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February 19, 2016

The Honorable Sylvia Mathews Burwell
Secretary
United States Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell,

Thank you for talking with me ahead of the Food and Drug Administration's (FDA) release of its Opioids Action Plan. I appreciate your attention and commitment to taking steps to combat the prescription opioid and related heroin epidemic gripping the country.

I am pleased to see that, in response to concerns I raised with you in December about FDA's opioid approval process, the agency will broaden its view of an opioid's "safety" and begin to consider the broader public health impact and risks associated with opioid use and abuse. That is an important step. I am, however, very disappointed that FDA has not agreed to my request that it convene advisory committees for all opioid approval decisions. Instead — and inexplicably — FDA has committed to automatically empanel these important expert advisory groups only when FDA is considering a new drug application for a non-abuse-deterrent opioid.

FDA needs outside expert advice on *all* opioid approval decisions. FDA's own guidance recognizes that "the fact that a product has abuse-deterrent properties does not mean that there is no risk of abuse." Whether an opioid is abuse deterrent or not hasn't prevented tens of thousands of people who have had their wisdom teeth removed or experienced lower back pain from getting addicted to these painkillers. Furthermore, because, as FDA has stated, abuse-deterrent technology is in its infancy and rapidly evolving, advice from external experts would be most helpful as FDA is grappling with the complexities, risks, and benefits of abuse-deterrent technologies.

In 1995, FDA approved the original formulation of OxyContin, which FDA considered to be abuse deterrent based on the fatally mistaken premise that its extended-release properties would make it less likely to be abused. And as the enclosed analysis of FDA's opioid decisions dating back to the original OxyContin approval demonstrates, the agency has repeatedly bypassed advisory committees when considering opioids with abuse-deterrent claims — many of which subsequent experience disproved. It therefore appears that the proposed action limiting

mandatory advisory committees to non-abuse-deterrent formulations will do nothing more than preserve the dangerous status quo.

FDA must commit to empanel advisory committees for all opioid-approval decisions — including reconsideration of its decision authorizing a new pediatric indication for OxyContin, which I also requested when I placed my hold on Dr. Califf's nomination to serve as FDA Commissioner. Until FDA does, I will continue to oppose his nomination.

Sincerely,

Edward J. Markey

Edward J. Markey
United States Senator