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March 12, 2018

Dear Members of the United States House of Representatives:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, respectfully urges you to oppose the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018,” which was released on March 9. Although the bill has several improvements over the Senate-passed version of this legislation (S. 204), it still has fundamental flaws that make it dangerous for patients.

In particular, the bill would:

- Offer false hope to patients by creating a dangerous pathway for access to experimental drugs and biological products that bypasses the Food and Drug Administration (FDA)’s existing Expanded Access Program. By requiring review and approval by the FDA and an institutional review board (IRB), this program helps to ensure that proposed uses of experimental drugs outside of the context of clinical trials do not pose unacceptable risks to patients.
- Specify completion of a single phase 1 clinical trial as the evidentiary threshold for allowing use of experimental drug products under the legislation. Such a threshold is insufficient for allowing use of an experimental drug outside of the context of a clinical trial because initial phase 1 clinical trials often only involve healthy volunteers, typically involve testing of a single dose of an experimental drug in each enrolled subject, provide no meaningful data on efficacy, and yield only very limited preliminary data on safety. Importantly, a large proportion of experimental drugs that progress beyond phase 1 testing are ultimately found to be unsafe or ineffective upon further clinical testing and, therefore, are not approved by the FDA.
- Broadly immunize from liability (a) manufacturers and sponsors for any act or omission related to the provision of an eligible investigational drug to an eligible patient and (b) licensed physicians, clinical investigators, and hospitals for any act or omission related to provision of an eligible investigational drug to an eligible patient, unless the relevant conduct constitutes willful or criminal misconduct, reckless misconduct, gross negligence relative to the applicable standard of care and practice with respect to the administration or dispensing of such an investigational drug, or an intentional tort under applicable state law. This broad immunization from liability also would apply to the provision of an investigational drug to a single patient or small group of patients for treatment use under section 561 of the Food, Drug, and Cosmetic Act, which governs the FDA’s existing Expanded Access Program. In this way, the bill would interfere with states’ traditional role in deciding the scope and limitations of state-law tort remedies and would eliminate a strong incentive for manufacturers and health care providers to act responsibly and in the best interests of patients.

The “No Liability” provisions would bar suits in a variety of situations in which state law might reasonably impose liability. For example, it would immunize manufacturers from being held accountable for harm caused by contamination of an investigational drug product, which can be serious. It also would bar state-law negligence suits against the physician prescribers — for example, if the physician negligently prescribed an investigational drug that was known to be contraindicated for a particular patient’s set of circumstances, but the situation did not arise to “gross negligence.” Decisions about liability in such situations are properly based on consideration of the specific facts, and the bill’s immunity provision may cause physicians to be less careful in making prescribing decisions for seriously ill patients.

We urge you to oppose the Right to Try Act of 2018 unless the following amendments are made:

- Include provisions that would require FDA and IRB review and approval of each request for use of an investigational drug by a patient outside of the context of an approved investigational new drug application.
- In the definition of “eligible investigational drug,” change “for which a phase 1 clinical trial has been completed” to “for which at least one phase 2 clinical trial has been completed and has provided a reasonable basis for continued testing of the drug.”
- Delete the “No Liability” section of the bill.

Thank you for considering our views on this important matter.

Sincerely,



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