Congress of the United States
Washington, DC 20515

February 7, 2017

The Honorable Mark Sandy
Acting Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Acting Director Sandy:

We write today requesting clarification about whether the January 23rd executive order imposing a federal hiring freeze applies to the U.S. Food and Drug Administration (FDA). Hiring top scientific talent is critical to fulfilling FDA's mission of advancing public health. We are concerned that hampering FDA's ability to hire puts important, bipartisan priorities like successful implementation of *21st Century Cures Act* and the agency's commitments under the user fee agreements at risk. By clarifying whether the freeze applies to FDA, the Office of Management and Budget (OMB) could help ensure that we do not undermine these goals.

Timely development and approval of drugs and devices depends on maintaining sufficient FDA staff with appropriate scientific expertise. Chronic understaffing already hampers FDA's ability to meet agreed upon deadlines for drug and device approvals. FDA currently has nearly 1,000 unfilled positions. Delays caused by understaffing threaten FDA's ability to keep pace with evolving science and postpone patients' ability to access potentially life-changing treatments.

Understaffing also delays market entry of lower-cost generic and biosimilar alternatives to branded products. Timely entry of generic products is key to reducing the burden of high drug costs for patients and the health system as a whole. Abbreviated new drug applications (ANDAs) for generics are already severely backlogged. According to the Generic Pharmaceutical Association, there are 4,000 generic applications pending at FDA and over 150 vacant generic reviewer positions in CDER. In addition, the biosimilar approval pathway established under the Biologics Price Competition and Innovation Act (BPCIA) is in its infancy, but it has the potential to save both patients and the government billions of dollars. Cutting-off hiring during this critical early phase could setback BPCIA implementation and jeopardize the biosimilar pathway's ability to deliver on its goals over the long-term.

Congress also committed to bolstering FDA staffing through several laws, including a law that we co-authored, the *21st Century Cures Act* (Pub. L. 114-255). *Cures* drew strong bipartisan support in both chambers, passing by a vote of 392 to 26 in the House of Representatives and 94 to 5 in the Senate. The law provides FDA with direct hiring authority and ability to provide more competitive compensation in order to recruit the most talented scientists. FDA's ability to carry out numerous new responsibilities under *Cures*—such as antibiotic approvals, validation of drug development tools, patient-focused drug development, and issuance of new guidance—will depend on the agency's ability to staff-up. We must not jeopardize implementation of the very bipartisan *Cures* law by hampering FDA's ability to hire the best people.

The hiring freeze could also disrupt commitments negotiated under various user fee agreements, including the *Food and Drug Administration Safety and Innovation Act* (FDASIA) (Pub. L. 112-144), which is already law, and the new user fee agreements that Congress must pass this year. The executive order does not appear to exempt user fee-funded hires, as it applies to "all executive departments and agencies regardless of the sources of their operational and programmatic funding." User fee agreements are funded by private dollars paid by the regulated entity—not taxpayer dollars. Sponsors agree to pay a fee in exchange for commitments from FDA, including timelines for FDA review, extra meetings with officials, public workshops, and new guidance. Some commitments even directly call for new personnel. For example, this year's Prescription Drug User Fee Agreement (PDUFA VI) calls for 200 new FDA employees to carry out new responsibilities under the agreement. We believe user fee dollars should be available for hiring and their other intended purposes.

With these issues in mind, we respectfully ask that OMB issue additional guidance clarifying whether FDA is subject to the hiring freeze. Last year, we made a strong bipartisan commitment to advancing medical innovation through *21st Century Cures*. We hope to continue that commitment this year through the user fee reauthorization. FDA's ability to hire and retain top scientific talent is crucial to advancing these shared, bipartisan goals. Thank you for your consideration of this request.

Sincerely,

FRED UPTON
Member of Congress

DIANA DEGETTE
Member of Congress