

United States Senate

WASHINGTON, DC 20510

April 25, 2017

Dr. Scott Gottlieb
Nominee, Commissioner of the Food and Drug Administration
c/o U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. Gottlieb:

The Senate Health, Education, Labor, and Pensions (HELP) Committee is scheduled to vote on your nomination this week. In advance of the committee vote, and in light of President Trump's draconian federal hiring policies, we write to request additional information regarding your plans to ensure the Food and Drug Administration (FDA) will have the resources and capacity necessary to protect the health and safety of the American people.

Earlier this year, we sent a letter to Acting Commissioner Ostroff, expressing our concern about how President Trump's federal hiring freeze would impact the FDA's ability to carry out its mission, fulfill statutory requirements and utilize new hiring authorities from the *21st Century Cures Act*, and carry out obligations agreed to under the medical product user fee agreements negotiated with industry.¹ We have not received a response to our inquiry.

The Trump Administration has failed to present a clear view about hiring policies at the FDA and whether the agency will be prepared to meet its commitments. FDA officials testified before the HELP Committee in March that most user fee-funded positions would be exempt from President Trump's January hiring freeze.² Then, earlier this month, the Office of Management and Budget (OMB) Director Mulvaney lifted the hiring freeze but directed executive departments and agencies to take "immediate actions to achieve near-term workforce reductions and cost savings, including planning for funding levels in the President's Fiscal Year (FY) 2018

¹ Letter to Dr. Stephen Ostroff, Acting Commissioner, FDA (January 30, 2017) (online at: https://www.warren.senate.gov/files/documents/2017-1-30_Letter_to_FDA_re_Trump_hiring_freeze_impact.pdf). Accessed April 20, 2017.

² U.S. Senate Committee on Health, Education, Labor, and Pensions, Full Committee hearing, "FDA User Fee Agreements: Improving Medical Product Regulation and Innovation for Patients Part I" (March 21, 2017) (online at: <https://www.help.senate.gov/hearings/fda-user-fee-agreements-improving-medical-product-regulation-and-innovation-for-patients-part-i>). Accessed April 20, 2017.

Budget Blueprint.”³ Yet, the Department of Health and Human Services has reportedly opted to keep the hiring freeze in place.⁴

The FDA currently has about 1,000 vacancies, and attracting and retaining highly qualified senior staff remains a key challenge. Congress recognized this challenge and granted FDA additional hiring authorities in the *21st Century Cures Act* – President Trump’s current proposals run directly counter to this goal.

Given its crucial public health role, it is imperative that the FDA remain a strong regulatory agency equipped with sufficient, reliable funding and a robust workforce. During your confirmation hearing before the Senate HELP Committee, senators from both parties reiterated their concern about the President’s hiring policies. We were encouraged by your statements that “[i]t’s incumbent upon us to have a world-class workforce that we’re providing the proper tools to and the proper training to maintain [FDA’s] very high standard,” and that you would “continue to make my views known on [the workforce] issue.”⁵ Further, in your written response to a question for the record from Senator Whitehouse, you said, “FDA’s ability to fulfill its mission to protect and promote public health depends on its world-class workforce of talented and dedicated public servants.” You added that, should you be confirmed, you will, “commit to working with my colleagues in the Administration, as well as Congress, to ensure FDA is appropriately resourced and staffed.”⁶

We hope that you will keep your commitment and work to ensure FDA has the critical workforce necessary. We request that you answer the following questions before a Senate floor vote on your nomination.

1. If confirmed, how will you work to ensure the FDA has sufficient funding and personnel to fulfill its mission?
2. Do you agree that positions not funded by the user fee dollars are critical to ensuring the agency can fulfill the commitments in the user fee agreements?
3. What steps would you take to implement the hiring authority provisions under *21st Century Cures*?

³ “Comprehensive Plan for Reforming the Federal Government and Reducing the Federal Civilian Workforce,” OMB Director Mick Mulvaney (April 12, 2017) (online at: <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-22.pdf>). Accessed April 20, 2017.

⁴ Sarah Karlin-Smith, “HHS continuing hiring freeze despite OMB’s memo,” *Politico Pro Health Care Whiteboard* (April 14, 2017) (online at: <https://www.politicopro.com/health-care/whiteboard/2017/04/hhs-continuing-hiring-freeze-despite-ombs-memo-086358>). Accessed April 21, 2017.

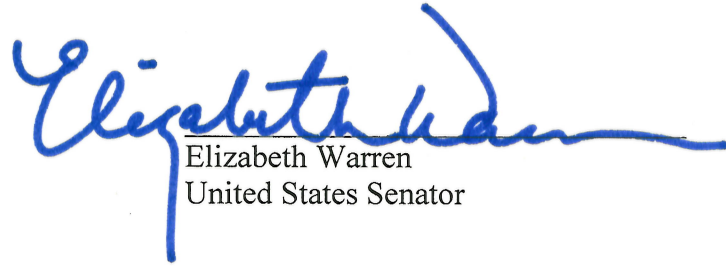
⁵ U.S. Senate Committee on Health, Education, Labor, and Pensions, Full Committee Hearing, “Nomination of Scott Gottlieb, MD, to serve as Commissioner of Food and Drugs” (April 5, 2017) (online at: <https://www.help.senate.gov/hearings/nomination-of-scott-gottlieb-md-to-serve-as-commissioner-of-food-and-drugs>). Accessed April 20, 2017.

⁶ Dr. Scott Gottlieb, responses to questions for the record, U.S. Senate Committee on Health, Education, Labor, and Pensions, “Nomination of Scott Gottlieb, MD, to Serve as Commissioner of Food and Drugs” (April 5, 2017).

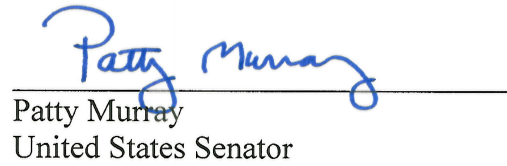
4. How would your ability to successfully lead the FDA be hampered by the imposition of a hiring freeze or by requirements for the agency to shrink the workforce?

If you have any questions concerning this letter, you may contact Beth Pearson (beth_pearson@warren.senate.gov) in Senator Warren's office.

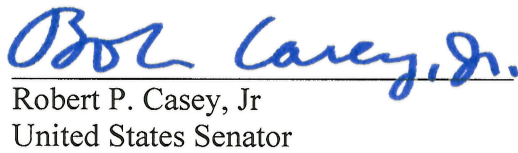
Sincerely,



Elizabeth Warren
United States Senator



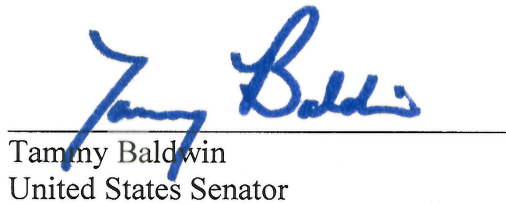
Patty Murray
United States Senator



Robert P. Casey, Jr
United States Senator



Sheldon Whitehouse
United States Senator



Tammy Baldwin
United States Senator