June 13, 2025

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW,
Washington, DC 20201

RE: Request for issuance of authorization and consent to use federal rights in three patents to supply enzalutamide to patients in government programs

Dear Secretary Kennedy:

We hereby request that the Department of Health and Human Services enter into non-exclusive contracts to provide generic versions of enzalutamide to patients who benefit from Medicare, Medicaid, health care provided by the Department of Veterans Affairs, or are federal government employees.

This is NOT a request to use the federal government's march-in rights under 35 U.S.C. § 203.

This is a request to use the federal government's rights in patented inventions under 35 U.S.C. § 202, and to eliminate the possibility of injunctions by providing contracts with an authorization and consent clause, similar to the standard provision in Federal Acquisition Regulation (FAR) 52.227-1, combined with a similar authorization under 28 U.S.C. § 1498(a).

The specific patents for which the federal government has a royalty-free right are patents 7709517, 8183274 and 9126941. The current expiration dates for these three patents range from May 15, 2026 to August 13, 2027.

Enzalutamide is a drug sold by Astellas/Pfizer in the United States under the brand name Xtandi. Xtandi was invented on grants from the US Army and the National Institutes of Health (NIH), and eventually licensed to Astellas, a drug company headquartered in Japan.

Astellas has consistently charged US residents far more than residents in other high income countries. For example, Drugs.com reports a coupon price of $15,922 for 120 40-mg oral capsules, or $132.68 per capsule. The average 2023 Medicare Part D price for the same presentation was $146.13. Prices in other high income countries have typically ranged from $20 to $35 for the same product. Note for the normal dose is 160 mg (4x40-mg pills) per day, or $193,712.80 per year at the 2023 current Drugs.Com coupon price.

When Xtandi was placed on the market, the US price was originally about twice as high as the price in Japan. Over the years Astellas has consistently increased the US price while the price in Japan has decreased. In recent years prices in the US have been more than six times the prices in Japan where Astellas is headquartered.[1]

The price of Xtandi in Australia in 2025 is AUD$ 3,313.23 for 112 capsules or AUD$ 29.59 per capsule, or $18.94 in US dollars at the current exchange rate, or seven times the price quoted by Drugs.com for US residents.

There have been multiple requests to HHS as well as agencies within HHS and the DoD to use the federal government rights in three patented inventions for Xtandi. All of these petitions have been rejected.

The previous cases were complex, and certainly more complex than recognized by any of the federal agencies in their official responses.

Three different legal mechanisms have been involved in past requests, including:

1. **March-in right**. The federal government has a march-in right, under **35 U.S.C. § 203** of the Bayh-Dole Act. This statute allows a funding agency to grant licenses under four grounds. In all of the Xtandi cases, the petitions argued that the patent holder had not made the benefits of the inventions "available to the public on reasonable terms,"[2] a statutory requirement to bring an invention to practical invention. For several years HHS and DoD took the position that Astellas could put the drug on the market at ANY price and as long as the drug was available in pharmacies and used by cancer patients the price was irrelevant. In the most recent march-in request, the NIH relied on a different rationale for rejecting the march-in request. A challenge in using the federal march-in right are the procedural delays set out in the statute and regulations. 35 U.S.C. § 203(b) provides for a mandatory stay pending the appeals of both administrative and judicial decisions. In 2023, seven years after the original march-in case was filed, the NIH raised the issue of the procedural delays to justify another rejection.[3]

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[1] The price in Japan was 3,138.80 Yen in 2014 and has been decreased several times since, while the US price has increased. For example, in 2021 the price in Japan was 2,354.10 yen per capsule, or $21.64 at an exchange rate of 108.7892 yen to the dollar. In 2024 prices for Xtandi were decreased 11.5 percent, while the Yen is now trading at 143 to the dollar, making the price considerably lower in USD. (https://www.navlindaily.com/article/20870/japan-slashes-drug-prices-by-4-67-in-fy2024-health-insurance-revision).

[2] The obligation in 35 USC 203(a) to bring inventions to practical application, where practical application is defined in 35 USC 201(f) to include the obligation to make the benefits of an invention "available to the public on reasonable terms."

[3] Letter from Secretary Xavier Becerra rejecting appeal of the NIH rejection of the Xtandi petition, February 5, 2024. https://www.keionline.org/40729; Secretary Becerra citing the March 21, 2023 NIH decision signed by Lawrence A. Tabak. https://web.archive.org/web/20230325031505/https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_Decision_Xtandi_March-In_Request(2023)

2. **Government use license**. As required by **35 U.S.C. § 202(c)(4)**, the government holds a "nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." Federal agencies have been asked to use this to license three subject patents, in order to enable the supply of generic versions of enzalutamide for use by federal programs. Unlike the march-in right, there is no automatic stay of an administrative decision, although appeals and injunctions are possible.

