

From: Coriell, Scott [Scott.Coriell@vermont.gov]
Sent: Wednesday, September 23, 2015 7:33 AM
To: Coriell, Scott
Subject: Gov. Shumlin Urges U.S. Senate Leaders to Oppose FDA Nominee
Attachments: GPS Letter on FDA Nominee.pdf

FOR IMMEDIATE RELEASE
September 23, 2015

Gov. Shumlin Urges U.S. Senate Leaders to Oppose FDA Nominee

MONTPELIER – Gov. Peter Shumlin is urging leaders in the U.S. Senate to oppose the nomination of Dr. Robert Califf to head the Food and Drug Administration (F.D.A), citing concerns over Dr. Califf’s close ties to the pharmaceutical industry. According to the *New York Times*, Dr. Califf would have [“deeper ties to the pharmaceutical industry than any F.D.A. commissioner in recent memory.”](#)

Approving the nomination of Dr. Califf “is reckless and unwise and sends the exact wrong signal to an American public that has already lost faith in the F.D.A.’s ability to prioritize public health over the pharmaceutical industry’s profits,” Gov. Shumlin said in a letter to the Chairman and Ranking Member of the U.S. Senate Health, Education, Labor, and Pension Committee, which is charged with vetting the nomination.

Gov. Shumlin cites the recent F.D.A decision to approve OxyContin for use by children as young as 11 years old as an example of the cozy relationship between the F.D.A and the pharmaceutical industry it regulates.

In his letter the Governor wrote, “According to the *Washington Post*, the F.D.A asked the maker of OxyContin, Purdue, to evaluate [“the safety and effectiveness of OxyContin in pediatric patients.”](#) Asking a company that will benefit from the approval of a drug to evaluate the safety of approving that drug is beyond belief. It’s the fox guarding the henhouse but worse because Purdue has a history of lying to pad their own pockets. In 2007, several of the company’s top executive pleaded guilty to [“falsely marketing OxyContin in a way that played down the drug’s risk of addiction and potential for abuse.”](#) according to the *Washington Post*.”

Gov. Shumlin has been working to combat the opiate and heroin crisis gripping America. In 2014, the Governor devoted his entire State of the State Address to the issue. Vermont has since expanded treatment options for those suffering from addiction, distributed thousands of overdose reversal kits that have saved hundreds of lives, and implemented a system where addicts who are arrested for non-violent crimes can be sent to treatment instead of jail.

The Governor’s letter to U.S. Senators Lamar Alexander and Patty Murray is attached.

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PETER SHUMLIN
Governor



State of Vermont
OFFICE OF THE GOVERNOR

September 22, 2015

The Honorable Lamar Alexander
Chairman, U.S. Senate HELP Committee
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, U.S. Senate HELP Committee
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

I am writing to urge you to oppose confirmation of Dr. Robert M. Califf as head of the Food and Drug Administration (FDA). The FDA's history is riddled with examples of a too-cozy relationship with the industry it regulates. To appoint as head of that Agency someone who has, according to the *New York Times*, "deeper ties to the pharmaceutical industry than any F.D.A. commissioner in recent memory" is reckless and sends the exact wrong signal to an American public that has already lost faith in the FDA's ability to prioritize public health over the pharmaceutical industry's profits.

The most recent example of the cozy relationship between the FDA and the pharmaceutical industry is the approval last month of OxyContin for use by children as young as 11 years old. Expanding the availability of OxyContin at a time when states like Vermont are working so hard to combat the rising tide opiate and heroin addiction across this country is an unwise policy. Almost more concerning, however, is how the policy was developed. According to the *Washington Post*, the FDA asked the maker of OxyContin, Purdue, to evaluate "the safety and effectiveness of OxyContin in pediatric patients." Asking a company that will benefit from the approval of a drug to evaluate its safety is beyond belief. It is the fox guarding the henhouse but worse because Purdue has a history of lying to pad their own pockets. In 2007, several of the company's top executives pled guilty to "falsely marketing OxyContin in a way that played down the drug's risk of addiction and potential for abuse." according to the *Washington Post*.

These types of examples seriously erode trust in the FDA's impartiality. To confirm someone to lead the FDA who has extensive ties to an industry that has repeatedly shown an ability to pull the strings of the regulatory process to get its way is unacceptable.

Sincerely,

A handwritten signature in black ink, appearing to read 'Peter Shumlin', with a long horizontal line extending to the right.

Peter Shumlin
Governor of Vermont

cc: U.S. Senate Majority Leader Mitch McConnell, U.S. Senate Minority Leader Harry Reid