

AMENDMENT NO. 5

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

Purpose: To require a GAO report on unique considerations  
for certain entities in implementing the VALID Act.

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. MARSHALL

Viz:

1 At the end of subtitle C of title VIII, insert the fol-  
2 lowing:

3 **SEC. 832. GAO REPORT ON UNIQUE CONSIDERATIONS.**

4 Not later than 3 years after the date of enactment  
5 of this Act, the Comptroller General of the United States  
6 shall submit to the Committee on Health, Education,  
7 Labor, and Pensions of the Senate and the Committee on  
8 Energy and Commerce of the House of Representatives  
9 a report—

10 (1) evaluating the unique considerations for  
11 hospital-based laboratories, laboratories serving aca-

1       demic medical centers, and other health care practi-  
2       tioners, as appropriate, in implementing this sub-  
3       title, including the amendments made by this sub-  
4       title; and

5               (2) including recommendations based on the  
6       findings of the report.