AMENDMENT TO RULES COMMITTEE PRINT 119-8
OFFERED BY MR. ROUZER OF NORTH CAROLINA

Add at the end of subtitle D of title VIII the following:

SEC. 8___. PROGRAM TO RE-SHORE THE MANUFACTURING OF CRITICAL MEDICINES FOR THE DEPARTMENT OF DEFENSE.

(a) PROGRAM REQUIRED.—Not later than one year after the date of the enactment of this Act, and subject to the availability of appropriations, the Secretary of Defense, acting through the Under Secretary of Defense for Personnel and Readiness and the Under Secretary of Defense for Acquisition, and in coordination with Industrial Base Policy and Health Affairs, shall establish a program to re-shore domestic manufacturing of critical medicines that are essential for military readiness and national security.

(b) COLLABORATION.—In carrying out the program under this section, the Under Secretaries shall collaborate with the Secretary of Health and Human Services, the Director of the Biomedical Advanced Research and Development Authority, and the Commissioner of Food and Drugs to—

(1) ensure timely regulatory approval of critical medicines;

(2) enable pathways for the commercial production of critical medicines; and

(3) ensure that the program under this section supports civilian access to critical medicines and Federal procurement preferences.

(c) PROGRAM OBJECTIVES.—The program established under this section shall—

(1) identify and prioritize for commercial production drugs (including active pharmaceutical ingredients, biological products, and finished dosage forms) the domestically-manufactured availability of which are at risk due to reliance on high-risk sources;

(2) support the establishment or modernization of dual-use drug manufacturing facilities using advanced platforms;

(3) incentivize public-private partnerships, including institutions of higher education and research and manufacturing consortiums, for accelerated capability development of critical medicine;

(4) ensure disclosure and traceability of supply chain origins, consistent with the requirement the Secretary of Defense only procure generic drugs if

the country of origin for the drug and each active pharmaceutical ingredient of the drug is disclosed; and

(5) provide for eventual commercialization to civilian markets and inclusion in the Strategic National Stockpile.

(d) RISK REPORTING AND SUPPLY CHAIN TRANSPARENCY.—Not later than 2 years after the date of enactment of this Act, the Under Secretary of Defense for Personnel and Readiness shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report that includes—

(1) an assessment of the vulnerabilities in the sourcing of active pharmaceutical ingredients and finished dosage forms of critical medicines, especially those sourced from adversarial or high-risk sources;

(2) updated critical medicines supply-chain risk guidance; and

(3) data on merger and acquisition trends that impact pharmaceutical industrial base competition.

(e) USE OF AUTHORITIES.—The program under this section may use the authorities under the following:

(1) The Defense Production Act (50 U.S.C. 4501 et seq.).

(2) Section 816 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021.

(3) Section 4022 of title 10, United States Code.

(4) Section 4841 of title 10, United States Code.

(f) REPORT TO CONGRESS.—Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Under Secretary of Defense for Personnel and Readiness shall submit to the Committees on Armed Services of the Senate and the House of Representatives a report that includes—

(1) a prioritization of critical medicines;

(2) the status of the efforts under the program to re-shore domestic manufacturing of critical medicines that are essential for military readiness and national security, including the establishment or modernization of manufacturing facilities in the United States.

(3) disclosures of supply chain origins for critical medicines and risk mitigation measures implemented under the program related to the manufacturing of such critical medicines;

(4) interagency coordination milestones under the program; and

(5) recommendations for legislative or administrative action.

(g) DEFINITIONS.—In this section:

(1) The term ''critical medicine'' means a drug that the Secretary of Defense determines is deemed vital to the national security of the United States or the protection of the health of the Armed Forces.

(2) The term ''high-risk source'' means any country that the Secretary of Defense determines poses elevated supply-chain risk due to geopolitical, economic, or reliability concerns.

(3) The term ''re-shore'' means, with respect to a critical medicine produced outside of the United States, the process of increasing production of the medicine in the United States.