DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 7, 2017

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

Dear Mr. Goldman:

Thank you for your letter to Dr. Thomas E. Price, Secretary of Health and Human Services (HHS), and James Mattis, Secretary of Defense, which is a follow-up to your January 14, 2016, request to Sylvia Mathews Burwell, former Secretary of HHS; Ashton Carter, former Secretary of Defense; and me requesting that each or both federal agencies (1) exercise their 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).

Xtandi® is a prescription medicine approved by the Food and Drug Administration used to treat men with prostate cancer that has spread to other parts of the body and no longer responds to testosterone-lowering medical or surgical treatment. NIH's support to the University of California in small molecule research led to three patents that Medivation, Inc. and Astellas Corporation further developed into the commercial product Xtandi®. In 2016, Pfizer Pharmaceutical bought Medivation, Inc., and Pfizer and Astellas Corporation have entered into a joint venture to manufacture and distribute Xtandi®.

NIH has the authority under 35 U.S.C. § 203(a)(1) to utilize march-in rights 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, means 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. In 2016, KEI's request to NIH and the Army to use their respective march-in authorities or their government use licenses for Xtandi® was said by KEI to be based on its determination that the price of Xtandi® was higher in the United States than in Europe.

In the June 20, 2016, response to the first KEI request for NIH and the Army to use their march-in authorities or government use licenses, NIH explained that Xtandi® is widely available on the market, its sales have increased since it became available by more than ten percent (10%) each year, and there have been no public reports that Xtandi® is in short supply or is not being prescribed or used because of its price.

A public statement by Astellas on March 29, 2016, indicated that during 2015, Astellas provided Xtandi® for free under the Astellas Access Program to eligible patients who did not have insurance or were underinsured and have an annual adjusted household income of $100,000 or less. Astellas also reported that, in 2015, over 2,000 men fighting advanced prostate cancer received Xtandi® for free.

Based on the information we reviewed last year, and again in response to this current request, NIH declines to initiate a march-in investigation or to utilize the government's license in the patents. NIH is sensitive to the impact of pricing on access to Xtandi® by patients and continues to believe the broader issue of drug pricing would be most appropriately addressed through legislative channels to develop remedies that have implications for the cost of healthcare overall.

Sincerely yours,

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

cc: The Honorable James Mattis
Secretary of Defense

The Honorable Thomas E. Price, M.D.
Secretary of Health and Human Services