

Regulatory Policy

New Money Plus New Authority Could Overcome FDA Hiring Challenges

BY JEANNIE BAUMANN

Will the unprecedented funding boost the White House proposed for the FDA on Feb. 12 resolve any lingering challenges in the agency's ability to recruit the best minds?

The Food and Drug Administration is getting ready to use the new hiring authority provided in the biomedical innovation law 21st Century Cures (Pub. L. 114-255), FDA Commissioner Scott Gottlieb said in a recent speech. The new authority aims to address an ongoing challenge that the agency couldn't compete with academic centers and drug and device companies that could pay top dollar for leading scientists. The slow hiring process further hindered the agency's ability to recruit.

"We lose a lot of talent just waiting for a job offer to come through," Gottlieb said Feb. 6 at an event organized by the Alliance for a Stronger FDA, which represents consumers, patient groups, and industry seeking more congressional funding for the FDA. A clinician or senior scientist who is open to changing careers and has multiple offers on the table may not want to wait for the FDA's 12-month hiring process, he said. "You're going to lose a lot of good people."

The new hiring authority and changes Gottlieb announced are underway and are important as the FDA is poised to review increasingly advanced medical products in gene therapy, immunotherapy, and advanced devices and diagnostics using technologies like next generation sequencing.

To the extent that the new hiring authority applies to the FDA's drug, device, and biologics centers, they might not have the resources for the salary levels allowed under that pay authority, Gottlieb said. "And so even if they can bring on very senior scientists and specialized talent at a cap of \$400,000 a year—which is what the Cures bill allows—there might not be a lot of resources to get up those pay levels, CDRH in particular." CDRH refers to the Center for Devices and Radiological Health.

'The Math Is Simple' Jeff Allen, chief executive officer of Friends of Cancer Research, who was at the event and is a member of the alliance, said Congress's actions to help the FDA recruit and retain top talent through competitive pay programs prove that the FDA's work is too important to not have the best and the brightest.

"However, the math is quite simple," he said in a Feb. 9 statement to Bloomberg Law. "If Congress doesn't add the resources to make these hires, the FDA will continue to be hamstrung."

President Donald Trump called for a \$473 million increase to the FDA's budget in the fiscal year 2019 request released Feb. 12. "This is the largest increase ever proposed for the FDA," the alliance said in a statement, noting that most of those monies would be targeted "for major expansion of FDA's capabilities in advancing the availability of innovative drugs and medical devices." But Congress must ultimately decide whether to grant the president's request when it determines federal spending.

The new authority under Cures was very helpful, Gottlieb said, and it's part of an agencywide effort to address human resources challenges, he said.

"But that new authority also exacerbates the issues around the haves and the have-nots," he said. Additional hiring authorities and pay for full-time employees for those working on medical product innovation will create higher-paying positions in certain centers. He said that could cause a migration of people out of those other centers into those higher-paying jobs.

An attorney who moves from the FDA chief counsel's office to a position in the drug center, for example, could substantially increase his or her salary.

"It's important that we try to maintain some equity across the agency," Gottlieb said. "You start to see people moving across different centers and across different functions into those higher paid jobs."

Rarely Discussed "Dr. Gottlieb raised an issue that is discussed inside the agency, but rarely outside: the disparity among centers and programs in their ability to pay higher salaries and give more promotions," Steven Grossman, deputy executive director of the alliance, told Bloomberg Law in a Feb. 9 statement.

Gottlieb said the agency will be unveiling soon a pilot project that "dramatically compresses the hiring process" and cuts the time spent to bring on a new hire. "We'll be piloting that with 140 of the open slots in CBER and CDER starting in February and we'll be doing our first hires under that pilot," he said, referring to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research. "We'll also be doing our first hires under the new Cures authority."

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More information on the alliance event is available at
<https://strengthenfda.org/2018/01/27/advocacy-at-a->

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