

Comments of Reshma Ramachandran, MD MPP, Ravi Gupta, MD and Joseph S. Ross, MD MHS on the Department of Commerce’s National Institute of Standards and Technology (NIST) on changes in regulations related to the Bayh-Dole Act governing “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions”

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As practicing physicians, we frequently witness the struggles of our patients to afford the medicines we prescribe. National polling data have confirmed that this is not just anecdotal experience, but one shared by increasingly numbers of Americans regardless of age or insurance status. The U.S. government has a limited number of policy tools to intervene on behalf of patients to ensure access to medicines and vaccines. One such tool is the Bayh-Dole Act, which can enable access to federally-funded health technologies “on reasonable terms” including at an affordable price.¹

The scope of this protection for patients is significant as the federal government and ultimately, taxpayers, substantially underwrite the development of prescription drugs and vaccines. The National Institutes of Health, for example, was found to have contributed to the development of all 210 drugs approved by the Food and Drug Administration between 2010 and 2016.² Considered the costliest and most resource intensive stage of drug development, late-stage clinical trials for at least one in four drugs were also found to have significant public support.³

Federal funding has played an even more catalytic role in the development of COVID-19 vaccines. Research on vaccine technologies published between 2000 and 2019, which led to the rapid development of currently available COVID-19 vaccines, was supported by \$17.2 billion in NIH funding.⁴ Another federal program, Operation Warp Speed, contributed \$18 billion towards the development, manufacturing, and purchasing of COVID-19 vaccines.⁵

The National Institute of Standards and Technologies, however, has recently proposed a number of changes to regulations related to the Bayh-Dole Act that would hamper one of the few safeguards available for the U.S. government to ensure access to federally-funded health technologies. **We write to strongly oppose these changes that would significantly weaken the federal government’s ability to wield a key policy tool to mitigate the increasing financial barriers our patients face in taking their treatments and vaccines as prescribed.** Our comments will focus specifically on three proposed changes and their ramifications for patients if such safeguards are eliminated or restricted.

¹ Bayh B, Dole B. *Patent and Trademark Law Amendments Act*. Vol 35.; 1980.

<https://www.law.cornell.edu/uscode/text/35/203>

² Cleary EG, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. Contribution of NIH funding to new drug approvals 2010–2016. *PNAS*. 2018;115(10):2329-2334. doi:[10.1073/pnas.1715368115](https://doi.org/10.1073/pnas.1715368115)

³ Nayak RK, Avorn J, Kesselheim AS. Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *BMJ*. 2019;367:15766. doi:[10.1136/bmj.15766](https://doi.org/10.1136/bmj.15766)

⁴ Kiszewski AE, Cleary EG, Jackson MJ, Ledley FD. NIH funding for vaccine readiness before the COVID-19 pandemic. *Vaccine*. Published online March 8, 2021. doi:[10.1016/j.vaccine.2021.03.022](https://doi.org/10.1016/j.vaccine.2021.03.022)

⁵ Baker S, Koons C. Inside Operation Warp Speed’s \$18 Billion Sprint for a Vaccine. *Bloomberg Businessweek*. <https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine>. Published October 29, 2020.

1. Eliminating Pricing as Basis for Exercising March-In Rights (Modify 37 CFR § 401.6)

NIST proposes language to state that march-in rights “shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from practical application of the invention.” This would prevent Americans from being able to petition agencies when companies set exorbitant or unaffordable prices for taxpayer-funded technologies. These petitions when approved enable federal agencies such as the NIH to exercise march-in rights and reclaim the patent licensed to the manufacturer who set a prohibitively high price for patients and award it to another company. The original licensee would still receive reasonable royalties in return, but patients would now also have access to an alternative, more affordable option.

The high price of prescription drugs has proven to be a key financial barrier for patient access. Before the onset of COVID-19, a national poll found that 25% American reported difficulty affording their prescription drugs.⁶ Approximately three in ten adult patients report not being able to take their medications as prescribed due to the price, either not filling their prescriptions, taking an over-the-counter medicine instead, or cutting their pills or skipping doses.

