

# Memorandum in support of the petition to HHS to exercise the march-in or paid up royalty right in patents on the prostate drug Xtandi

To: The Honorable Xavier Becerra  
Secretary of the Department of Health and Human Services

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Acting Principal Deputy Director, the National Institutes of Health

Date: January 25, 2022

Regarding: Petition to exercise the march-in or paid up royalty-free rights in patents on the prostate cancer drug Xtandi

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## 1. Introduction

The following is submitted to the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), regarding the petition to HHS to exercise the march-in or paid up royalty right in patents on the prostate drug Xtandi.

## 2. Legal Basis for Government Action

The U.S. government holds rights in all three Xtandi FDA Orange Book patents. For each of these patents, the U.S. government has two important rights.

1. The U.S. government holds a worldwide “paid-up license to practice or have practiced for or on behalf of the United States” the patented inventions. The statutory basis for this right is 35 U.S.C. § 202(c)(4).
  
2. The U.S. government has the right to “march-in” and grant one or more licenses “in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances,” when a federal agency determines that any of four grounds are met. [35 U.S.C. § 203] The specific ground relied upon for this request is that the action is necessary because the contractor or assignee has not taken effective steps to bring the inventions to “practical application.” The Bayh-Dole Act defines practical application to include an obligation to make the benefits of the inventions “available to the public on reasonable terms.” [35 U.S.C. § 201(f)] In this case, the petitioners assert that charging U.S. residents far more for Xtandi than the residents of other high income countries is contrary to the obligation to make the benefits of the inventions “available to the public on reasonable terms.”

**Table 1: The three FDA Orange Book patents on Xtandi**

Patent	Patent Disclosure
Patent no: 7709517. Diarylhydantoin compounds. Drug substance and Drug product patents. Patent expiration August	This invention was made with United States Government support under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number

13, 2027.	W81XWH-04-1-0129. The Government has certain rights in the invention.
Patent no: 8183274. Treatment of hyperproliferative disorders with diarylhydantoin compounds. Patent expiration August 24, 2026.	This invention was made with United States Government support under National Institutes of Health SPORE grant number 5 P50 CA092131 and Department of Defense (Army) grant number W81XWH-04-1-0129. The Government has certain rights in the invention.
Patent no: 9126941. Treatment of hyperproliferative disorders with diarylhydantoin compounds. Patent expiration May 15, 2026.	This invention was made with Government support under Grant No. W81XWH-04-1-0129 awarded by the United States Army, Medical Research and Materiel Command; Grant No. CA092131 awarded by the National Institutes of Health. The Government has certain rights in this invention.

**3. The primary grounds for the request are that U.S. residents should not face prices higher than Astellas charges for Xtandi in other high income countries.**

The standard sought in the Xtandi case is not to create a general standard for drug pricing, but to set one for products that were invented on a government grant. Specifically, the petitioners ask that U.S. residents not pay more than other high income countries for products invented on a U.S. government grant. The rationale for this standard is that it is not reasonable for the parties that paid for the R&D to invent a product to pay more than others with similar incomes. This is a modest standard, since one could easily argue that U.S. residents should pay less and even much less than others, having funded the most risky stage of the drug’s development.

The government may consider other standards for determining if prices are acceptable. However in this case, the petitioners ask HHS to focus on the reasonableness of the price discrimination against U.S. residents, when U.S. taxpayers have underwritten the costs of the drug discovery.

As illustrated in Table 1, the United States faces prices for Xtandi that are not only higher than other countries with similar incomes, but are radically higher.

**Table 1: Prices of 40 mg capsules of Xtandi in 16 high income countries compared to FSS, Medicaid, Medicare Part D, Drugs.Com coupon, AWP and WAC prices**

Country	Date	Price per unit in USD	Jan 2022 FSS price / national price	USA Medicaid price 2021:Q1 / national price	USA Net price per SSR / national price	USA AWP Jan 2022 price / national price
Australia	Dec 17, 2021	\$22.42	2.9	4.5	3.9	5.8

Canada	Nov 16, 2020	\$22.30	3.0	4.5	4.0	5.8
Cyprus	Nov 16, 2020	\$32.93	2.0	3.1	2.7	3.9
Denmark	Nov 16, 2020	\$41.31	1.6	2.4	2.1	3.1
Finland	Nov 16, 2020	\$36.04	1.8	2.8	2.5	3.6
France	Nov 16, 2020	\$31.49	2.1	3.2	2.8	4.1
Germany	Nov 16, 2020	\$35.32	1.9	2.9	2.5	3.7
Iceland	Nov 16, 2020	\$36.94	1.8	2.7	2.4	3.5
Japan	May 25, 2021	\$21.64	3.0	4.7	4.1	6.0
Luxembourg	Nov 17, 2020	\$32.92	2.0	3.1	2.7	3.9
Netherlands	Nov 16, 2020	\$35.34	1.9	2.9	2.5	3.7
Norway	Nov 16, 2020	\$32.76	2.0	3.1	2.7	4.0
Spain	May 17, 2018	\$33.43	2.0	3.0	2.6	3.9
Sweden	Nov 16, 2020	\$26.47	2.5	3.8	3.3	4.9
Switzerland	Nov 16, 2020	\$39.25	1.7	2.6	2.3	3.3
UK	Nov 16, 2020	\$32.22	2.0	3.1	2.7	4.0
USA VA/FSS	Jan 19, 2022	\$65.91				
USA (Medicare Part D)	2019	\$97.81				
USA (WAC)	2020:Q4	\$99.32				
USA (Net price per SSR Health)	2020:Q4	\$88.54				
USA (Medicaid)	2021:Q1	\$101.12				
USA (Drugs.com)	Jan 19, 2022	\$113.18				
USA (AWP)	Jan 12, 2022	\$130.00				

For several countries in Table 1, Astellas offers confidential rebates to purchasers. SSF Health makes estimates of the net prices in the United States, which vary by quarter. In 2020:Q4, the SSR Health estimated net price of \$88.54 was 89 percent of the wholesale acquisition cost (WAC) price of Xtandi.

We do not have estimates of the rebates in non-U.S. countries. In a march-in proceeding, the NIH can require Astellas to disclose the net prices for sales in the U.S. and in other high income countries.

