

117TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Mr. PAUL (for himself, Mr. BOOKER, Mr. BRAUN, Mr. KENNEDY, and Mr. LUJÁN) introduced the following bill; which was read twice and referred to the Committee on _____

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. NEW APPROACH METHODOLOGIES.**

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 “pre-
9 clinical tests (including tests on animals)” and
10 inserting “nonclinical tests”; and

11 (B) in paragraph (2)(B), by striking “ani-
12 mal” and inserting “nonclinical tests or stud-
13 ies”; and

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

16 “(z) NONCLINICAL TEST OR STUDY DEFINED.—For
17 purposes of this section, the term ‘nonclinical test or
18 study’ means a test or study conducted in vitro, in silico,
19 in chemico, or in vivo that occurs before or during the
20 clinical trial phase of the investigation of the safety and
21 effectiveness of a drug, and may include the following:

22 “(1) Cell-based assays.

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

25 “(3) Computer models.

1 “(4) Other non-animal or human biology-based
2 test methods.

3 “(5) Animal tests.”.