

By: Representative Moak

To: Public Health and Human Services

HOUSE BILL NO. 1387

1 AN ACT TO CREATE NEW SECTION 73-21-118, MISSISSIPPI CODE OF
2 1972, TO AUTHORIZE THE SUBSTITUTION OF INTERCHANGEABLE BIOLOGICAL
3 PRODUCTS FOR A PRESCRIBED PRODUCT BY A PHARMACIST UNDER CERTAIN
4 CIRCUMSTANCES; AND FOR RELATED PURPOSES.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

6 **SECTION 1.** The following shall be codified as Section
7 73-21-118, Mississippi Code of 1972:

8 73-21-118. **Biosimilars; substitution of interchangeable**
9 **biological products.** (1) As used in this section:

10 (a) "Biological product," "biosimilar,"
11 "interchangeable," have the meanings that apply to * * *~~such~~ those
12 terms under Section 351 of the Public Health Service Act (42 USC
13 Section 262).

14 (b) "Prescription," with respect to this section, means
15 such a product that is subject to Section 503(b) of the Federal,
16 Food, Drug, and Cosmetic Act (21 USC Section 353(b)).

17 (2) A pharmacist may substitute a prescription biosimilar
18 product for a prescribed product only if:



19 (a) The biosimilar product has been determined by the
20 United States Food and Drug Administration to be interchangeable
21 with the prescribed product for the specified indicated use;

22 (b) The prescriber has not expressly prohibited product
23 selection in writing, verbally or electronically;

24 (c) The person presenting the prescription is notified
25 and consents to the substitution;

26 (d) The pharmacist or pharmacist's agent notifies the
27 prescriber or the prescriber's agent of the substitution within
28 five (5) business days by facsimile, telephone, voice mail,
29 e-mail, or other electronic means; and

30 (e) The pharmacist and prescriber retain a written
31 record of the biosimilar substitution for a period of no less than
32 ten (10) years.

33 (3) The State Board of Pharmacy shall maintain on its public
34 website a current list of biosimilar biological products
35 determined to be interchangeable * * * ~~pursuant to~~ under subsection
36 (2)(a) of this section.

37 **SECTION 2.** This act shall take effect and be in force from
38 and after July 1, 2013.

