Congress of the United States

Washington, D.C. 20515

April 28, 2017

Stephen Ostroff, MD
Acting Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

We write with great concern about the ongoing and accumulating safety concerns for patients using defibrillators manufactured by St. Jude Medical (which was recently acquired by Abbott) and the lack of action on behalf of the Food and Drug Administration (FDA). Those concerns have only grown in response to the letter the FDA sent to St. Jude Medical on April 12, 2017 citing the ongoing safety issues and the lack of action taken by St. Jude Medical to correct those problems. This is not the first time that the FDA has warned patients of the defects associated with those devices, and yet, the FDA has done little to rebuke St. Jude Medical for jeopardizing the health of patients utilizing its devices. We write to strongly urge the FDA to take immediate action to protect patients and to hold St. Jude Medical accountable for its actions.

We are deeply troubled that the FDA has not penalized St. Jude Medical for selling defibrillators that it knew to be faulty for years and downplayed the seriousness of battery failure in its defibrillators. In addition, the FDA confirmed that St. Jude Medical failed to tell their own management and advisory board after a patient died due to battery failure, and yet, the FDA has not taken any action against St. Jude Medical. Simply put, there is no excuse for inaction. We are extremely concerned the FDA has yet to outline exactly what corrective actions, if any, will be taken against St. Jude Medical. In your letter, you state that the FDA could take corrective actions within the next fifteen business days and that you may impose penalties after that if St. Jude Medical's response is inadequate. To that end, we request answers to the following questions:

1) What actions does the FDA plan to take against St. Jude Medical in response to the significant problems outlined in your warning letter? If any actions have already occurred, please advise us of what those actions were and what the outcome was.
2) What is the FDA doing to ensure that the faulty devices sold by St. Jude Medical through December 2016 are not implanted in patients? Has the FDA contacted medical device wholesalers and providers who typically perform those procedures to alert them of the danger?
3) How is the FDA working to inform patients who had faulty devices implanted? What remedies will be provided to those patients?

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4) What steps will the FDA take to prevent St. Jude Medical from engaging in similar practices in the future?

We strongly believe that serious actions need to be taken against St. Jude Medical to deter this incredibly dangerous behavior. Moreover, we believe that patients who have been given faulty devices need to be notified and provided with appropriate remedies at no cost to the patient. We sincerely hope that the FDA will treat this situation with the seriousness it deserves. We look forward to your response to those questions no later than May 26, 2017.

Sincerely,

JAN SCHAKOWSKY
Member of Congress

ROSA L. DELAURO
Member of Congress