House Passes "Right to Try" bill – Compromising Public Health and Drug Development

On March 21, only one week after an initial defeat in the U.S. House, the controversial "Right to Try" bill was resurrected and passed on March 21 by a vote of 267-149. The legislation is now on its way to the U.S. Senate.

"Right to Try" would provide access to experimental therapies to patients with life-threatening illnesses while weakening FDA oversight and compromising public health and medical research. The FDA already offers patients access to experimental drugs or medical devices outside of clinical trials via the Expanded Access (sometimes called Compassionate Care) program and approves the overwhelming majority of all applications received—about 99%. Under Expanded Access, the FDA continues to supervise administration of the experimental drugs which both helps reduce individual patient risk and works to improve overall public health outcomes.

The current "Right to Try" bill permits patients and their doctors to bypass the FDA and work directly with pharmaceutical companies for access to drugs which have merely completed Phase I clinical trials. Some patient groups argue that by cutting out FDA oversight and creating an alternative avenue for accessing experimental drugs, Right to Try actually increases patient risks and is demonstrably less safe than Expanded Access.

Over 75 patient groups sent a letter to the House opposing passage of the bill, citing the dangers it presented to patients such as the seven-day lagtime between patient access to the investigational therapies and FDA notification of any possible side effects or negative outcomes. Additionally, the patient groups cited the removal of FDA-sanctioned dosing and safety measures. They also cited shortcomings of the bill such as its failure to address significant barriers to patients such as access and cost.

The bill strips patients of potential legal remedies by protecting doctors and drug companies from liability in the case of negative outcomes for patients.

The legislation is also poised to compromise medical research and drug development by preventing the FDA from using any data from negative clinical outcomes in its drug-approval assessments. Barring FDA from using such data would shroud the successes or failures of the experimental drugs in obscurity—possibly preventing further large-scale advances in overall research and development.

Ultimately, “Right to Try” strips the FDA of established regulatory authority and protections, increases risk to patients, and obfuscates outcomes vital to continued success in research and development–all of which could result in serious, wide-ranging public health issues.

We at Contracts Associates will continue to monitor this important issue.