

(3) recognizes the challenges that individuals with medically determined ALS face on a daily basis; and

(4) commends the dedication of the family members, friends, organizations, volunteers, researchers, and caregivers across the United States that are working to improve the quality and length of life of ALS patients.

#### AMENDMENTS SUBMITTED AND PROPOSED

SA 1588. Mr. BRAUN submitted an amendment intended to be proposed by him to the bill S. 658, to provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries; which was referred to the Committee on Health, Education, Labor, and Pensions.

#### TEXT OF AMENDMENTS

**SA 1588.** Mr. BRAUN submitted an amendment intended to be proposed by him to the bill S. 658, to provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries; which was referred to the Committee on Health, Education, Labor, and Pensions; as follows:

Strike all after the enacting clause and insert the following:

##### SECTION 1. SHORT TITLE.

This Act may be cited as the "Accelerated Drug Approval for Prescription Therapies Act" or the "ADAPT Act".

##### SEC. 2. ACCELERATED APPROVAL OF CERTAIN DRUGS THAT ARE AUTHORIZED TO BE LAWFULLY MARKETED IN OTHER COUNTRIES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506 the following:

##### "SEC. 506-1. ACCELERATED APPROVAL OF CERTAIN DRUGS THAT ARE AUTHORIZED TO BE LAWFULLY MARKETED IN OTHER COUNTRIES.

"(a) IN GENERAL.—The Secretary may approve an application for approval for a drug or vaccine under subsection (c) or (j) of section 505 of this Act or under subsection (a) or (k) of section 351 of the Public Health Service Act that is currently authorized to be marketed in one or more of the countries included in the list under section 802(b)(1) or the United Kingdom, upon a determination by the Secretary that the sponsor has submitted evidence sufficient to demonstrate all of the criteria under subsection (b)(1).

"(b) CRITERIA.—

"(1) IN GENERAL.—The Secretary may approve a drug or vaccine under subsection (a) only if the Secretary determines that there is evidence that—

"(A) at the time of application, the drug or vaccine is authorized to be marketed in a country included in the list under section 802(b)(1) or the United Kingdom;

"(B) the drug or vaccine is safe and clinically effective;

"(C) the manufacturer is capable of manufacturing the drug or vaccine safely and consistently, and can assure the safety of the supply chain outside the United States;

"(D) all relevant United States patents or legal exclusivities are expired;

"(E) absent reciprocal marketing approval, the drug or vaccine is not approved for marketing in the United States;

"(F) the Secretary has not, because of any concern relating to safety or effectiveness, rescinded or withdrawn any such approval; and

"(G) the drug or vaccine is intended for the treatment or prevention of a disease or condition that poses a threat of epidemic or pandemic, including with respect to the coronavirus, or the drug is intended to treat the coronavirus, including reduced risk of death, severe disease, and progression of symptoms in individuals exposed to the virus.

"(2) LIMITATION.—Approval of a drug or vaccine under this section may, as the Secretary determines appropriate, be subject to 1 or both of the following requirements:

"(A) The sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the drug or vaccine.

"(B) The sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(c) TIMELINE.—

"(1) IN GENERAL.—The Secretary shall make a determination on an application described in subsection (a) not later than 30 days after the date of submission of such application.

"(2) REVIEW OF APPLICATIONS DURING EPIDEMICS AND PANDEMICS.—In the case of an epidemic or pandemic, including with respect to the coronavirus, the Secretary shall accept and review various portions of an application submitted under this section on a rolling basis, and the review of any part of an application so submitted shall be completed not later than 3 weeks after submission.

"(d) CORONAVIRUS DEFINED.—The term 'coronavirus' means SARS-CoV-2, COVID-19, or another coronavirus with epidemic potential.

"(e) REAL-TIME EPIDEMIC AND PANDEMIC VACCINE APPROVAL.—

"(1) IN GENERAL.—In the case of a vaccine approved under the authority of this section that is intended to treat or prevent diseases or conditions that pose a threat of an epidemic or pandemic, including the coronavirus, the Secretary shall share data information regarding the approval of the vaccine with the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention as the review nears completion.

"(2) EVALUATION.—Any vaccine that has been approved under the authority of this section for an epidemic or pandemic-related disease or condition, including the coronavirus, shall be evaluated by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention not later than 1 week after the date of submission to the Advisory Committee by the Secretary of the vaccine."

#### AUTHORITY FOR COMMITTEES TO MEET

Mr. THUNE. Mr. President, I have 3 requests for committees to meet during today's session of the Senate. They have the approval of the Majority and Minority leaders.

Pursuant to rule XXVI, paragraph 5(a), of the Standing Rules of the Senate, the following committees are authorized to meet during today's session of the Senate:

#### COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

The Committee on Banking, Housing, and Urban Affairs is authorized to

meet during the session of the Senate on Tuesday, May 19, 2020, at 10 a.m., to conduct a hearing.

#### SELECT COMMITTEE ON INTELLIGENCE

The Select Committee on Intelligence is authorized to meet during the session of the Senate on Tuesday, May 19, 2020, at 9:30 a.m., to conduct a hearing.

#### SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR SAFETY

The Subcommittee on Clean Air and Nuclear Safety of the Committee on Environment and Public Works is authorized to meet during the session of the Senate on Tuesday, May 19, 2020, at 3 p.m., to conduct a hearing on the following nominations: Beth Harwell and Brian Noland to be Members of the Board of Directors, and Katherine Crytzer to be Inspector General of the Tennessee Valley Authority.

Mr. INHOFE. Mr. President, I have a request for one committee to meet during today's session of the Senate. It has the approval of the Majority and Minority leaders.

Pursuant to rule XXVI, paragraph 5(a), of the Standing Rules of the Senate, the following committee is authorized to meet during today's session of the Senate:

#### COMMITTEE ON ARMED SERVICES

The Committee on Armed Services is authorized to meet during the session of the Senate on Tuesday, May 19, 2020, at 2:30 p.m., to conduct a hearing on nominations.

#### RESOLUTIONS SUBMITTED TODAY

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate now proceed to the en bloc consideration of the following Senate resolutions which were submitted earlier today: S. Res. 584, S. Res. 585, S. Res. 586, S. Res. 587, and S. Res. 588.

There being no objection, the Senate proceeded to consider the resolutions en bloc.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the resolutions be agreed to, the preambles, where applicable, be agreed to, and the motions to reconsider be considered made and laid upon the table, all en bloc.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The resolution (S. Res. 584) was agreed to.

(The resolution is printed in today's RECORD under "Submitted Resolutions.")

The resolutions (S. Res. 585, S. Res. 586, S. Res. 587, and S. Res. 588) were agreed to.

The preambles were agreed to.

(The resolutions, with their preambles, are printed in today's RECORD under "Submitted Resolutions.")

#### ORDERS FOR WEDNESDAY, MAY 20, 2020

Mr. MCCONNELL. Mr. President, I ask unanimous consent that when the