

Compassionate Access to Cancer Treatments

By Senator Sam Brownback

While it sometimes seems the Senate can hardly agree on anything, this year 92 senators sent an open letter to the White House making the case for an aggressive strategy to end death and suffering from cancer by 2015.

An important part of the war against cancer is the ACCESS Act, which provides seriously ill patients with cancer or other life-threatening diseases with accelerated access to promising treatments still in the investigation stage.

We need the ACCESS Act because it takes an average of 12 years to approve new drugs. But time is not on the side of late-stage cancer patients who have exhausted every treatment option. The least we can do is to provide these patients, under the supervision and sanction of their doctors, with quicker access to treatments that could improve their condition.

Through this legislation we can supplement the FDA's regular approval process by creating a parallel system for terminally ill patients who are currently blocked from clinical studies and compassionate access programs because of bureaucratic hurdles.

The ACCESS Act would create a new three-tiered approval system specifically for products that treat serious or life-threatening diseases. In essence, if a drug shows promise in one or both of the first two phases of the FDA's current approval process—meaning that it passes safety tests and holds meaningful promise as an effective treatment—patients with life-threatening diseases could access the drug before the traditional approval process is complete.

Furthermore, before providing early access to a new treatment, the FDA would evaluate the potential benefits of the treatment against the potential risks. If the risk of a patient's condition outweighs the risk of the treatment, and if the treatment holds promise to benefit the patient, the FDA could approve the product.

Only seriously ill patients who have exhausted all treatment options would have access to drugs approved under this new expedited approach. Given their terminal condition, when a drug meets safety standards and offers treatment promise the least we can do is offer these patients a chance at life.

To prevent companies from sidestepping the regular FDA approval process, the bill gives the FDA authority to withdraw this new kind of approval if a drug sponsor fails to conduct post-marketing studies.

The ACCESS Act would also simplify the current cumbersome application procedures for expanded access by shifting the decision process from Washington bureaucrats to patients and doctors.

While some critics fear that creating exceptions to the approval process will compromise the FDA's ability to safely screen drugs, the ACCESS Act takes a narrow and limited approach to addressing the unique needs of seriously ill patients.

When I faced cancer myself I was fortunate to have several treatment options. I can only imagine what it must be like to feel helpless in the face of a terminal condition where treatments options range from little to none. These patients and their doctors have the right to make the personal decisions that affect their health and quality of life.

Sam Brownback represents Kansas in the U.S. Senate and co-chairs the Senate Cancer Coalition.