

*Bill Cassidy, M.D.*

AMENDMENT NO. 1

Calendar No. 4

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications.

**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 CASSIDY-SMITH-MURKOWSKI

Viz:

- 1 At the end of title II, add the following:
- 2 **SEC. 2 . AMENDMENTS TO ANDA APPROVAL PROVISION.**
- 3 Section 505 of the Federal Food, Drug, and Cosmetic
- 4 Act (21 U.S.C. 355), as amended by section 202, is fur-
- 5 ther amended—
- 6 (1) in subsection (b)(1) by adding at the end
- 7 the following:
- 8 “(C) In the case of an application that includes more
- 9 than 1 such patent, the applicant shall select one patent
- 10 with respect to which such owner or licensee may receive
- 11 the 30-month stay under subsection (c)(3)(C), as applica-

1 ble; for purposes of subsection (c)(3)(C) and (j)(5)(D)(iii),  
2 such patent shall be referred to as the ‘covered patent’.”.

3 (2) in subsection (c)(3)(C)—

4 (A) in the matter preceding clause (i)—

5 (i) by striking “infringement of the  
6 patent” and inserting “infringement of a  
7 covered patent (as described in subsection  
8 (b)(1)(C))”; and

9 (ii) by striking “an action is brought  
10 before” and inserting “an action with re-  
11 spect to a covered patent is brought be-  
12 fore”; and

13 (B) in clause (i), by striking “decides that  
14 the patent” and inserting “decides that the cov-  
15 ered patent”; and

16 (3) in subsection (j)(5)(B)(iii)—

17 (A) in the matter preceding subclause  
18 (I)—

19 (i) by striking “infringement of the  
20 patent” and inserting “infringement of a  
21 covered patent (as described in subsection  
22 (b)(1)(C))”; and

23 (ii) by striking “an action is brought  
24 before” and inserting “an action with re-

1           spect to a covered patent is brought be-  
2           fore”; and

3           (B) in subclause (I), by striking “decides  
4           that the patent” and inserting “decides that the  
5           covered patent”.