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116TH CONGRESS
2D SESSION

H. R. 8588

To provide for a study on the current and historical production of drugs in the United States and in foreign countries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 13, 2020

Mr. HUDSON (for himself and Ms. BLUNT ROCHESTER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Foreign Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To provide for a study on the current and historical production of drugs in the United States and in foreign countries, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving the American Drug Supply Chain Act of 2020''.

SEC. 2. STUDY AND REPORTING ON DOMESTIC AND FOREIGN PRODUCTION.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the ''National Academies'') under which, not later than 24 months after the date of enactment of this Act, the National Academies will—

(1) study the current and historical production of drugs and key ingredients thereof (including active pharmaceutical ingredients) in the United States and in foreign countries;

(2) formulate recommendations for promoting increased production of drugs and key ingredients thereof (including active pharmaceutical ingredients) in the United States; and

(3) in a manner that does not compromise national security or disclose trade secrets or other confidential commercial information that is subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, submit a report to the Congress on—

(A) the findings and conclusions of the study under paragraph (1); and

(B) the recommendations under paragraph (2).

(b) STUDY TOPICS.—The study pursuant to subsection (a)(1) shall include—

(1) evaluation of—

(A) the extent to which production of drugs for use in the United States and key ingredients thereof (including active pharmaceutical ingredients) takes place in the United States; and

(B) the extent to which such production takes place in foreign countries;

(2) identification of the foreign countries in which such production takes place;

(3) evaluation of historical changes in the countries in which such production takes place;

(4) determination of the reasons why such production takes place in foreign countries, including why such production takes place in particular foreign countries, including consideration of—

(A) the reasons for historical migration of such production to foreign countries, or from foreign countries to other foreign countries or the United States;

(B) economic factors, including economic impediments to domestic production and incentives for foreign production; and

(C) regulatory, intellectual property, international trade, and other legal and policy factors; and

(5) evaluation of the benefits of redundancies in the supply chain of drugs in the United States in the event of a public health emergency.

(c) RECOMMENDATIONS.—The agreement under subsection (a) shall—

(1) provide for inclusion in the recommendations under subsection (a)(2) of measures (which may include statutory, regulatory, and other policy changes) that should be taken—

(A) to encourage the domestic production of drugs for use in the United States and key ingredients thereof (including active pharmaceutical ingredients); or

(B) to otherwise reduce the risks to the availability of drugs in the United States in the event of a public health emergency; and

(2) require consideration, in developing such recommendations, of—

(A) factors affecting the production of drugs, including—

(i) access to skilled labor;

(ii) the cost of raw materials, the cost of energy, and related costs;

(iii) taxes and other incentives; and

(iv) the effects of regulations; and

(B) the costs and consequences of implementing, or failing to implement, each such recommendation.

(d) INPUT.—The agreement under subsection (a) shall require—

(1) consideration of input from the Department of Health and Human Services, the Department of Commerce, and, as appropriate, other Federal agencies; and

(2) consultation with relevant stakeholders, which—

(A) may include conducting public meetings and other forms of engagement, as appropriate;

(B) shall include consultation with experts in—

(i) the manufacturing of drugs;

(ii) pharmaceutical industry business and economics;

(iii) drug purchasing, pricing, and reimbursement;

(iv) regulatory and intellectual property issues affecting drug manufacturing;

(v) economics;

(vi) international trade policy; and

(vii) emergency planning; and

(C) may include consultation with other entities with experience in drug manufacturing and pricing, as appropriate.

(e) DEFINITIONS.—In this section, the term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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