114TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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 ''Promise for Antibiotics and Therapeutics for Health Act'' or the ''PATH Act''.

SEC. 2. LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL DRUGS.

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

(1) by transferring subsection (e) so that it appears before subsection (f); and

(2) by adding at the end the following:

''(g) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL DRUGS.—

''(1) IN GENERAL.—The Secretary shall establish a program under which the Secretary may, at the request of a sponsor, approve an antibacterial drug, alone or in combination with one or more drugs, as a limited population antibacterial drug, upon a determination that such drug is intended to treat a serious or life-threatening disease, condition, or infection and address an unmet medical need for such disease, condition, or infection within an identifiable limited population.

''(2) LIMITED POPULATION PATHWAY.—

''(A) IN GENERAL.—The sponsor of an antibacterial drug that the Secretary determines to be eligible for approval as a limited population antibacterial drug shall be required to demonstrate the safety and effectiveness of such drug, as required under section 505(d) or section 351(a) of the Public Health Service Act, for the intended use of the drug. The Secretary shall determine the safety and effectiveness of

an antibacterial drug under the limited population pathway for antibacterial drugs in accordance with subparagraph (B). An antibacterial drug shall be eligible for approval under the limited population pathway only upon the request of the sponsor.

''(B) CONSIDERATIONS.—

''(i) BENEFIT-RISK PROFILE.—The Secretary's determination of safety and effectiveness of a limited population antibacterial drug shall reflect the benefit-risk profile of the drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment for such infection. Approval of a drug under the limited population antibacterial drug pathway shall not be denied due to a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

''(ii) TYPES OF EVIDENCE.—In determining whether to approve a drug under

the limited population pathway, the Secretary—

"(I) shall rely on sufficient evidence, which may include traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, small clinical data sets; and

"(II) may rely on supplemental data, including preclinical evidence, pharmacologic or pathophysiologic evidence, nonclinical susceptibility, pharmacokinetic data, and other such confirmatory evidence as the Secretary determines appropriate.

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

"(A) the labeling of such antibacterial drug, such as through a logo or other means, to indicate that the drug has been approved for use only in a limited population and that the safety and efficacy of the drug has been demonstrated only with respect to such limited population; and

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

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

"(5) GUIDANCE.—Not later than 18 months after the date of enactment of the Promise for Antibiotics and Therapeutics for Health Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial drugs and how the pathway can be expanded to other therapeutic areas in addition to antibacterial infections. The Secretary may approve antibacterial drugs through such limited population pathway prior to issuing guidance under this paragraph.

"(6) POSTAPPROVAL MONITORING PROGRAMS FOR ANTIBACTERIAL DRUGS.—The Secretary, in consultation with the Commissioner and other relevant heads of agencies, shall conduct postapproval

monitoring programs to study how antibacterial drugs approved through the pathway under this subsection are used and to monitor changes in bacterial resistance to drugs, including drugs approved under this pathway.

''(7) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval through the limited population pathway for antibacterial drugs to enable the sponsor to plan a development program to obtain the necessary data for approval of such drug through the limited population pathway for antibacterial drugs and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

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

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

''(9) RULES OF CONSTRUCTION.—

''(A) STANDARDS OF EVIDENCE AND AUTHORITY OF SECRETARY.—Nothing in this subsection shall be construed to alter the standards of evidence applicable to the review and approval of a drug under this Act or the Public Health Service Act, or to modify or limit the authority of the Secretary to approve or monitor drugs pursuant to this Act or the Public Health Service Act as authorized prior to the date of enactment of the Promise for Antibiotics and Therapeutics for Health Act.

''(B) PRESCRIBING AUTHORITY.—Nothing in this subsection shall be construed to restrict the prescribing of antibiotics or other products, including drugs approved under the limited population pathway, by health care professionals, or to limit the practice of health care.

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

shall be subject to the considerations and requirements described in this subsection, unless the Secretary delivers a report to Congress prior to that date explaining why such pathway should not be used for other therapeutic areas in addition to antibacterial infections.''.