AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5247 OFFERED BY MR. PALLONE OF NEW JERSEY

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018''.

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. 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 application under section 505 of this Act or section 351 of

the Public Health Service Act for an 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 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''(A) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue draft guidance with a public comment period regarding the use of clinical outcomes associated with the use of an investigational drug that a sponsor or manufac-

turer 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''(B) FINAL GUIDANCE.—Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue final guidance.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 investigational drug under subsection (b) or (c) of section 561; and

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

(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.—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 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.''.

(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 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 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 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 adminis-

tration 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), 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 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, nor the Secretary, 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 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.''.