AMENDMENT TO RULES COMMITTEE PRINT 114–22

OFFERED BY MS. SCHAKOWSKY OF ILLINOIS

At the end of title II of the bill (on page 229, after line 14) add the following:

Subtitle R—Improving Drug Cost Transparency

SEC. 2321. IMPROVING DRUG COST TRANSPARENCY.

Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2151, is further amended by inserting after section 505H of such Act the following:

"SEC. 505J. IMPROVING DRUG COST TRANSPARENCY.

''(a) DISCLOSURE TO FDA.—In submitting an application for approval of a drug under section 505 of this Act or licensing of a biological product under section 351 of the Public Health Service Act, the sponsor of the drug or biological product shall include in such application—

''(1) a statement of the total costs incurred for research on, and development of, such drug or biological product;

''(2) a statement of the portion of such costs funded by the National Institutes of Health; and

''(3) permission for the Secretary to make the statements under paragraphs (1) and (2) publicly available.

''(b) DISCLOSURE TO PUBLIC.—The Secretary shall make each statement submitted under paragraph (1) or (2) of subsection (a) publicly available.''.

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