AMENDMENT TO

RULES COMMITTEE PRINT 116–14

OFFERED BY MR. DESAULNIER OF CALIFORNIA

At the end of title I, add the following:

Subtitle D—Study on Role of Federal Assistance in Drug Development

SEC. 131. STUDY ON ROLE OF FEDERAL ASSISTANCE IN DRUG DEVELOPMENT.

(a) IN GENERAL.—Not later than two years after the date of the enactment of this Act, the Secretary of the Health and Human Services shall enter into a contract with the National Academy of Medicine to conduct a study on, and submit to Congress a report on, the following:

(1) The percentage of drugs developed in the United States using at least some amount of Federal funding from any Federal source.

(2) The average cost incurred by a drug developer to develop a drug.

(3) The average amount of revenue and profits made by drug developers from the sales of drugs.

(4) The percentage of such revenue and profits that are reinvested into research and development of new drugs.

(5) The appropriate percentage, if any, of such revenue and profits the Secretary, in consultation with the National Academy of Medicine, recommends should be returned to Federal entities for Federal funding used in the development of the drugs involved.

(b) ENFORCEMENT.—A drug developer shall, as a condition of receipt of any Federal funding for the development of drugs, comply with any request for the data necessary to perform the study under subsection (a).

(c) CONFIDENTIALITY.—This section does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(d) DEFINITIONS.—In this section:

(1) The term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term ''drug developer'' means an entity that submitted, and received approval of, an application under section 505 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

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