#### **4. Xtandi is an extraordinarily expensive drug.**

Xtandi is used for the treatment of prostate cancer, one of the most common types of cancer. Despite the fact that the disease is common and not rare, and that the treatment does not cure or eliminate the cancer, the product is exorbitantly expensive. The recommended dose is 160 mg of

enzalutamide per day. At the average wholesale acquisition cost in January 2022, Xtandi has an annual cost of \$189,800. At the 2021:Q1 average price for Medicaid, the annual cost was \$147,635.

The U.S. has a relatively high per capita income, but even taking this into account, no country comes close to the U.S. in terms of ability to pay, using the ratio of the cost of Xtandi to the per capita Gross National Income (GNI).

**Table 2: Annual Xtandi cost to a patient in the United States and selected countries**

Country*	40 mg price	Cost per 30 days, @160mg per day	Cost per year @160mg per day	2020 GNI per capita, WB Atlas method	Cost / GNI per capita
Australia	\$22.42	\$2,690	\$32,733	\$53,690	61%
Canada	\$22.30	\$2,676	\$32,558	\$43,530	75%
France	\$31.49	\$3,779	\$45,975	\$39,480	116%
Germany	\$35.32	\$4,238	\$51,567	\$47,470	109%
Japan	\$21.64	\$2,597	\$31,594	\$40,360	78%
Sweden	\$26.47	\$3,176	\$38,646	\$54,050	72%
Switzerland	\$39.25	\$4,710	\$57,305	\$82,620	69%
UK*	\$32.22	\$3,866	\$47,041	\$39,700	118%
USA (VA/FSS, Jan 2022)	\$65.91	\$7,909	\$96,229	\$64,550	149%
USA (Net price per SSR Health 2020)	88.54	\$10,625	\$129,268	\$64,550	200%
USA (Medicaid, 2021:Q1)	\$101.12	\$12,134	\$147,635	\$64,550	229%
USA (Drugs.com Coupon)	\$113.18	\$13,582	\$165,243	\$64,550	256%
USA (AWP, Jan 2022)	\$130.00	\$15,600	\$189,800	\$64,550	294%
*UK and other countries require confidential rebates					

## 5. Enzalutamide was included in the World Health Organization list of Essential Medicines in 2021.

Enzalutamide was included in the World Health Organization list of Essential Medicines in 2021.

## 6. High prices have consequences.

Health plans generally place Xtandi on a Tier with restrictions on access such as higher copayments or requiring prior authorization for use.

Humana:	Tier 5
Aetna:	Tier 5
United Health Care:	Tier 5
Wellcare Value Script	Tier 5
CareFirst Exchange Formulary	Tier 0, Prior Authorization required

If approved for use, Medicare Part D beneficiaries are often faced with initial \$7,050 in annual deductibles and copayments (premiums are excluded) followed by coinsurance payments of 5 percent of the price, which can exceed \$700 per month.

Tier 5 drugs typically involve the highest copayment obligations. Some health plans require copayments of 25 to 33 percent of the retail price for Tier 5 products.

Additional cost management programs for drugs typically include a combination of prior authorization, and step therapy before coverage is offered. According to GoodRx, most Medicare Part D prescription drug plans require prior authorization for Xtandi. Prior authorization for some patients can involve processes that are challenging to navigate. Step therapy requires a patient to use a different less expensive drug, and only have access to enzalutamide after the patient has failed the less expensive option.

There are a variety of insurance and “insurance-like” products’ in the United States, including plans that have relatively high standards for coverage, but also plans that have limited or even called “junk” coverage. See, for example:

- “Shortchanged: How the Trump Administration’s Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk,” Democratic Staff Report, U.S. House of Representatives, Committee on Energy and Commerce. June 2020.
- Erin Mershon, “This Tennessee insurer doesn’t play by Obamacare’s rules — and the GOP sees it as the future,” *STATNews*. Nov. 13, 2017.
- “UNDER-COVERED: How “Insurance-Like” Products Are Leaving Patients Exposed,” Partnership to Protect Coverage. March 2021.
- Reed Abelson, “It Looks Like Health Insurance, but It’s Not. ‘Just Trust God,’ Buyers Are Told: Some state regulators are scrutinizing nonprofit Christian cost-sharing ministries that enroll Americans struggling to pay for medical care, but aren’t legally bound to cover their members’ claims,” *New York Times*. Jan. 2, 2020.
- Grandfathered health insurance plans also may offer substandard coverage, and include as many as 1/7th of covered workers. Patients can face huge coinsurance costs because those plans do not have to limit annual cost-sharing (out-of-pocket expenses). See also, Katie

Keith, "Final Rule on Grandfathered Health Plans Will Allow Higher Consumer Costs," December 14, 2020. *Health Affairs*. DOI:10.1377/forefront.20201214.170819

For expensive drugs, reimbursements may be limited or not available on some plans.

As is discussed below, high prices raise insurance premiums and taxes, and lead to noncompliance by patients struggling with the treatment costs.

## **7. High drug prices make U.S. employers less competitive internationally.**

The direct or indirect costs of health insurance influence the costs of employing workers in the United States. If U.S. employers share in the costs of prescription drug coverage, the higher those costs, the less competitive are the U.S. Businesses. If the cost of Xtandi is \$150,000 to \$190,000 per year in the United States, and \$30,000 to \$50,000 per year in other high income industrialized countries, it makes the U.S. workers more expensive or the U.S. wages lower, all other factors being equal.

## **8. Prostate cancer is not rare.**

According to the Prostate Cancer Foundation, prostate cancer is the most common non-skin cancer in America, and 1 in 8 men will be diagnosed with prostate cancer in their lifetime.

The American Cancer Society estimates that in 2022 there will be 268,490 new cases of and 34,500 deaths from prostate cancer.

## **9. There are well known racial disparities in prostate cancer outcomes.**

A September 2, 2021 article in *Nature* titled, "Racial disparities in prostate cancer among black men: epidemiology and outcomes," focused on the disparities in prostate cancer between black and white men, spanning from disparities in prevention and screening to clinical outcomes. The article concluded that "Prostate cancer has the widest racial disparities of any cancer, and these disparities appear at every stage of the cancer continuum." [Chowdhury-Paulino, I.M., Ericsson, C., Vince Jr., R. et al. Racial disparities in prostate cancer among black men: epidemiology and outcomes. *Prostate Cancer Prostatic Dis* (2021). <https://doi.org/10.1038/s41391-021-00451-z>]



## 10. Astellas' global sales revenue for Xtandi does not justify charging U.S. residents more than other high income countries.

