

February 9, 2016

President Barack Obama
1600 Pennsylvania Ave NW,
Washington, DC 20500

Dear President Obama,

I am writing to you today to ask that you withdraw your nomination of Dr. Robert Califf to head the FDA. The Project On Government Oversight is a nonpartisan independent watchdog that champions good government reforms. POGO's investigations into corruption, misconduct, and conflicts of interest achieve a more effective, accountable, open, and ethical federal government.

Although Dr. Califf has been hailed as an expert on the clinical testing of prescription drugs and as an exceptional candidate to head the FDA,¹ POGO's investigations suggest otherwise. We have concluded that his track record does not inspire the kind of confidence required in the leader of this crucial agency.

In general, Dr. Califf's longtime close relationship with the pharmaceutical industry certainly gave us pause. However, it was not until after our in-depth investigation into one of the clinical trials he chaired that we concluded he is not fit to be the FDA commissioner.

Specifically, POGO conducted an investigation into the clinical trial of blood thinner Xarelto.² The executive committee for that trial was co-chaired by Dr. Califf. According to a senior FDA reviewer, a "lack of care" in the trial's design and execution might have led to "unnecessary strokes" among test subjects.³ Furthermore, at least one member of an FDA advisory committee looked back on that history and worried that the clinical trial put commercial considerations ahead of health and safety. Addressing a difference between the FDA's recommendations and the trial's design "[M]y concern was that the dose was selected more for a marketing advantage rather than for the scientific data that was available," the advisory committee member said.⁴

¹ Abigail Xie, "Colleagues Defend Califf Amid Criticisms of Industry Ties," *The Duke Chronicle*, November 24, 2015. <http://www.dukechronicle.com/article/2015/11/colleagues-defend-califf-amid-criticisms-of-industry-ties> (Downloaded February 1, 2016)

² David Hilzenrath, "Drug Problems: Nominee to Head FDA Led Clinical Trial FDA Faulted," POGO Blog, November 12, 2015. <http://www.pogo.org/blog/2015/11/fda-nominee-robert-califf-led-faulted-fda-trial.html> (hereinafter "Nominee to Head FDA Led Clinical Trial FDA Faulted"); David Hilzenrath, "Drug Problems: European Regulator Investigating Trial Led by FDA Nominee," POGO Blog, November 30, 2015. <http://www.pogo.org/blog/2015/11/regulator-investigating-clinical-trial-led-by-fda-nominee.html>

³ Summary Review, Center for Drug Evaluation and Research, page 6. http://www.pogoarchives.org/m/fda/fda_decisional_memo_xarelto_20111104.pdf

⁴ "Nominee to Head FDA Led Clinical Trial FDA Faulted"

Furthermore, POGO has found that Dr. Califf was incomplete and possibly misleading in his response to Questions for the Record submitted by Senator Elizabeth Warren as part of the nomination process. Senator Warren asked, “For the clinical trials you conducted or oversaw while at the Duke University School of Medicine and the Duke University Medical Center, can you detail for us exactly what input pharmaceutical sponsors did and did not have in the design of the trials?”⁵ In response, Dr. Califf stated that the design of clinical trials “is subject to review and approval by FDA.” However, in the case of the Xarelto trial, Dr. Califf’s team ignored the FDA’s suggested regimen⁶ and continued to test a dosing regimen that was more attractive for marketing the drug but had the potential to compromise the safety of the treatment. This decision was a significant departure from the FDA’s recommendation, which in this case was not the final word.

Dr. Califf committed to addressing “the FDA’s willingness to stand up to industry preferences in the design and conduct of clinical trials,”⁷ but based on this example, it is hard to feel confident that he would do so if confirmed.

The FDA is an agency that is constantly under pressure from all sides, and the FDA Administrator is a particularly difficult post to fill with someone who has both the expertise and independence to protect public health and safety, but it is not impossible to find such a person. POGO is willing to submit a list of possible nominees who are far more appropriate for this position.

We urge you to withdraw Dr. Califf’s nomination.

If you have any questions or need additional information, please contact Elizabeth Hempowicz at ehempowicz@pogo.org or (202) 347-1122.

Sincerely,



Danielle Brian
Executive Director

⁵ Questions for the Record, HELP Committee Hearing, “Hearing on the Nomination of Dr. Robert Califf to serve as FDA Commissioner,” November 17, 2015.

http://www.pogoarchives.org/m/fda/califf_answers_to_warren_questions_20151117.pdf

⁶ “Nominee to Head FDA Led Clinical Trial FDA Faulted”

⁷ “Nominee to Head FDA Led Clinical Trial FDA Faulted”