December 13, 2016

21st Century Cures Act – Provisions Relating to Medical Device Innovation

On December 13, 2016, President Obama signed into law the 21st Century Cures Act (the Act), just days after it passed in the U.S. House of Representatives and Senate. With an overarching goal of advancing biomedical innovation, the Act makes numerous changes to laws that govern Food and Drug Administration (FDA) programs, clinical research regulations, and Medicare coverage and reimbursement rules.

To see Ropes & Gray's analysis of key provisions of the Act, please click on the hyperlinks below:

- Promoting Drug Development
- Development Incentives for Certain Classes of Drugs
- Digital Health
- Regulation of Clinical Research
- Reimbursement & Fraud and Abuse

Partners in Ropes & Gray's FDA Regulatory practice have also recorded a podcast to discuss some key implications of the Act for biopharmaceutical and medical device manufacturers. Click here to listen to the podcast.

This Alert highlights select provisions of the Act related to FDA's regulation of medical devices. The Act includes several provisions modifying FDA's regulation of medical devices to promote the development and accessibility of certain products, including those intended for unmet public health needs and specific categories of software. The device provisions of the Act also aim to encourage reliance on international standards to meet certain FDA requirements, ensure that device sponsors are able to correct the record at classification panel meetings, clarify standards for granting CLIA waivers, and enhance the statutory requirement that FDA consider the "least burdensome" means of demonstrating substantial equivalence or reasonable assurance of safety and effectiveness. We briefly summarize key provisions related to medical device innovation below.

Breakthrough Devices [Section 3051].[1]

This provision establishes an expedited review program for breakthrough devices, similar in concept to FDA's existing breakthrough designation program for drugs.[2] The breakthrough designation program facilitates the expedited development and priority review of certain devices intended for unmet needs. Specifically, FDA designates a device as breakthrough if it is intended to treat or diagnose life-threatening or irreversibly debilitating diseases or conditions, and (i) represents breakthrough technology; (ii) no approved or cleared alternatives exist; (iii) offers significant advantages over existing approved or cleared alternatives; or (iv) the availability of which is in the best interest of patients. While the drug breakthrough designation criteria are narrower in scope (e.g., limited to those drugs demonstrating a substantial improvement over existing alternatives), both programs confer similar features: a streamlined review process, such as staffing individuals with appropriate expertise on the review team; adopting a

[1] Sections cited in this Alert refer to the relevant provisions in the Act.
[2] *See* section 506(a) of the Federal Food, Drug, and Cosmetic Act (FDCA).

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process for efficient dispute resolution; and allowing early and frequent interactions between the FDA and the sponsor. This program is broader than the current Expedited Access Pathway in that it applies to 510(k) applications and de novo petitions, in addition to premarket approval applications (PMAs).

Humanitarian Device Exemption [Section 3052].

The Act broadens the Humanitarian Device Exemption (HDE) program for devices intended to treat or diagnose a condition that affects a small patient population, by increasing the cap on the number of patients affected from 4,000 to 8,000. FDA incentivizes the development of devices intended for rare conditions by exempting such devices from the effectiveness requirements of the PMA review standard, although the devices must meet the safety standard and demonstrate that the probable benefit outweighs the risk of injury or illness from its use. In addition to expanding the HDE program, the Act also calls on FDA to publish draft guidance within 18 months, defining criteria for determining a HDE device's "probable benefit." The increase in the patient population cap should make the HDE pathway more available to device sponsors and facilitate more devices intended for the treatment or diagnosis of rare diseases to enter the market.

Recognition of Standards [Section 3053].

Under this provision, FDA is required to determine within 60 days of a submitted request whether officially to recognize a standard (in whole or in part) issued by a nationally or internationally recognized standard development organization. Within 60 days after receipt of a request, FDA must issue a response to the requester setting forth FDA's rationale, which will be made publicly available. Under this provision, all FDA employees who review premarket device submissions must receive training on recognized standards, and FDA must update existing guidance and standard operating procedures that address the recognition of standards. Prior to the Act, FDA on its own, or at the request of a third party, could decide to adopt a standard, but was not required to disclose publicly its rationale for adopting or declining to adopt, and was not obligated to act within a specified time frame. This provision should strengthen FDA's recognition program and facilitate greater harmonization with international standards.

