AMENDMENT TO THE AMENDMENT OFFERED BY MR. UPTON TO H.R. 6

(PAGE AND LINE NUMBERS REFER TO

UPTON 006)

OFFERED BY MS. SCHAKOWSKY OF ILLINOIS

Page ____, after line ____, insert the following the following:

Subtitle R—Improving Drug Cost Transparency

3 SEC. 2321. IMPROVING DRUG COST TRANSPARENCY.

Chapter V of the Federal Food, Drug, and Cosmetic
Act, as amended by section 2063, is further amended by
inserting after section 505H of such Act the following:

7 "SEC. 505I. IMPROVING DRUG COST TRANSPARENCY.

8 "(a) DISCLOSURE TO FDA.—In submitting an appli-9 cation for approval of a drug under section 505 of this Act or licensing of a biological product under section 351 10 of the Public Health Service Act, the sponsor of the drug 11 12 or biological product shall include in such application— 13 "(1) a statement of the total costs incurred for 14 research on, and development of, such drug or bio-15 logical product;

((2)) a statement of the portion of such costs 1 2 funded by the National Institutes of Health; and "(3) permission for the Secretary to make the 3 statements under paragraphs (1) and (2) publicly 4 available. 5 "(b) DISCLOSURE TO PUBLIC.—The Secretary shall 6 make each statement submitted under paragraph (1) or 7 (2) of subsection (a) publicly available.". 8

X