ROPES & GRAY

ALERT

FDA Regulatory

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Cures Are on the House: House Passes 21st Century Cures Act, but Senate Awaits

On July 10, 2015, the House of Representative passed H.R. 6, the 21st Century Cures Act ("Cures Act"), with strong bipartisan support, by a vote of 344-77. This medical innovation reform legislation represents the culmination of more than a year of work by the House Energy & Commerce Committee ("E&C Committee") on the 21st Century Cures Initiative, led by E&C Committee Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO). The Cures Act now moves to the Senate, which has separately been considering medical innovation reforms.

As Ropes & Gray previously reported here and here, the E&C Committee released discussion drafts of the Cures Act in January and April 2015. The April discussion draft had been significantly pared down relative to the January discussion draft, eliminating several potentially controversial proposals, including those relating to drug exclusivity and laboratory-developed tests. Since the release of the April discussion draft, the Cures Act has evolved once again. As enacted by the House, the Cures Act, which currently spans 362 pages, contains various new proposals affecting drug and device manufacturers, as well as substantial changes to a number of proposals found in the April discussion draft. The only significant proposal to be axed from the Cures Act since the April discussion draft related to the sharing of data from NIH-funded research.

The key FDA-related provisions that have been added to or substantially changed in the Cures Act since the April discussion draft are described below. Ropes & Gray has summarized Cures Act provisions related to Medicare and Medicaid, health information/digital health, and regulation of clinical research in separate Alerts.

What Is New?

The Cures Act contains numerous new proposals that were not found in the April discussion draft. The key FDA-related additions include proposals relating to:

- *Communication of Truthful, Non-Misleading Off-Label Information*: This provision would require that, within 18 months of enactment, FDA issue a draft guidance facilitating the dissemination of truthful and non misleading scientific information that is not in the approved labeling of drugs and devices. Notably, in June 2014, when the FDA granted a citizen petition submitted by the Medical Information Working Group (as Ropes & Gray previously reported), the FDA announced its own plans to issue guidance "by the end of the calendar year" (i.e., 2014) on distributing scientific and medical information on unapproved new uses and manufacturer discussions regarding scientific information. These guidance documents have yet to be issued. The Cures Act provision would impose a statutory deadline on the FDA's plans.

- *Extended Exclusivity for Previously Approved Drugs and Biologics That Are Approved for a New Rare Disease Indication*: This provision would provide an additional six months of exclusivity for already approved drugs and biologics that are approved for a new indication for a rare disease or condition. The additional six months of exclusivity would tack on to the end of any patent protection or exclusivity applicable to the drug or biologic.

- *Reauthorization of Rare Pediatric Disease Priority Review Voucher Program*: This provision would reauthorize the FDA's rare pediatric disease priority review voucher program, which encourages the development of drugs to treat rare diseases that primarily affect children by rewarding successful rare disease

product applicants with a voucher that can be used to obtain priority review for a subsequent new drug application or biologics license application. (See Ropes & Gray's prior alert for more information.) Without congressional action, the program is scheduled to sunset in March 2016. This provision would extend eligibility in the program to all rare disease product applications submitted through December 31, 2018.

- *Combination Products Review*: This provision would require that, within 18 months of enactment, FDA issue a final guidance document describing the responsibilities of each Center regarding the review of combination products.

- *User Fee Exemption From Sequestration*: This provision would permanently exempt from sequestration various FDA user fees, including fees for medical devices, prescription drugs, generics drug, biosimilars, animal drugs, and generic animal drugs. The provision would ensure the agency's access to user fees and provide funding for drug and device review and other critical agency functions.

What Else Has Changed?

FDA-related proposals that have substantially changed since the April discussion draft include those relating to:

- *Third-Party Quality System Assessment for Medical Devices*: A placeholder in the April discussion draft has been replaced with a provision that would establish a program by which accredited third-parties could review and certify if a device manufacturer's quality system can reasonably assure the safety and effectiveness of devices subject to certain "device related changes." The provision provides that a device-related change covered by such a certification would not be subject to premarket notification, 30-day notice, or Special PMA supplement requirements that might otherwise apply.

- *510(k)-Exemptions for Certain Class I and II Medical Devices*: A placeholder in the April discussion draft related to marketing notifications for class I devices has been replaced with a provision that would require FDA to publish rules identifying any class I and II devices that FDA determines no longer require a 510(k) notification.

- *Expanded Access Programs for Investigational Drugs*: A provision calling for drug manufacturers to disclose details on their expanded access programs for any investigational new drug within 60 days after initiating a phase 2 or phase 3 study has been modified to require publication of an expanded access policy at "the first initiation" of a phase 2 or 3 study. In addition, a provision has been added expressly permitting manufacturers to modify publicly available expanded access policies at any time.

- *Reduction of Additional Incentive for Use of New Antimicrobial Drugs*: This provision, part of a package of antibiotic-related reforms, decreases the additional payment incentive under Medicare for "DISARM drugs"—approved new antimicrobials intended to treat an infection for which there is an unmet medical need and which is associated with high mortality or patient morbidity—to a set percentage of total hospital payments per fiscal year.

Prospects for the Legislation

Although the Cures Act has cleared the hurdle of the House, the prospects of passage in the Senate remain uncertain. The Senate Health, Education, Labor & Pensions Committee ("HELP Committee") has held numerous hearings over the past several months as it considers its own medical innovation legislation. However, the HELP Committee has not yet released even a discussion draft of its legislation, and one is not expected until at least the end of the Senate recess in August. Following the House's passage of the Cures Act, HELP Committee Chairman Lamar Alexander (R-TN) stated that the Senate's work would continue "on a parallel track . . . to produce a bill that [the Senate] can combine with 21st Century Cures and send to the President's desk."

Prior passage of the Cures Act, the White House, via a statement of administration policy, objected to the bill's use of the government's Strategic Petroleum Reserve to offset the bill's funding increases. The White House would have preferred that the bill directly address sequestration and ensure that FDA has sufficient funding to support all the programs established in the bill. The White House also expressed concern regarding the proposals relating to drug exclusivity and drug manufacturer communications with payors. Whether the Senate's proposed legislation will address the White House's concerns remains to be seen.

Re-authorization of the Prescription Drug User Fee Act ("PDUFA VI") is slated to occur in 2017. Given that PDUFA VI is considered "must-pass" legislation, it is possible that a number of issues under consideration in the Cures Act, particularly those issues lacking consensus, will be deferred until that latter debate.

Ropes & Gray will continue to monitor legislative developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice, health care practice or your usual Ropes & Gray advisor.