

Mike Braun

AMENDMENT NO. 3 Calendar No. _____

Purpose: To improve the bill.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

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 _____

Viz:

- 1 At the appropriate place, insert the following:
- 2 (iv) LIMITATIONS ON EXCLUSIVITY.—
- 3 (I) IN GENERAL.—Only one 18-
- 4 month period under this subpara-
- 5 graph shall be granted, under each
- 6 order described in clause (i), with re-
- 7 spect to changes (to the drug subject
- 8 to such order) which are either—
- 9 (aa) changes described in
- 10 clause (ii)(I), relating to active
- 11 ingredients; or

1 (bb) changes described in
2 clause (ii)(II), relating to condi-
3 tions of use.

4 (II) NO EXCLUSIVITY AL-
5 LOWED.—No exclusivity shall apply to
6 changes to a drug which are—

7 (aa) the subject of a Tier 2
8 OTC monograph order request
9 (as defined in section 744L);

10 (bb) safety-related changes,
11 as defined by the Secretary, or
12 any other changes the Secretary
13 considers necessary to assure
14 safe use; or

15 (cc) changes related to
16 methods of testing safety or effi-
17 cacy.

18 (III) LOSS OF EXCLUSIVITY.—If
19 an order requestor does not begin to
20 market drugs described in clause (i)
21 within 180 days of the first date on
22 which such requestor may lawfully
23 market such drugs pursuant to the
24 final administrative order, the period
25 of exclusivity described in clause (i)

1 shall be extinguished, effective on the
2 date that is 180 days after the first
3 date on which such requestor may
4 lawfully market such drugs.