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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Market Access for Generic Insulin Competition'' or the ''MAGIC Act''.

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

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

(1) in subparagraph (B), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and moving the margins of such subclauses (as so redesignated) two ems to the right;

(2) in subparagraph (A), by striking ''such biological product'' and inserting ''(i) such biological product'';

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

(4) in clause (ii) (as so redesignated), by striking the period at the end and inserting ''; or''; and

(5) by adding at the end the following:

''(B) notwithstanding paragraphs (3) and (4), the application is submitted under subsection (j) of such section for chemically synthesized insulin or any analogue of chemically synthesized insulin for which the listed drug is a biological product that is, pursuant to para-

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

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to applications submitted on or after January 1, 2020.

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