DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 2, 2022

Joe Panetta
President and CEO
Biocom California

Richard White
Associate Manager of Federal Advocacy
Biocom California
rwhite@biocom.org

Dear Mr. Panetta and Mr. White:

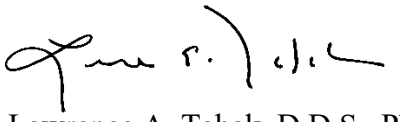
We have received your letter to Health and Human Services (HHS) Secretary Xavier Becerra, expressing concern about the use of march-in authority to address high drug prices. As the Acting Director of the National Institutes of Health (NIH), I am pleased to respond on his behalf.

NIH is assessing the November 2021 petition requesting the government to use its march-in authority for Xtandi® (enzalutamide). 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 reviewing the information submitted in the 2021 petition to determine whether the initiation of the march-in procedures outlined in 37 CFR §401.6 may be warranted.

Sincerely,



Lawrence A. Tabak, D.D.S., Ph.D.
Acting Director, National Institutes of Health