MOTION TO RECOMMIT S. 204, WITH INSTRUCTIONS

OFFERED BY M__. _____

M__._____ of _____

moves to recommit the bill S. 204 to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith, with the following amendment:

Strike all after section 1 and insert the following:

SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

"SEC. 561B. ELIGIBLE INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.

''(a) USE OF CLINICAL OUTCOMES.—

''(1) IN GENERAL.—The Secretary shall issue guidance describing the Secretary's consideration and evaluation, for purposes of the review of, and decision on whether to approve, a marketing applica-

tion under section 505 of this Act or section 351 of the Public Health Service Act for an eligible investigational drug, of clinical outcomes associated with the provision by a sponsor or manufacturer of such drug under subsection (b) or (c) of section 561. Such guidance shall address—

''(A) specific instances in which the Secretary will determine that the public health requires such consideration and evaluation;

''(B) specific instances in which a sponsor may request such consideration and evaluation; and

''(C) the context in which such consideration and evaluation will occur, particularly with regard to information and data relevant to the evaluation of a marketing application under section 505 of this Act or section 351 of the Public Health Service Act for the eligible investigational drug.

''(2) GUIDANCE.—

''(A) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue draft guidance with a public comment period regarding the use of clinical outcomes associated with the use of an

eligible investigational drug that a sponsor or manufacturer has provided under subsection (b) or (c) of section 561, as described in paragraph (1).

''(B) FINAL GUIDANCE.—Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue final guidance.

''(b) POSTING OF INFORMATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall post on the internet website of the Food and Drug Administration and update annually, categorized by therapeutic area—

''(1) the number of requests that were received by the Food and Drug Administration for the provision by a sponsor or manufacturer of an eligible investigational drug under subsection (b) or (c) of section 561; and

''(2) the number of such requests that were granted.

''(c) DEFINITION.—In this section, the term 'eligible investigational drug' means an investigational drug (as such term is used in section 561)—

''(1) for which a Phase 1 clinical trial has been completed;

''(2) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act;

''(3)(A) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act; or

''(B) that is under investigation in a clinical trial that—

''(i) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 505 of this Act or section 351 of the Public Health Service Act; and

''(ii) is the subject of an active investigational new drug application under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, as applicable; and

''(4) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 505(i); and''.

(b) REPORTING.—Section 561A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0) is amended adding at the end the following:

''(g) REPORTING.—

''(1) IN GENERAL.—The manufacturer or sponsor of an eligible investigational drug shall post on the same publicly available internet website used by the manufacturer for purposes of subsection (b) of this section an annual summary of any provision by the manufacturer or sponsor of an eligible investigational drug under subsection (b) or (c) of section 561. The summary shall include the number of requests received, the number of requests granted, the number of patients treated, the therapeutic area of the drug made available, and any known or suspected serious adverse events. Such annual summary shall be provided to the Secretary upon request.

''(2) DEFINITION.—In this subsection, the term 'eligible investigational drug' has the meaning given to such term in section 561B(c).''.

(c) LIABILITY.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following:

''(e) LIABILITY.—

''(1) ALLEGED ACTS OR OMISSIONS.—

''(A) MANUFACTURER OR SPONSOR.—No manufacturer or sponsor (or their agent or representative) of an eligible investigational drug provided to a single patient or small group of patients for treatment use shall be liable for any alleged act or omission related to the provision of such drug, so long as such drug was provided in accordance with subsection (b) or (c), including the reporting of safety information, from clinical trials or any other source, as required pursuant to section 312.32 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) PHYSICIAN, CLINICAL INVESTIGATOR, OR HOSPITAL.—

''(i) No licensed physician, clinical investigator, or hospital shall be liable for any alleged act or omission related to the provision to a single patient or small group of patients for treatment use of an eligible investigational drug in accordance with the requirements described in clause (ii), unless such act or omission constitutes on the part of such physician, clinical investigator,

or hospital with respect to such eligible investigational drug—

''(I) willful or criminal misconduct;

''(II) reckless misconduct;

''(III) gross negligence relative to the applicable standard of care and practice with respect to the administration or dispensing of such eligible investigational drug; or

''(IV) an intentional tort under applicable State law.

''(ii) The requirements described in this clause are the requirements under subsection (b) or (c), including—

''(I) the reporting of safety information, from clinical trials or any other source, as required pursuant to under section 312.32 of title 21, Code of Federal Regulations (or any successor regulations);

''(II) ensuring that the informed consent requirements of part 50 of title 21, Code of the Federal Regula-

tions (or any successor regulations) are met; and

''(III) ensuring that review by an institutional review board is obtained in a manner consistent with the requirements of part 56 of title 21, Code of the Federal Regulations (or any successor regulations).

''(2) DETERMINATION NOT TO PROVIDE DRUG.—No manufacturer, sponsor, licensed physician, clinical investigator, or hospital, nor the Secretary, shall be liable for determining not to provide access to an eligible investigational drug under this section or for discontinuing any such access that it initially determined to provide.

''(3) LIMITATION.—

''(A) IN GENERAL.—Except as set forth in paragraphs (1) and (2), nothing in this section or section 561B shall be construed to modify or otherwise affect the right of any person to bring a private action against a manufacturer or sponsor (or their agent or representative), physician, clinical investigator, hospital, prescriber, dispenser, or other entity under any State or

Federal product liability, tort, consumer protection, or warranty law.

''(B) FEDERAL GOVERNMENT.—Nothing in this section or section 561B shall be construed to modify or otherwise affect the authority of the Federal Government to bring suit under any Federal law.

''(2) DEFINITION.—In this subsection, the term 'eligible investigational drug' has the meaning given to such term in section 561B(c).''.