DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

To be e-mailed to: andrew.goldman@keionline.org

June 20, 2016

Andrew S. Goldman
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009

Dear Dr. Goldman:

Thank you for your January 14 letter and your follow-up correspondence to the Department of Health and Human Services, the Department of Defense, and me requesting that each or both federal agencies (1) exercise its march-in authorities found at 35 U.S.C. § 203, or (2) exercise the federal government's non-exclusive royalty-free government use license for Xtandi® (enzalutamide). Based on the information provided in your letter and follow-up correspondence, and information that is publically available, we decline to initiate a march-in investigation or utilize the government's license in the patents.

More specifically, a federal agency that funded an invention has the right, consistent with 35 U.S.C. § 203(a)(1), to grant a license to a third party if "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time effective steps to achieve practical application of the subject invention in such field of use." Practical application as defined at 35 U.S.C. § 201 is "...to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

As set forth in NIH's prior march-in determinations (1997 Cell Pro; 2004 and 2013 Norvir®; 2004 Xalatan®, see www.ott.nih.gov/policies-reports), practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public..." Xtandi® is broadly available as a prescription drug. Your letter states that sales of enzalutamide increased 77% from Fiscal Year 2013 to Fiscal Year 2014 and are projected to increase 51% from Fiscal Year 2014 to Fiscal Year 2015 (from your letter, pages 9-10); however, it provides no information and no information was identified from public sources to suggest that enzalutamide is currently or will be in short supply.

In view of the above information presented in your letter and your follow-up correspondence and public information identified by the NIH, we decline to proceed with the government's march-in authorities at this time or utilize the government's license to the patents. Enclosed for your information is the June 7 Department of Health and Human Services response to Representative Doggett on holding a public hearing.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director

Enclosure

cc: The Honorable Ashton Carter
Secretary of Defense

The Honorable Secretary Burwell
Secretary of Health and Human Services

Union for Affordable Cancer
Treatment (UACT)

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

JUN 07 2016

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

Dear Representative Doggett:

Thank you for your letter of March 28 expressing your and your colleagues' ongoing concerns about the price of Xtandi® (enzalutamide). I can assure you that Dr. Collins and I share your concerns about the rising costs of drugs and the impact these costs have on Americans' access to life-saving treatments.

In your letter, you encourage the National Institutes of Health (NIH) to hold a public hearing on the use of the Bayh-Dole Act march-in authority for the patented inventions funded by the NIH and U.S. Army that cover Xtandi® (enzalutamide). The NIH considers the application of the statutory criteria for march-in very carefully, according to the process outlined in the statute and implementing regulations at 37 CFR 401.6. At this time, NIH believes this process allows the agency to collect sufficient information to consider the petition without a public hearing.

Over the past decade, the NIH has evaluated three prior march-in requests. The NIH's determinations in these cases, which are publicly available at www.ott.nih.gov/policies-reports, demonstrate how the agency evaluates the evidence regarding the statutory conditions that would justify the exercise of its march-in authority.

The Department of Health and Human Services' goal is to foster a health care system that leads in innovation, delivers affordable, high-quality medicines, and results in healthier people. Thank you for your concern and ongoing leadership as we work on our broader efforts to ensure patients have timely access to innovative, quality, and affordable medications.

If you have additional questions or concerns, please contact Jim Esquea, Assistant Secretary for Legislation at (202) 690-7627. I have sent this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell