

113TH CONGRESS  
2D SESSION

# S. 2996

To create a limited population pathway for approval of certain antibacterial drugs.

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IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2014

Mr. BENNET (for himself and Mr. HATCH) 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 create a limited population pathway for approval of certain antibacterial drugs.

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 “Promise for Antibiotics  
5 and Therapeutics for Health Act” or the “PATH Act”.

6 **SEC. 2. LIMITED POPULATION PATHWAY FOR ANTI-**  
7 **BACTERIAL DRUGS.**

8 Section 506 of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 356) is amended—

1 (1) by transferring subsection (e) so that it ap-  
2 pears before subsection (f); and

3 (2) by adding at the end the following:

4 “(g) LIMITED POPULATION PATHWAY FOR ANTI-  
5 BACTERIAL DRUGS.—

6 “(1) IN GENERAL.—The Secretary shall estab-  
7 lish a program under which the Secretary may, at  
8 the request of a sponsor, approve an antibacterial  
9 drug, alone or in combination with one or more  
10 drugs, as a limited population antibacterial drug,  
11 upon a determination that such drug is intended to  
12 treat a serious or life-threatening disease, condition,  
13 or infection and address an unmet medical need for  
14 such disease, condition, or infection within an identi-  
15 fiable limited population.

16 “(2) LIMITED POPULATION PATHWAY.—

17 “(A) IN GENERAL.—The sponsor of an  
18 antibacterial drug that the Secretary deter-  
19 mines to be eligible for approval as a limited  
20 population antibacterial drug shall be required  
21 to demonstrate the safety and effectiveness of  
22 such drug, as required under section 505(d) or  
23 section 351(a) of the Public Health Service Act,  
24 for the intended use of the drug. The Secretary  
25 shall determine the safety and effectiveness of

1 an antibacterial drug under the limited popu-  
2 lation pathway for antibacterial drugs in ac-  
3 cordance with subparagraph (B). An anti-  
4 bacterial drug shall be eligible for approval  
5 under the limited population pathway only upon  
6 the request of the sponsor.

7 “(B) CONSIDERATIONS.—

8 “(i) BENEFIT-RISK PROFILE.—The  
9 Secretary’s determination of safety and ef-  
10 fectiveness of a limited population anti-  
11 bacterial drug shall reflect the benefit-risk  
12 profile of the drug in the intended limited  
13 population, taking into account the sever-  
14 ity, rarity, or prevalence of the infection  
15 the drug is intended to treat and the avail-  
16 ability or lack of alternative treatment for  
17 such infection. Approval of a drug under  
18 the limited population antibacterial drug  
19 pathway shall not be denied due to a lack  
20 of evidence to fully establish a favorable  
21 benefit-risk profile in a population that is  
22 broader than the intended limited popu-  
23 lation.

24 “(ii) TYPES OF EVIDENCE.—In deter-  
25 mining whether to approve a drug under

1 the limited population pathway, the Sec-  
2 retary—

3 “(I) shall rely on sufficient evi-  
4 dence, which may include traditional  
5 endpoints, alternate endpoints, or a  
6 combination of traditional and alter-  
7 nate endpoints, and, as appropriate,  
8 small clinical data sets; and

9 “(II) may rely on supplemental  
10 data, including preclinical evidence,  
11 pharmacologic or pathophysiologic evi-  
12 dence, nonclinical susceptibility, phar-  
13 macokinetic data, and other such con-  
14 firmatory evidence as the Secretary  
15 determines appropriate.

16 “(3) REQUIREMENTS.—With respect to a drug  
17 approved through the limited population pathway,  
18 the Secretary shall require—

19 “(A) the labeling of such antibacterial  
20 drug, such as through a logo or other means,  
21 to indicate that the drug has been approved for  
22 use only in a limited population and that the  
23 safety and efficacy of the drug has been dem-  
24 onstrated only with respect to such limited pop-  
25 ulation; and

1           “(B) the sponsor to submit copies of all  
2           promotional materials related to the limited  
3           population antibacterial drug, at least 30 days  
4           prior to dissemination of the materials.

