

AMENDMENT TO RULES COMMITTEE PRINT

116-41

OFFERED BY MRS. AXNE OF IOWA

At the end of subtitle B of title VII, add the following:

1 SEC. 712. REPORT ON SINGLE SOURCE DRUGS.

2 Not later than 90 days after the date of the enact-
3 ment of this Act, the Secretary of Health and Human
4 Services, acting through the Commissioner of Food and
5 Drugs, shall submit to the Congress a report on—

6 (1) with respect to drugs that are subject to
7 section 503(b) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 353(b)), which of such drugs
9 meet the definition of a qualifying single source drug
10 under section 1192(e) of the Social Security Act (as
11 added by section 101); and

12 (2) the prospective analysis, if any, that the
13 Secretary performs on the impact of the discontinu-
14 ance of the manufacture of such a drug by the man-
15 ufacturer of such drug.