Despite these struggles, prescription drug prices have continued to increase. Between 2015 and 2020, the wholesale acquisition cost or “list price” of medicines as set by the pharmaceutical companies increased by 7.1%.⁷ For Medicare Part D, the largest purchaser of prescription drugs in the world, half of all covered drugs had price increases that exceeded the rate of inflation between 2018 and 2019. The median price increase of these drugs was found to be at 6.4%, or 3.5 times that of inflation.⁸

For cancer drugs, prices set by the pharmaceutical industry have only risen. One study found that the launch prices for 58 cancer medications approved between 1995 and 2013 increased by 10% annually at an average of \$8,500 per year after adjusting for health benefits and inflation.⁹ The initial prices for the next generation of treatments, gene therapies, also portends a dire picture for patient access. Zolgensma, a gene therapy approved for spinal muscular atrophy (SMA) in May 2019 and developed as a result of significant NIH and charitable contributions, launched at a price of \$2.1 million per patient.¹⁰ Launch prices for other recently approved gene therapies that

⁶ Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It’s Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age. Kaiser Family Foundation. Published March 1, 2019. <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

⁷ *Medicine Spending and Affordability in the United States: Understanding Patients’ Costs for Medicines*. IQVIA; 2020. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?_=1617330244196

⁸ Cubanski J, Neuman T. Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs. Kaiser Family Foundation. Published February 4, 2021. <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/>

⁹ Howard DH, Bach PB, Berndt ER, Conti RM. Pricing in the Market for Anticancer Drugs. *Journal of Economic Perspectives*. 2015;29(1):139-162. doi:[10.1257/jep.29.1.139](https://doi.org/10.1257/jep.29.1.139)

¹⁰ Charity and NIH funding related to Zolgensma. Knowledge Ecology International. Published June 14, 2019. <https://www.keionline.org/charity-nih-funding-related-to-zolgensma>

received considerable public funding support¹¹ were set at \$350,000 or more per patient.¹² While these therapies are thought to be transformative for patients, their use has been limited, in part due to price.¹³

COVID-19 has only further exacerbated patients' hardship in accessing their prescriptions. In a recent national poll by GoodRx, 37.3% of respondents found it somewhat or very difficult to pay for their regular prescriptions in the past year.¹⁴ Over 20% also reported difficulty this past year paying for basic necessities such as housing and food due to the prices of their prescription drugs.¹⁵ A similar percentage also reported taking on financial debt or declaring bankruptcy in 2020 due to high prescription drug prices. Nevertheless, the pharmaceutical industry has continued business as it had before the pandemic, raising the prices of 783 medicines, all above inflation between January 2020 and January 2021.¹⁶

Especially during an ongoing, devastating pandemic when patients are facing increasing financial challenges in accessing their prescription medications, the U.S. government should not weaken a critical safeguard against high drug prices. As taxpayers, patients have already invested in the research and development of numerous drugs that are later priced out of their reach. By exercising march-in rights and reclaiming the patent of a federally-owned health technology, the U.S. government could award a new license to another manufacturer on the condition of reasonable pricing. Additionally, instead of awarding an exclusive license limited to a single manufacturer, the federal government could employ a non-exclusive license to allow for additional manufacturers to supply the drug affordably.

The use of march-in rights could also have positive implications for federal health budgets. Rising prescription drug prices are significantly contributing to increased national health expenditures¹⁷ that could otherwise be mitigated if march-in rights were exercised, particularly towards costly brand-name drugs developed through public support. Maintaining that price should remain as a basis for exercising march-in rights could also be critical when considering COVID-19 vaccines. While manufacturers have currently made these vaccines available to the U.S. government at lower, pandemic prices secured through bulk purchasing agreements,

¹¹ Singhroy D. The public sector role in funding CAR T technologies. Presented at the: Workshop: Patents, the Public Interest and Two New Medical Technologies: CRISPR and CAR T; September 15, 2017; Washington, D.C. https://www.keionline.org/sites/default/files/CAR-T_Singhroy.pdf

¹² Stein R. At \$2.1 Million, New Gene Therapy Is The Most Expensive Drug Ever. *NPR*. <https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever>. Published May 24, 2019.

