



New York Times Editorial Ignores Modern Science; Advocates for Policies that Could Hurt Patients

June 11, 2018 - Washington, DC - On Friday, June 8, 2018, *The New York Times* published an editorial titled “Easier Drug Approval Isn’t Cutting Drug Prices.” In it, The Times Editorial Board claims the FDA is lowering standards by working to get treatments to patients more quickly and instituting a “less regulation” approach to reviewing new drugs and medical devices. The Editorial Board also recommended that the FDA require “at least two successful clinical trials for any drug.”

The misguided editorial omits many important pieces, including the need for flexibility in clinical trials, particularly for those with serious illnesses. Additionally, the recommendation that FDA should require two successful clinical trials for any drug is rigid, and in some cases, unethical.

“As a patient advocate who lost her sister to cancer at the age of 40, I read this editorial with dismay,” said Ellen Sigal, Chair and Founder of Friends of Cancer Research. **“This piece is devoid of today’s science and instead advocates for policies that would create an arbitrary barrier for men and women in urgent need of treatment.”**

Years ago, in order to determine if a drug had an effect, it was necessary to conduct multiple, randomized trials. While the randomized trial remains an important part of developing a new drug, many of today’s medicines are based on complex biologic processes and yield unprecedented effects that can be observed very early on. When this occurs, especially treatments addressing life-threatening illnesses, multiple trials may not be necessary and every effort should be made to get those treatments to patients quickly and safely.

This is why a pathway like the FDA’s Breakthrough Therapy Designation was created. This pathway helps speed access to lifesaving drugs for the patients that need them most, and it is crucial we

do not lose sight of the benefits and positive impact the breakthrough therapy designation has brought to so many patients.

Arcane rules that tether medicine to a bygone era should not grind our drug approval system to a halt. Such rules will not protect anyone and will only deprive patients of their best chance at recovery.

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org.