

117TH CONGRESS
2D SESSION

H. R. 8877

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded 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

SEPTEMBER 19, 2022

Mrs. MILLER-MEEKS (for herself, Mr. MURPHY of North Carolina, Ms. BARRAGÁN, and Ms. KUSTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded 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 2022”.

4 **SEC. 2. STUDY ON CERTAIN IMPEDIMENTS TO THE SUBSTI-
5 TUTION OF INTERCHANGEABLE BIOLOGICAL
6 PRODUCTS.**

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

10 (1) complete a study to evaluate the extent to
11 which the substitution of interchangeable biological
12 products licensed under section 351 of the Public
13 Health Service Act (42 U.S.C. 262) may be impeded
14 by differences between the system for determining a
15 biological product to be interchangeable under sec-
16 tion 351(k)(4) of such Act (42 U.S.C. 262(k)(4))
17 and the system for assigning therapeutic equivalence
18 ratings to drugs approved under section 505 of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355);

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

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

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

6 (A) minimizing impediments to the substi-
7 tution of interchangeable biological products;
8 and

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

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