AMENDMENT TO RULES COMMITTEE PRINT 119-8
OFFERED BY MR. VINDMAN OF VIRGINIA

Page 927, insert after line 16 the following:

SEC. 17___. SCHEDULE I CLASSIFICATION OF NITAZENES.

(a) AMENDMENT.—Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of Schedule I the following:

''(f) Benzimidazole-opioids, commonly referred to as nitazenes, including any substance (including its salts, isomers, and salts of isomers) that has a chemical structure that is substantially similar to that of etonitazene or isotonitazene, including:

''(1) A benzimidazole core substituted at the 2-position with a benzyl or substituted benzyl group; and

''(2) A basic nitrogen-containing side chain at the 1-position; and

''(3) Exhibits agonist activity at the mu-opioid receptor.

Such substances include, but are not limited to: etonitazene, clonitazene, metonitazene, isotonitazene, protonitazene, butonitazene, etodesnitazene, flunitazene,

N-pyrrolidino etonitazene, N-desethyl isotonitazene, and N-piperidinyl etonitazene.‴".

(b) REMOVAL OF TEMPORARY STATUS.—Any substance included in the amendment to section 202(c) of the Controlled Substances Act made by this section that was temporarily scheduled under section 201(h) of the Controlled Substances Act shall be deemed permanently scheduled and subject to the requirements of Schedule I as of the date of enactment of this section.

(c) RULEMAKING AUTHORITY.—The Attorney General, in consultation with the Secretary of Health and Human Services, may issue rules to clarify the scope of the nitazene class as necessary to enforce this section, provided such rules are consistent with the chemical definition in subsection (a)(1).

(d) RESEARCH EXEMPTION.—

(1) Notwithstanding the amendments made by subsection (a), a researcher who, as of the date of enactment of this section, is conducting research involving a substance described in subsection (a) that was not previously listed in Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), shall not be required to obtain a registration under section 303(f) of such Act (21 U.S.C.

823(f)) solely due to the inclusion of that substance in Schedule I, provided that:

(A) the research is being conducted pursuant to an active investigational new drug (IND) application or other applicable regulatory exemption recognized by the Food and Drug Administration or Drug Enforcement Administration;

(B) the research was approved by an institutional review board (IRB) prior to the enactment of this secto;

(C) the researcher notifies the Attorney General, in a manner determined by the Attorney General, within 90 days of enactment of this section.

(2) The exemption under paragraph (1) shall remain in effect for a period not to exceed 18 months from the date of enactment, during which time the researcher may apply for a registration under section 303(f), and the Attorney General shall expedite such applications to ensure continuity of research.

(3) Nothing in this subsection shall be construed to authorize the initiation of new research

using substances described in subsection (a) without proper registration and scheduling compliance.

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