¹³ <https://hbr.org/2019/10/making-life-saving-medical-treatments-more-affordable>

¹⁴ Nguyen A. Survey: How Has COVID-19 Affected Americans' Ability to Afford Their Medications? The GoodRx Prescription Savings Blog. Published March 22, 2021. <https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/>

¹⁵ Nguyen A. Survey: How Has COVID-19 Affected Americans' Ability to Afford Their Medications

¹⁶ *Pandemic Worsens, But It's Price Hikes As Usual For Pharma*. Patients for Affordable Drugs; 2021. <https://patientsforaffordabledrugs.org/2021/02/02/jan-price-hikes-pt-2/>

¹⁷ Keehan SP, Cuckler GA, Poisal JA, et al. National Health Expenditure Projections, 2019–28: Expected Rebound In Prices Drives Rising Spending Growth. *Health Affairs*. 2020;39(4):704-714. doi:[10.1377/hlthaff.2020.00094](https://doi.org/10.1377/hlthaff.2020.00094)

company executives have stated they would appreciably raise these prices in anticipation of an endemic market where booster doses will be required.¹⁸

The currently available Moderna vaccine offers a compelling case where march-in rights could be exercised. This vaccine was developed fully through public financial support from both the NIH and Operation Warp Speed.¹⁹ Besides being federally funded, the NIH also played a key role designing and conducting late-stage clinical trials²⁰ as well as ongoing studies to test modified vaccines against variants²¹. Moderna's CEO has stated that current prices for the vaccine are "well-below market" and that future pricing will follow the market prices for other commercial vaccines.²² Despite this below-market pandemic price, Moderna estimates \$18.4 billion in sales from its vaccine.²³

Should Moderna set a significantly higher price for its vaccine in the future when additional booster doses of such vaccines will be required to prevent the onset of a recurrent pandemic, this would unduly impact both patients and public health budgets. Private payers would likely offload these higher costs to patients through raised insurance premiums, while federal and state government programs may face the opportunity cost of not being able to invest in much-needed public health infrastructure in order to pay for these expensive, taxpayer-funded vaccines. Here, the U.S. government, if petitioned, could intercede and exercise march-in rights to ensure access to an affordable alternative with another manufacturer, while Moderna would continue to benefit from reasonable royalties.

Adopting NIST's proposal to prevent price – a known barrier to access – from being the basis for exercising march-in rights would preclude the federal government's ability to intervene should prices set by manufacturers such as Moderna for new vaccines and medicines become a burden for patients and government programs like Medicaid and Medicare. While march-in rights have not yet been exercised for prescription drugs and vaccines, there is also a possibility that should this safeguard be weakened, manufacturers may be emboldened to set and raise prices further, aware that this recourse would no longer be available.

The pharmaceutical industry has also repeatedly claimed that any government intervention to lower drug and vaccine prices could have a chilling effect on collaborations with federal research

¹⁸ Fang L. Drugmakers Promise Investors They'll Soon Hike Covid-19 Vaccine Prices. *The Intercept*. <https://theintercept.com/2021/03/18/covid-vaccine-price-pfizer-moderna/>. Published March 18, 2021.

¹⁹ Herman B. Moderna skirts disclosures of coronavirus vaccine costs. *Axios*. Published online August 5, 2020. Accessed February 21, 2021. <https://www.axios.com/moderna-barda-coronavirus-funding-disclosure-2775a517-a775-485a-a509-b6906c8535a9.html>

²⁰ Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *New England Journal of Medicine*. 2021;384(5):403-416. doi:[10.1056/NEJMoa2035389](https://doi.org/10.1056/NEJMoa2035389)

²¹ NIH clinical trial evaluating Moderna COVID-19 variant vaccine begins. National Institutes of Health. Published March 31, 2021. <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-evaluating-moderna-covid-19-variant-vaccine-begins>

²² Lovelace Jr. B. Moderna is pricing coronavirus vaccine at \$32 to \$37 per dose for some customers. *CNBC*. <https://www.cNBC.com/2020/08/05/moderna-is-pricing-coronavirus-vaccine-at-32-to-37-per-dose-for-some-customers.html>. Published August 5, 2020.

