AMENDMENT

TO RULES COMMITTEE PRINT 116–41

OFFERED BY MR. GOTTHEIMER OF NEW JERSEY

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

SEC. 712. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall conduct a study to identify—

(1) diseases or conditions that lack a treatment approved by the Food and Drug Administration and instances in which development of a treatment for such diseases or conditions could fill an unmet medical need for the treatment of a serious or life-threatening disease or condition or a rare disease or condition; and

(2) appropriate incentives that would lead to the development, approval, and marketing of such treatments.

(b) REPORT TO CONGRESS; RECOMMENDATIONS.—Not later than one year after the date of enactment of this Act, the Secretary shall submit to the Congress a report that includes—
(1) findings from the study under subsection (a); and
(2) recommendations regarding legislation necessary to create appropriate incentives identified pursuant to subsection (a)(2).