

117TH CONGRESS
2D SESSION

S. 5002

To allow for alternatives to animal testing for purposes of drug and biological product applications.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2022

Mr. PAUL (for himself, Mr. BOOKER, Mr. BRAUN, Mr. CRAPO, Mr. MARSHALL, Ms. COLLINS, Mr. KING, Mr. PADILLA, Mr. SANDERS, Mr. TUBERVILLE, Mr. LUJÁN, and Mr. SCOTT of Florida) introduced the following bill; which was read twice, considered, read the third time, and passed

A BILL

To allow for alternatives to animal testing for purposes of drug and biological product applications.

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 2.0”.

6 **SEC. 2. ALTERNATIVES TO ANIMAL TESTING.**

7 (a) IN GENERAL.—Section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

9 (1) in subsection (i)—

1 (A) in paragraph (1)(A), by striking “pre-
 2 clinical tests (including tests on animals)” and
 3 inserting “nonclinical tests”; and

4 (B) in paragraph (2)(B), by striking “ani-
 5 mal” and inserting “nonclinical tests”; and

6 (2) after subsection (y), by inserting the fol-
 7 lowing:

8 “(z) NONCLINICAL TEST DEFINED.—For purposes
 9 of this section, the term ‘nonclinical test’ means a test con-
 10 ducted in vitro, in silico, or in chemico, or a non-human
 11 in vivo test that occurs before or during the clinical trial
 12 phase of the investigation of the safety and effectiveness
 13 of a drug, and may include animal tests, or non-animal
 14 or human biology-based test methods, such as cell-based
 15 assays, microphysiological systems, or bioprinted or com-
 16 puter models.”.

17 (b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
 18 TIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the
 19 Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I))
 20 is amended to read as follows:

21 “(bb) an assessment of tox-
 22 icity (which may rely on, or con-
 23 sist of, a study or studies de-

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- 1 scribed in item (aa) or (cc));
- 2 and”.

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