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119TH CONGRESS
1ST SESSION

H. R. 1405

To direct the Comptroller General of the United States to conduct a study to assess the key regulatory barriers that impede the expansion or siting of new pharmaceutical manufacturing facilities in the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 18, 2025

Mr. BUCHANAN (for himself and Mr. DONALDS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Comptroller General of the United States to conduct a study to assess the key regulatory barriers that impede the expansion or siting of new pharmaceutical manufacturing facilities in the United States, 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 ''Enhancing Domestic Drug Manufacturing Competitiveness Act''.

SEC. 2. STUDY ON KEY REGULATORY BARRIERS TO EXPANDING PHARMACEUTICAL MANUFACTURING IN THE UNITED STATES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to identify, and to assess on a time and cost basis, the key regulatory barriers that—

(1) impede the expansion or siting of new pharmaceutical manufacturing facilities in the United States; or

(2) make the United States less competitive than other countries as a location for such facilities.

(b) QUESTIONS.—In conducting the study under subsection (a), the Comptroller General shall consider the following questions:

(1) Do environmental or other regulations significantly delay, and increase the costs for manufacturers of, expanding or siting pharmaceutical manufacturing facilities in the United States relative to environmental or other regulations in other countries?

(2) What is the potential impact of environmental and other regulations on pharmaceutical supply chain resiliency?

(3) What specific actions (such as expediting reviews, inspections, and approvals of new facilities

or changes to existing facilities) could be taken by regulators to address the regulatory barriers described in subsection (a)?

(c) ENGAGING STAKEHOLDERS.—In conducting the study under subsection (a), the Comptroller General shall engage stakeholders—

(1) to identify and assess the barriers described in subsection (a);

(2) to identify whether there are promising technological solutions, including manufacturing processes, that could help to address the regulatory barriers described in subsection (a); and

(3) to identify the policies needed to support and foster any solutions identified pursuant to paragraph (2).

(d) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(2) CONTENTS.—The report required by paragraph (1) shall—

(A) identify, and assess on a time and cost basis, the regulatory barriers described in subsection (a);

(B) address each question listed in subsection (b); and

(C) include recommendations for streamlining the regulatory barriers described in subsection (a), and facilitating the use of technological solutions described in subsection (c)(2), to foster increased pharmaceutical manufacturing in the United States.

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