THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 15 2017

The Honorable Patty Murray
Ranking Member
Health, Education, Labor and Pensions Committee
United States Senate
Washington, DC 20510

Dear Senator Murray:

This letter is to convey the Administration's steadfast commitment to ensuring that Americans have access to safe and effective medical products in as timely a manner as possible. The Administration supports the Food and Drug Administration's (FDA's) user fee programs and looks forward to working with you to ensure that the reauthorization of these vital programs reflects the policy set forth in the President's *America First* Budget Blueprint.

The law required the previous Administration to submit legislative reauthorization proposals to Congress no later than January 15, 2017, for four FDA user fee programs (under the Prescription Drug User Fee Amendments, Medical Device User Fee Amendments, Generic Drug User Fee Amendments, and Biosimilar User Fee Act) that will expire on October 1, 2017. Our Administration remains committed to programmatic commitments and objectives outlined in the reauthorization proposals as submitted, and we look forward to working with you to ensure a timely reauthorization of these user fee programs this year. However, as outlined in the President's *America First* Budget Blueprint, the current Administration is seeking to recalibrate how the FDA finances its medical product review work in order to better serve the American people.

The medical products field is ever-changing and advancing on behalf of patients. To ensure the FDA has the critical resources needed to keep pace with this field, the President's Budget Blueprint proposes to increase and restructure the medical product user fee programs at FDA to be 100 percent user fee supported programs, with no funding triggers that require budget authority financing. This would replace the need for new budget authority to cover pre-market review costs – while maintaining our commitment to speed the approval of safe and effective medical products. This will benefit both taxpayers and patients.

The Administration is committed to improving government performance while reducing the burden on taxpayers to achieve FDA's mission – a commitment underscored by this policy – so that we might better serve Americans. Therefore, as Congress reauthorizes FDA's medical product user fee programs, we strongly urge you to include the medical product user fee policy set forth in the President's Budget Blueprint so that the industries which benefit from these review processes pay the full cost of FDA's evaluation activities of their products.

We look forward to working with Congress on the new user fee structure proposed and to ensure there are sufficient user fee resources for FDA's essential role in advancing medical products on behalf of patients.

Yours truly,

Thomas E. Price, M.D.