

January 27, 2021

Dear Senator Warren,

Thank you for your letter. I am honored by President Biden's nomination to serve as Commissioner of the Food and Drug Administration (FDA) for a second time. I share your commitment to restoring public trust in government and, if confirmed, it will be a priority of mine as FDA Commissioner.

The Biden-Harris Administration has set the highest ethical standards of any Administration for its political appointees. However, in response to your letter, I am willing to voluntarily extend the recusal period from two years to four years for all particular matters involving companies with which I have a previous working relationship.

I have also gone beyond the Biden-Harris Administration Ethics Pledge and agreed to recuse myself from matters before the Agency involving Duke University. Although I retired from my role at the University in 2019, I believe it is important to reassure the public at the outset that my previous positions will not bias or influence any of my decision making on behalf of the Agency. I do not intend or expect to seek a waiver from any of these recusals. However, if unanticipated circumstances were to arise, I also commit to considering all available alternatives – in close consult with Agency ethics officials – prior to seeking a waiver.

Finally, I have agreed to comply with the post-government employment ethics rules set by statute and extended by the Biden-Harris Administration Ethics Pledge. I will also further commit to not seek employment with or compensation from, including as a result of board service, any pharmaceutical or medical device company that I interact with during my time in government for four years following my tenure, if confirmed as FDA Commissioner. I intend to pursue opportunities in higher education to help educate the next generation of medical leaders. I have, and will always be, a physician and researcher first. The interests and well-being of patients will continue to be my top priority, and that will guide my work as the Agency protects and promotes public health.

Thank you for the opportunity to answer your questions. I welcome the chance to discuss these or any other issues further at your convenience.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robt Califf". The signature is fluid and cursive, with the first name "Robt" and last name "Califf" clearly distinguishable.

Dr. Robert Califf