SQUIRE PATTON BOGGS

21st Century Cures Act Signed into Law by President Obama

On December 13, 2016, President Barack Obama signed H.R. 34, the 21st Century Cures Act, into law. This sweeping healthcare law addresses the discovery, development and delivery of new drugs and medical treatments. It also includes substantial mental health reforms and assorted Medicare- and Medicaid-related provisions.

The law is a product of the bipartisan 21st Century Cures Initiative, spearheaded by US House of Representatives Committee on Energy and Commerce Chairman Fred Upton (R-MI) and Representative Diana DeGette (D-CO). The Initiative held various events and authored policy papers on topics such as innovating public health agencies, incorporating patient perspectives into the regulatory process, and improving medicine and medical product regulation. The House passed a first version of the bill in July 2015.

On the other side of the Capitol, US Senate Committee on Health, Education, Labor and Pensions (HELP) Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) worked diligently on medical innovation legislation this past year, holding hearings and favorably reporting several pieces of legislation. The majority of these bills, however, did not reach the Senate floor.

Prior to the November elections, Senate Majority Leader Mitch McConnell (R-KY) and House Speaker Paul Ryan (R-WI) signaled their commitment to passing this legislation during the lame duck session, and the Act is a product of post-election bipartisan and bicameral negotiations.

The Act, which totals more than 300 pages, includes many provisions of interest to medical device and pharmaceutical manufacturers:

- **Patient Experience Data**: The Act directs the Secretary of the Department of Health and Human Services to collect, review and report on patient experience data she receives in a new drug application (NDA). The provision also requires the Secretary to publish guidance regarding the collection of patient experience data and the use of such data in drug development. (Sec. 3001-3002)
- **Clinical Trials**: The Secretary will conduct a public meeting to gather information and issue a guidance document on adaptive and other novel clinical trial designs in the development and regulatory review and approval for drugs and biologics. The Act specifies that the guidance shall address the use of complex adaptive and other novel trial designs, the types of quantitative and qualitative information that should be submitted for review, and any recommended analysis methodologies. (Sec. 3021)
- **Using Real-World Evidence**: The Act requires the Secretary to establish a program to evaluate the potential use of real-world evidence (as opposed to evidence gathered in a clinical trial) to help support the approval of an abbreviated new drug application (ANDA). The framework of the program includes sources of real-world evidence, standards and methodologies to collect and analyze the real-world evidence, and any priority areas the program will address. (Sec. 3022)
- **Accelerated Approval Pathway for Regenerative Advanced Therapies**: The Secretary will establish a program that allows drugs designated as regenerative advanced therapies to undergo an expedited review, and create guidance documents for medical devices used in the recovery, isolation or delivery of such regenerative advanced therapies. The Secretary, in consultation with the National Institute of Standards and Technology (NIST), will create standards for such regenerative advanced therapies to facilitate the expedited review. (Sec. 3033-3036)
- **Combination Products**: The Act directs the Secretary to designate a primary center to regulate combination products or products with components that may be regulated by more than one center. These products shall only need one application to undergo premarket review, whenever appropriate. (Sec. 3038)
- **Breakthrough Devices**: The Act "encourages" the Secretary to provide an expedited review pathway for devices that are designated as breakthrough devices. The Secretary will also draft a guidance document that explains the breakthrough device review program and criteria it will use when determining whether a medical device is a "breakthrough" device, and will provide a template for breakthrough designation requests. (Sec. 3051)
- **Exempt Devices**: The Act requires the Secretary to publish a list of Class I and II medical devices that it determines will no longer require a 510(k) report. (Sec. 3054)
- **Least Burdensome Review**: The Act requires the Secretary ensure all Food and Drug Administration (FDA) employees are trained to, and utilize, the least burdensome review requirements. (Sec. 3058)

The Act includes cost offsets, determined after months of negotiations. The offsets include a drawdown of the strategic petroleum reserve; reductions in funding available from the Affordable Care Act, including the Prevention and Public Health Fund and funding available to territories; limitations of federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics and supplies to Medicare reimbursement rates; elimination of federal Medicaid matching funds for prescription drugs used for cosmetic purposes or hair growth, unless medically necessary; increased oversight of termination of Medicaid providers; and measures to reduce Medicare spending, including provisions focusing on payments for infusion drugs and home infusion drug services, and contracting and fraud penalties. (Secs. 5001-5012)

If you would like to discuss the implications of the Act for your business, or would like more information on expected legislation in the 115th Congress, please speak to one of the individuals listed in this publication or your firm contact.

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