The primary defense for price discrimination against U.S. residents is the argument that a company needs higher prices in the United States to reasonably recover its risk adjusted investments in R&D. This justification plainly does not apply for Xtandi.

Astellas has published sales data for Xtandi, in Japanese Yen, for its fiscal years 2013 through 2020. The Astellas fiscal year ends March 31. For that period, Astellas has reported sales of ¥1,941,800,000,000. At U.S. IRS exchange rates, this is equal to \$17.3 billion in U.S. dollars, and does not include the sales from April 1, 2020 to the present, which would add another approximately \$7 or \$8 billion in sales.

**Table 3: Xtandi sales in Japanese Yen and U.S. dollars, for Astellas fiscal years (ending the 31st of March)**

Astellas fiscal year	Worldwide	IRS Yen to USD exchange rate (calendar year)	Fiscal year adjusted exchange rate (.25y + .75y-1)	Sales in million USD
2020	¥458,400	106.725	108.437	\$4,227
2019	¥400,000	109.008	110.070	\$3,634
2018	¥333,000	110.424	115.106	\$2,893
2017	¥294,300	116.667	114.020	\$2,581
2016	¥252,100	113.138	122.718	\$2,054
2015	¥137,200	125.911	114.054	\$1,203
2014	¥54,600	110.101	103.663	\$527
2013	¥12,200	101.517	87.635	\$139
2012		83.008		

## 11. The United States has made up a disproportionate share of global sales.

The United States has been the primary market for Xtandi. Beginning in fiscal year 2017, Astellas reported both worldwide and USA sales for Xtandi.

From fiscal year 2017 to 2020, global sales of Xtandi were ¥1,485,700,000,000. Over the same period of time, Astellas reported that the U.S. sales were ¥747,200,000,000, or more than half of global sales.

The rejection of the first march-in petition took place in calendar year 2016, but Astellas fiscal year 2017. After the NIH rejected the earlier march-in case, the U.S. share of global sales increased from 47.7 percent to 52.1 percent.

**Table 4: Xtandi sales in the United States compared to world sales**

Astellas fiscal year	Worldwide sales	USA sales	USA/World
2013	¥12,200	n/a	
2014	¥54,600	n/a	
2015	¥137,200	n/a	
2016	¥252,100	n/a	
2017	¥294,300	¥140,400	47.7%
2018	¥333,000	¥164,700	49.5%
2019	¥400,000	¥203,500	50.9%
2020	¥458,400	¥238,600	52.1%

## 12. The United States government is the largest customer of Xtandi.

### *Federal spending on Xtandi through Medicare*

The U.S. Medicare program is the single largest customer for Xtandi. For U.S. fiscal years 2012 to 2019 (the most recent years data is available), Medicare spending on Xtandi was more than \$5.8 billion, and spending on Xtandi grew sharply in seven of eight years.

**Table 5a: Xtandi spending and prices for Medicare Part D, 2012 to 2019**

Year	Medicare Part D spending	Average price per 40mg	Change in price	% change in price	Change in CPI
2012	\$34,898,756	\$63.72			2.1%
2013	\$231,503,731	\$64.85	\$1.13	1.8%	1.5%
2014	\$447,311,084	\$69.41	\$4.56	7.0%	1.6%
2015	\$790,655,731	\$73.94	\$4.53	6.5%	0.1%
2016	\$907,585,915	\$76.69	\$2.75	3.7%	1.3%
2017	\$854,552,284	\$85.00	\$8.31	10.8%	2.1%
2018	\$1,182,615,333	\$91.48	\$6.48	7.6%	2.4%
2019	\$1,420,960,113	\$97.81	\$6.33	6.9%	1.8%

<b>2012-2019</b>	\$5,870,082,948				

Note that Medicare Part D prices for Xtandi rose by 3.7 percent in 2016, when the march-in case was pending, and by 10.8, 7.6 and 6.9 percent in the next three years, respectively, following the rejection of the march-in petition. From 2016 to 2019, Medicare spending on Xtandi increased by 57 percent.

The Medicare spending data available from the Medicare Part D dashboard is reported by calendar year and the Astellas fiscal year ends March 31. The Medicare Part D spending for calendar year 2019 can be compared to 3/4 of Astellas fiscal year 2020 spending, and 1/4th of Astellas fiscal year 2019 spending.

**Table 5b: Medicare spending on Xtandi as a share of global revenue**

Year	Xtandi worldwide sales by fiscal year, million Japanese Yen	Fiscal year adjusted exchange rate (.25y + .75y-1)	Xtandi sales by Astellas fiscal year, million USD	Calendar year weighted average Xtandi sales in USD $.75*y+1 + .25*y$	Medicare Part D 2019 spending (million USD)	Medicare Part D spending as share of global sales
2020	¥458,400	108.437	\$4,227			
2019	¥400,000	110.070	\$3,634	\$4,079	\$1,420.96	34.8 percent
2018	¥333,000	110.424	\$2,893	\$3,078	\$1,182.6	38.4 percent
2017	¥294,300	116.667	\$2,581	\$2,659	\$854.6	32.1 percent
2016	¥252,100	113.138	\$2,054	\$2,186	\$907.6	41.5 percent

***Federal spending on Xtandi through Medicaid and other federal programs***

In addition to Medicare, the United States government also purchases or reimburses Xtandi through Medicaid, the Department of Defense, the Department of Veterans Affairs, employee insurance, and other programs.

For 2019 (the last year for which annual data is available), the Medicaid program reported spending \$66.6 million on Xtandi, a 62 percent increase over the outlays in 2016, the year the first Xtandi march-in case was rejected.

**13. The 2017 Senate Armed Services Committee NDAA directive**

In 2017, the Senate Armed Services Committee (ASC) adopted a directive to the Department of Defense that reads as follows:

### **Licensing of federally owned medical inventions**

The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

*115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173. July 10, 2017.*

The Department of Defense has thus far ignored this directive.

