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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

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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.

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 ''Patient Safety and Toxicology Modernization Act of 2016''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Preclinical testing serves a fundamental role in characterizing the potential risks and benefits associated with regulated medicines and products.

(2) Critical gaps remain in the understanding of the relationship between patient response and preclinical findings.

(3) Serious, rare, and unexpected adverse events may be observed in clinical trials or post-approval, particularly toxicology effects not identified in animals that may harm human organs.

(4) Patient efficacy, safety, dosage information, and speedier access to new medicines will benefit from models that are more predictive than animals and that mimic key elements of human organs.

(5) A 2011 report by the Food and Drug Administration, entitled ''Advancing Regulatory Science at FDA'', prioritized toxicology testing and the development of models of human adverse response as one of the areas of regulatory science where new or enhanced engagement by the agency is essential to the continued success of the public health and regulatory mission of the Food and Drug Administration.

(6) The Food and Drug Administration's 2016 draft commitment letter concerning the reauthoriza-

tion of fees relating to drugs under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) proposes a process to add new preclinical models that will not be finalized until at least 2021.

(7) Peer-reviewed data is readily available to illustrate the benefits of commercially available human tissue models to improve the drug discovery process by replicating key elements of living human tissue.

(8) The Food and Drug Administration should take immediate steps to validate new models, including three-dimensional human tissue models, that improve regulatory decisionmaking in preclinical, clinical, labeling, and postmarket safety and efficacy testing, or other uses by product sponsors.

SEC. 3. GUIDANCE WITH RESPECT TO THREE-DIMENSIONAL HUMAN TISSUE MODELS.

(a) IN GENERAL.—Not later than December 31, 2018, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance addressing—

(1) the development and use of novel tools for toxicology and efficacy testing, including three-dimensional human tissue models; and

(2) the use of three-dimensional human tissue models for preclinical, clinical, and postmarket safety and efficacy testing, labeling, or other uses by product sponsors.

(b) PERIODIC UPDATES.—The Secretary shall periodically update the guidance issued under subsection (a).

SEC. 4. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to prohibit or limit the use of three-dimensional human tissue models by product sponsors with respect to—

(1) obtaining approval or licensure of a drug or biological product, including a combination product, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) meeting the requirements of a regulatory decision issued by the Secretary of Health and Human Services.

SEC. 5. DEFINITIONS.

In this Act:

(1) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(2) COMBINATION PRODUCT.—The term ''combination product'' means a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

(3) DRUG.—The term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(4) THREE-DIMENSIONAL HUMAN TISSUE MODEL.—The term ''three-dimensional human tissue model'' means a three-dimensional model that—

(A) approximates human tissue composition and physiology using spatially controlled deposition of adult human cells or cell-containing materials in user-defined, geometric patterns;

(B) can be used to detect toxicity that is not identifiable in animal models;

(C) can be used to test the efficacy of a drug that is not possible or not able to be sufficiently tested in an animal model; and

(D) can predict toxicity in clinical testing or detect toxicity in known clinical failures.

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