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FDA Faces Uncertainty Implementing 21st Century Cures Act

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One of the last bills President Barack Obama signed into law was the 21st Century Cures Act, sweeping legislation intended to accelerate the development and delivery of "21st century cures." The act promotes innovative projects, supports state efforts to curb opioid abuse, promotes the discovery of new medical products, and accelerates U.S. Food and Drug Administration approval of new medicines and medical devices.


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The act sailed through Congress with broad bipartisan support, and the FDA stood ready to implement its provisions. Three months later, however, uncertainties created by two presidential actions — the 90-day hiring freeze and the "one in, two out" executive order — have stalled the act's implementation.

The 21st Century Cures Act

The act authorizes more than $6.3 billion for the funding of health care initiatives, including $500 million to the FDA over 10 years. The act also reforms the development and approval processes for medical products. Among other things, it streamlines the clinical research process; incorporates the patient perspective into the approval process; requires the FDA to evaluate the potential use of "real world evidence"; and provides the FDA with resources to hire scientific, technical and professional staff. These reforms are intended to bring medical products to patients more quickly, without compromising the agency's standards for safety and effectiveness.

Presidential Actions

In his first month in office, President Donald Trump took two actions that may impact the FDA's implementation of the 21st Century Cures Act. On Jan. 23, 2017, the president ordered a freeze on the hiring of federal employees. A week later, on Jan. 30, 2017, the president signed an executive order, "Reducing Regulation and Controlling Regulatory Costs" (the "one in, two out" executive order). While neither action targets the 21st Century Cures Act specifically, each may hinder the FDA's implementation of the act.

90-Day Hiring Freeze

Hiring employees with medical, scientific and technical expertise has been a long-standing challenge for the FDA. The agency estimates that it has 1,000 open positions, more than 600 of which are in the Center for Drugs Evaluation and Research. In an attempt to address this deficit, the 21st Century Cures Act expands the commissioner's hiring authority. The act gives the commissioner the authority to "appoint outstanding and qualified candidates to scientific, technical or professional positions" and determine their annual pay rate (up to a limit). These new hires are essential if the FDA is to fulfill the act's goals without compromising its standards.

On Jan. 23, 2017, Trump imposed a 90-day hiring freeze on executive branch agencies. The freeze prevents the filling of vacant positions or the creation of new positions, other than in limited circumstances. Once the freeze expires, future hiring will be subject to a long-term government reduction plan that the Office of Management and Budget must complete by April 23, 2017.

On Jan. 30, 2017, eight Democratic senators sent a letter to Acting FDA Commissioner Dr. Stephen Ostroff expressing their concern "that a hiring freeze at the FDA will have a negative impact on the development programs and application reviews of new drugs and medical devices." The senators warned that "[s]uspending efforts to fill vacant positions, and create new positions required to implement the 21st Century Cures Act and the new user fee agreements will do serious damage to the FDA's capacity to carry out its mission."

However, the hiring freeze may not be as limiting on the FDA as initially believed. The president's memorandum allows the head of any executive department or agency to exempt from the freeze "any positions that it deems necessary to meet ... public safety responsibilities." The Acting Deputy Secretary of Health and Human Services, Colleen Barros, has deemed various medical and scientific positions at the FDA to be exempt from the freeze. Additionally, many of the FDA's medical officers, epidemiologists and toxicologists are members of the Public Health Service Commissioned Corps, which is specifically exempted from the hiring freeze.

The hiring freeze also permits the "[f]illing of positions under programs where limiting the hiring of personnel would conflict with applicable law." As a result, the FDA may assert that its hiring is permitted under the 21st Century Cures Act and the Prescription Drug User Fee Act (PDUFA). Indeed, the FDA has already collected fees under PDUFA for the hiring of new employees, and commentators have argued that these hirings should be allowed to proceed.

One In, Two Out

The "one in, two out" executive order may present greater challenges to the FDA than the hiring freeze. The executive order is intended "to manage the costs associated with the governmental imposition of private expenditures required to comply with federal regulations. Toward that end, it is important that for every one new regulation issued, at least two prior regulations be identified for elimination." Thus, the order requires that "whenever an executive department or agency publicly ... promulgates a new regulation, it shall identify at least two existing regulations to be repealed."

The "one in, two out" rule is not limited to regulations, but also applies to guidance documents. This creates particular problems for the FDA since the agency regularly issues guidance documents to clarify its regulations. Indeed, between Nov. 7, 2016, and Feb. 17, 2017, the FDA issued 42 new guidance documents.

The FDA will have to issue new regulations and guidance documents to implement the 21st Century Cures Act. For example, Section 3011 of the act, "Qualification of Drug Development Tools," will not only require new regulations; that section expressly requires the FDA to issue a draft guidance document to implement its provisions within three years of its enactment. The guidance must set forth the standards and scientific approaches that will support the development of biomarkers, as well as the requirements and process for the qualification program.

Another example, Section 3012 of the act, "Targeted Drugs for Rare Diseases," facilitates the development, review and approval of drugs to address unmet medical needs in rare disease subgroups. Under Section 3012, sponsors who seek to have these new drugs approved may be able to rely on data and information that they had previously submitted to the FDA for other, similar drugs. However, absent FDA regulations or guidances, these sponsors will not know what data qualifies or how it must be submitted.

The FDA may be able to obtain relief from the "one in, two out" executive order to the extent that new regulations relate to lifesaving medicines. On Feb. 2, 2017, the Office of Information and Regulatory Affairs issued an interim guidance clarifying that the executive order excludes regulations relating to "[e]mergencies addressing critical health, safety or financial matters." There are provisions of the 21st Century Cures Act, such as Section 3012, that relate to "conditions that are serious or life-threatening." Regulations that implement these provisions may be exempt from the "one in, two out" requirement.

Conclusion

In sum, the implementation of the 21st Century Cures Act faces much uncertainty. Due to the extensive hiring that must be accomplished and the myriad regulations and guidances that must be be developed, this sweeping legislation is currently at a standstill. Whether this continues to be the case remains to be seen. The only certainty is that the act is going to take longer to implement than had originally been anticipated.

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