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December 7, 2016

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

I am writing today to express my deep concern about the Sorin 3T heater-cooler device, which has been used in thousands of heart surgery operations across Maine and which has also been shown to put patients at risk of acquiring a dangerous mycobacterial infection.

The heater-cooler devices associated with these infections are used for heart surgeries in Maine and across the country. While no infections have yet been reported as a result of this device's use in Maine and the risk remains low, the dozens of reported cases in the U.S. and abroad are a serious cause for concern for me and for my constituents who were exposed to the device.

What I find particularly troubling is that, despite evidence presented to federal regulators in August 2014 of the device's link to these infections, the Food and Drug Administration (FDA) demurred on releasing a safety alert until more than a year later, and furthermore did not give hospitals and patients detailed recommendations to deal with the issue at hand for another year after that.

I am left to ask: given the severe safety concerns associated with the device, why did the FDA choose not to alert the public of the risks associated with the device until 14 months after regulators were made aware of the infections it caused? Furthermore, why did hospitals and patients have to wait two years after the FDA was first informed of the infection risk to be given detailed advice and recommendations?

Thank you for your attention to these concerns. I look forward to your response to this letter.

Sincerely,

Angus S. King, Jr.
United States Senator

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