

*Mike Braun*  
Amendment #4

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To strengthen the authority of the Food and Drug Administration with respect to foreign drug facility inspections.

**IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.**

**S. 3799**

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BRAUN

Viz:

- 1 Strike section 513 and insert the following:
- 2 **SEC. 513. STRENGTHENING FOREIGN DRUG FACILITY IN-**
- 3 **SPECTIONS.**
- 4 Section 704 of the Federal Food, Drug, and Cosmetic
- 5 Act (21 U.S.C. 374) is amended by adding at the end the
- 6 following:
- 7 “(i)(1) When the Secretary, and officers or employees
- 8 duly designated by the Secretary, conduct inspections
- 9 under this section of establishments engaged in the manu-
- 10 facturing, processing, packing, or holding of drugs that
- 11 are located outside of the United States, the Secretary

1 shall not notify the owner or operator of such establish-  
2 ment of the planned inspection before the inspection oc-  
3 curs unless—

4           “(A) notification to the establishment owner or  
5 operator in advance of an inspection is mandated  
6 under the laws of the country where the establish-  
7 ment is located, in which case, the Secretary shall  
8 provide not more than the minimum advanced notice  
9 so mandated; or

10           “(B) the Secretary determines that notification  
11 to the establishment owner or operator in advance of  
12 an inspection is needed to protect the public health.

13           “(2)(A) With respect to all inspections described in  
14 paragraph (1), the Secretary shall attempt to minimize the  
15 time between advance notification to an establishment  
16 owner or operator and the conduct of a surveillance in-  
17 spection.

18           “(B) If the Secretary determines that notification to  
19 an owner or operator of a foreign establishment of an in-  
20 spection in advance of a surveillance inspection pursuant  
21 to paragraph (1)(B) is needed, the Secretary shall provide  
22 such notification only as far in advance as is needed to  
23 protect the public health.

24           “(3) If an establishment is located in a country that,  
25 on or after the date of enactment of this subsection, enacts

1 a law that prevents the Secretary from carrying out in-  
2 spections as described in this subsection, the manufacturer  
3 shall agree to waive any right to enforce any advanced-  
4 notice requirement pursuant to such a law, to the extent  
5 expressly permitted under applicable local law. If the man-  
6 ufacturer does not agree to such a waiver, the manufac-  
7 turer shall be deemed to have refused to permit entry or  
8 inspection in violation of section 301(f).

9 “(4) The requirement of paragraph (1) shall not  
10 apply to preapproval, prelicensure, or for-cause inspec-  
11 tions.”.