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118TH CONGRESS
1ST SESSION

# H. R. 6897

To require the Secretary of Defense to establish a pilot program to evaluate novel pharmaceutical manufacturing technologies to reduce the reliance of the Department on foreign manufacturers for active pharmaceutical ingredients and key starting materials.

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IN THE HOUSE OF REPRESENTATIVES

DECEMBER 22, 2023

Ms. SLOTKIN (for herself and Mr. GALLAGHER) introduced the following bill; which was referred to the Committee on Armed Services

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# A BILL

To require the Secretary of Defense to establish a pilot program to evaluate novel pharmaceutical manufacturing technologies to reduce the reliance of the Department on foreign manufacturers for active pharmaceutical ingredients and key starting materials.

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

**SECTION 1. DOMESTIC SYNTHETIC BIOLOGY PHARMACEUTICAL MANUFACTURING PILOT PROGRAM.**

(a) SHORT TITLE.—This Act may be cited as the ''Synthetic Biology and Active Pharmaceutical Ingredients Act''.

(b) IN GENERAL.—Not later than January 1, 2025, the Secretary of Defense shall establish a pilot program to evaluate the use of novel technologies using synthetic biology to expand domestic manufacturing of covered active pharmaceutical ingredients and covered key starting materials to reduce the reliance of the Department of Defense on foreign countries for such covered active pharmaceutical ingredients and covered key starting materials.

(c) SUNSET.—The pilot program established under subsection (a) shall terminate on the date that is three years after the date of the enactment of this Act.

(d) DEFINITIONS.—

(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) COVERED ACTIVE PHARMACEUTICAL INGREDIENT.—The term ''covered active pharmaceutical ingredient'' means an active pharmaceutical ingre-

dient of which a sufficient quantity or quality is not available from domestic manufacturers to meet the needs of the Department and which the Secretary determines to be of strategic importance to the United States.

(3) COVERED KEY STARTING MATERIAL.—The term ''covered key starting material'' means a key starting material of which a sufficient quantity or quality is not available from domestic manufacturers to meet the needs of the Department and which the Secretary determines to be of strategic importance to the United States.

(4) KEY STARTING MATERIAL.—The term ''key starting material'' means any material that is—

(A) used in the manufacture of an active pharmaceutical ingredient; and

(B) incorporated as an integral part of the active pharmaceutical ingredient.

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