## **14. The September 13, 2020 Executive Order on drug pricing**

President Trump issued [Executive Order 13948](#) of September 13, 2020, titled Lowering Drug Prices by Putting America First.

Section 1. Purpose. Americans pay more per capita for prescription drugs than residents of any other developed country in the world. It is unacceptable that Americans pay more for the exact same drugs, often made in the exact same places. . . .

In addition to being unfair, high drug prices in the United States also have serious economic and health consequences for patients in need of treatment. High prices cause Americans to divert too much of their scarce resources to pharmaceutical treatments and away from other productive uses. High prices are also a reason many patients skip doses of their medications, take less than the recommended doses, or abandon treatment altogether. The consequences of these behaviors can be severe. For example, patients may develop acute conditions that result in poor clinical outcomes or that require drastic and expensive medical interventions. . . .

Sec. 2. Policy. (a) It is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price. (b) The “most-favored-nation price” shall mean the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product.

. . .

The proposed implementation of this Executive Order included a demonstration project for Medicare Part B. Litigation from drug companies blocked the demonstration project on procedural grounds, but the Executive Order itself has not been revoked.

## **15. The January 4, 2021 proposal by NIST to eliminate prices as a sole ground for a march-in petition**

On January 4, 2021, the Department of Commerce’s National Institute of Standards and Technology (NIST) published a request for comments on changes in regulations related to the Bayh-Dole Act governing “Rights to Federally Funded Inventions and Licensing of Government Owned Invention.” Among the proposed changes was a proposal to:

Clarify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.

NIST [received](#) 81,772 comments, most of which were in opposition to the proposal to eliminate pricing as a grounds for a march-in request (examples of the comments from a variety of stakeholders and experts are available here: <https://www.keionline.org/35432>).

## **16. The July 9, 2021 Presidential Executive Order on competition**

On July 9, 2021, President Biden issued [Executive Order 14036](#), Promoting Competition in the American Economy. This Executive Order called upon NIST to withdraw the proposed limitation on the use of march-in rights on the basis of the pricing of goods and services.

(r) The Secretary of Commerce shall:

...

(ii) acting through the Director of NIST, consistent with the policies set forth in section 1 of this order, consider not finalizing any provisions on march-in rights and product pricing in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," 86 Fed. Reg. 35 (Jan. 4, 2021);

## **17. The September 9, 2021 HHS Report on addressing high drug prices**

On September 9, 2021, HHS Secretary Xavier Becerra forwarded a [report](#) to the White House on measures to address drug prices, titled “Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy,” (U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, September 9, 2021).

The report included these comments:

Americans pay too much for prescription drugs. We pay the highest prices in the world, which leads to higher spending. Higher spending puts pressure on private and government payers to raise premiums or make benefits less generous. Lack of affordable access to prescription drugs and other health care services leads to worse health outcomes.

Patients in other comparable countries regularly pay substantially less for prescription drugs than Americans. U.S. prescription drug prices are more than double (2.56 times as high) those in other countries that are members of the Organisation for Economic Co-operation and Development (OECD) – see Figure 1. Even after taking rebates and other discounts into account, the U.S. pays at least 1.9 times as much. 4 The price gap between the U.S. and other nations is even larger for some critical medications.

...

High drug prices result in access and affordability challenges for many Americans. Twenty-four percent of adults taking prescription drugs say they are hard to afford,<sup>6</sup> and nearly 10 percent of adults report not taking medication as prescribed in order to save money.<sup>7</sup> Some have died as a result.<sup>8</sup> Additionally, racial and income-based disparities in medication access are pervasive across numerous health conditions.<sup>9</sup>

...

The uninsured and underinsured suffer most from high list prices. Increased spending on drugs makes it harder to afford insurance and puts pressure on payers to offer less generous benefits. . . .

Not only are U.S drug prices too high, but for brand name drugs, they often rise far faster than inflation. . . .

All Americans pay for higher drug spending through insurance premiums and taxes to pay for drug costs in programs including Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), the Veterans Health Administration (VA), and the Indian Health Service. Medicare spending on drugs is growing faster than Medicare spending on other services: . . .

High drug prices result in higher out-of-pocket costs for consumers, and larger premiums and government and private sector expenditures. The burden of these costs falls most heavily on those who are uninsured, who are more likely to have lower incomes; people with disabilities and chronic conditions, who often face higher prescription drug costs; and communities of color, which experience economic and geographic barriers to medication access. President Biden’s Competition Executive Order stated, “It is also the policy of my Administration to support aggressive legislative reforms that would lower prescription drug

prices, including by allowing Medicare to negotiate drug prices.”<sup>33</sup> Lowering drug prices through negotiation is key to lowering out-of-pocket costs for consumers, governments, and total drug spending.

The report included the following discussion of the use of march-in and government use rights.

### **March-In Rights and Government Use**

The Bayh-Dole Act was designed to address the absence of incentives to commercialize government funded inventions by allowing small businesses or nonprofit organizations, such as universities, to claim title to inventions generated during performance of a federal grant or contract. Before the Bayh-Dole Act became law in 1980, the federal government owned any inventions it funded and none of them were used to develop therapeutics or vaccines; since then, 245 therapeutics and vaccines have been brought to market using university and federal laboratory patents. <sup>85</sup> The federal government may grant a license to use the intellectual property arising from government funding without the permission of the rights-holder under certain circumstances, including when “action is necessary to alleviate health and safety needs which are not reasonably satisfied” or when the benefits of the patented product are not “available to the public on reasonable terms.”<sup>86</sup>

HHS, NIH, and other agencies have been petitioned to take action under these provisions, and HHS will continue to give such petitions due consideration.\* HHS will also engage other government agencies to address barriers to accessing government-funded inventions as emphasized in the Competition Executive Order, which directs the Director of the National Institute for Standards and Technology to consider not finalizing any provisions on march-in rights and product pricing in the proposed rule, “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions.” <sup>87</sup>

\* Another provision, 28 U.S.C. § 1498, allows the federal government to “use or manufacture” technologies protected under current U.S. patents, while giving the patent owner “recovery of his reasonable and entire compensation for such use and manufacture”; <sup>85</sup> Unpublished NIH research.

