



AMENDMENT NO. 1

Calendar No. \_\_\_\_\_

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to banned devices.

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

**S. 4348**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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. MURPHY

Viz:

1 At the appropriate place in title IX, insert the fol-  
2 lowing:

3 **SEC. 9 \_\_\_\_\_. BANNED DEVICES.**

4 (a) IN GENERAL.—Section 516 of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 360f) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1), by inserting “for one  
8 or more of its intended uses” before the semi-  
9 colon; and

1 (B) in the flush text following paragraph

2 (2), by inserting “for any such intended use or

3 uses” before the period; and

4 (2) by adding at the end the following:

5 “(c) SPECIFIC DEVICES.—Adverse conditioning de-  
6 vices, including electrical stimulation devices, that apply  
7 a noxious electrical stimulation to an individual’s skin in-  
8 tended to reduce or cease self-injurious or aggressive be-  
9 havior are deemed to be banned devices, as described in  
10 subsection (a), without the need for the Secretary to pro-  
11 mulgate a regulation with respect to such devices as de-  
12 scribed in such subsection.”.

13 (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
14 tion shall be construed to limit the authority of the Sec-  
15 retary of Health and Human Services to amend, in accord-  
16 ance with section 516 of the Federal Food, Drug, and Cos-  
17 metic Act (21 U.S.C. 360f) and chapter 5 of title 5,  
18 United States Code, regulations promulgated pursuant to  
19 such section 516.