

November 18, 2021

Xavier Becerra
Secretary
Department of Health & Human Services
United States of America

Via Email: xavier.becerra@hhs.gov

Dear Secretary Becerra:

The undersigned individuals are writing to formally ask the Department of Health and Human Services (HHS) to grant march-in rights for the patents on the prostate cancer drug enzalutamide (marketed as Xtandi).

As prostate cancer patients we have previously petitioned the U.S. Department of Defense (DoD) to grant march-in rights for the patents on this life saving drug.

Clare Love and David Reed submitted a petition to the DoD on February 4, 2019, following a Directive from the Senate Armed Services Committee to the DoD to grant such march-in requests when the price of a drug developed with a DoD grant is higher than the median price in seven large high income economies. That is the case in this petition, in which enzalutamide—which was invented at UCLA on grants from the U.S. Army and the National Institutes of Health (NIH)—are roughly 3 to 5 times more expensive in the United States than in other high income countries. The drug, which is inexpensive to manufacture, is priced in the United States at \$106.865 per 40 mg pill. With a required dose of four pills per day, Xtandi costs \$427.50 per day and more than \$156,000 per year. The price in other high income countries generally ranges from \$20 to \$40 per 40mg pill. A Canadian generic manufacturer has offered to sell enzalutamide to the U.S. government for \$3 per pill.

(See: <https://www.drugs.com/price-guide/xtandi> and <http://drugdatabase.info/drug-prices/>)

Robert Sachs wrote to the DoD on April 12, 2021 to join the Love and Reed march-in request. To date, the DoD has not acknowledged nor acted on these petitions.

Clare Love is a Vietnam veteran. David Reed is an accomplished computer scientist,¹ best known for developing the concept of the end to end principle for the Internet. Robert Sachs is an attorney, former Board Chair of the National Coalition for Cancer Survivorship (NCCS), and member of the board of trustees of the Dana Farber Cancer Institute.

We ask that our petition be adjudicated by an impartial decision maker. Under two previous Administrations, HHS has been petitioned to grant a march-in request for the patents on enzalutamide. Each time HHS delegated the case to the NIH, and each time, including on the

¹ https://en.wikipedia.org/wiki/David_P._Reed.

administrative appeals, such requests and appeals were summarily rejected, in line with a then standing policy position that the NIH would not question the reasonableness of company pricing of NIH funded inventions. It is our understanding that HHS is now willing to consider the merits of a march-in request, when the basis is that the price is demonstrably unreasonable.

Attached are copies of the 2019 and 2021 march-in petitions DoD. We are asking that HHS address this issue in a timely manner, which has dragged on for years at this point. A first step is to grant a hearing on the petition, where the patent holders and the persons supporting the march-in petitions can present evidence. This was done once by NIH for a march-in petition on the HIV/AIDS drug ritonavir in 2004.

A group known as the Bayh-Dole Coalition has lobbied against any use of the march-in rights to deal with pricing concerns. This well resourced and powerful group of patent holders has generated a steady stream of misleading information about the march-in rights issue. We welcome their input in any evaluation of our march-in petitions, and only ask that the facts are actually addressed by HHS. We also ask that any groups or individuals interested in the petition be allowed to provide evidence for the record.

We are pleased that the HHS Comprehensive Plan for Addressing High Drug Prices and the President's Executive Order on Competition recognize the use of march-in rights to address abusive pricing of drugs.

Xtandi was invented with NIH funding. The Orange Book lists three patents for enzalutamide: U.S. Patent Nos. 7709517, 8183274, and 9126941, and all three acknowledge support from NIH grant number 5 P50 CA092131. The patent expiration dates are from May 2026 to August 2027.

In the past, the use of march-in rights for enzalutamide has been supported by more than a dozen organizations (see Annex 1) and several members of Congress in both the U.S. Senate and the House of Representatives. When the Trump Administration made a last minute attempt to change the Bayh-Dole regulations to eliminate pricing concerns as a sole ground for a march-in petition, more than 80 thousand persons submitted comments in opposition.

Thank you for considering our request. We ask HHS to move forward and incorporate the two previous march-in petitions to the DoD, which are attached.

Sincerely,

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ANNEX 1: Organizations that have previously supported march-in rights on enzalutamide

Alliance for Retired Americans
American Medical Students Association (AMSA)
Center for the Study of Responsive Law
Community Catalyst
Essential Information
Knowledge Ecology International (KEI)
National Physicians Alliance (NPA)
Public Citizen
RxRights
The Other 98%
U.S. PIRG
Union for Affordable Cancer Treatment (KEI)
Universities Allied for Essential Medicines (UAEM)

ANNEX 2: Members of the Bayh-Dole Coalition



1. Association of University Research Parks
2. AUTM
3. BIOCOM
4. BIO
5. BIOHealth Innovation
6. Bio NJ
7. California Life Sciences Association
8. Carnegie Mellon University
9. Center for Innovation and Free Enterprise (CIFE)
10. Conservatives for Property Rights
11. Council on Government Relations
12. Columbia Technology Ventures
13. Council on Competitiveness
14. CSU Ventures
15. Duke Licensing & Ventures
16. Eagle Forum

17. ExploraMed
18. Funtek
19. US Chamber of Commerce Global Innovation Policy Center
20. Incubate
21. India University
22. Innovation Associates
23. IPWatchdog
24. Information Technology and Innovation Foundation
25. International Economic Development Council
26. K2 Biotechnology Ventures
27. Licensing Executives of USA and Canada
28. Lehigh University
29. LSU Business and Technology Center
30. Magee-Womens Research Institute and Foundation
31. NVCA
32. Patent Docs
33. PhRMA
34. Pristine Surgical
35. Purdue University
36. Small Business and Entrepreneurship Council
37. Stanford University Office of Technology Licensing
38. UNM Rainforest Innovations
39. Taxpayer Protection Alliance
40. UNEMED - Technology Transfer for Nebraska
41. University of Notre Dame
42. USIJ Alliance for U.S. Startups & Inventors for Jobs
43. University of Michigan Tech Transfer
44. VirginiaBio
45. Wisconsin Alumni Research Foundation
46. Yale Office of Cooperative Research

<https://bayhdolecoalition.org/about/>