

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Enhancing Domestic
5 Drug Manufacturing Competitiveness Act”.

1 **SEC. 2. STUDY ON KEY REGULATORY BARRIERS TO EX-**
2 **PANDING PHARMACEUTICAL MANUFAC-**
3 **TURING IN THE UNITED STATES.**

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

8 (1) impede the expansion or siting of new phar-
9 maceutical manufacturing facilities in the United
10 States; or

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

13 (b) QUESTIONS.—In conducting the study under sub-
14 section (a), the Comptroller General shall consider the fol-
15 lowing questions:

16 (1) Do environmental or other regulations sig-
17 nificantly delay, and increase the costs for manufac-
18 turers of, expanding or siting pharmaceutical manu-
19 facturing facilities in the United States relative to
20 environmental or other regulations in other coun-
21 tries?

22 (2) What is the potential impact of environ-
23 mental and other regulations on pharmaceutical sup-
24 ply chain resiliency?

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

1 or changes to existing facilities) could be taken by
2 regulators to address the regulatory barriers de-
3 scribed in subsection (a)?

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

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

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

13 (3) to identify the policies needed to support
14 and foster any solutions identified pursuant to para-
15 graph (2).

16 (d) REPORT.—

17 (1) IN GENERAL.—Not later than 1 year after
18 the date of enactment of this Act, the Comptroller
19 General shall complete the study under subsection
20 (a) and submit to the Congress a report on the re-
21 sults of such study.

22 (2) CONTENTS.—The report required by para-
23 graph (1) shall—

1 (A) identify, and assess on a time and cost
2 basis, the regulatory barriers described in sub-
3 section (a);

4 (B) address each question listed in sub-
5 section (b); and

6 (C) include recommendations for stream-
7 lining the regulatory barriers described in sub-
8 section (a), and facilitating the use of techno-
9 logical solutions described in subsection (c)(2),
10 to foster increased pharmaceutical manufac-
11 turing in the United States.

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