Classification Panels [Section 3055].

This provision establishes new requirements for medical device classification panels to ensure that each reviewing panel has "adequate expertise," defined in the Act as (i) two or more voting members with a specialty or other expertise clinically relevant to the device under review and (ii) at least one voting member knowledgeable about the technology of the device. Under this provision, a representative designated by the sponsor will be provided an opportunity, subject to the discretion of the panel chairperson, to correct misstatements, provide clarifying information, and call on experts to address specific issues. These statutory changes will amplify the role and input of sponsors' device classification panel meetings in an effort to assure that sponsors' positions are not misrepresented and are reviewed by sufficiently qualified panel members.

CLIA Waiver Improvements [Section 3057].

This provision requires FDA to revise a particular section of its 2008 guidance document, "Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" (CLIA Waiver Guidance). A manufacturer of an in vitro diagnostic (IVD) test may label and promote the test for use by CLIA-waived users (e.g., many physicians' offices), provided that FDA has determined that the test is a simple laboratory procedure that has an insignificant risk of an erroneous result. Section V of the CLIA Waiver Guidance recommends the study methods that should be used when evaluating the accuracy of a test in a CLIA-waived environment. This provision requires FDA to revise the CLIA Waiver Guidance to describe the appropriate use of studies that compare the performance of a test by waived users against users in CLIA "moderately complex" laboratory setting. By mandating that FDA reconsider its guidance on CLIA waiver eligibility, the Act

may allow IVD manufacturers to demonstrate that a test is appropriate for a CLIA waiver based on more flexible data standards.

Least Burdensome Device Review [Section 3058].

This provision would enhance the statutory requirement that FDA consider the least burdensome means of demonstrating substantial equivalence or reasonable assurance of safety and effectiveness. Under this provision, all FDA employees involved in reviewing 510(k) or PMA submissions would receive training on the meaning and implementation of the least burdensome concept. Additionally, FDA would be required to periodically assess the implementation of the least burdensome requirement and conduct an audit of the training within 18 months. Further, FDA must take into account the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness when requesting additional information for a PMA application. The Act reiterates the long-standing least burdensome principle and ensures its continued and consistent application during CDRH's review of 510(k) notifications and PMA applications.

Clarifying Medical Software Regulation [Section 3060].

The Act exempts five categories of software functions from the definition of "device" under the FDCA, thereby removing them from FDA jurisdiction. The statutory provision builds on FDA's efforts to limit the regulation of low-risk medical devices. Specifically, the types of medical software excluded from the definition of "device" under the FDCA include software intended for:

1. Administrative support of a healthcare facility;

2. Maintaining or encouraging a healthy lifestyle, when unrelated to diagnosis, cure, mitigation, prevention, or treatment;

3. Transferring, storing, formatting conversion, or displaying certain electronic medical records;

4. Transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, so long as the software is not intended to interpret or analyze clinical laboratory test or other device data; and

5. Displaying, analyzing, or printing certain medical information about a patient, supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment, and enabling such healthcare professional to independently review the basis for such recommendations so that it is not the intent that such healthcare professional rely primarily on such recommendations to make an individual clinical diagnosis or treatment decisions.

However, the software function may not be excluded from the device definition if FDA makes a formal finding that the use of the software function would reasonably be likely to have serious adverse health consequences. The Act clarifies that, to the extent a product has multiple functions, including a non-device function, only the device functions could be subject to FDA regulation. The Act also amends the FDCA to provide that FDA must classify device accessories based on the intended use of the accessory rather than the classification of any other device with which the accessory is intended to be used. FDA issued draft guidance in 2015 adopting a similar approach to accessories.[3]

If you have any questions, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.

[3] *See* FDA Draft Guidance on "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types" (January 2015).

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