²³ Lovelace Jr. B. Moderna expects \$18.4 billion in 2021 sales from Covid vaccine, chief medical officer to depart. *CNBC*. <https://www.cNBC.com/2021/02/25/covid-vaccine-moderna-expects-18point4-billion-in-2021-sales.html>. Published February 25, 2021.

agencies and other publicly supported institutions that support innovation. However, there is no evidence that this would occur. Spending on research and development for largest pharmaceutical manufacturers has continued to be approximately 20% of their budgets²⁴ with a continued reliance by companies on publicly supported research in developing new products.²⁵

2. *Limiting standing to appeal awarding of exclusive licenses for federally-owned technology to only entities seeking to commercialize technology (Modify 37 CFR § 404.11)*

NIST proposes further amending the Bayh Dole Act such that an individual or entity who may be damaged by a license must also demonstrate that they incurred damages by losing the “opportunity to promote the commercialization” of the licensed invention. Through this change, only those seeking to market and earn revenue from the health technology could contest the awarding of an exclusive license to a single company. Under this amended regulation, patients who are directly impacted would not be able to similarly appeal these licenses. When granted these exclusive rights to federally-owned research, those entities who hold the license are able to retain control of both supply and price of derived products. A few examples of such treatments, as well as their manufacturers and wholesale acquisition costs (WAC) that have benefitted from such exclusive licensing agreements with the NIH^{26,27} include:

- Yescarta (axicabtagene ciloleucel) - a gene therapy marketed by Kite Pharmaceuticals, a subsidiary of Gilead Sciences approved for the treatment of relapsed or refractory large B-cell lymphoma with a WAC of \$447,600 per patient;
- Velcade (bortezomib) - a chemotherapy agent marketed by Millennium Pharmaceuticals approved for the treatment of multiple myeloma and mantle cell lymphoma with a WAC of \$41,678 per patient for 9 cycle course for multiple myeloma and \$38,472 per patient for a 6 cycle course for mantle cell lymphoma; and
- Synagis (palivizumab) - a monoclonal antibody treatment marketed by Sobi for the prevention of severe lower respiratory infection due to the respiratory syncytial virus in premature and high-risk infants and young children with a WAC of \$3074.65 per 100 mg/mL vial.

Despite public contributions towards their development, manufacturers have been able to secure and set high, monopolistic WACs or list prices for these treatments.

Exclusive licensing has also become an increasing concern, particularly in the face of public health emergencies such as COVID-19 where an adequate and affordable supply of both vaccines and therapeutics are necessary. Even recently, unexpected delays have impacted supply

²⁴ Mikulic M. U.S. pharmaceutical R&D spending as percent of total revenue 2019. Statista. Published November 18, 2020. <https://www.statista.com/statistics/265100/us-pharmaceutical-industry-spending-on-research-and-development-since-1990/>

²⁵ Kesselheim AS, Tan YT, Avorn J. The Roles Of Academia, Rare Diseases, And Repurposing In The Development Of The Most Transformative Drugs. *Health Affairs*. 2015;34(2):286-293. doi:10.1377/hlthaff.2014.1038

²⁶ Brennan Z. NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes. Regulatory Affairs Professionals Society. Published May 10, 2016. <https://www.raps.org/regulatory-focus™/news-articles/2016/5/nih's-exclusive-licenses-to-biotech,-pharma-start-ups-lots-of-secrecy,-few-successes>

²⁷ Manufacturers and wholesale acquisition costs obtained from Micromedex Red Book

that would otherwise have been avoided if the federal government had instead awarded a non-exclusive license for the taxpayer-funded technology that undergirds the available vaccines.²⁸ These licenses awarded to pharmaceutical companies also have ramifications on future pricing as through current terms, manufacturers largely have negotiated to retain control of setting prices of these products. Organizations including PrEP4All and Public Citizen as well as other academics across the country have noted that the government has yet to license a key federally-owned technology to Moderna used in its vaccine development.²⁹ As a result, they have called upon the NIH and Department of Health and Human Services (HHS) to award a non-exclusive license to allow for other manufacturers to produce this vaccine and scale up production.

