AMENDMENT TO DIVISION B OF THE RULES

COMMITTEE PRINT 115–31

OFFERED BY MR. DEFAZIO OF OREGON

At the end of division B (before the short title), insert the following:

SEC. ____. (a) None of the funds made available by this Act may be used for Federally funded health care research and development to be carried out by a Federal agency or a non-profit entity for purposes of conveying or providing a patent for a drug, biologic, or other health care technology developed through such research, unless the entity (including a non-profit entity) that will receive such patent first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (c).

(b)(1) For purposes of subsection (a), any reasonable pricing formula used in a reasonable pricing agreement referred to in such subparagraph shall be cost-based and shall not result in discriminatory pricing for the drug, biologic, or other health care technology involved regardless

of the number of bidders involved. In carrying out this paragraph, the Secretary shall ensure that the Federal Government, with respect to the drug, biologic, or other health care technology involved, is charged an amount that is not more than the lowest amount charged for the same drug, biologic, or technology to countries in the Organization for Economic Co-Operation and Development and that have the largest gross domestic product of countries with a per capita income that is not less than half the per capita income of the United States.

(2) For the purposes of paragraph (1), a reasonable pricing formula described in such paragraph shall be considered to result in discriminatory pricing if the contract for sale of the drug, biologic, or other health care technology places a limit on supply, or employs any other measure, that has the effect of—

(A) providing access to such drug, biologic, or technology to the Federal Government or entity in the United States on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the drug, biologic, or technology; or

(B) restricting access to the drug, biologic, or technology under this section.

(c) No waiver under subsection (a) shall take effect before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

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