<sup>86</sup> 35 U.S.C. §203(a)(2), §201(f), see also 37 C.F.R. Part 401.

<sup>87</sup> 86 Fed. Reg. 35 (Jan. 4, 2021).

## **18. President Biden’s December 6, 2021 remarks on drug pricing**

President Biden has made a number of statements about the need to control high drug prices. From his published [remarks](#) on prescription drug costs in a December 6, 2021 discussion of prescription drug costs and the Build Back Better legislation:

DECEMBER 06, 2021, SPEECHES AND REMARKS, East Room

...

Here in America, it will not surprise you to know that we pay the highest prescription drug prices of any developed nation in the world.

Let me say that again: We pay the highest — highest prescription drug prices of any developed nation in the world.

That may surprise you — what may surprise you is we pay about two to three times what other countries pay for the same drug.

An example: One anti-cancer drug costs \$14,000 in the United States. That same exact drug by the same manufacturer costs \$6,000 in France.

Today, one in four Americans who take prescription drugs struggle to afford them. Nearly 30 percent — nearly 30 percent of these — these patients have skipped doses of essential drugs they have to take.

Others have simply not fulfilled — filled a prescription, tried to use over-the-counter drug, and cut pills in half, or — because they can't afford the cost of their prescription.

You know, even if you think this doesn't affect you, it does. Everyone has less money in their pockets because high drug costs make health insurance more expensive for everyone.

There aren't a lot of things that almost every American agree — can agree on. But I think it's safe to say that all of us — all of us — whatever our background, our age, where we live — we can agree that prescription drugs are outrageously expensive in this country.

...

What I'm proposing is that we negotiate a fair price — one that reflects the cost of research and development and a need for significant progress — excuse me, need for significant profit — but that is still affordable for consumers.

Right now, drug companies will set the price at whatever the market will bear.

It is hard to read the President's remarks without seeing the relevance to the Xtandi march-in petition. The cost for one month supply of Xtandi is \$15,600 based upon the January 2022 average wholesale price. The cost in France is less than \$4,000 and the cost in Japan is less than \$3,000. The out-of-pocket costs, for those with insurance, are significant. A patient with Medicare Part D will pay \$7,050 in copayments and deductibles and then 5 percent of the drug cost, which can exceed \$700 per month, a significant expense for anyone, let alone persons living on retirement savings.



More significantly, the high cost of the drug drives up premiums, and forces the drug into more restrictive formularies, in some cases requiring prior authorization and for the patient to use less expensive options first, even when the decision to defer access to enzalutamide increases the risks to the patient. As noted in President Biden's remarks and the earlier Trump Executive Order on drug prices, some patients skip or avoid treatments even when they have insurance.

President Biden says he is proposing a "fair price" be negotiated, and a "significant profit." Xtandi has already generated well over \$20 billion in sales, mostly on the backs of U.S. residents, and there is no question that the company has already realized a very significant profit.

### **19. Two drug companies have received FDA approval to sell generic versions of enzalutamide, once patent barriers are resolved.**

On May 14, 2021, Actavis received tentative FDA approval ([ANDA #209614](#)) to sell generic versions of enzalutamide.

On July 16, 2019, Eugia Pharma, a subsidiary of Aurobindo Pharma, received tentative FDA approval (ANDA #211465) to sell generic versions of enzalutamide.

Tentative approval indicates that the generic product satisfies the safety and efficacy standards needed for authorization in the U.S. market, but that full authorization is not granted due to patent or other exclusivities. In the case of Xtandi, the only exclusivity preventing full approval of the generic products is the patents on which the NIH has been requested to exercise march-in rights. If the NIH grants the petition, generic competition can begin almost immediately.

There are several other potential entrants that could enter the market to sell very inexpensive versions of enzalutamide if the government uses its paid up license or grants a march-in request.

### **20. The government can use its rights in the Xtandi patents to negotiate more affordable prices, right now, without waiting for action from the Congress.**

If the administration wants to negotiate prices for expensive drugs, they can do that right now in the case of Xtandi, using the government's rights in the Xtandi patents as leverage.

If the government does not put the patent monopoly at risk, negotiations on prices will typically involve a combination of threats to place a drug on restrictive formulary or increase patients co-payments, measures designed to reduce utilization of an expensive drug. Drug companies lobby and organize patient groups to oppose such measures, and affordability for the payer is pitted against access and affordability for the patient.

If the government uses as its leverage the ability to end the patent monopoly by using its rights in the Xtandi patents, there is no need to put the patients at risk on the issues of restrictive formularies or higher copayments.

Drug companies would prefer to limit the government's negotiating power to threats to withhold or limit reimbursements rather than anything that would weaken the patent monopoly, because the companies believe they can charge higher prices and make bigger profits when patent rights are not subject to curbs on the abuse of the patent rights over the pricing of a product.

**21. There is a massive lobby against the use of march-in rights by entities and persons who are defending their right to charge whatever the market will bear on federally-funded biomedical inventions.**

The entities that benefit from unconstrained and excessive pricing of government funded medical inventions include drug companies, universities and research institutions, venture capitalists, institutional investors and individual researchers. Collectively they form a powerful lobby to prevent the U.S. government from using the public interest safeguards in the Bayh-Dole Act, and are a source of self-serving and biased propaganda about technology transfer policies.

Drug companies and nonprofit universities and research institutions have created the Bayh-Dole Coalition to lobby against the use of march-in rights. The members of this rent seeking coalition include trade associations like PhRMA and BIO, university technology transfer offices, investors, and others benefiting from the privatization of federally-funded R&D. Groups like AUTM lobby members of Congress from their home state universities that receive federal R&D grants.

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



## 22. The choice before HHS

Astellas, a company headquartered in Japan, has licensed a drug invented at UCLA on grants from the U.S. Army and the NIH. The prices for Xtandi are exorbitantly high, with an annual cost at current AWP price of \$189,800 per year for the treatment of one of the most common types of cancer. High prices limit access and create fiscal strains on households, health systems and government budgets.

The Astellas prices for Xtandi are radically different in the United States than anywhere else, and are generally three to five times higher in the United States than in other high income countries. By 2021, Xtandi has generated more than \$20 billion in sales revenue. The United States provides more than half of all of the global revenue from Xtandi sales.

