along the coastline within Acadia's boundaries. There was no warning about changing a practice that had, frankly, gone on for decades. I appreciate the fact that park officials quickly ended their enforcement, but the actions sent shock waves throughout the area.

Washington County is the poorest county in Maine, and families there simply just can't afford to lose any source of income. H.R. 4266 would give the communities a sense of security by very explicitly stating that harvesters have a right to work within the park. It is a critical step to ensuring that Acadia National Park remains an attraction not only for its natural beauty, but for its unique way of life.

Again, I want to thank my colleague, Mr. POLIQUIN, for recognizing the issue, for working with his harvesters, and for moving this forward. I am proud to be an original cosponsor. I urge its passage and urge all my colleagues to support it.

Mr. LOWENTHAL. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I thank both Mr. POLIQUIN and Ms. PINGREE for introducing this legislation to protect a true New England treasure, Acadia National Park.

Mr. Speaker, I urge a ''yea'' vote on this bill, and I yield back the balance of my time.

Mr. CURTIS. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Utah (Mr. CURTIS) that the House suspend the rules and pass the bill, H.R. 4266.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

MODIFYING THE BOUNDARY OF VOYAGEURS NATIONAL PARK

Mr. CURTIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1350) to modify the boundary of Voyageurs National Park in the State of Minnesota, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1350

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

SECTION 1. MODIFICATION OF VOYAGEURS NATIONAL PARK.

(a) BOUNDARIES.—

(1) IN GENERAL.—Section 102(a) of Public Law 91–661 (16 U.S.C. 160a–1(a)) is amended—

(A) in the first sentence, by striking ''the drawing entitled'' and all that follows through ''February 1969'' and inserting ''the map entitled 'Voyageurs National Park, Proposed Land Transfer & Boundary Adjustment', numbered 172/80,056, and dated June 2009 (22 sheets)''; and

(B) in the second and third sentences, by striking ''drawing'' each place it appears and inserting ''map''.

(2) TECHNICAL CORRECTIONS.—Section 102(b)(2)(A) of Public Law 91–661 (16 U.S.C. 160a–1(b)(2)(A)) is amended—

(A) by striking ''paragraph (1)(C) and (D)'' and inserting ''subparagraphs (C) and (D) of paragraph (1)''; and

(B) in the second proviso, by striking ''paragraph 1(E)'' and inserting ''paragraph (1)(E)''.

(b) LAND ACQUISITIONS.—Section 201 of Public Law 91–661 (16 U.S.C. 160b) is amended—

(1) by striking the section designation and heading and all that follows through ''(a) The Secretary'' and inserting the following:

''SEC. 201. LAND ACQUISITIONS.

''(a) AUTHORIZATION.—

''(1) IN GENERAL.—The Secretary'';

(2) in subsection (a)—

(A) in the second sentence, by striking ''When any tract of land is only partly within such boundaries'' and inserting the following:

''(2) CERTAIN PORTIONS OF TRACTS.—

''(A) IN GENERAL.—In any case in which only a portion of a tract of land is within the boundaries of the park'';

(B) in the third sentence, by striking ''Land so acquired'' and inserting the following:

''(B) EXCHANGE.—

''(i) IN GENERAL.—Any land acquired pursuant to subparagraph (A)'';

(C) in the fourth sentence, by striking ''Any portion'' and inserting the following:

''(ii) PORTIONS NOT EXCHANGED.—Any portion'';

(D) in the fifth sentence, by striking ''Any Federal property'' and inserting the following:

''(C) TRANSFERS OF FEDERAL PROPERTY.—Any Federal property''; and

(E) by striking the last sentence and inserting the following:

''(D) ADMINISTRATIVE JURISDICTION.—Effective beginning on the date of enactment of this subparagraph, there is transferred to the National Park Service administrative jurisdiction over—

''(i) any land managed by the Bureau of Land Management within the boundaries of the park, as depicted on the map described in section 102(a); and

''(ii) any additional public land identified by the Bureau of Land Management as appropriate for transfer within the boundaries of the park.

''(E) LAND OWNED BY STATE.—

''(i) DONATIONS AND EXCHANGES.—Any land located within or adjacent to the boundaries of the park that is owned by the State of Minnesota (or a political subdivision of the State) may be acquired by the Secretary only through donation or exchange.

