# What Does the 21st Century Cures Act Mean for Medical Devices?

Congress passed the 21st Century Cures Act December 13, 2016. This new legislation brings hope for innovation…and more. It also means opening a more efficient pathway to bring your medical devices to market.

Given that Trump is no fan of government regulation, his comments about FDA regs were right in character. In September, according to salon.com, a fact sheet accompanied Trump's tax plan, which implied he'd call for drastic change in FDA regulations.

In order to save $1 trillion over the next ten years, he stated his government would dissolve a significant number of food safety regulations. I wondered if he'd also target FDA regulations surrounding medical devices. Fast forward to now, and these are far more frightening thoughts than they were in September.

Regulations undeniably are in place to ensure public safety. Just the same, the idea of fewer FDA regulations could look like the best Christmas gift under the tree…

But only if safety is guaranteed to *not* be compromised. If it just means a quicker application process, bring it on!

I'd like to suggest a few ways in which the Act may benefit your medical device company. I categorized 8 sections of the new Act into the following 3 categories:

1. Your medical devices are safer for consumers
2. Your medical devices move quicker to market
3. Things are generally better

Here are brief summaries of each of those 8 sections.

## 1. Your Medical Devices are Safer for Consumers

**Section 3059** means that data on reusable devices has to be cleaned and validated.

**Section 3060** identifies five categories of medical software that, under certain conditions, will *not* have to be regulated as a medical device. Based on their low level of risk to patients. It also also gives the FDA authority to regulate software in these categories *if* safety concerns are discovered.

## 2. Your Medical Devices Move Quicker to Market

**Section 3051** establishes a pathway for breakthrough devices to come quickly to market. This builds on the Expedited Access Program[1] (EAP), already in full swing before the 21st Century Cures Act was passed.

Fast tracking, then, is more probable now. You can request a priority review of certain new breakthrough devices. The review would take place before you submit an application to register the new device. So the program is being re-designed to fast-track review for devices that greatly improve treatment or diagnosis of life-threatening or debilitating disease/conditions.

**Section 3053** seeks to expedite the medical device review by establishing a more clear process for submission and review.

**Section 3056** does away with the need for a sponsor of a medical device trial to only use a local institutional review board. This change will allow the option to use other models, which could mean getting through the review process faster.

In addition, regulatory requirements are now generally more straight forward. This is especially true for certain Class I and Class II medical devices, which will be more quickly brought to market.

**3. <u>Things Are Generally Better</u>**

**Section 3055** seeks to improve the review process in more ways than one. For instance, by:

- ensuring greater expertise among panel members
- allowing device sponsors to do their own presentations

Among other changes, the FDA's scientific expertise and outreach is going to improve. Also significant is that more FDA staff will be trained to review pre-market applications. This approach is meant to be less burdensome.

**Section 3054** requires the FDA to keep current, updated lists regarding the approval of Class I and Class II devices. This means better lines of communication, and could prevent unnecessary waiting to find out if your device application has been approved.

- Expansion of humanitarian device exemptions
- Institutional review boards charged with reviewing plans for clinical testing would not need to be in the same location as the trial.

**Sec. 3052** gives the FDA authority to apply the humanitarian device[2] exemption to devices that treat diseases and conditions that affect up to 8,000 individuals in the U.S. The current cap is 4,000.

In conclusion, the 21st Century Cures Act is by no means perfect. But as you saw in the brief summaries of these 8 sections, the Act allows for more safety, quicker approval, and is generally better in a few other respects.

Notes:

*Now at the end of its first full year of operation, EAP has granted 24 devices entry. The program, according to FDA Voice, "helps speed the development and availability of certain medical devices that demonstrate the potential to address unmet medical needs for life-threatening or irreversibly-debilitating diseases or conditions."*
http://blogs.fda.gov/fdavoice/index.php/2016/12/21st-century-cures-act-making-progress-on-shared-goals-for-patients/

*Humanitarian Use Device (HUD) is a device that was intended to benefit patients by treating or diagnosing a disease or condition that affected or was manifested in fewer than 4,000 individuals in the United States per year. A device manufacturer`s research and development costs could exceed its market returns for diseases or conditions affecting small patient populations.*