AMENDMENT TO RULES COMMITTEE PRINT 117–31

OFFERED BY MS. CRAIG OF MINNESOTA

Page 829, after line 23, add the following:

TITLE V—ONSHORING ESSENTIAL ANTIBIOTICS

SEC. 20501. ESSENTIAL GENERIC ANTIBIOTIC PROGRAM.

(a) GRANT PROGRAM.—

(1) ESTABLISHMENT.—Not later than 60 days after the date of enactment of this Act, the Secretary shall establish a program to provide grants to manufacturers of essential generic antibiotic drugs, or the active pharmaceutical ingredient or key starting material of an essential generic antibiotic drug, to support activities described in paragraph (3).

(2) ELIGIBLE ENTITIES.—The Secretary shall award grants under this subsection to not more than 3 manufacturers of an essential generic antibiotic drug. Each such recipient shall be a manufacturer that—

(A) has implemented and maintains an effective quality management system, under parts

210 and 211 of title 21, Code of Federal Regulations (or any successor regulations);

(B) has a strong record of compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(C) uses complex pharmaceutical manufacturing to produce a finished drug product or active pharmaceutical ingredient pursuant to an application approved under section subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(D) commits to using advanced manufacturing in its manufacturing operations; and

(E) has existing manufacturing facilities and operations in the United States.

(3) USE OF FUNDS.—A recipient of a grant under this subsection may use such grant funds to—

(A) with respect to manufacturing an essential generic antibiotic drug—

(i) expand, upgrade, or recommission an existing manufacturing facility located in the United States; or

(ii) construct a new manufacturing facility in the United States; and

(B) manufacture essential generic antibiotic drugs.

(b) USE OF FUNDS TO PURCHASE ESSENTIAL GENERIC ANTIBIOTIC DRUGS FOR STOCKPILING.—The Secretary may use amounts appropriated under this section to purchase, store, stockpile, or disposition essential generic antibiotic drugs manufactured in the United States.

(c) DEFINITIONS.—For purposes of this section:

(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term ''active pharmaceutical ingredient'' has the meaning given such term in section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41).

(2) ESSENTIAL GENERIC ANTIBIOTIC DRUG.—The term ''essential generic antibiotic drug'' means an antibacterial or antifungal drug approved by the Food and Drug Administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that the Secretary determines to be medically necessary to have available at all times in an amount adequate to serve patient needs, including beta-lactams (including penicillin and cephalosporin derivatives) and non-beta lactams (including tetracycline and aminoglycoside derivatives).

(3) KEY STARTING MATERIAL.—The term ''key starting material'' means any component of a drug that the Secretary determines to be critical to the safety and effectiveness of the drug.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(5) UNITED STATES.—The term ''United States'' means the 50 States, the District of Columbia, territories, and Tribal lands.

(d) FUNDING.—For purposes of carrying out this section, there is appropriated, out of amounts in the Treasury not otherwise appropriated, $500,000,000 for fiscal year 2023, to remain available through September 30, 2025.

SEC. 20502. STUDY AND REPORT.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall enter into a contract with an entity under which such entity carries out a study on the manufacture of essential generic antibiotic drugs and issues a report that includes—

(1) recommendations about which antibiotics the Secretary should prioritize for purposes of the program under section 20501, based on factors that include necessity of use, vulnerability to foreign sup-

ply chain disruptions, and availability of alternatives; and

(2) the expected effect of increased domestic manufacturing of drugs on drug costs to consumers.

(b) AUTHORIZATION.—To carry out this section, there is authorized to be appropriated $2,000,000 for fiscal year 2023, to remain available until September 30, 2024.

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