

As you know, my Administration is pursuing the renegotiation of the North American Free Trade Agreement—something many have promised but have failed to deliver. In addition, my Administration is exploring potential trade agreement partners, including in Africa and Southeast Asia.

I hope my Administration can continue to work with the Congress to pursue new and better trade deals for America's workers, farmers, ranchers, and businesses. Extension of trade authorities procedures is essential to fulfill that task and to demonstrate to our trading partners that my Administration and the Congress share a common goal when it comes to trade.

DONALD J. TRUMP.
THE WHITE HOUSE, March 20, 2018.

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, March 21, 2018.

Hon. PAUL D. RYAN,
The Speaker, House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on March 21, 2018, at 8:52 a.m.:

That the Senate passed S. 899.
With best wishes, I am
Sincerely,

KAREN L. HAAS.

PROTECT SPECIAL COUNSEL MUELLER

(Mr. COHEN asked and was given permission to address the House for 1 minute.)

Mr. COHEN. Mr. Speaker, on Monday, I addressed this House on the issue of Mr. Mueller and his important investigation in the Special Counsel's Office.

I am concerned, as we leave on Thursday or Friday, that the President could fire Mr. Rosenstein—who has authority over Mr. Mueller—or fire Mr. Sessions and put somebody in who will jeopardize Mr. Mueller's investigation.

Accordingly, a bill I have, H.R. 4669, was filed in December to protect Mr. Mueller. It gives him due process rights—if he is fired—to go to court before a three-judge Federal panel to show that he was fired for purposes which were political and not relating to his job performance.

I am filing a discharge petition today. I will be filing it in 10 minutes, asking all Members of the House to sign it; to bring this bill to the floor immediately for a vote so that we can protect the special counsel, protect Mr. Mueller, and protect America.

God Bless America.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 11 o'clock and 21 minutes a.m.), the House stood in recess.

□ 1300

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. POE of Texas) at 1 p.m.

TRICKETT WENDLER, FRANK
MONGIELLO, JORDAN McLINN,
AND MATTHEW BELLINA RIGHT
TO TRY ACT OF 2018

Mr. BURGESS. Mr. Speaker, pursuant to House Resolution 787, I call up the bill (H.R. 5247) to authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Pursuant to House Resolution 787, the bill is considered read.

The text of the bill is as follows:

H.R. 5247

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) 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) 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