

AMENDMENT TO RULES COMM. PRINT 115-23
OFFERED BY MS. PLASKETT OF VIRGIN ISLANDS

At the end of subtitle B of title VII, add the following new section:

1 **SEC. 7 ____ . REASONABLE PRICE AGREEMENT RELATING TO**
2 **ZIKA VIRUS.**

3 (a) IN GENERAL.—If the Department of Defense or
4 any nonprofit entity using funding provided by the De-
5 partment undertakes health care research and develop-
6 ment and is to convey or provide a patent for a drug, bio-
7 logic, or other health care technology, relating to Zika
8 virus, the Department or entity shall not make such con-
9 veyance or provide such patent until the entity (including
10 a nonprofit entity) that will receive such patent first
11 agrees to a reasonable pricing agreement with the Sec-
12 retary of Defense (referred to in this section as the “Sec-
13 retary”) or the Secretary makes a determination that the
14 public interest is served by a waiver of the reasonable pric-
15 ing agreement provided in accordance with subsection (c).

16 (b) EXCLUSIVE RIGHTS TO RESEARCH.—

17 (1) IN GENERAL.—In cases where the Depart-
18 ment of Defense (or a nonprofit entity described in
19 subsection (a)) conveys or licenses exclusive rights to

1 a drug, biologic, or other health care technology, re-
2 lating to Zika virus developed through federally
3 funded research under subsection (a), the Secretary
4 may—

5 (A) apply for, obtain, and maintain patents
6 or other forms of protection in the United
7 States and in foreign countries on a drug, bio-
8 logic, or other health care technology resulting
9 from such research in which the Federal Gov-
10 ernment owns a right, title, or interest;

11 (B) grant nonexclusive, exclusive, or par-
12 tially exclusive licenses under a drug, biologic,
13 or other health care technology resulting from
14 such research, royalty-free or for royalties or
15 other consideration, and on such terms and
16 conditions, including the grant to the licensee of
17 the right of enforcement pursuant to the provi-
18 sions of chapter 29 of title 35, United States
19 Code, as determined appropriate in the public
20 interest;

21 (C) undertake all other suitable and nec-
22 essary steps to protect and administer rights to
23 a drug, biologic, or other health care technology
24 resulting from such research on behalf of the
25 Federal Government either directly or through

1 contract, including acquiring rights for and ad-
2 ministering royalties to the Federal Government
3 for any such drug, biologic, or technology, but
4 only to the extent the party from whom the
5 rights are acquired voluntarily enters into the
6 transaction, to facilitate the licensing of such
7 drug, biologic, or technology; and

8 (D) transfer custody and administration,
9 in whole or in part, to another Federal agency,
10 of the right, title, or interest in any drug, bio-
11 logic, or other health care technology resulting
12 from such research.

13 (2) PROHIBITION OF DISCRIMINATION.—

14 (A) IN GENERAL.—For purposes of para-
15 graph (1), any cost based reasonable pricing
16 formula that is utilized shall not result in dis-
17 criminatory pricing for the drug, biologic, or
18 other health care technology, relating to Zika
19 virus involved. In carrying out this subpara-
20 graph, the Secretary shall ensure that the De-
21 partment of Defense, with respect to the drug,
22 biologic, or other health care technology in-
23 volved, is charged an amount that is not more
24 than the lowest amount charged to countries in
25 the Organization for Economic Co-Operation

1 and Development for the same drug, biologic, or
2 technology, that have the largest gross domestic
3 product with a per capita income that is not
4 less than half the per capita income of the
5 United States.

6 (B) DISCRIMINATORY PRICING.—For the
7 purposes of subparagraph (A), a cost based rea-
8 sonable pricing formula that is utilized shall be
9 considered to result in discriminatory pricing if
10 the contract for sale of the drug, biologic, or
11 other health care technology, relating to Zika
12 virus places a limit on supply, or employs any
13 other measure, that has the effect of—

14 (i) providing access to such drug, bio-
15 logic, or technology on terms or conditions
16 that are less favorable than the terms or
17 conditions provided to a foreign purchaser
18 (other than a charitable or humanitarian
19 organization) of the drug, biologic, or tech-
20 nology; or

21 (ii) restricting access to the drug, bio-
22 logic, or technology under this section.

23 (c) WAIVER.—No waiver shall take effect under sub-
24 section (a) before the public is given notice of the proposed
25 waiver and provided a reasonable opportunity to comment

1 on the proposed waiver. A decision to grant a waiver shall
2 set out the Secretary's finding that such a waiver is in
3 the public interest.

