

support of which is needed to ensure the effective implementation of the State and local elements of the management plan; and

(F) the management plan demonstrates sufficient partnerships among the Local Coordinating Entity, the Federal Government, State and local governments, regional planning organizations, nonprofit organizations, or private sector parties to implement the management plan.

(3) ACTION FOLLOWING DISAPPROVAL.—If the Secretary disapproves the management plan under paragraph (1), the Secretary shall—

(A) advise the Local Coordinating Entity in writing of the reasons for the disapproval;

(B) make recommendations for revisions to the management plan; and

(C) not later than 180 days after the receipt of any proposed revision of the management plan, approve or disapprove the proposed revision.

(e) AMENDMENTS.—

(1) IN GENERAL.—The Secretary shall review and approve any substantial amendments to the management plan in accordance with subsection (d).

(2) USE OF FUNDS.—Funds made available under this Act shall not be expended by the Local Coordinating Entity to implement any changes made by an amendment described in paragraph (1) until the Secretary approves the amendment.

(f) IMPLEMENTATION.—In implementing the management plan, the Local Coordinating Entity shall give priority to—

(1) carrying out programs that recognize important resource values within the Heritage Area;

(2) encouraging economic viability in the affected communities;

(3) establishing and maintaining interpretive exhibits within the Heritage Area;

(4) improving and interpreting heritage trails;

(5) increasing public awareness of, and appreciation for, the natural, historic, and cultural resources of the Heritage Area, including the contributions of local Indian tribes;

(6) providing opportunities for expanding the public perception of the need for modern resource development of the Heritage Area;

(7) restoring historic buildings and structures that are located within the Heritage Area; and

(8) ensuring that clear, consistent, and appropriate signs identifying public access points and sites of interest are appropriately placed in the Heritage Area.

#### SEC. 7. DUTIES AND AUTHORITIES OF THE SECRETARY.

(a) MEMORANDUM OF UNDERSTANDING.—The Secretary shall enter into a memorandum of understanding with the Secretary of the Interior to establish a general framework for cooperation and consultation in the development and implementation of the management plan.

(b) AUTHORITIES.—The Secretary may—

(1) subject to the availability of funds, provide technical and financial assistance for the development and implementation of the management plan;

(2) enter into cooperative agreements with interested parties to carry out this Act; and

(3) in partnership with the Local Coordinating Entity, provide information on, promote understanding of, and encourage research on the Heritage Area.

(c) INFORMATION RELEASED BY THE SECRETARY OF THE INTERIOR.—The Secretary of the Interior shall include the Heritage Area in all nationwide releases, listings, or maps that provide public information about the system of national heritage areas.

#### SEC. 8. PRIVATE PROPERTY PROTECTIONS.

(a) IN GENERAL.—Nothing in this Act—

(1) grants powers of zoning or management of land use to the Local Coordinating Entity;

(2) modifies, enlarges, or diminishes any authority of the Federal Government or any State, tribal, or local government to manage or regulate any use of land under applicable laws (including regulations);

(3) requires any private property owner to allow public access to the private property, including access by the Federal Government or tribal, State, or local governments;

(4) modifies any provision of Federal, tribal, State, or local law with respect to public access to, or use of, private property;

(5) obstructs or limits—

(A) business activities on private developments; or

(B) resource development activities;

(6) affects the rights of private property owners;

(7) restricts or limits an Indian tribe from protecting cultural or religious sites on tribal or Native Corporation land; or

(8) requires the owner of any private property located within the boundaries of the Heritage Area to participate in, or be associated with, the Heritage Area.

(b) APPLICABLE LAW.—Designation of the Heritage Area under this Act does not convey status to the Heritage Area as a conservation system unit (as defined in section 102 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3102)).

(c) LIABILITY.—Designation of the Heritage Area does not create any liability for, or affect any liability under any other law of, any private property owner with respect to a person injured on the private property.

(d) EFFECT OF ESTABLISHMENT.—Designation of the Heritage Area does not establish any regulatory authority on land use within the Heritage Area or the viewshed for the Federal Government or any State or local government.

#### SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Subject to subsection (b), there are authorized to be appropriated and made available to the Local Coordinating Entity to carry out the development and implementation of the management plan—

(1) \$350,000 for fiscal year 2008; and

(2) \$500,000 for fiscal year 2009 and each fiscal year thereafter.

(b) LIMITATION.—Notwithstanding subsection (a), not more than \$7,500,000 is authorized to be appropriated for the Heritage Area.

(c) COST SHARING REQUIREMENT.—To the maximum extent practicable, the Federal share of the total cost of any activity carried out using assistance under this Act shall be not more than 75 percent, including the contribution of in-kind services.

#### SEC. 10. TERMINATION OF AUTHORITY.

The authority of the Secretary to provide assistance under this Act terminates on the date that is 15 years after the date of enactment of this Act.

By Mr. BROWNBACK (for himself, Mr. CASEY, Mr. COLEMAN, Mr. SPECTER, and Mr. INHOFE):

S. 3046. A bill to amend the Federal Food, Drug, and Cosmetic Act to create a new conditional approval system for drugs, biological products, and devices that is responsive to the needs of seriously ill patients, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. BROWNBACK. Mr. President, I rise to speak about a bill I introduced today: the Access, Compassion, Care and Ethics for Seriously-ill Patients Act, ACCESS, Act. I would like to thank the original Senate cosponsors: Senators BOB CASEY, NORM CROLEMAN,

ARLEN SPECTER and JAMES INHOFE. I also especially thank Representative DIANNE WATSON who will be introducing the companion bill in the U.S. House of Representatives.

In the current era, certain cancers and other chronic diseases touch the lives of almost every American. If you have had the experience of a family member or friend struggling with terminal illness, you were probably aware of their need and limited timeline to access promising treatments. Unfortunately, the current system often does not work for the benefit of terminally-ill patients—during emotionally-charged times, patients and their families may face regulatory and bureaucratic hurdles if they wish to access investigational treatment options in order to preserve their lives. Many terminally-ill patients exhaust their treatment options and do not qualify for a clinical trial. They also do not physically have months to wait for an individual investigational treatment application to be approved.

In this day and age of scientific breakthroughs, we must embrace these advances and do so with a “patient-centered” mindset. Terminally-ill patients often reach a point where the potential benefits of these breakthrough treatments outweigh their inevitable risk of death from their disease.

I introduced the ACCESS Act to offer these patients an ethical option—compassionate access to treatments that show promise earlier in the drug development process. The average time for a treatment to go through the entire FDA approval process is 15 years. As a result, the current system tends to benefit future generations of patients with life-threatening diseases, rather than patients of the present time.

The ACCESS Act offers a new Compassionate Investigational Access approval system for treatments showing efficacy during clinical trials, for use by the seriously-ill patient population. Seriously-ill patients who have exhausted all alternatives and are seeking new treatment options, would be offered access to these treatments with the consent of their physician. This bill also improves upon the existing accelerated approval system, using a patient-centered framework. The ACCESS Act also makes a technical correction that will increase patient access to drugs used off-label to treat life-threatening diseases.

I ask my colleagues to join me in supporting the ACCESS Act that would offer patients, with little hope, a chance at life.

By Mr. BROWN:

S.J. Res. 33. A joint resolution recognizing the efforts of the Ohio Department of Mental Health and the Ohio Department of Alcohol and Drug Addiction Services to address the stigma associated with mental health and substance use disorders; to the Committee on Health, Education, Labor, and Pensions.