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.

Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Congress a report on—

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

(2) the prospective analysis, if any, that the Secretary performs on the impact of the discontinuance of the manufacture of such a drug by the manufacturer of such drug.