What Does the Cures Act Really Mean for Patients?

When signed by President Obama last December, the 21st Century Cures Act—which was the culmination of seven revisions written after the House of Representatives first introduced it in January 2015—was applauded by some as a huge step toward getting much-needed drugs and medical devices to the patients who need them. In particular, supporters praised the law's provisions that allow the Food and Drug Administration (FDA) to dramatically streamline its approval process for drugs and medical devices, as well as increase research for brain diseases and cancer, improve mental health treatments, and address the increasing problem of opioid addiction around the country.

In order to make good on the promise to get drugs and medical devices to market faster, the Cures Act gives the FDA the power to loosen its standards of evidence when considering these products. Instead of requiring a series of clinical trials—a process that has historically been seen as the gold standard in the industry—medical devices and medications could be approved through weaker criteria, such as the use of "real-world evidence," which is defined as "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials," and patient-reported outcomes. In addition, the law allows pharmaceutical companies that create drugs for rare tropical diseases to obtain vouchers that will expedite the review of another drug of their choice, and medical devices to be approved via the "least burdensome means."

Those who support the Cures Act argue that the law will encourage the innovation needed to find cures and treatments for several medical conditions. For example, Dr. Kevin R. Campbell of the University of North Carolina explained it this way: "The less costly approval process is likely to allow smaller entrepreneurs and startup companies to put innovative drugs and devices forward—resulting in newer treatments reaching the patients who need them. Any time we are able to involve more people in the research and development, we are more likely to succeed."

However, not surprisingly, opponents of the law are not so optimistic. Massachusetts Senator Elizabeth Warren referred to the Cures Act as "legalized fraud," "extortion," and "bribery." Similarly, consumer rights advocacy group Public Citizen said the law "comes at the expense of patient safety by undermining requirements for ensuring safe and effective medications and medical devices."

The concerns about the impact the Cures Act will have on patient care are further exacerbated because of Dr. Scott Gottlieb, who is expected to be confirmed as commissioner of the FDA later this month. Gottlieb, the former FDA deputy commissioner under George W. Bush, has been a long-time critic of the agency's regulatory practices. In 2012, he wrote an article for *National Affairs* where he complained that the FDA has an "unreasonable hunger for statistical certainty" and added "In so heavily prioritizing one of its obligations—the protection of consumers—the FDA has sometimes subordinated and neglected its other key obligation, which is to guide new medical innovations to market."

And the problems with Gottlieb don't end there. Over the years, he has cultivated what can best be described as a cozy relationship with the pharmaceutical business through his consulting and board

positions with drug companies, as well as his partnership in a venture capital fund that has several health care investments. In fact, Gottlieb's association with the industry runs so deep that he was actually congratulated by the head of a pharmaceutical lobby association when President Trump tapped him as FDA commissioner.

What does this all mean for patients? It's too soon to tell. According to an article in *Lexology*, Gottlieb may have difficulty implementing parts of the Cures Act because of Trumps "two for one" executive order, which requires that two regulations be removed for every one that a federal agency implements. However, the article also points out the argument can be made that the legislation itself is a form of deregulation and therefore the "two for one" EO does not apply.

Either way, putting pharmaceuticals and medical devices that have not been adequately tested on the market means patient safety is at significant risk. The end result may be that the Cures Act is worse than the disease.