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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products is impacted by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products is impacted by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Biologics Competition
3 Act of 2023”.

4 **SEC. 2. STUDY ON THE SUBSTITUTION OF INTERCHANGE-**
5 **ABLE BIOLOGICAL PRODUCTS.**

6 Not later than 12 months after the date of enactment
7 of this Act, the Secretary of Health and Human Services
8 shall—

9 (1) complete a study to evaluate the extent to
10 which the substitution of interchangeable biological
11 products licensed under section 351 of the Public
12 Health Service Act (42 U.S.C. 262) may be im-
13 pacted by differences between the system for deter-
14 mining a biological product to be interchangeable
15 under section 351(k)(4) of such Act (42 U.S.C.
16 262(k)(4)) and the system for assigning therapeutic
17 equivalence ratings to drugs approved under section
18 505 of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 355);

20 (2) submit a report to the Congress on the re-
21 sults of the study under paragraph (1); and

22 (3) update the list published under section
23 351(k)(9)(A) of the Public Health Service Act (42
24 U.S.C. 262(k)(9)(A)) (commonly referred to as the
25 “Purple Book”) to implement such changes as the
26 Secretary deems necessary to harmonize the ap-

1 proach for communicating the substitutability of
2 interchangeable biological products with the ap-
3 proach for communicating therapeutic equivalence
4 ratings assigned to drugs, with the goals of—

5 (A) minimizing any impediments to the
6 substitution of interchangeable biological prod-
7 ucts; and

8 (B) maintaining the distinct pathways by
9 which biological products are licensed under
10 section 351 of the Public Health Service Act
11 (42 U.S.C. 262) and drugs are approved under
12 section 505 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355).