EXHIBIT 17
DATE 2-11-15
SB 142

F a c t s About "Right To Try"

F o r terminal patients who have exhausted their conventional treatment options, obtaining access to potentially life-saving investigational medications is often extremely difficult. The patient can attempt to enroll in a clinical trial, but many of the sickest individuals do not qualify. In fact, only **3** percent of patients today are enrolled in clinical trials. For everyone else, their only hope for obtaining potentially life-saving medications is to ask the FDA for special permission.

Only about **1,000** people make it through the FDA's "compassionate use" application process each year. The process is complicated, time-consuming, and expensive. The first step in the process requires a doctor to complete an application that the FDA estimates takes **100** hours. After the doctor submits the application to the FDA, the manufacturer must also submit lengthy documentation requirements. The FDA then has a month to review the submission and either grants or denies the request, but if there are any questions the one-month clock starts over. After the FDA approves a request, a separate committee not affiliated with the FDA, called an Institutional Review Board, also must approve the patient's use of the drug. The Institutional Review Board can sometime take up to a month to reach a decision.

Sadly, there are many documented cases of patients dying while their application is being considered. The FDA recently announced plans to shorten the application, but the other steps will still remain in place. A shorter application for the first step is helpful, but it only addresses one part of the approval process. And ultimately, it's still an application to the government to ask permission to try to save your own life.

If you have a terminal illness, you don't have time for a multi-step government process. If your child is dying from a terminal illness and you know there's an investigational medication that is already helping other children survive, a shorter form isn't good enough.

We need to remove barriers that limit doctors from providing the care they are trained to give—and this is exactly what "Right To Try" does.

"Right To Try" allows terminally ill Americans to try medicines that have passed Phase 1 of the FDA approval process but are not yet on pharmacy shelves. Right To Try expands access to potentially life-saving treatments years before patients would normally be able to access them.

Under "Right To Try", a terminal patient would be able to access an investigational medicine if:

✓ **The patient has a terminal disease and has exhausted all conventional treatment options;**

✓ **The patient's doctor has advised the use of an investigational medication;**

✓ **The medication has successfully completed basic safety testing and is part of the FDA's on-going approval process;**

✓ **The patient has provided "informed consent" acknowledging the potential risk of the drug; and**

✓ **The company developing the medication is willing to make it available to the patient.**

"Right To Try" includes important protections. The basic safety testing and informed consent requirements protect the patient. And doctors and the manufacturer are protected from liability if the investigational medication doesn't work. But this is not protection from medical malpractice.

"Right To Try" is already law in Arizona, Colorado, Louisiana, Michigan and Missouri, where it passed with overwhelming bipartisan support. It has been introduced in 26 more states this year. "Right To Try" is a human dignity issue. That's why lawmakers from both sides of the aisle are coming together to give their citizens the "Right To Try".

The FDA says providing dying people with investigational medications should be an exception. We think it should be the rule. People fighting for their lives should have access to medicines that could save them without needing a permission slip from the government.