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

MAR 0 2 2016

The Honorable Lloyd Doggett
U.S. House of Representatives
Washington, DC 20515

Dear Representative Doggett:

Thank you for your letter concerning the development of guidelines on the use of the Bayh-Dole Act march-in authority. I share your concern about the impact rising drugs costs are having on American patients and their families, as does this Administration.

The Department of Health and Human Services has taken action on the topic of the rising cost of drugs, including a notice to all 50 state Medicaid directors and letters to the CEOs of several drug manufacturers about providing access to therapy for Hepatitis C patients; convening a forum with stakeholders to discuss opportunities to improve patient access to affordable prescription drugs; driving innovation through the President's Precision Medicine Initiative; incorporating value-based and outcomes-based models into purchasing programs in both the public and private sectors; and publishing the Medicare Drug Spending Dashboard to provide information on the most expensive drugs in Medicare Part B and Part D. The FY 2017 President's Budget builds on this work with a number of proposals to improve the access and value Americans get from their medications, without discouraging important and lifesaving innovations.

As you are aware, some drugs utilize patented inventions that were supported by United States Government funding, such as NIH grants. The Bayh-Dole Act lays out the responsibilities of recipients of research grant and contract funding for inventions the institutions make under these awards. The Act, under certain specific circumstances, provides the government with the march-in authority (35 U.S.C. §203) - to ensure that a government-funded invention that covers a drug does not block it from entering the market.

As you mentioned, the government's march-in right allows the funding agency, on its own initiative or at the request of a third party, to grant additional licenses to other responsible applicants. This right is strictly limited and can only be exercised if the agency conducts an investigation and determines that specific criteria are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of the inventions.

The NIH considered using its march-in authority to address drug pricing concerns in 2004 for Norvir® (ritonavir)[1] and Xalatan® (latanoprost),[2] and in 2013 for the pricing of Norvir® a second time.[3] Links to NIH's reviews and determinations are provided below. In each review,

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1 www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

2 www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.

3 www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

the NIH considered whether the marketed drug met the statutory requirements to justify use of the march-in authority and determined that it did not.

NIH considers the application of the march-in statute on a case-by-case basis, and is prepared to use its authority if presented with a case where the statutory criteria are met regarding the commercialization and use of an NIH-funded, patented invention, and where march-in could in fact alleviate health or safety needs or address a situation where effective steps are not being taken to achieve practical application of the inventions. After consulting with the NIH, we believe the statutory criteria are sufficiently clear and additional guidance is not needed.

Thank you again for your leadership on this important issue. I look forward to working with you as part of our broader efforts to ensure patients have timely access to innovative, quality, and affordable medications.

If you have further questions, please contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I am also sending this response to the co-signers of the letter.

Sincerely,

Sylvia M. Burwell