Moreover, patients in collaboration with consumer advocacy organizations and other experts have repeatedly urged federal agencies³⁰ including the NIH to consider incorporating specific price and supply safeguards in exchange for these licenses, exclusive or otherwise. These include reasonable pricing clauses or allowing for a sub-license to be awarded to other manufacturers or entities to ensure access to low- and middle-income countries. They have also asked for federal agencies to include language within licensing agreements that would allow them to revoke the license should these supply and pricing conditions not be met. In addition to calling on NIH and HHS to grant a non-exclusive license to Moderna as mentioned above, advocates and academics have also outlined additional conditions including requirements for accessible pricing as well as technology sharing with the World Health Organization to bolster global production.²⁵ If the NIST proposal is adopted, these organizations as well as patients impacted would be unable to contest an exclusive license awarded to Moderna without such protections.

3. Making the licensing process less transparent by removing requirement that agencies inform the public of prospective licensees (Removal of “and the prospective licensee” from 37 C.F.R. § 404.7(a)(1)(I))

NIST is further proposing to no longer require federal agencies to notify the public of the identify of prospective licensees. Currently, when a federal agency plans to award an exclusive license to a federally-owned technology, they must first notify the public of the exact invention as well as the prospective licensee. For at least a 15-day period thereafter, written objections can be filed and the agency cannot award the license until these objections are considered.

Removing the requirement to inform the public of the intended licensee would further restrict patients, consumer advocates, and others from effectively commenting on such a license. Transparency of the prospective licensee offers valuable information in understanding their

²⁸ LaFraniere S, Weiland N. Some Johnson & Johnson Covid Vaccine Doses Delayed in U.S. by Factory Mix-Up - The New York Times. *The New York Times*. <https://www.nytimes.com/2021/03/31/world/johnson-and-johnson-vaccine-mixup.html>. Published March 31, 2021

²⁹ PrEP4All, Public Citizen, I-MAK, HealthGAP, Health Justice Initiative, AVAC et al. Re: Moderna and Its Use of an NIH-Owned Patent For COVID-19 Vaccines. Published online March 24, 2021. <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/605c7d657cca1206e17b4d87/1616674150606/Moderna+and+the+%27070+Patent+24+March+2021.pdf>

³⁰ Licensing NIH owned patents and data, including KEI comments on proposed exclusive licenses. Knowledge Ecology International. <https://www.keionline.org/nih-licenses>

experience and qualifications in pharmaceutical development and whether there will be a continued pattern of monopolistic behavior based on their prior market history. Finally, further obscuring information about these licensees will only worsen an already fraught situation. Prior and ongoing efforts from patient advocacy groups, consumer organizations, and academics to query the NIH and other federal agencies about proposed licenses has been incredibly difficult, often necessitating the use of multiple Freedom of Information Act requests and even lawsuits.

The Path Forward

As patients across the nation continue facing difficulties affording their prescriptions, stripping the U.S. government and the public who are the primary investors of these health technologies of safeguards, as proposed by NIST, may only exacerbate growing barriers to access. NIST's proposed changes to regulations related to the Bayh-Dole Act of eliminating price as the basis for exercising march-in rights, limiting standing to appeal awarding of exclusive licenses to only those who seek to commercialize the federally-owned technology involved, and removing the requirement to inform the public of prospective licensees should not be implemented. Rather than proceed forward with such measures that would further stifle the potential of the Bayh Dole Act to ensure affordable access to treatments built on taxpayer-funded research, federal agencies could instead further clarify how these safeguards could be effectively harnessed to do so.

