Statement from FDA Commissioner Scott Gottlieb, MD, on the Signing of the Right to Try Act

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For patients with serious or immediately life-threatening diseases, the FDA remains committed to enhancing access to promising investigational medicines for those unable to access products through clinical trials. This is the mission of our expanded access program. The agency is dedicated to these purposes, and it has been for more than three decades.

We've taken many steps to improve our process through which patients can access promising investigational drugs. We understand that treatment decisions for those facing terminal illnesses are best made by patients and families, with the support of their treating physicians. When appropriate, those suffering from a terminal illness who've exhausted available options should be able to access promising treatments being studied in clinical trials, or products under active review by the FDA. The agency is faithfully committed to these goals, to protecting patients, and to making sure they're able to make informed decisions.

Today, the President signed into law the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act). At the FDA, we stand ready to implement this legislation in a way that achieves Congress' intent to promote access and protect patients. The FDA is dedicated to achieving the goals that Congress set forth in this legislation, so that patients facing terminal conditions have an additional avenue to access promising investigational medicines.

This new law amends the Federal Food, Drug, and Cosmetic Act to establish a new pathway aimed at increasing access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial. Our implementation of the Right to Try Act will build on our long-standing efforts to help patients and families who are facing life-threatening diseases or conditions, in a way that seeks to protect their autonomy, their safety, and the safety of others following in their paths.

The decisions we reach related to products that can serve as an effective treatment for a terminal illness, or that can arrest a devastating and debilitating condition, are among the most important and carefully considered judgments that we make. We recognize the important balance between making sure patients have the assurances Congress intends, while enabling timely access to promising treatments in these devastating circumstances. And we'll implement this new law consistent with these longstanding values.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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