

*Mike Braun*  
**Amendment #1**

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

Purpose: To allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

**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. BRAUN *(for himself and Sen. Hickenlooper)*

Viz:

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

3 **SEC. 9 \_\_\_\_ . PREDETERMINED CHANGE CONTROL PLANS**  
 4 **FOR DEVICES.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,  
 6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
 7 ed by inserting after section 515B (21 U.S.C. 360e–3) the  
 8 following:

1 **"SEC. 515C. PREDETERMINED CHANGE CONTROL PLANS**  
2 **FOR DEVICES.**

3 **"(a) APPROVED DEVICES.—**

4 **"(1) IN GENERAL.—**Notwithstanding section  
5 515(d)(5)(A), a supplemental application shall not  
6 be required for a change to a device approved under  
7 section 515, if such change is consistent with a pre-  
8 determined change control plan that is approved  
9 pursuant to paragraph (2).

10 **"(2) PREDETERMINED CHANGE CONTROL**  
11 **PLAN.—**The Secretary may approve a predetermined  
12 change control plan submitted in an application, in-  
13 cluding a supplemental application, under section  
14 515 that describes planned changes that may be  
15 made to the device (and that would otherwise re-  
16 quire a supplemental application under section 515),  
17 if the device remains safe and effective without any  
18 change.

19 **"(3) SCOPE.—**The Secretary may require that a  
20 change control plan include labeling required for  
21 safe and effective use of the device as such device  
22 changes pursuant to such plan, notification require-  
23 ments if the device does not function as intended  
24 pursuant to such plan, and performance require-  
25 ments for changes made under the plan.

26 **"(b) CLEARED DEVICES.—**

1           “(1) IN GENERAL.—Notwithstanding section  
2       510(k), a premarket notification shall not be re-  
3       quired for a change to a device cleared under section  
4       510(k), if such change is consistent with an estab-  
5       lished predetermined change control plan granted  
6       pursuant to paragraph (2).

7           “(2) PREDETERMINED CHANGE CONTROL  
8       PLAN.—The Secretary may clear a predetermined  
9       change control plan submitted in a notification sub-  
10      mitted under section 510(k) that describes planned  
11      changes that may be made to the device (and that  
12      would otherwise require a new notification), if—

13           “(A) the device remains safe and effective  
14      without any such change; and

15           “(B) the device would remain substantially  
16      equivalent to the predicate.

17           “(3) SCOPE.—The Secretary may require that a  
18      change control plan include labeling required for  
19      safe and effective use of the device as such device  
20      changes pursuant to such plan, notification require-  
21      ments if the device does not function as intended  
22      pursuant to such plan, and performance require-  
23      ments for changes made under the plan.

24           “(c) PREDICATE DEVICES.—In making a determina-  
25      tion of substantial equivalence pursuant to section 513(i),

1 the Secretary shall not compare a device to changed  
2 versions of a device implemented in accordance with an  
3 established predetermined change control plan as a predi-  
4 cate device. Only the version of the device cleared or ap-  
5 proved, prior to changes made under the predetermined  
6 change control plan, may be used by a sponsor as a predi-  
7 cate device.”.

8 (b) CONFORMING AMENDMENTS.—

9 (1) CLEARED DEVICES.—Section 510(l)(1) of  
10 the Federal Food, Drug, and Cosmetic Act (21  
11 U.S.C. 360(l)(1)) is amended, in the first sentence,  
12 by inserting “, or with respect to a change that is  
13 consistent with a predetermined change control plan  
14 cleared under section 515C” before the period at the  
15 end.

16 (2) APPROVED DEVICES.—Section  
17 515(d)(5)(A)(i) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended  
19 by striking “A supplemental” and inserting “Unless  
20 the change is consistent with a predetermined  
21 change control plan approved under section 515C, a  
22 supplemental”.

23 (3) DOCUMENTATION OF RATIONALE FOR SIG-  
24 NIFICANT DECISIONS.—Section 517A(a)(1) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 360g-1(a)(1)) is amended to read as follows:

3 “(1) IN GENERAL.—The Secretary shall provide  
4 a substantive summary of the scientific and regu-  
5 latory rationale for any significant decision of the  
6 Center for Devices and Radiological Health regard-  
7 ing submission or review of a report under section  
8 510(k), a petition for classification under section  
9 513(f), an application under section 515, or an ap-  
10 plication for an exemption under section 520(g), in-  
11 cluding documentation of significant controversies or  
12 differences of opinion and the resolution of such con-  
13 troversies or differences of opinion.”.