AMENDMENT TO RULES COMMITTEE
PRINT 117–31
OFFERED BY MR. STAUBER OF MINNESOTA

At the end of division E, add the following:

SEC. 40103. REQUIREMENT TO PURCHASE PHARMACEUTICALS FROM THE UNITED STATES.

(a) IN GENERAL.—Except as provided in subsection (b), the head of an executive agency may only purchase a covered drug if the drug is over 50-percent sourced, manufactured, and assembled in the United States.

(b) EXCEPTION.—The head of an executive agency may waive the requirement of subsection (a)—

(1) if the covered drug is not available in sufficient quantity or quality as over 50-percent sourced, manufactured, and assembled in the United States; or

(2) during an emergency period (as defined in section 1135(g)(1)(A) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(A))).

(c) MODIFICATIONS TO TRADE AGREEMENTS.—

(1) IN GENERAL.—Not later than 30 days after the date of the enactment of this Act, the United States Trade Representative shall modify United

States product coverage under all free trade agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of essential medicines and medical countermeasures.

(2) MODIFICATION OF WAIVERS.—Subsequent to the modifications made under paragraph (1), the United States Trade Representative shall make any necessary corresponding modifications of existing waivers under section 301 of the Trade Agreements Act of 1979 (19 U.S.C. 2511).

(3) NOTIFICATION TO THE PRESIDENT.—Subsequent to the modifications made under paragraphs (1) or (2), the United States Trade Representative shall notify the Director of the Office of Management and Budget.

(d) DEFINITIONS.—In this section:

(1) COVERED DRUG.—The term ''covered drug'' means a drug (including the active pharmaceutical ingredients thereof) marketed in the United States pursuant to an approval or licensure under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) EXECUTIVE AGENCY.—The term ''executive agency'' has the meaning given that term in section 133 of title 41, United States Code.

(3) UNITED STATES.—The term ''United States'' means each of the several States, the District of Columbia, and each territory or possession of the United States.

(e) SEVERABILITY CLAUSE.—If any provision of this section (or the application of that provision to particular persons or circumstances) is held invalid, the remainder of this section (or the application of that provision to other persons or circumstances) shall not be affected.

(f) EFFECTIVE DATE.—The provisions of this section shall apply beginning on the date that is one year after the last day of the emergency period (as defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b–5(g)).

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