An earlier petition to use the government's rights in Xtandi patents to remedy the price discrimination against U.S. residents was filed in 2016, and rejected by the NIH and DoD. Following the rejection of the march-in petition Astellas sharply increased the U.S. price of Astellas, even while prices in some high income countries, including Japan, have declined.

If the United States rejects the current petition to use the Bayh-Dole rights to end the monopoly on the sales of enzalutamide, a precedent will be set that no drug pricing discrimination against U.S. residents will be sanctionable, hardening expectations that the public interest safeguards in the Bayh-Dole Act are a paper tiger, and making it even more difficult for future decision makers to revisit price discrimination issue in future.

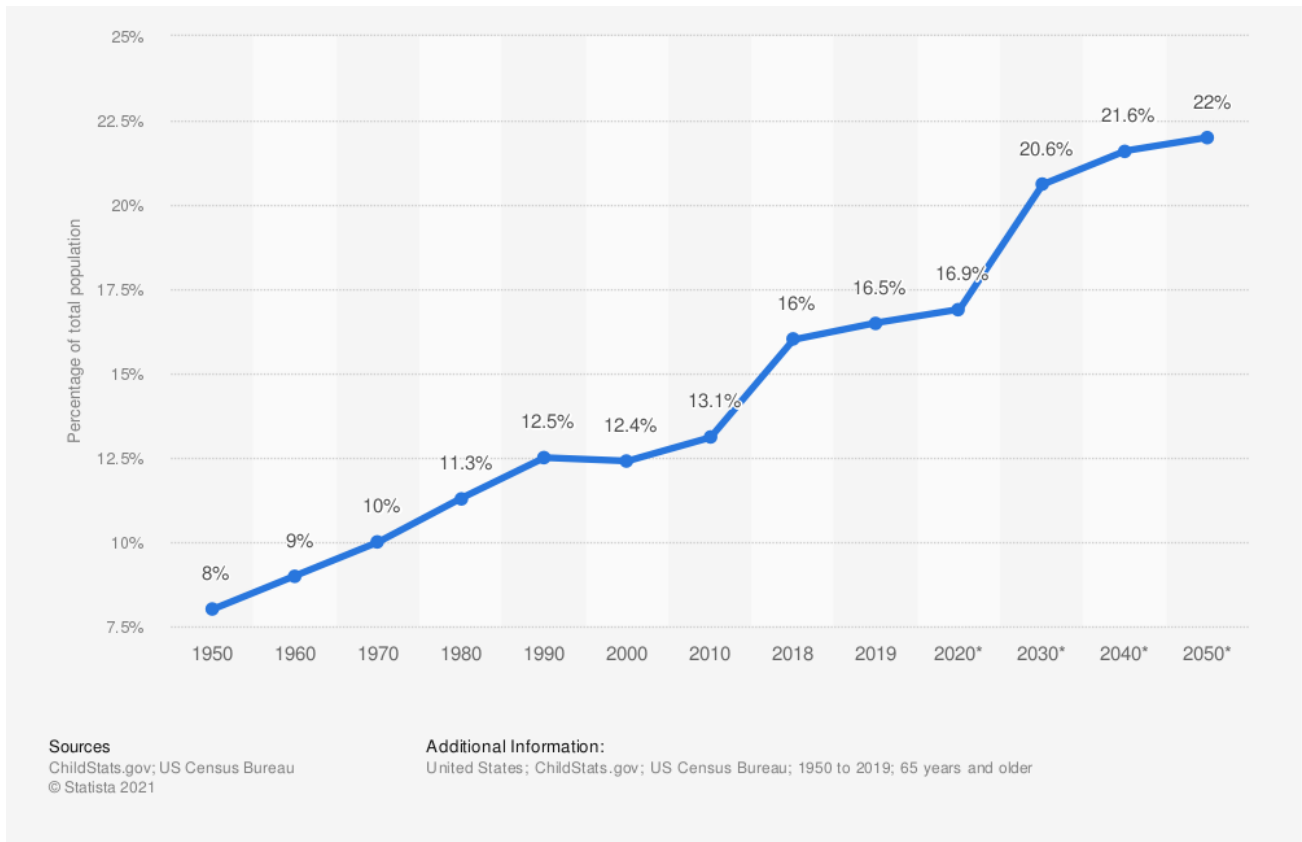
The standard sought in the Xtandi case is not to create a general standard for drug pricing, but to set one for products that were invented on a government grant. HHS could qualify the decision by limiting the precedent for now to products with sufficient returns to eliminate any doubt that the products have been highly profitable, and/or limiting it to products that place hardships on patients regarding copayments and other restrictions on access.

The biggest government failure will be to reject the petition and sanction the practice of charging the United States more, and significantly more, despite the U.S. taxpayer's role in funding the invention and development of a treatment.

## **ANNEX 1 - The population over 65 is growing faster than the general population.**

As the population of the U.S. gets older, the sustainability of the Medicare drug benefit will depend upon the ability of the government to control exorbitant prices.

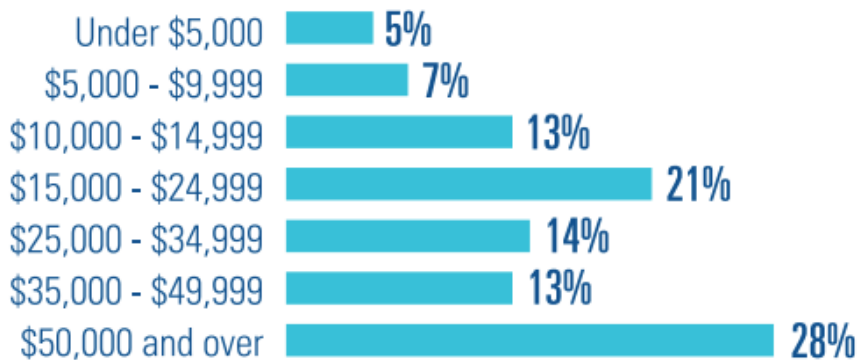
**Figure 1: Share of U.S. population that is 65 years and older from 1950 to 2050**



**ANNEX 2 - In 2019, 72 percent of the persons 65 and older reporting income earned less than \$50,000 per year.**

In 2019, 72 percent of the persons 65 and older reporting income earned less than \$50,000 per year. Forty-five percent reported earning less than \$25,000 per year.