5           “(4) OTHER PROGRAMS.—A sponsor of a drug  
6           that seeks approval of a drug through the limited  
7           population pathway for antibacterial drugs may also  
8           seek approval of such drug under subsections (a),  
9           (b), and (c), and sections 505E and 524.

10          “(5) GUIDANCE.—Not later than 18 months  
11          after the date of enactment of the Promise for Anti-  
12          biotics and Therapeutics for Health Act, the Sec-  
13          retary shall issue draft guidance describing criteria,  
14          processes, and other general considerations for dem-  
15          onstrating the safety and effectiveness of limited  
16          population antibacterial drugs and how the pathway  
17          can be expanded to other therapeutic areas in addi-  
18          tion to antibacterial infections. The Secretary may  
19          approve antibacterial drugs through such limited  
20          population pathway prior to issuing guidance under  
21          this paragraph.

22          “(6) POSTAPPROVAL MONITORING PROGRAMS  
23          FOR ANTIBACTERIAL DRUGS.—The Secretary, in  
24          consultation with the Commissioner and other rel-  
25          evant heads of agencies, shall conduct postapproval

1 monitoring programs to study how antibacterial  
2 drugs approved through the pathway under this sub-  
3 section are used and to monitor changes in bacterial  
4 resistance to drugs, including drugs approved under  
5 this pathway.

6 “(7) ADVICE.—The Secretary shall provide  
7 prompt advice to the sponsor of a drug for which the  
8 sponsor seeks approval through the limited popu-  
9 lation pathway for antibacterial drugs to enable the  
10 sponsor to plan a development program to obtain the  
11 necessary data for approval of such drug through  
12 the limited population pathway for antibacterial  
13 drugs and to conduct any additional studies that  
14 would be required to gain approval of such drug for  
15 use in a broader population.

16 “(8) TERMINATION OF LIMITATIONS.—If, after  
17 approval of a drug through the limited population  
18 pathway for antibacterial drugs, the Secretary ap-  
19 proves a broader indication for such drug for which  
20 the sponsor applies under section 505(b) or section  
21 351 of the Public Health Service Act, the Secretary  
22 may remove any postmarketing conditions, including  
23 requirements with respect to labeling and review of  
24 promotional materials under paragraph (3) and  
25 postapproval monitoring under paragraph (6), appli-

1 cable to the approval of the drug through the limited  
2 population pathway for antibacterial drugs.

3 “(9) RULES OF CONSTRUCTION.—

4 “(A) STANDARDS OF EVIDENCE AND AU-  
5 THORITY OF SECRETARY.—Nothing in this sub-  
6 section shall be construed to alter the standards  
7 of evidence applicable to the review and ap-  
8 proval of a drug under this Act or the Public  
9 Health Service Act, or to modify or limit the  
10 authority of the Secretary to approve or mon-  
11 itor drugs pursuant to this Act or the Public  
12 Health Service Act as authorized prior to the  
13 date of enactment of the Promise for Anti-  
14 biotics and Therapeutics for Health Act.

15 “(B) PRESCRIBING AUTHORITY.—Nothing  
16 in this subsection shall be construed to restrict  
17 the prescribing of antibiotics or other products,  
18 including drugs approved under the limited pop-  
19 ulation pathway, by health care professionals,  
20 or to limit the practice of health care.

21 “(10) EXPANSION OF PATHWAY.—Beginning on  
22 October 1, 2016, the limited population pathway for  
23 antibiotic drugs may be expanded to apply to ap-  
24 proval of other drugs intended to treat a serious or  
25 life-threatening illness. The approval of such drugs

1 shall be subject to the considerations and require-  
2 ments described in this subsection, unless the Sec-  
3 retary delivers a report to Congress prior to that  
4 date explaining why such pathway should not be  
5 used for other therapeutic areas in addition to anti-  
6 bacterial infections.”.

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