

117TH CONGRESS
1ST SESSION

H. R. 2565

To amend the Federal Food, Drug, and Cosmetic Act to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 2021

Mr. BUCHANAN (for himself, Mrs. LURIA, Ms. MACE, Ms. SHERRILL, and Mr. BRENDAN F. BOYLE of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug, 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 “FDA Modernization
5 Act of 2021”.

1 **SEC. 2. ANIMAL TESTING ALTERNATIVES.**

2 Section 505 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 355) is amended—

4 (1) in subsection (b)(5)(B)(i)(II), by striking
5 “animal” and inserting “nonclinical tests or stud-
6 ies”;

7 (2) in subsection (i)—

8 (A) in paragraph (1)(A), by striking “(in-
9 cluding tests on animals)”;

10 (B) in paragraph (2)(B), by striking “ani-
11 mal or human studies” and inserting “nonclin-
12 ical tests or studies”;

13 (3) after subsection (y), by inserting the fol-
14 lowing:

15 “(z) **NONCLINICAL TEST OR STUDY DEFINED.**—For
16 purposes of this section, the term ‘nonclinical test or
17 study’ means a test or study that is most likely to predict
18 human response based on scientific evidence and occurs
19 before or during the clinical trial phase of the investigation
20 of the safety and effectiveness of a drug. Such test or
21 study may include the following:

22 “(1) Cell-based assays.

23 “(2) Organ chips and microphysiological sys-
24 tems.

25 “(3) Sophisticated computer modeling.

26 “(4) Other human biology-based test methods.

3

1 “(5) Animal tests.”

○