

116TH CONGRESS
1ST SESSION

H. R. 4244

To provide for a pathway for chemically synthesized insulin to be approved under an abbreviated new drug application submitted under the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 9, 2019

Mr. KELLY of Pennsylvania introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for a pathway for chemically synthesized insulin to be approved under an abbreviated new drug application submitted under the Federal Food, Drug, and Cosmetic Act, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Market Access for Ge-
5 neric Insulin Competition” or the “MAGIC Act”.

1 **SEC. 2. PROVIDING FOR A PATHWAY FOR APPROVAL OF**
2 **CHEMICALLY SYNTHESIZED INSULIN UNDER**
3 **AN ABBREVIATED NEW DRUG APPLICATION.**

4 (a) IN GENERAL.—Section 7002(e)(2) of the Patient
5 Protection and Affordable Care Act (42 U.S.C. 262 note)
6 is amended—

7 (1) in subparagraph (B), by redesignating
8 clauses (i) and (ii) as subclauses (I) and (II), respec-
9 tively, and moving the margins of such subclauses
10 (as so redesignated) two ems to the right;

11 (2) in subparagraph (A), by striking “such bio-
12 logical product” and inserting “(i) such biological
13 product”;

14 (3) by redesignating subparagraph (B) as
15 clause (ii) and moving the margin of such clause (as
16 so redesignated) two ems to the right;

17 (4) in clause (ii) (as so redesignated), by strik-
18 ing the period at the end and inserting “; or”; and

19 (5) by adding at the end the following:

20 “(B) notwithstanding paragraphs (3) and
21 (4), the application is submitted under sub-
22 section (j) of such section for chemically syn-
23 thesized insulin or any analogue of chemically
24 synthesized insulin for which the listed drug is
25 a biological product that is, pursuant to para-

1 graph (4), deemed to be licensed under section
2 351 of the Public Health Service Act.”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to applications sub-
5 mitted on or after January 1, 2020.

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