3. **Government use under 28 U.S.C. § 1498(a).** Separately from rights the federal government has in inventions it has funded is the more general right to use or authorize third parties to use patents granted by the US government for any invention. The Section 1498 authority can be exercised in a variety of ways, including either explicit or implicit authorizations. Most commonly a federal agency will provide a sentence in a contract that incorporates by reference the standard Authorization and Consent clause set out in the FAR regulation 52.227-1. This clause has been used thousands of times in a wide range of cases, including dozens of times during the COVID-19 pandemic. In the past, HHS has been asked to use Section 1498 authority for products for cancer, HIV, anthrax poisoning and other illnesses. When rejecting the requests, HHS sometimes has expressed concern over the uncertain magnitude of court ordered compensation for using patents without permission from patent holders. However, in the case of enzalutamide, a drug invented with the support of federal grants, the cost would be zero for uses that are consistent with the Bayh-Dole license the federal government already holds.

At present there are five firms that have received tentative FDA approval to sell generic versions of enzalutamide.

1. ENZALUTAMIDE (ENZALUTAMIDE) | ANDA #211465 | UNKNOWN | None (Tentative Approval) | EUGIA PHARMA
2. ENZALUTAMIDE (ENZALUTAMIDE) | ANDA #216068 | TABLET;ORAL | None (Tentative Approval) | SANDOZ INC
3. ENZALUTAMIDE (ENZALUTAMIDE) | ANDA #217322 | TABLET;ORAL | None (Tentative Approval) | ZYDUS PHARMS USA INC
4. ENZALUTAMIDE (ENZALUTAMIDE) | ANDA #217920 | CAPSULE;ORAL | None (Tentative Approval) | HUMANWELL PURACAP
5. ENZALUTAMIDE (ENZALUTAMIDE) | ANDA #218187 | TABLET;ORAL | None (Tentative Approval) | TEVA PHARMS INC

Retail prices for generic enzalutamide outside the United States are less than $2 per 40-mg tablet or capsule in some markets.

In 2016, the Canadian generic company Biolyse wrote to CMS Director Andy Slavitt and NIH Director Dr. Francis Collins, offering to sell 40-mg enzalutamide to Medicare and other federal programs for $3 per tablet. Slavitt ignored the offer.

On April 9, 2024, three non-profit organizations asked Chiquita Brooks-LaSure, the Administrator of Centers for Medicare and Medicaid Services, to use the federal government rights as set out in 35 U.S.C. § 202(c)(4) and the right of the government to use patents under 28 U.S.C. § 1498, to authorize qualified companies to make and sell generic versions of enzalutamide. On April 11, 2024, *Inside Health Policy* subsequently reported that Costplusdrugs.com had offered to distribute generic versions of the drugs to patients on CMS programs. On August 6, 2024, Stacy Sanders, the HHS Chief Competition Officer, wrote to the three groups (KEI, UAEM and UACT), declining to take any action with regard to the federal government's license to the Xtandi patents.

The most recent data on Medicare outlays on the Astellas/Pfizer version of enzalutamide are not yet available, but according to the Medicare Part D Dashboard, the 2023 Medicare outlays were $2.6 billion, with an average price per dosage of $146.13. The 2023 Medicaid spending on Xtandi was an additional $156.4 million. The federal government also spends money on Xtandi on programs of the Veterans Administration, the Department of Defense and employee health insurance programs.

It is astonishing that several CMS administrators and other HHS officials have consistently refused to use the federal government's rights in the Xtandi patents, given the enormous disparities between the prices in the United States and EVERY SINGLE other high income country, and the enormous profits Astellas and Pfizer have already received on this US government-funded invention.

We request a meeting with HHS to discuss this issue. At a very minimum the U.S. taxpayers would save more than $2 billion per year, and it is also likely that access would be expanded for U.S. prostate cancer patients.

I am also attaching sample language for authorization and consent that HHS could issue, today, to enable the five already-FDA-approved companies to enter the market immediately.

Sincerely,

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Cc:
Dr. Mehmet Oz, Administrator for the Centers for Medicare & Medicaid Services (CMS)
Kimberly Brandt, Deputy Administrator & Chief Operating Officer, CMS
Stephanie Carlton, Deputy Administrator and Chief of Staff, CMS
John Brooks, Deputy Administrator & Chief Policy and Regulatory Officer, CMS
John Czajkowski, Deputy Chief Operating Officer, CMS
Abe Sutton, Deputy Administrator and Director, CMS
Chris Klomp, Deputy Administrator and Director, Medicare, CMS
Cheri Rice, Deputy Director, Parts C and D, Medicare, CMS

Heather Flick Melanson, Chief of Staff for the U.S. Department of Health and Human Services
Jim O'Neill, Deputy Secretary of the U.S. Department of Health and Human Services

ANNEX, sample authorization and consent

AUTHORIZATION and consent to use three US-granted patents to supply patients in U.S. government health programs with generic versions of enzalutamide.

This is an authorization and consent for _(company name)_ to use three US-granted patents in order to import, make, distribute and sell generic versions of enzalutamide to patients who benefit from Medicare, Medicaid, health care provided by the Department of Veterans Affairs, and persons receiving health insurance as federal government employees. This authorization and consent applies to the inventions described in and covered by the following United States patents:

- 7709517
- 8183274
- 9126941