**Figure 2: Distribution of Income of Persons Age 65 and Older Reporting Income in 2019**



Source: U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement

For all older persons reporting income in 2019 (52.8 million), 12% reported less than \$10,000 and 55% reported \$25,000 or more.

### **ANNEX 3 - Pfizer played no role in the invention or development of Xtandi.**

Pfizer played no role at all in the development of Xtandi. The FDA approved Xtandi August 31, 2012. Pfizer's interest in the drug began in August 2016, four years after Xtandi had been on the market and weeks after the 2016 march-in requests were rejected.

August 12, 2005. Medivation [licensed](#) patents for the U.S. government funded inventions from UCLA.

October 26, 2009. Medivation entered into a [collaboration agreement](#) with Astellas to jointly develop MDV3100 (generic name enzalutamide, brand name Xtandi). The collaboration agreement provided upfront and milestone payments from Astellas to Medivation, granted Astellas exclusive commercialization rights outside the United States subject to a royalty, and provided that Astellas then Medivation would share the profits from the Xtandi sales in the United States.

June 20, 2016. The NIH rejected the original march-in/royalty-free request.

August 5, 2016. The DoD followed suit rejecting the march-in case.

August 22, 2016. The *New York Times* reported that Pfizer had offered \$14 billion to acquire Medivation.

September 28, 2016. Pfizer completed the acquisition of Medivation for \$14.3 billion. Medivation's assets included its interest in Xtandi and two development-stage oncology assets in its pipeline:

talazoparib, which was in a Phase 3 study for the treatment of BRCA-mutated breast cancer, and pidilizumab, a candidate to treat diffuse large B-cell lymphoma and other hematologic malignancies. According to Note 2.A. of Pfizer's [2016 Financial Report](#), \$8.7 billion of the purchase price were for Xtandi, described as "the Developed technology rights with an average useful life of approximately 12 years." This was the financialization of future sales from an existing drug.

#### **ANNEX 4 - The federal government's paid up license (royalty-free) for use by or for the federal government license provides additional leverage.**

One of the challenges of using Bayh-Dole march-in rights is the fact that a decision to grant a march-in right is granted an automatic stay under 35 U.S.C. § 203(b), if the contractor or exclusive licensee chooses to appeal. However, in the case of Xtandi, where federal programs such as Medicare, Medicaid, the Veterans Health Administration and health insurance for federal employees play such a significant role, the government's right to use the Xtandi patents, without a finding or abuse, can be exercised without the rights holders having the automatic stay that applies to march-in rights. If HHS determines that the dramatic pricing discrimination of Xtandi against U.S. residents is not reasonable, a rights holder could face a choice of a march-in case that provides a royalty to the rights holder, or a Section 202 license for sale to federal programs with no royalty, and the government could proceed with the Section 202 license while the 203 march-in case appeal is being considered.

See: Engelberg, A., Kesselheim, A. Use the Bayh-Dole Act to lower drug prices for government healthcare programs. *Nature Medicine* 22, 576 (2016). <https://doi.org/10.1038/nm0616-576>.

#### **ANNEX 5 - Earlier precedents rejecting unreasonable pricing as a grounds for using the government march-in authority.**

As noted above, the federal government has different rights in federally-funded inventions, including a march-in right and a paid up royalty for use by or for the government. The NIH has previously been asked to use the march-in right to address the price discrimination against U.S. residents for three products. The first of the two cases (both of which were filed January 29, 2004) involved ritonavir, a drug used in the treatment of HIV and sold under the brand name of Norvir as a standalone product (as opposed to use coformulated with another drug). The second 2004 case involved latanoprost, a drug sold under the brand name of Xalatan by Pfizer for the treatment of glaucoma.

Both cases involved a complaint that U.S. residents paid more for a government funded drug than any other high income country. For Norvir, the pricing difference was more than five to ten to one, following a one day 400 percent price increase that only applied in the United States. For Xalatan, the prices in the U.S. were two to five times more expensive than in other high income countries. The 2004 Norvir case was granted a hearing, which attracted considerable news coverage. In

comments leading up to and during the NIH hearing, Abbott promised to freeze the price of Norvir to federal programs and to expand its patent access programs.

The NIH rejected both petitions, focusing on the fact that both drugs were “available” and used in the United States, but declined to directly address the issue of whether the price discrimination against U.S. residents was reasonable, given the government’s role in funding the R&D. In both cases, the NIH said that drug pricing concerns, including the discrimination against U.S. residents, were “appropriately addressed by Congress.” The NIH repeated these views in a second ritonavir case in 2012.

In 2016, the original Xtandi case was filed with HHS and the Department of Defense. The petitioners argued that Xtandi was not available “on reasonable terms,” because it was priced three to five times higher in the United States than in other high income countries. NIH Director Francis Collins rejected the petition, and also designated himself to review the appeal, which was also rejected. The DoD then followed the NIH lead. In the June 7, 2017 response to the appeal, Collins stated that Xtandi was “widely available on the market” and there were no public reports it was “in short supply or is not being prescribed or used because of its price,” and while the “NIH is sensitive to the impact of pricing on access” it “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.”

Collectively, the prior decisions by the NIH in the Norvir, Xalatan and Xtandi march-in cases is to accept radically higher prices in the United States, on drugs invented on NIH grants, and to justify the failure to enforce the statutory obligation that the benefits of inventions be made available to the public “on reasonable terms” by stating that Congress alone would need to change the law.

Lobbied by rights holders to eliminate any references to pricing for march-in petitions, in early 2021, NIST proposed to modify the march-in regulations to eliminate pricing as a stand alone grounds for march-in rights. There was massive opposition to the proposed rule, which received more than 80,000 comments in the public comment period. As noted above, President Biden’s Executive Order on Competition and Secretary Becerra’s report on drug pricing both indicated the NIST rule would not be finalized, and that prices would be considered as a grounds for a march-in request, effectively signaling a reversal of federal policy.

