

Mr. Speaker, I rise to introduce the “Compassionate Freedom of Choice Act.” This legislation allows terminally ill patients to use drugs, treatments and devices that have not yet been approved by the Food and Drug Administration (FDA) if their physicians certify: (i) such patients have no other treatment options; and (ii) the patient executes written, informed consent that they are aware of any potential risks from the drug, device, or treatment.

It is important to remember that this legislation only applies to otherwise terminally ill patients. Denying these patients a possible opportunity to cure their illness—or at least reduce their suffering—is nonsensical and cruel. The FDA’s approval process for drugs, devices, and treatments is costly and time consuming. Yet, time is the luxury terminally ill patients do not enjoy. So why should the FDA deny terminally-ill patients access to drugs, devices, and treatments that the patient’s physicians have determined represents the patient’s only possible chance for survival?

For example, the FDA refused to allow Abigail Burroughs (who was diagnosed with head and neck cancer at the age of 19) access to the cancer drugs Iressa and Erbitux by the FDA. Never mind that a renowned oncologist at Johns Hopkins had determined there was a significant chance of saving her life if she could use these new drugs. With her only chance of survival denied by the federal government, Abigail passed away on June 9, 2001, at the age of twenty-one.□

Another example of why this bill is necessary is the case of thirteen-year old Anna Tomalis, who enjoyed horseback riding and soccer until she was diagnosed with embryonal sarcoma. Chemotherapy and surgery failed to reverse the cancer, so Anna’s parents decided to try experimental drugs. They petitioned the FDA for approval to use Deforolimus, developed by Merck and ARIAD. Unfortunately, the FDA decided Anna was too sick to be admitted in Deforolimus’s clinical trials and did not grant her a “compassionate use” exemption until three weeks before she died.

Mr. Speaker, I have attached a list of other patients who were denied access to treatments by the FDA even though their doctors believed these treatments were the only option left to potentially save their lives. I ask my colleagues to help make sure that no more Americans with terminal disease are denied treatments simply because the FDA has decided these Americans are better off facing certain death than using an “unapproved” drug, treatment, or device. Please cosponsor the Compassionate Freedom of Choice Act.