AMENDMENT TO RULES COMMITTEE PRINT 118-10

OFFERED BY MS. DEAN OF PENNSYLVANIA

At the appropriate place in subtitle A of title XVIII, insert the following:

SEC. ___. CURRENTLY ACCEPTED MEDICAL USE WITH SEVERE RESTRICTIONS.

(a) DEFINITIONS.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) by redesignating paragraph (58) (defining a serious violent felony) as paragraph (59);

(2) by redesignating the second paragraph (57) (defining a serious drug felony) as paragraph (58); and

(3) by adding at the end the following:

''(60)(A) Subject to subparagraph (B), the term 'currently accepted medical use with severe restrictions', with respect to a drug or other substance, includes a drug or other substance that is an active metabolite, moiety, or ingredient (whether in natural or synthetic form) of an investigational new drug for which a waiver is in effect under section 505(i) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) and that the Secretary—

''(i) designates as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)); or

''(ii) authorizes for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), either alone or as part of a therapeutic protocol, to treat patients with serious or life-threatening diseases for which no comparable or satisfactory therapies are available.

''(B) A drug or other substance shall not be treated as meeting the criteria under subparagraph (A) for having a currently accepted medical use with severe restrictions if—

''(i) in the case of a drug or other substance described in subparagraph (A)(ii)—

''(I) the Secretary places the expanded access or protocol for such drug on clinical hold as described in section 312.42 of title 21, Code of Federal Regulations (or any successor regulations);

''(II) there is no other investigational new drug containing the drug or other substance for which expanded access has been authorized under section 561(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(a)); and

''(III) the drug or other substance does not meet the requirements of subparagraph (A)(i); or

''(ii) the drug or other substance is approved 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).''.

(b) AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES.—Section 201(j) of the Controlled Substances Act (21 U.S.C. 811(j)) is amended—

(1) in paragraph (1), by inserting ''a drug designated as a breakthrough therapy under section 506(a) of the Food Drug and Cosmetic Act (21 U.S.C. 356(a)), or a drug authorized for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb),'' after ''subsection (f),'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(B) in subparagraph (B), by striking the period at the end and inserting a semicolon ; and

(C) by adding at the end the following:

''(C) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has designated the drug as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) or authorized the drug for expanded access under subsection (b) or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb); or

''(D) the date on which the Attorney General receives any written notification demonstrating that the Secretary, before the date of enactment of this subparagraph, designated the drug as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) or authorized the drug for expanded access under subsection (b)

or (c) of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).'';

(3) in paragraph (3), by inserting ''or paragraph (4)'' after ''paragraph (1)''; and

(4) by adding at the end the following:

''(4) With respect to a drug moved from schedule I to schedule II pursuant to paragraph (1) and the expedited procedures described under this subsection, if the drug no longer has a currently accepted medical use with severe restrictions and the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule I pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after receiving written notification from the Secretary, issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3) of this subsection.''.