

*Richard Blumenthal Ref*  
S.L.C.

*5-22-12  
11:15c  
gm*

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

Purpose: To provide civil monetary penalties for the failure to provide the Secretary with a required notification regarding the discontinuance or interruption of the manufacture of certain drugs.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

	<b>AMENDMENT NO 2136</b>	
To an	By <u><i>Blumenthal - others</i></u>	to
re		ion
dr	To: _____	ro-
gr	<u><i>S.3187</i></u>	ner
pt	<u><i>2</i></u>	
Refer	<b>Page(s)</b>	id

GPO: 2010 63-870 (mac)

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BLUMENTHAL

*and  
Mr. Franken  
Mr. Schumer  
Mr. Cardin  
Ms. Hironaka*

Viz:

- 1 At the end of title X, add the following:
- 2 **SEC. 10 . CIVIL PENALTIES FOR FAILURE TO SUBMIT NO-**
- 3 **TIFICATION.**
- 4 Section 303 (21 U.S.C. 333) is amended—
- 5 (1) in subsection (f)(5), by inserting “or sub-
- 6 section (h)” after “or (9)” each place such term ap-
- 7 pears; and
- 8 (2) by adding at the end the following:

1       “(h)(1) Any manufacturer that knowingly fails to  
2 submit a notification in violation of section 506C(a) shall  
3 be subject to a civil money penalty not to exceed \$10,000  
4 for each day on which the violation continues, and not to  
5 exceed \$1,800,000 for all such violations adjudicated in  
6 a single proceeding.

7       “(2) Not later than 180 days after the date of enact-  
8 ment of the Food and Drug Administration Safety and  
9 Innovation Act, the Secretary shall, subject to paragraph  
10 (1), promulgate final regulations establishing a schedule  
11 of civil monetary penalties for violations of section  
12 506C(a).”.