Public Health Service Act (42 U.S.C. 262); or

16 (2) meeting the requirements of a regulatory

17 decision issued by the Secretary of Health and

18 Human Services.

19 **SEC. 5. DEFINITIONS.**

20 In this Act:

21 (1) BIOLOGICAL PRODUCT.—The term "biologi-

22 cal product" has the meaning given such term in

23 section 351(i) of the Public Health Service Act (42

24 U.S.C. 262(i)).

1 　　　(2) COMBINATION PRODUCT.—The term "com-

2 bination product" means a combination product de-

3 scribed in section 503(g) of the Federal Food, Drug,

4 and Cosmetic Act (21 U.S.C. 353(g)).

5 　　　(3) DRUG.—The term "drug" has the meaning

6 given such term in section 201 of the Federal Food,

7 Drug, and Cosmetic Act (21 U.S.C. 321).

8 　　　(4) THREE-DIMENSIONAL HUMAN TISSUE

9 MODEL.—The term "three-dimensional human tissue

10 model" means a three-dimensional model that—

11 　　　　　(A) approximates human tissue composi-

12 tion and physiology using spatially controlled

13 deposition of adult human cells or cell-con-

14 taining materials in user-defined, geometric pat-

15 terns;

16 　　　　　(B) can be used to detect toxicity that is

17 not identifiable in animal models;

18 　　　　　(C) can be used to test the efficacy of a

19 drug that is not possible or not able to be suffi-

20 ciently tested in an animal model; and

21 　　　　　(D) can predict toxicity in clinical testing

22 or detect toxicity in known clinical failures.

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