## **ANNEX 6 - Pricing clauses in U.S. government contracts for COVID-19 products**

In 2020 and 2021, several U.S. government contracts for the development of COVID-19 vaccines, therapeutics, diagnostic tests and other related products included provisions on pricing. Some contracts include a most favored nation pricing clause that specifically requires the company to provide the U.S. government with “a price lower” than the price offered to any centralized federal authority that is “a member of the Group of Seven plus Switzerland.” The non-U.S. members of the G7 are Canada, France, Germany, Italy, Japan, and the United Kingdom.



**Table A1: U.S. government COVID-19 contracts containing reference price constraints on resultant products**

Contractor, Agency, and Contract Number	Subject	Page	Reference Price Term Excerpt
<a href="#">ANP Technologies, Inc.</a> The Army W911QY20D0019 May 29, 2020	Development and purchase of a diagnostic.	11	<p><b><u>"MOST FAVORED CUSTOMER"</u></b>                      H.1 Most Favored Customer</p> <p>Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within thirty days (30) of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the Parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD."</p>
<a href="#">Becton, Dickson &amp; Company</a> The Army W911SR2030001 July 1, 2020	Needle Production	17	<p><b>"9. Government Preference</b></p> <p>9.1 Pricing. During the term of the Agreement, the Recipient agrees that, in the event that it enters into a Group Purchasing Organization (GPO) contract with a Qualifying Third Party (as defined below) with respect to a Qualifying Product (as defined below) with a per unit GPO price lower than that offered for the same Qualifying Product to the Government, the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. . . ."</p>
<a href="#">Eli Lilly</a> The Army W911QY21D0012 P0002 April 7, 2021	Monoclonal Antibody Treatment Production	7-8	<p><b>"H. 7 Sales to Covered Nations</b></p> <p>(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 September 2021 sell any COVID-19 bamlanivimab/etesevimab combination therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . ."</p>
<a href="#">Eli Lilly</a> The Army W911QY21C0016 October 26, 2020	Monoclonal Antibody Treatment Production	18	<p><b>"H.7 Sales to Covered Nations</b></p> <p>(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . ."</p>
<a href="#">Emergent BioSolutions Canada Inc.</a>	"the research and development of an	16	<p><b>"ARTICLE 9. Most Favored Customer</b></p>

<p>The Army W911QY2090013 June 24, 2020</p>	<p>advanced human immune globulin manufactured from human plasma with antibodies to SARS-CoV-2 (COVID-HIG) for post-exposure prophylaxis (PEP) of Coronavirus Disease (COVID-19)"</p>		<p>A. Awardee agrees that it shall not offer, sell, or otherwise provide the production model of the Prototype to any entity at a price lower than it offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer (S) and the price sold to the DoD multiplied by the number of items sold . . . ."</p>
<p><a href="#">Immunome Inc</a> The Army W911QY2090019 July 3, 2020</p>	<p>"research and development of a standardizable and scalable [redacted] compromise of [redacted] antibodies . . . ."</p>	<p>16</p>	<p><b>"ARTICLE 9. Most Favored Customer</b>  A. Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a lower price than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."</p>
<p><a href="#">Inovio Pharmaceuticals, Inc.</a> The Army W911QY2090016 June 22, 2020</p>	<p>"the development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery of INO-4800 against COVID-19, with demonstrated capability to be produced at a large scale, as well as full automation for production of the device arrays, (hereinafter referred to as the 'Prototype Project')."</p>	<p>17</p>	<p><b>"ARTICLE 9. Most Favored Customer</b> A. For a period of six (6) years from the Effective Date, Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."</p>
<p><a href="#">Maxim Biomedical, Inc.</a> The Army W911QY20D0018 May 11, 2020</p>	<p>Production of diagnostic</p>	<p>10</p>	<p><b>"H.1 Most Favored Customer</b> A. Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. . . ."</p>
<p><a href="#">Murtech, Inc.</a> The Army W911QY20D0017 May 11, 2020</p>	<p>Production of diagnostic</p>	<p>15</p>	<p><b>"H.1 Most Favored Customer</b> A. Awardee agrees that during the term of this contract and for a period of 2 years thereafter, it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (herein the 'Items') (for the avoidance of doubt, CLIN 0001 production model end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products) to any entity at a price lower than that offered to the DoD."</p>
<p><a href="#">Novavax</a></p>	<p>"Vaccine</p>	<p>4</p>	<p>"The Contractor shall maintain a most favored customer provision for</p>

<p>The Army W911QY20C0077 P0002 June 4, 2020</p>	<p>Development and Production”</p>		<p>the product once authorized or licensed by the FDA, such that the Contractor shall not give any entity a better price than the DoD for a period of five (5) years from the award of this contract, limited to customers in the U.S. and purchases made in the U.S to include sale prices as compared to commercial clients with respect to quantity, location of delivery, fundamental differences in deliverable formulation, and material differences in terms and conditions for commercial contracts.”</p>
<p><a href="#">Sanofi</a> The Army W15QKN1691002; MCDC2011-005 July 30, 2020</p>	<p>Vaccine research and development (including clinical trials) and production.</p>	<p>28</p>	<p><b>“5.1 Most Favored Nation Clause</b> (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health and in recognition of the long historical partnership between the U.S. Government and Sanofi Pasteur working on global pandemic solutions, as well as the investments made towards the development of a safe and effective vaccine against COVID-19, Sanofi Pasteur agrees that it will not sell any COVID-19 vaccine licensed under this Agreement to any nation that is a member of the Group of Seven plus Switzerland (‘Covered Nation’) at a price that is more favorable than those set forth in this Project Agreement.”</p>
<p><a href="#">SIO2 Medical Products, Inc.</a> The Army W911NF2030003 June 5, 2020</p>	<p>Research and development on a vaccine delivery vial.</p>	<p>13</p>	<p><b>“9. Government Preference</b> 9.1 Pricing. During the period of performance and the exercised optional availability periods, the Recipient agrees that, in the event that it offers, sells or otherwise provides a Qualifying Product (as defined below) to any Qualifying Third Party (as defined below) at a per unit price lower than that offered for the same Qualifying Product to the Government or a third party purchasing Qualifying Product pursuant to a designation by the Government pursuant to Section 9.2 or 9.3 (an ‘MCM Partner’), the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government or an MCM Partner.”</p>