

United States Senate

WASHINGTON, DC 20510

January 30, 2017

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff,

President Trump's January 23 memorandum ordering a freeze on the hiring of Federal employees states that "no vacant positions existing at noon on January 22, 2017, may be filled and no new positions may be created, except in limited circumstances."¹ This executive order and the January 25th memorandum from the Office of Management and Budget, both lack clarity about how the freeze will impact the Food and Drug Administration (FDA).²

We are deeply concerned 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. As you are well aware, the *21st Century Cures Act* gave the FDA two important new tools to attract and retain outstanding talent to help the agency meet the next generation of scientific challenges. It provides the FDA with new hiring authority for positions supporting the review and regulation of medical products and authorizes \$500 million in funding for the FDA implement the law.³ New drug, medical device, biosimilar, and generic user fee agreements, expected to go into effect pending congressional action to reauthorize the programs later this year, will also provide funding for FDA to hire more staff in order to support the review of drug and medical devices.

A hiring freeze at the FDA would conflict with and do significant damage to these bipartisan efforts to fill vacant positions and expand the scientific and technical workforce needed for a robust review of drugs and medical devices. Patients and their families can't freeze the progress of a disease while the FDA waits to fill critical positions. Drug and device manufacturers can't freeze their research and development while the new administration imposes its political ideology. Suspending 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.

¹ White House Office of the Press Secretary, "Presidential Memorandum Regarding the Hiring Freeze" (January 23, 2017) (online at: <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-hiring-freeze>).

² Memorandum from Mark Sandy, Acting Director of the Office of Management and Budget, "Immediate Actions and Initial Guidance for Federal Hiring Freeze" (January 25, 2017).

³ Sections 1002, 3071, and 3072 of the *21st Century Cures Act*, Public Law No.114-255.

The President's memorandum allows the head of any agency to "exempt from the hiring freeze any positions that it deems necessary to meet national security or public safety responsibilities" and further allows the Director of the Office of Personnel Management (OPM) to "grant exemptions from this freeze where those exemptions are otherwise necessary."⁴ However it is unclear if those exemptions will apply to FDA positions.⁵

Finally, the President's memorandum directs the Director of the Office of Management and Budget and the Director of OPM to recommend a long-term plan to reduce the size of the Federal workforce through attrition. Applying such a plan to the scientific and technical workforce at the FDA would severely hamper the agency's ability to meet its commitments and carry out its mission.

In order for us to better understand the impact of President Trump's memorandum on the FDA workforce, please provide us with an answer to the following questions:

1. How would a hiring freeze affect the FDA's ability to meet the commitments agreed to in PDUFA V, MDUFA III, BsUFA I and GDUFA I?
2. How would a hiring freeze, if still in place, affect the FDA's ability to meet the commitments agreed to in PDUFA VI, MDUFA IV, BsUFA II and GDUFA II?
3. How would a hiring freeze impact FDA's ability to implement provisions of the 21st Century Cures Act and meet its statutory deadlines?
4. Will you exempt any positions at the FDA from the hiring freeze because they are necessary "to meet national security or public safety responsibilities"? How many positions will be exempted in this manner? Are these positions funded through appropriations or user fees? Please provide a detailed list of these positions.
5. Absent any national security or public safety exemptions, what will be the impact on the drug and device review process?
6. Will you request exemptions from this hiring freeze from the Director of the Office of Personnel Management? How many exemptions will be requested from OPM? Are these positions funded through appropriations or user fees? Please provide a detailed list of positions for which you intend to ask for an exemption. Absent such exemptions, what will be the impact on the drug and device review process?
7. How would a plan to "reduce the size of the Federal Government's workforce through attrition" affect the FDA's overall ability to meet its commitments?

⁴ White House Office of the Press Secretary, "Presidential Memorandum Regarding the Hiring Freeze" (January 23, 2017) (online at: <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-hiring-freeze>).

⁵ InsideHealthPolicy, "Trump Signs Federal Hiring Freeze, But Impact on FDA Unclear" (January 23, 2016) (online at: <https://insidehealthpolicy.com/daily-news/trump-signs-federal-hiring-freeze-impact-fda-unclear>),

8. How will the President's memorandum and the longer-term plan to reduce the size of the Federal workforce through attrition affect the FDA's ability to implement provisions contained in the *21st Century Cures Act* and meet its statutory deadlines?

Please provide answers to these questions in writing by February 10, 2016. If you have any questions concerning this letter, you may contact Beth Pearson (beth_pearson@warren.senate.gov) in Senator Warren's office.

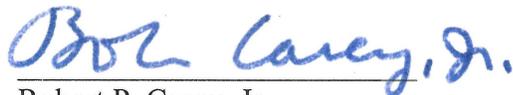
Sincerely,



Elizabeth Warren
United States Senator



Patty Murray
United States Senator



Robert P. Casey, Jr.
United States Senator



Al Franken
United States Senator



Michael F. Bennet
United States Senator



Sheldon Whitehouse
United States Senator



Tammy Baldwin
United States Senator



Margaret Wood Hassan
United States Senator