## AMENDMENT TO RULES COMMITTEE PRINT 117– 10

## OFFERED BY MR. BUCSHON OF INDIANA

In section 2—

- (1) redesignate subsections (d) and (e) as subsections (e) and (f), respectively; and
  - (2) insert after subsection (c) the following:
- 1 (d) Drugs and Devices.—No person shall be liable
- 2 under the Comprehensive Environmental Response, Com-
- 3 pensation, and Liability Act of 1980 (42 U.S.C. 9601 et
- 4 seq.) for the costs of responding to, or damages resulting
- 5 from, a release to the environment of a perfluoroalkyl or
- 6 polyfluoroalkyl substance designated as a hazardous sub-
- 7 stance under section 102(a) of such Act that is related
- 8 to the manufacture of a drug or device (as such terms
- 9 are defined in section 201 of the Federal Food, Drug, and
- 10 Cosmetic Act (21 U.S.C. 321)) that is approved, licensed,
- 11 cleared, or authorized by, or otherwise legally registered
- 12 and listed with, the Food and Drug Administration.
  - Page 9, line 14, strike "For a period" and insert "Except as provided in paragraph (3), for a period".
    - Page 10, after line 2, insert the following:

1 "(3) EXEMPTION FOR MANUFACTURE OF 2 DRUGS AND DEVICES.—This subsection shall not 3 apply with respect to a notice described in para-4 graph (1) that is related to the manufacture of a 5 drug or device (as such terms are defined in section 6 201 of the Federal Food, Drug, and Cosmetic Act 7 (21 U.S.C. 321)) that is approved, licensed, cleared, 8 or authorized by, or otherwise legally registered and 9 listed with, the Food and Drug Administration.".

Section 8(b) is amended by adding at the end the following: "In revising such list, the Administrator shall exclude from any category or subcategory so listed a source whose emissions of such a substance are related to the manufacture of a drug or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is approved, licensed, cleared, or authorized by, or otherwise legally registered and listed with, the Food and Drug Administration.".

Page 25, after line 13, insert the following:

"(3) EXEMPTION.—Paragraph (1)(C) shall not apply with respect to a drug or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) containing perfluoroalkyl and polyfluoroalkyl substances, that is approved, licensed, cleared, or authorized by, or otherwise legally registered and listed with, the Food and Drug Administration.".

