

117TH CONGRESS
2D SESSION

H. R. 6980

To direct the Secretary of Health and Human Services to conduct a pilot program under which the Secretary increases the conduct of unannounced inspections of foreign human drug establishments and evaluates the differences between inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in advance of an inspection.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 2022

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

A BILL

To direct the Secretary of Health and Human Services to conduct a pilot program under which the Secretary increases the conduct of unannounced inspections of foreign human drug establishments and evaluates the differences between inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in advance of an inspection.

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

1 **SECTION 1. UNANNOUNCED FOREIGN FACILITY INSPEC-**
2 **TIONS PILOT PROGRAM.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services (referred to in this section as the “Sec-
5 retary”) shall conduct a pilot program under which the
6 Secretary increases the conduct of unannounced inspec-
7 tions of foreign human drug establishments and evaluates
8 the differences between inspections of domestic and for-
9 eign human drug establishments, including the impact of
10 announcing inspections to persons who own or operate for-
11 eign human drug establishments in advance of an inspec-
12 tion. Such pilot program shall evaluate—

13 (1) differences in the number and type of viola-
14 tions of section 501(a)(2)(B) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B))
16 identified during unannounced and announced in-
17 spections of foreign human drug establishments and
18 any other significant differences between each type
19 of inspection;

20 (2) costs and benefits associated with con-
21 ducting announced and unannounced inspections of
22 foreign human drug establishments;

23 (3) barriers to conducting unannounced inspec-
24 tions of foreign human drug establishments and any
25 challenges to achieving parity between domestic and
26 foreign human drug establishment inspections; and

1 (4) approaches for mitigating any negative ef-
2 fects of conducting announced inspections of foreign
3 human drug establishments.

4 (b) PILOT PROGRAM INITIATION.—The Secretary
5 shall initiate the pilot program under this section not later
6 than 180 days after the date of enactment of this Act.

7 (c) REPORT.—The Secretary shall, not later than 180
8 days following the completion of the pilot program, make
9 available on the website of the Food and Drug Administra-
10 tion a final report on the pilot program under this section,
11 including—

12 (1) findings and any associated recommenda-
13 tions with respect to the evaluation under subsection
14 (a), including any recommendations to address iden-
15 tified barriers to conducting unannounced inspec-
16 tions of foreign human drug establishments;

17 (2) findings and any associated recommenda-
18 tions regarding how the Secretary may achieve par-
19 ity between domestic and foreign human drug in-
20 spections; and

21 (3) the number of unannounced inspections
22 during the pilot that would not be unannounced
23 under existing practices.

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