

AMENDMENT NO. 3

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

Purpose: To establish transparency requirements for reliance on third party data with respect to the regulation of 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. MARSHALL

Viz:

*Braun*

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

3 **SEC. 9 \_\_\_\_\_. THIRD PARTY DATA TRANSPARENCY.**

4 (a) IN GENERAL.—To the extent the Secretary of  
5 Health and Human Services (referred to in this section  
6 as the “Secretary”) seeks to rely on any data, analysis,  
7 or other information or findings provided by entities that  
8 has been funded in whole or in part by, or otherwise per-  
9 formed under contract with, the Food and Drug Adminis-

1 tration, in regulatory decision-making with respect to de-  
2 vices, the Secretary shall—

3           (1) request access to the datasets, inputs, clin-  
4 ical or other assumptions, methods, analytical code,  
5 results, and other components underlying or com-  
6 prising the analysis, conclusions, or other findings  
7 upon which the Secretary seeks to rely; and

8           (2) in the event that information described in  
9 paragraph (1) is used to support regulatory decision-  
10 making, and as otherwise appropriate, to the extent  
11 practicable, provide the manufacturer or manufac-  
12 turers subject to such decision a summary of such  
13 information, subject to protection of confidential  
14 commercial information or trade secret information  
15 or personally identifiable information.

16       (b) REPORT.—Not later than September 30, 2023,  
17 and biennially thereafter, the Secretary shall submit to the  
18 Committee on Health, Education, Labor, and Pensions of  
19 the Senate and the Committee on Energy and Commerce  
20 of the House of Representatives, and publish on the  
21 website of the Food and Drug Administration, a report  
22 on the number of postmarket device signals communica-  
23 tions issued by the Secretary, the sources of data for such  
24 signals, and how such signals were revised or resolved.