''(ii) REVISION.—On completion of an acquisition from the State under clause (i), the Secretary shall revise the boundaries of the park to reflect the acquisition.''; and

(3) in subsection (b), by striking ''(b) In exercising his'' and inserting the following:

''(b) OFFERS BY INDIVIDUALS.—In exercising the''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Utah (Mr. CURTIS) and the gentleman from California (Mr. LOWENTHAL) each will control 20 minutes.

The Chair recognizes the gentleman from Utah.

GENERAL LEAVE

Mr. CURTIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous material on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Utah?

There was no objection.

Mr. CURTIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, Voyageurs National Park, established in 1975, is a 218,200-acre national park located on the northern border of Minnesota. The name ''Voyageurs'' commemorates the French-Canadian fur traders who were the first European settlers to frequent the area. The park has remarkable water resources and islands and is popular with canoeists, kayakers, other boaters, and fishermen.

The Bureau of Land Management currently manages lands within the boundaries of the park that were not transferred to the National Park Service at the park's establishment. H.R. 1350 formally transfers these Bureau of Land Management lands to the National Park Service. Enactment of the legislation is expected to save taxpayer money and agency time by eliminating duplicative land management.

In addition, this legislation resolves an outstanding land management issue faced by the State of Minnesota and a county by authorizing a land exchange between the State and the National Park Service. Certain State tax-forfeited tracts within the boundaries of Voyageurs National Park will be traded for a National Park Service-owned tract outside the park boundary.

Mr. Speaker, I urge adoption of the measure, and I reserve the balance of my time.

Mr. LOWENTHAL. Mr. Speaker, I yield such time as he may consume to the gentleman from Minnesota (Mr. NOLAN), the bill's sponsor. I thank him for his excellent work on this issue.

Mr. NOLAN. Mr. Speaker, I want to thank my dear friend and colleague from California (Mr. LOWENTHAL) for his distinguished service. I thank Mr. CURTIS for his distinguished service as well. I also thank Mr. BISHOP, all the members of the committee, and the staff, of course, for the wonderful work they have done on this.

Mr. Speaker, I rise here to join in support of H.R. 1350.

Basically, as was explained by Mr. CURTIS, the bill authorizes a land transfer between the Bureau of Land Management and the National Park Service, a move that would greatly improve the overall land management and efficiency within the Voyageurs National Park in my district in northern Minnesota. I might add, we are very proud of that accomplishment.

Specifically, the bill permits the transfer of 49 acres of land within the park from the jurisdiction of the Bureau of Land Management to the National Park Service, as was originally intended by the original legislation for the park when it was signed into law; but, for a variety of reasons, these 49 acres, including 61 separate tracts of land, were not included in the original Federal legislation that established the park in 1975.

It may interest some of my colleagues to know that I was here in 1975 and was able to, of course, register my support for the establishment of that park.

Now, to be clear, the National Park Service administration already manages the 49 acres; but without a change in the law that permanently transfers the lands, a cumbersome and duplicative renewal process is required every 20 years. The procedure involves a notice, a publication in the Federal Register, and a review of comments, all of which are, essentially, a waste of taxpayers' money and everybody's time within the government who has to deal with it.

So make no mistake about it, as Mr. CURTIS pointed out, this bill saves the taxpayers' money and the bureaucracy time.

In addition, the bill would also authorize the National Park Service to acquire and integrate new land into Voyageurs National Park through land exchanges with the State and local governments that own land within or adjacent to the park's boundaries.

In short, Mr. Speaker, this bill would eliminate any future concerns related to the Department of the Interior's ownership and jurisdiction, facilitating the ease of management for the National Park Service, the State, and the county; and it would do so at no cost, in addition, of course, to saving money for the Federal Government as determined by the Congressional Budget Office.

Mr. Speaker, I urge my colleagues to adopt the measure.

Mr. LOWENTHAL. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, H.R. 1350 is a commonsense, good governance measure, and I want to congratulate Mr. NOLAN for his hard work in getting this bill through the legislative process.

Mr. Speaker, I urge my colleagues to support this bill, and I yield back the balance of my time.

Mr. CURTIS. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Utah (Mr. CURTIS) that the House suspend the rules and pass the bill, H.R. 1350.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

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

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass 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.

The Clerk read the title of the bill.

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 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