

**Amendment to the Amendment in the Nature of a Substitute to H.R. 3  
Offered by Rep. Kelly of Pennsylvania**

The amendment would 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.

**AMENDMENT TO \_\_\_\_\_**  
**OFFERED BY M\_\_ . \_\_\_\_\_**

[HR3 as noticed by Ways and Means]

Add at the end the following (and conform the table  
of contents accordingly):

1 **TITLE \_\_\_\_\_—MARKET ACCESS**  
2 **FOR GENERIC INSULIN COM-**  
3 **PETITION (MAGIC)**

4 **SEC. \_\_01. PROVIDING FOR A PATHWAY FOR APPROVAL OF**  
5 **CHEMICALLY SYNTHESIZED INSULIN UNDER**  
6 **AN ABBREVIATED NEW DRUG APPLICATION.**

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

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

14 (2) in subparagraph (A), by striking “such bio-  
15 logical product” and inserting “(i) such biological  
16 product”;

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

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

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

7                   “(B) notwithstanding paragraphs (3) and  
8 (4), the application is submitted under sub-  
9 section (j) of such section for chemically syn-  
10 thesized insulin or any analogue of chemically  
11 synthesized insulin for which the listed drug is  
12 a biological product that is, pursuant to para-  
13 graph (4), deemed to be licensed under section  
14 351 of the Public Health Service Act.”.

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



