AMENDMENT TO

RULES COMMITTEE PRINT 117–31

OFFERED BY MR. POSEY OF FLORIDA

At the end of the Rules Committee Print, add the following new division:

DIVISION M—SAFE MEDICINE

SEC. 120001. DOMESTIC MANUFACTURING TO END OVER-DEPENDENCE OF THE UNITED STATES ON CHINESE DRUGS.

(a) IN GENERAL.—The Secretaries of Health and Human Services and Defense, acting jointly and in consultation with the Commissioner of Food and Drugs, shall—

(1) not later than 180 days after the date of enactment of this Act, develop a procurement strategy, including for long-term contracts, to strengthen and mobilize the Public Health Industrial Base to increase the manufacture in the United States of essential medicines, medical countermeasures, and critical inputs, including the 227 essential medicines, medical countermeasures, and critical inputs published on October 30, 2020, by the Food and Drug

Administration in accordance with Executive Order 13944; and

(2) beginning as soon as feasible after the development of such strategy, and not later than 5 years after the development of such strategy, implement such strategy.

(b) CONTENTS.—The strategy under subsection (a) shall—

(1) be consistent with all applicable Federal law;

(2) identify essential components, including key starting materials, active ingredients, and critical inputs, necessary for manufacturing the essential medicines and medical countermeasures published on October 30, 2020, by the Food and Drug Administration in accordance with Executive Order 13944; and

(3) address the capacity of the supply chain and industrial base to strengthen and mobilize the Public Health Industrial Base to increase the manufacture in the United States of essential medicines, medical countermeasures, and critical inputs.

(c) DEFINITIONS.—In this section:

(1) The term ''critical inputs'' means active pharmaceutical ingredients, active pharmaceutical

ingredient starting material, and other ingredients of drugs and components of medical devices that the Commissioner of Food and Drugs determines to be critical in assessing the safety and effectiveness of essential medicines and medical countermeasures.

(2) The term ''essential medicine'' means medicine—

(A) that is needed to protect the American public at all times, including from outbreaks of emerging infectious diseases, such as COVID–19, as well as chemical, biological, radiological, and nuclear threats; and

(B) of which sufficient and reliable, long-term domestic production of these products, mostly generic drugs, their active pharmaceutical ingredients, and key starting materials, is needed to minimize potential shortages by reducing the Nation's dependence on foreign manufacturers of these products.

(3) The term ''medical countermeasure'' means—

(A) a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a));

(B) a qualified pandemic or epidemic product (as defined in section 319F–3 of such Act (42 U.S.C. 247d–6d));

(C) a security countermeasure (as defined in section 319F–2 of such Act (42 U.S.C. 247d–6b)); or

(D) personal protective equipment (such as gloves, respirators (face masks), and ventilators).

(4) The term ''Public Health Industrial Base'' means the facilities and associated workforces within the United States, including research and development facilities, that help produce essential medicines, medical countermeasures, and critical inputs for the health care and public health sector.

SEC. 120002. REQUIRING BOXED WARNINGS ON POTENTIALLY CONTAMINATED DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) issue an order deeming a drug or active pharmaceutical ingredient (or a category thereof) to be misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 352) if such drug or active pharmaceutical ingredient (or category thereof)—

(A) is manufactured in a country that the Secretary determines may be producing contaminated drugs or active pharmaceutical ingredients because of systemic problems of supervision in the manufacture of drugs or active pharmaceutical ingredients; and

(B) the labeling of such drug or active pharmaceutical ingredient (or category thereof) does not bear a boxed warning of the potential for contamination;

(2) make each such order effective for a period of not more than 180 days; and

(3) renew each such order each time the preceding order ends and the criteria listed in paragraph (1) continue to apply.

(b) WAIVERS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) may waive the requirement to issue or renew an order under subsection (a) so long as the labeling of the drug or active pharmaceutical ingredient (or category thereof) bears a boxed warning of the potential for contamination;

(2) shall make any such waiver effective for a period not to exceed 180 days; and

(3) may renew any such waiver one or more times.

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