

116TH CONGRESS  
1ST SESSION

# S. 2103

To improve access to affordable insulin.

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IN THE SENATE OF THE UNITED STATES

JULY 11, 2019

Mr. DURBIN (for himself, Mr. CRAMER, and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To improve access to affordable insulin.

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 “Affordable Insulin Ap-  
5       provals Now Act”.

6       **SEC. 2. DEEMED APPROVAL UNDER SECTION 351.**

7       Section 7002(e)(4) of the Biologics Price Competition  
8       and Innovation Act of 2009 (Public Law 111–148) is  
9       amended—

10               (1) by striking “An amended” and inserting the  
11       following:

1           “(A) IN GENERAL.—An amended”; and  
2           (2) by adding at the end the following:

3           “(B) TREATMENT OF CERTAIN PENDING  
4           APPLICATIONS.—With respect to an application  
5           for an insulin biological product submitted  
6           under subsection (b)(2) or (j) of section 505 of  
7           the Federal Food, Drug, and Cosmetic Act (21  
8           U.S.C. 355) with a filing date that is not later  
9           than December 31, 2019, until the Secretary  
10          makes a determination on final approval with  
11          respect to such application, the Secretary shall  
12          continue to review and approve (as appropriate)  
13          such application under such section 505, even if  
14          such review and approval process continues  
15          after March 23, 2020. For purposes of com-  
16          pleting the review and approval process for such  
17          an application, any listed drug referenced in the  
18          application shall be treated as a listed drug  
19          under section 505(j)(7) of the Federal Food,  
20          Drug, and Cosmetic Act, even if such listed  
21          drug is deemed licensed under section 351 of  
22          the Public Health Service Act during such re-  
23          view and approval process. Effective on the  
24          later of March 23, 2020, or the date of ap-  
25          proval under subsection (c) or (j) of section 505

1 of the Federal Food, Drug, and Cosmetic Act  
2 of any such application, such approved applica-  
3 tion shall be deemed to be a license for the bio-  
4 logical product under section 351 of the Public  
5 Health Service Act.”.

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