ROPES & GRAY ALERT

Health Care ▪ Life Sciences ▪ FDA Regulatory

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House Passes 21st Century Cures Act: What Does it Mean for Clinical Research?

On July 10, 2015, the U.S. House of Representative passed H.R. 6, the 21st Century Cures Act, with strong bipartisan support in a vote of 344-77. As Ropes & Gray has summarized Cures Act provisions related to Medicare and Medicaid, FDA regulatory and digital health in separate Alerts, the bill contains significant changes to FDA's regulation of drugs and devices as part of medical innovation reform, as well as modifications to Medicare and Medicaid programs. The bill includes several provisions related to federal oversight of clinical research, with implications for a wide range of stakeholders across the life sciences and health care industries, including drug and device manufacturers, hospitals, academic medical centers, universities/medical schools, institutional review boards, and contract research organizations.

Potential Impact of 21st Century Cures Act on Clinical Research

The Clinical Research provisions of the House-passed version of the 21st Century Cures Act signal a trend by Congress to minimize unnecessary and duplicative administrative (including federal and institutional) requirements, and to promote the broad availability of clinical research data, with adequate security and privacy measures, to advance medical product innovation. The bill also contains a provision to facilitate and encourage the inclusion of underrepresented subpopulations in clinical research.

Several key provisions relevant to Clinical Research:

- *Streamlining Clinical Trials [Section 2261]*. This provision would simplify and facilitate researcher compliance by harmonizing differences, to the extent possible and consistent with statute, between the HHS Human Subject Regulations (45 CFR Part 46) and FDA Human Subject Regulations (21 CFR Parts 50, 56, 312, and 812). The agencies would be instructed to modify regulations and relevant guidance documents to reduce regulatory duplication and unnecessary delays, facilitate multisite research, and incorporate local considerations, community values, and protections of vulnerable populations. The revised regulations and guidance would delineate IRB roles during multisite research, as well as clarify requirements and policies related to the regulatory and legal liability concerns of a sponsor when relying on local IRBs for multisite research.
- *Central IRB Review [Section 2262]*. This provision would delete the requirement that medical device studies be overseen by a "local" IRB. By striking "local," this provision would allow all clinical trials of FDA-regulated medical products to be overseen by a central IRB. FDA previously allowed for central IRB review of drug and biological product studies. With this provision, medical device studies also would be eligible for central IRB oversight.
- *Waiver of Informed Consent for Minimal Risk Research with Appropriate Safeguards [Section 2263]*. This provision would modify the investigational drug and device requirements to allow for waiver of informed consent if the proposed clinical testing poses no more than minimal risk to human subjects and includes appropriate safeguards to protect subjects' rights, safety, and welfare. Currently, a significant difference between FDA and HHS Human Subject Regulations is the authority of an IRB in the Common Rule, which is absent in FDA regulations, to waive consent for certain minimal risk research. With this new provision, Congress would allow FDA to harmonize with the Common Rule by permitting an IRB to waive informed consent for FDA-regulated minimal risk research if the subjects are adequately protected. FDA rule-making

would predictably reflect the safeguards contained in the Common Rule, such as the requirements that the waiver of consent will not adversely affect the rights and welfare of the subjects, that the research could not practicably be carried out without the waiver, and that, whenever appropriate, the subjects will be provided with additional pertinent information after the study ends.

- *Standardization of Data in Clinical Trial Registry Data Bank on Eligibility for Clinical Trials [Section 1101]*. This provision would amend the statute authorizing www.ClinicalTrials.gov, by requiring NIH to ensure that the registry and results databank is configured in a way easily used by the public and is in a standardized format that identifies the disease studied and each study's inclusion and exclusion criteria. Those process changes are intended to facilitate lay use as well as communication between the databank and electronic health records and other relevant health information technologies.
- *Facilitating Collaborative Research with Greater Data-Sharing [Sections 1121 and 1122]*. This subtitle would establish a pilot program to make available certain de-identified data from qualified clinical trials, with appropriate security measures in effect, for further study of such data by scientific and medical researchers. This subtitle also establishes a National Neurological Diseases Surveillance System to track and record scientific information related to the epidemiology, natural history, prevention, detection, management, and treatment of neurological diseases, such as multiple sclerosis and Parkinson's disease. The information in the System, with appropriate privacy and security protections, will be made available to the public, including researchers.
- *Grants to Collect Data on Natural History of Diseases [Section 1123]*. This provision would encourage FDA to enter into public-private partnerships and award grants to patient advocacy groups to establish and facilitate information collection and analysis regarding the natural history of diseases, with a particular focus on rare diseases. The partnerships' data relating to the natural history of diseases would be made available, as appropriate, to the public (including researchers and drug developers) to help facilitate and expedite medical product development programs.
- *Accessing, Sharing, and Using Health Data for Research Purposes [Section 1124]*. This provision would require HHS to amend the HIPAA Privacy Rule to: (1) allow the use and disclosure of protected health information by a covered entity for research purposes, including for studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for "health care operations"; (2) include research activities related to the quality, safety, or effectiveness of an FDA-regulated product as a public health activity to allow a covered entity to disclose protected health information under certain conditions; and (3) permit remote access to health information by a researcher if appropriate security and privacy safeguards are maintained and if the protected health information is not retained by the researcher.
- *Reducing Administrative Burdens on Researchers [Section 1023]*. This provision would require NIH to develop a policy to reduce administrative burdens on researchers who are funded by NIH, with input from the National Academy of Sciences and the Scientific Management Review Board. Within two years after enactment of the Act, NIH would be required to submit a report to Congress detailing how NIH has implemented the policy measures.
- *Increasing Inclusion of Underrepresented Communities in Clinical Trials [Section 1029]*. This provision would express the opinion of Congress that the National Institute on Minority Health and Health Disparities include within its strategic plan ways to increase representation of underrepresented communities in clinical research. This provision would be consistent with IRBs' mandate to ensure that the selection of subjects is equitable.
- *Promoting Pediatric and Geriatric Research through NIH [Sections 1081, 1082, and 1083]*. This section would recommend that NIH and FDA facilitate global pediatric clinical networks by increasing the salaries of new investigators participating in such studies, as well as by engaging the European Medicines Agency and other foreign regulatory entities to encourage their participation in such networks. These initiatives could be funded by the NIH and Cures Innovation Fund, to be established by the Act. In addition, NIH would publish guidelines addressing under what justifications age should be an inclusion or exclusion criterion for

research. NIH also would post on its website the number of children included in NIH-supported or conducted research, disaggregated by age group, race, and gender.

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 health care, life sciences, or FDA regulatory practices or your usual Ropes & Gray advisor.