162nd CONGRESS
1ST SESSION

S. 2

To expedite access to drugs previously authorized by foreign nations in order to expand options available to consumers and citizens.

IN THE SENATE

February 16, 2023,

Mr. Mark of Pacifica (for himself,) Mr. Holland of Lincoln (for himself) introduced the following bill

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A BILL

To expedite access to drugs previously authorized by foreign nations in order to expand options available to consumers and citizens

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

SECTION 1. SHORT TITLE

(a) SHORT TITLE.— This Act may be cited as the "American Drug Approval Reform Act of 2023".

SECTION 2. DEFINITIONS

(a) DEFINITIONS.— For the purposes of this Act, the word—

(1) "FDA" refers to the Food and Drug Administration;

(2) "Commissioner" refers to the Commissioner of the FDA; and

(3) "Drug" is defined as provided in paragraph (1) of subsection (g) of § 321 of Title 21 of the United States Code.

SECTION 3. FINDINGS

(a) FINDINGS.— Congress finds that—

(1) Eloxatin, a drug for advanced colorectal cancer, was rejected by the FDA at the start of the century despite it having been approved in almost thirty countries.

(2) The FDA delayed approval of Elocatin until August 2002, after approximately forty-thousand Americans had died without having been granted access to the life-saving drug.

(3) Erbitux, another cancer-treating drug, was rejected by the FDA in late 2001, when the agency refused to review it's application, and

delayed approval until early 2004, after one-hundred-and-seventy-nine thousand people with cancer died waiting for the drug.

(4) Patients were forced to wait until December 2005 for the FDA to approve Revlimid, a drug that treats multiple myeloma and myelodysplastic syndrome.

(5) Almost 75,000 patients with cancers that could've been healed with Revlimid died without gaining access to the drug due to the FDA withholding approval.

SECTION 4. ANALYSIS OF FOREIGN DRUG AND MEDICATION APPROVAL PROCESSES

(a) PROHIBITION.— The Commissioner, within ten days of the passage of this Act, shall initiate a review of the means by which drugs and medication are approved in the following countries—

(1) The United Kingdom of Great Britain and Northern Ireland;

(2) Canada;

(3) The Republic of Korea:

(4) The State of Japan:

(5) The Commonwealth of Australia;

(6) The Commonwealth of New Zealand;

(7) The French Republic;

(8) The Federal Republic of Germany;

(b) REPORT.— The Commissioner, upon conclusion of the review provided for by subsection (a) of this section, and no later than eighteen months after the passage of this Act, shall determine which of the countries provided for in subsection (a)

(1) Utilize standards consistent or equivalent with those set by 21 U.S. Code § 355 and 21 C.F.R. § 310.3 – 310.6

(2) Requires the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country to be adequate to preserve the identity, quality, purity, and strength of the drugs; and

(3) Requires the reporting of adverse reactions to drugs and establish procedures to recall, and withdraw approval of, drugs found not to be safe or effective.

(c) RENEWAL — The report delineated in Section 4 (b) of this Act shall be subject to renewal for a period of every 5 years following the publication of the first report.

SECTION 5. APPROVAL BY A FAVORABLE MAJORITY FOREIGN CONSENSUS

(a) APPROVAL.— In Part A of Subchapter V of Chapter 9 of Title 21 of the United States Code, insert the following after §360n-1 as §360o—

"§360o. EXPEDITED APPROVAL OF PHARMACEUTICAL PRODUCTS

"(a) AUTHORIZED COUNTRIES.— For the purposes of this section, the word "authorized countries" refers to nations that have met the qualifications set forth in Section 4(b) of this Act

"(b) APPROVAL.— Whenever more than one-half of authorized countries fully approve a drug for commercial use, the drug shall be considered approved by the Food and Drugs Administration, and be available for commercial distribution no earlier than six months thereafter.

"(c) ANNULMENT.— The Secretary of Health and Human Services, shall, within three months of the approval, reserve the right to revoke approval upon determination that it may pose a substantial threat to the Public Health of the United States.

"(d) REVIEW.— Every three years following commercial distribution, the Commissioner of the Food and Drugs Administration shall review the

drugs approved pursuant to subsection (b) of this section and may choose, with the approval of the Secretary of Health and Human Services, to revoke the approval made pursuant to subsection (b),

"(e) RETROACTIVE EFFECT.— The provisions of this section have no retroactive effect prior to the date on which they are enacted."

SECTION 6. CREATION OF STANDARDS FOR PRODUCTS AUTHORIZED UNDER FOREIGN CONSENSUS APPROVAL

(a) IN GENERAL .— 21 U.S. Code § 356 is amended by inserting the following after subsection (d)

(1) Drugs approved under Section 5 of the American Drug Approval Reform Act will be designated as Partner Country Approved

(2) Labeling

(1) To indicate the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to evidence by authorized partner countries,

a) all labeling and advertising of an drug approved under this

section shall contain the statement "Partner Country Approved" in a prominent manner and adjacent to, and not more prominent than—

i) The proprietary name of such drug, if any; or

ii) if there is no proprietary name, the established name of the drug, if any, as defined in section 353(e)(3) of this title, or, in the case of a drug that is a biological product, the proper name, as defined by regulation;

(b) IN GENERAL.— 21 U.S. Code § 384 is amended—

(1) In Section (a)(3)

(1) By striking subsection (b)

SECTION 7. APPROPRIATIONS

(c) APPROVAL.— The Commissioner shall be appropriated, for Fiscal Year 2023 and 2024, $30,500,000 to execute the provisions of this Act.

SECTION 8. SEVERABILITY

(a) SEVERABILITY.— Should any provision of this Act be deemed invalid or unconstitutional for any reason in a court with relevant jurisdiction, the rest of this Act, and the application of the remaining provisions, shall not be affected.

SECTION 9. ENACTMENT

(a) EFFECTIVE DATE.— The provisions of this Act shall come into force ten days after passage.

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Authored by Congressman Morse and Senator Mark