ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

U.S. House of Representatives
Washington, D.C. 20515

March 20, 2018

Dear Representative:

On behalf of Consumers Union, the advocacy division of nonprofit Consumer Reports, we are writing today to express our opposition to the Right to Try Act of 2018 (H.R.5247), currently being considered by the House of Representatives. Consumers Union has a long history of working for a fairer and more just marketplace for consumers, including advocating for effective and affordable drugs for consumers. We believe the Right to Try Act would erode FDA's current system of drug approval and oversight and, more importantly, could weaken consumer trust in the medications that are recommended and made available to them.

Right to Try legislation enables patients who are terminally ill to get experimental treatments. But the legislation seeks to address a problem that does not exist. FDA's expanded access program, between 2010-2015, approved 99% of requests it received from patients and their physicians to access investigational drugs. In recent years, the FDA has simplified the program's application process, forms and guidance information. The agency also takes emergency requests after hours and provides guidance regarding costs for the drugs included in the program. Occasionally, FDA has asked for changes to be made to treatments in order to protect patients--changing the amount of a dosage or increasing monitoring for safety, for example. The FDA should continue to be in the position to propose changes, like these, that safeguard the public and to monitor the experience of patients' use of these drugs.

The Right to Try legislation would allow access to experimental drugs after Phase I drug trials are completed. This would set a lower standard than the FDA's expanded access program, which requires at least some evidence that experimental treatments could be helpful. Phase I trials are frequently very small and are done with healthy volunteers, not the very sick patients the drugs are intended to treat. Subjecting seriously ill patients to treatments that have been tested on very small groups of healthy volunteers without evidence that the drug improves very sick patients' conditions is dangerous. At best, this legislation gives patients false hope and could misuse their limited resources. At worst, the legislation allows untested treatments that could cause serious harm into the marketplace.

By far, our greatest concern is in preserving the essential authority of the FDA in its oversight of our nation's drug supply – both before and after drugs are on the market. Bypassing this authority by allowing patients access to drugs after only Phase I tests sets us on a course where consumers are left to sort out whether drugs work and are safe based on advertising and marketing by companies that sell these products.

Congress should protect consumers who are in health crisis and who are, therefore, vulnerable to being harmed, both physically and financially, by inadequately tested treatments. We urge you to oppose the Right to Try Act of 2018.

Sincerely,

Victoria Burack