

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 3433  
OFFERED BY M. \_\_\_\_\_**

Page 11, before line 12, insert the following (and make such conforming changes as may be necessary):

1       (a) LIMITING ELIGIBLE SPONSORS TO SMALL  
2 BIOTECH COMPANIES.—

3           (1) DEFINITION.—Section 529(a) of the Fed-  
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360ff(a)) is amended—

6           (A) by redesignating paragraphs (1)  
7 through (4) as paragraphs (2) through (5), re-  
8 spectively; and

9           (B) by inserting before paragraph (2), as  
10 redesignated, the following:

11           “(1) ELIGIBLE SPONSOR OF A RARE PEDIATRIC  
12 DISEASE PRODUCT APPLICATION.—The term ‘eligible  
13 sponsor of a rare pediatric disease product applica-  
14 tion’ means a sponsor of a rare pediatric disease  
15 product application that has annual sales that are  
16 less than \$500,000,000. For purposes of the pre-  
17 ceding sentence, the sales of a sponsor shall be  
18 treated as including the sales of each entity that

1 controls, is controlled by, or is under common con-  
2 trol with such sponsor.”.

3 (2) CONFORMING CHANGE.—Section 529(b)(1)  
4 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 360ff(a)(2)) is amended by striking “sponsor  
6 of a rare pediatric disease product application” and  
7 inserting “eligible sponsor of a rare pediatric disease  
8 product application”.

