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116TH CONGRESS
2D SESSION

H. R. 8736

To amend the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug if such approach satisfies the requirements of the applicable statutes and regulations.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 12, 2020

Mr. BRENDAN F. BOYLE of Pennsylvania introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug if such approach satisfies the requirements of the applicable statutes and regulations.

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 ''Alternatives to Animals for Regulatory Fairness Act of 2020'' or the ''AARF Act of 2020''.

SEC. 2. FINDINGS.

The Congress finds that—

(1) the Food and Drug Administration (in this section referred to as the ''FDA'') often requires pharmaceutical companies to conduct or commission testing on dogs and other animals to assess the safety or effectiveness of new drugs, even though such testing is inefficient, expensive, and ineffective;

(2) the National Institutes of Health states, ''Approximately 30 percent of promising medications have failed in human clinical trials because they are found to be toxic despite promising preclinical studies in animal models. About 60 percent of candidate drugs fail due to lack of efficacy'';

(3) current FDA nonbinding pharmaceutical testing guidelines support the use of alternatives to animal testing to improve the effectiveness and efficiency of drug development;

(4) current FDA drug testing guidance for the pharmaceutical industry states, ''consideration should be given to use of new in vitro alternative methods for safety evaluation'';

(5) the FDA's drug testing guidance for industry additionally states, ''alternative approaches . . . can also be used . . . . The use of any of these ap-

proaches can reduce overall animal use in drug development'';

(6) the FDA writes that alternatives to animal testing, ''may help bring FDA-regulated products to market faster, with improved efficacy, or prevent products with increased toxicological risk from reaching the market. Also critical is the potential for these advances to replace, reduce, and/or refine animal testing'';

(7) pharmaceutical companies are reducing animal testing by investing in the development and use of alternative methods, which studies show are often more effective and efficient than traditional animal use;

(8) the FDA states, ''FDA encourages sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible''; and

(9) in some cases, drug manufacturers and sponsors have not been allowed by the FDA to use alternatives to animal testing to fulfill regulatory requirements, despite the FDA's support for this technology in its industry guidance document.

SEC. 3. ALTERNATIVES TO ANIMAL TESTS.

Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following new subsection:

''(z) ALTERNATIVES TO ANIMAL TESTS.—The Secretary shall allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug under this section if such approach satisfies the requirements of the applicable statutes and regulations.''.

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