

**AMENDMENT**

**OFFERED BY M**     .

In section 1192(e) of the Social Security Act, as added by section 101(a) of the bill, insert before the matter following paragraph (3) the following new paragraph:

1           “(4) ORPHAN DRUGS EXCLUDED.—Notwith-  
2           standing paragraphs (1), (2), and (3), the term  
3           ‘qualifying single source drug’ excludes any drug  
4           that is—

5                   “(A) designated under section 526 of the  
6                   Federal Food, Drug, and Cosmetic Act as a  
7                   drug for a rare disease or condition; or

8                   “(B) approved under section 505 of such  
9                   Act, or licensed under section 351 of the Public  
10                  Health Service Act, to treat a diffuse intrinsic  
11                  pontine glioma.”.

