National Association *for* Biomedical Research

Bill Summary

H.R.2565

"FDA Modernization Act of 2021"

"This bill allows an applicant for market approval for a new drug to use methods other than animal testing to establish the drug's safety and effectiveness. Under this bill, these alternative methods may include cell-based assays, organ chips and micro physiological systems, sophisticated computer modeling, and other human biology-based test methods."

INTRODUCTION

- Introduced in the House as H.R.2565 on 4/15/2021 by Rep. Vern Buchanan (R-FL).
- Full cosponsor list can be found here: https://www.congress.gov/bill/117th-congress/house-bill/2565/cosponsors?q=%7B%22search%22%3A%5B%22H.R.+1%22%5D%7D&r=33&s=1
- Referred to the House Energy and Commerce Committee's subcommittee on Health on 4/16/2021.
- Bill is being supported by numerous animal rights organizations including the Humane Society of the United States, Animal Wellness Action, and PETA.
- An identical Senate companion bill was introduced on Oct. 8 though text is not yet available.

BILL SUMMARY

- The FDA Modernization Act would amend Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) 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.
- The Act would amend subsection (b)(5)(B)(i)(II), by striking "animal" and inserting "nonclinical tests or studies"
- The bill defines "nonclinical tests or studies" as a test or study that is most likely to predict human response based on scientific evidence and occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test or study may include the following:
    - Cell-based assays
    - Organ chips and microphysiological systems
    - Sophisticated computer modeling
    - Other human biology-based test methods
    - Animal tests

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IMPLICATIONS

- Ultimately, the FDA Modernization Act of 2021 aims to end animal testing altogether. Animal rights activists falsely claim that the use of laboratory animals can be eliminated altogether because *"valid alternatives"* to the use of animal tests already exist to evaluate product safety.
- The FDA states that many procedures intended to replace animal tests are still in various stages of development. While the best means may begin with valuable adjunct tests, ultimately testing must progress to a whole intact, living system by use of an animal. Not using animal tests, when necessary, would subject humans and other animals to unreasonable risks.
- NABR is monitoring the legislation for any committee action or amendments.