The federal government should instead re-examine the Bayh-Dole Act with the intent of prioritizing the protection of patients instead of manufacturers seeking to maximize commercialization opportunities and revenue. The Secretary of Health and Human Services could convene stakeholders from relevant federal agencies as well as others including patients, health care professionals, and other experts to develop guidance around the use of the Bayh-Dole Act in ensuring access to licensed health technologies on reasonable terms. Towards this, the Secretary should also evaluate licensing agreements from federal agencies following passage of the Bayh Dole Act and their impact on patient access. Additionally, federal agencies could also take meaningful steps to make their licensing negotiations more transparent with direct input from the public and in particular, those communities most affected by the terms of these agreements. Congress could also amend current legislation to explicitly allow prices to be used as justification for march-in rights petition, recognizing the role of price in barring access for patients to drugs and vaccines derived from federally-funded research.

Re-examination of the Bayh-Dole Act and its implementation to date across agencies would also help operationalize one of President Biden's first executive orders proclaiming a "whole-of-government equity agenda."³¹ Through this order, federal agencies have been tasked to assess whether their "policies and actions create or exacerbate barriers to full and equal participation by all eligible individuals." Studies have shown the disproportionate negative impact of high prescription drug prices on patients of color, often forcing them to ration or be unable to take

³¹ The White House. Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Published online January 21, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

their medicines.^{32,33,34} Preserving and enhancing the Bayh-Dole Act to enable the U.S. government to address and prevent excessively high prices could be a meaningful step forward to ensuring equitable access to prescription drugs and vaccines for patients across the nation.

Relevant Experience

Reshma Ramachandran, MD MPP is a family medicine physician and health services researcher at the Yale National Clinician Scholars Program. One of her research focus areas is around examining the impact on patients of publicly-granted incentives along the drug development pipeline to pharmaceutical companies. On October 25, 2012, in her prior role as a fellow with the American Medical Student Association, she partnered with Knowledge Ecology International, U.S. Public Interest Research Group, and Universities Allied for Essential Medicines in filing a march-in rights petition for the anti-retroviral drug, ritonavir.³⁵ On October 17, 2016, she also sent a letter of support on behalf of the National Physicians Alliance and 10 other non-governmental organizations to NIH Director Francis Collins urging the agency to exercise march-in rights as petitioned earlier by Knowledge Ecology International and the Union for Affordable Cancer Treatment.³⁶

Ravi Gupta, MD is an internal medicine physician and health services researcher at the University of Pennsylvania National Clinician Scholars Program. Much of his research has focused on prescription drug affordability, generic drug policy, and FDA regulation.

Joseph S. Ross, MD, MHS, is a Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale School of Medicine, an Associate Physician of the Center for Outcomes Research and Evaluation at Yale-New Haven Health System, and Co-Director of the National Clinician Scholars Program at Yale. A practicing general internist with expertise in health services and outcomes research, his research examines the use and delivery of higher quality care and issues related to pharmaceutical and medical device regulation, evidence development, postmarket surveillance, and clinical adoption.

³² Post S, BP-Weeks M. *POISON: How Big Pharma's Racist Price Gouging Kills Black and Brown Folks*. Action Center on Race and Economy; 2020. <https://acrecampaigns.org/wp-content/uploads/2020/08/new-poison-final.pdf>

³³ Jung J, Feldman R. Racial-Ethnic Disparities in Uptake of New Hepatitis C Drugs in Medicare. *J Racial and Ethnic Health Disparities*. 2017;4(6):1147-1158. doi:[10.1007/s40615-016-0320-2](https://doi.org/10.1007/s40615-016-0320-2)

³⁴ Tseng C-W, Tierney EF, Gerzoff RB, et al. Race/Ethnicity and Economic Differences in Cost-Related Medication Underuse Among Insured Adults With Diabetes: The Translating Research Into Action for Diabetes Study. *Diabetes Care*. 2008;31(2):261-266. doi:[10.2337/dc07-1341](https://doi.org/10.2337/dc07-1341)

³⁵ Love J. 2012 October. Four NGOs ask NIH to grant open licenses to ritonavir patents under Bayh-Dole March-in provisions. Knowledge Ecology International. Published October 25, 2012. <https://www.keionline.org/22023>

³⁶ Struver Z. 11 Groups Urge NIH to Lower Price of Xtandi, NIH/Army-Funded Prostate Cancer Drug With \$129k/Year Price Tag. Knowledge Ecology International. Published March 22, 2016. <https://www.keionline.org/23041>