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FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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

(a) DEFINITIONS.—For purposes of this section:

(1) The term "eligible patient" means a patient—

(A) who has been diagnosed with an eligible illness;

(B) who has exhausted approved treatment options and is not eligible to participate in (for a reason such as the patient not meeting inclusion criteria) a clinical trial designed to evaluate an investigational drug for the treatment of such eligible illness with which the patient has been diagnosed, including one involving the eligible investigational drug, or for whom participation in such a clinical trial is not feasible (for a reason such as a lack of geographic proximity to the clinical trial), as certified by a physician, who—

(i) is in good standing with the physician's licensing organization or board; and

(ii) will not be compensated for so certifying; and

(C) who has provided to the treating physician written informed consent, as described in part 50 of title 21, Code of Federal Regulations (or any successor regulations), regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent.

(2) The term "eligible investigational drug" means an investigational drug (as such term is used in section 561)—

(A) for which a phase 1 clinical trial has been completed;

(B) 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;

(C)(i) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act, as applicable, that is active; or

(ii) 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

(D) the active development or production of which—

(i) is ongoing;

(ii) has not been discontinued by the manufacturer; and

(iii) is not the subject of a clinical hold under the regulations implementing section 505(i) or section 351(a)(3) of the Public Health Service Act, as applicable.

(3) The term "phase 1 trial" means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

(4) The term "eligible illness" means—

(A) a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months; or

(B) a disease or condition that would result in significant irreversible morbidity that is likely to lead to severely premature death.

(b) ALTERNATIVE PATHWAY FOR ELIGIBLE PATIENTS WITH A TERMINAL ILLNESS.—

(1) IN GENERAL.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), and subsections (a) and (i) of section 505 of this Act, and section 351(a) of the Public Health Service Act so long as the conditions specified in paragraphs (2), (3), and (4) are met with respect to the provision of such investigational drugs.

(2) COMPLIANCE WITH CERTAIN REGULATIONS.—The conditions specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), are that—

(A) the eligible investigational drug is labeled in accordance with section 312.6 of title 21, Code of Federal Regulations (or any successor regulations); and

(B) the provision of such eligible investigational drug occurs in compliance with the applicable requirements set forth in sections 312.7 and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs, subject to paragraph (5).

(3) NOTIFICATION.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor of such eligible investigational drug notifies the Secretary of the provision of such eligible investigational drug for use by an eligible patient pursuant to this section. Such notification shall be submitted within 7 business days of the provision of such eligible investigational drug as correspondence to the investigational new drug application described in subsection (a)(2).

(4) ADVERSE EVENT REPORTING.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor or manufacturer of such eligible investigational drug has required, as a condition of providing the drug to a physician for use by an eligible patient pursuant to this section, that such physician will immediately report to such sponsor or manufacturer any serious adverse events, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug by the eligible patient.

(5) APPLICATION.—For purposes of this section, the requirements set forth in sections 312.7 and 312.8(d)(1) of title 21 of the Code of Federal Regulations (or any successor regulations) are deemed to apply to any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section.

(c) USE OF CLINICAL OUTCOMES.—

(1) IN GENERAL.—Notwithstanding any other provision of this Act, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act unless—

(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

(B) the sponsor requests use of such outcomes.

(2) LIMITATION.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

(d) REPORTING.—The manufacturer or sponsor of an eligible investigational drug that provides an eligible investigational drug pursuant to this section shall post on the same publicly available internet website used by the manufacturer for purposes of section 561A(b) an annual summary of

any provision by the manufacturer or sponsor of an eligible investigational drug under this section. 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, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug.

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting the authority of the Secretary to require manufacturers or sponsors of investigational drugs to review and report information relevant to the safety of such investigational drug obtained or otherwise received by the sponsor pursuant to part 312 of title 21, Code of Federal Regulations (or successor regulations).

(f) LIABILITY.—

(1) ALLEGED ACTS OR OMISSIONS.—

(A) MANUFACTURER OR SPONSOR.—No manufacturer or sponsor (or their agent or representative) of an investigational drug shall be liable for any alleged act or omission related to the provision of such drug to a single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561 or the provision of an eligible investigational drug to an eligible patient in accordance with this section, including, with respect to the provision of an investigational drug under section 561 or an eligible investigational drug under this section, the reporting of safety information, from clinical trials or any other source, as required by 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 of an investigational drug to a single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561, as described in clause (ii), or the provision of an eligible investigational drug to an eligible patient in accordance with this section, unless such act or omission constitutes on the part of such physician, clinical investigator, or hospital with respect to such investigational drug or 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 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) of section 561, including—

(I) the reporting of safety information, from clinical trials or any other source, as required by 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 Regulations (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 shall be liable for determining not to provide access to an 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 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 shall be construed to modify or otherwise affect the authority of the Federal Government to bring suit under any Federal law.

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