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Health Policy Briefing

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Debate Continues Over 21st Century Cures

A second group of organizations have **written** to House and Senate leadership urging them not to pass the 21st Century Cures Act during the upcoming lame-duck session of Congress. The groups express concerns about the costs that accompany the extension of exclusivities for the pharmaceutical industry, as well as the "costly and potentially harmful regulatory changes and financial incentives for pharmaceutical and medical device companies that would put patient safety at risk and undermine public health." Thirteen organizations representing health care providers, clinical researchers, public health experts, and consumer advocates signed on to the letter. A group of fifty cancer and research organizations also **wrote** to Congressional leadership last week to reiterate their support for the 21st Century Cures Act. Members of the One Voice Against Cancer (OVAC) Coalition urged lawmakers to fund the Cancer Moonshot Initiative as soon as possible, and to pass the bill when Congress returns to Washington after the election on Tuesday. "Waiting until next year to act is not an option for cancer patients and their families," the groups write. Negotiations over offsets for the medical innovation package stalled movement on 21st Century Cures in the Senate since the bill passed the House with resounding bipartisan support last year. Democrats are insistent that the final package include new funding for the National Institutes of Health (NIH) and other priorities like the Cancer Moonshot Initiative. Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) and House Energy and Commerce Committee Chairman Fred Upton (R-Mich.) have pointed to S. 3056, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act as one means to offset the 21st Century Cures package. CREATES would address the use of the Risk Evaluation and Mitigation Strategies (REMS) drug safety program at the Food and Drug Administration (FDA) to increase competition in the marketplace. Lawmakers are considering making revisions to CREATES that would make it more acceptable to the branded drug industry and then use the bill to pay for Cures. Sponsors of the CREATES Act Sen. Patrick Leahy (D-Vt.) and Sen. Chuck Grassley (R-Iowa), however, have suggested that they would oppose any revisions to their legislation. The Senators could chose to block the medical innovation package from advancing should changes be made that weaken their bill. Congressional leadership aims to advance a revised 21st Century Cures package sometime next week, during the first week of the lame-duck session.

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Lawmakers Inquire About Device Cybersecurity

Rep. Diana DeGette (D-Colo.) and Rep. Susan Brooks (R-Ind.) have **written** to Commissioner of the Food and Drug Administration (FDA) Robert Califf and Director of the Center for Devices and Radiological Health (CDRH) Jeffrey Shuren requesting information about what the agency is doing about potential cybersecurity vulnerabilities in medical devices. "As technology will undoubtedly continue to evolve at a rapid pace, we must ensure that FDA is equipped with the appropriate cybersecurity expertise and resources to evaluate not only the current risks to new medical devices, but also how new threats effect the medical devices already in use," the lawmakers write. They ask the FDA to respond by December 16 with details about cybersecurity vulnerability mitigation efforts in both the premarket and postmarket settings. They also ask how FDA will ensure that patients and health systems are made aware of any vulnerabilities.

NIH Researchers Now Required to Share Data

Applicants for federal research funding will now be required to submit plans for how they will share the data resulting from their work with the public, according to an announcement from Director of the National Institutes of Health (NIH) Francis Collins. He said that the agency is still trying to determine how to standardize the policy across the different NIH centers. The data sharing requirements are a part of a larger effort by the administration to make the results of government research more transparent. The open sharing of data is also a main focus of the Cancer Moonshot Initiative.

FDA Examines Abuse-Deterrent Opioids

During a two-day meeting held last week, officials from the Food and Drug Administration (FDA) and representatives of both the generic and brand name pharmaceutical industries met to discuss development of abuse-deterrent opioid painkillers. Participants discussed the agency's draft guidance for the development and evaluation of generic versions of the drugs. There are currently no approved generic abuse-deterrent opioids. Branded industry voiced concerns that FDA's draft guidance does not go far enough to ensure that generic versions are no less abusable than the reference painkiller, arguing that assessment should not be based only on in vitro testing. The development of a standard in vitro testing method to characterize abuse-deterrent properties was also discussed. Questions about the effectiveness of abuse-deterrent properties, as well as their expense, have limited the uptake of abuse-deterrent opioids by insurers. The seven opioid products with abuse-deterrent properties only make up approximately two percent of the overall market for opioids. A component of FDA's strategic plan for addressing the opioid epidemic is incentivizing the development of more effective abuse-deterrent opioids, and transitioning to greater use of these products.

Upcoming Congressional Meetings and Hearings

Senate Judiciary Committee hearing to explore potential Mylan-Justice Department Settlement Over EpiPens; 10:00 a.m., November 30