DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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Dear Mr. Sachs and Mr. Love:

We have received your letter to Health and Human Services (HHS) Secretary Xavier Becerra, regarding the November 2021 petition requesting the government to use its march-in authority for Xtandi® (enzalutamide). As the Acting Principal Deputy Director of the National Institutes of Health (NIH), I am pleased to respond on his behalf.

NIH considers the use of march-in authority in a manner that is consistent with the policy and objective of the Bayh-Dole Act, promotes commercialization of NIH research results to maximize the potential for NIH-funded technologies to become products, and serves the broader interests of the American public. As you are aware, the march-in provision of the Bayh-Dole Act (35 USC §203), implemented by 37 CFR §401.6, authorizes the Government to require the funding recipient or its exclusive licensee to license a federally funded invention to a responsible applicant or applicants on reasonable terms, or to grant such a license itself, if the Federal agency determines that any of the following conditions are met:

- 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;
- action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- action is necessary because the agreement required by section 35 USC §204 [regarding a requirement to manufacture in the United States] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

We are currently coordinating with HHS to review and assess the information submitted in the 2021 petition requesting the government to use its march-in authority for Xtandi® (enzalutamide) to determine whether the initiation of the march-in procedures outlined in 37 CFR §401.6 may be warranted.

Sincerely,

Tara A. Schwetz, Ph.D.
Acting Principal Deputy Director, NIH