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Public Citizen Comments to the National Institutes of Health re: Maximizing NIH's Levers to Catalyze Technology Transfer

July 27, 2023

Thank you for the opportunity to provide written comments regarding the National Institutes of Health (NIH) Office of Science Policy's July 31, 2023 workshop on policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries.

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law.

Our comments will deliver two key messages:

- NIH has considerable power, and therefore responsibility, to improve affordable access to medicines in the United States and around the world.
- NIH's licensing policies, research and development (R&D) contract conditions, and rights under the Bayh-Dole Act are powerful tools to improve access to the medicines the agency helps develop.

NIH has considerable power, and therefore responsibility, to improve affordable access to medicines in the United States and around the world.

The United States government is the largest funder of biomedical research in the world, foremost through more than \$40 billion dollars in annual funding of NIH, the vast majority of which supports extramural research at universities and other research

institutions.¹ Recent research found that NIH funding contributed to research associated with 354 out of 356 new drugs approved from 2010-2019, totaling \$187 billion in public funding.² This extensive public investment in drug R&D gives the U.S. government and NIH significant power to condition the pricing and technology sharing behavior of manufacturers, and to facilitate access to publicly funded medicines.³ In our view, the agency has underused these powers, with serious consequences for global health and costs to U.S. consumers. In a [report](#) released in June 2023 by the Majority Staff of the United States Senate Health, Education, Labor and Pensions (HELP) Committee, it was found that “the average (median) price of new treatments that NIH scientists helped invent over the past twenty years is \$111,000.”⁴

The federal government’s early and robust investment in coronavirus research laid the foundation for the rapid development of many COVID-19 vaccine candidates.⁵ In a 2020 report titled “[Leading COVID-19 Vaccine Candidates Depend on NIH Technology](#),” Public Citizen revealed that several first-generation candidates were using the 2P approach that was developed by NIH scientists.⁶ Among these manufacturers, Moderna uniquely benefited from federal support. “We did the front end. They did the middle. And we did the back end,” said Dr. Barney Graham, a former top NIH official, referring to the process for designing the spike protein sequence, manufacturing vaccines, and running clinical trials.⁷

¹ Public Citizen, Civil Society Organizations Call on the Department of Health and Human Services to Combat Excessive Drug Prices, <https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf>; <https://www.nih.gov/about-nih/what-we-do/budget>

² Comparison of Research Spending on Ekaterina Galkina Cleary, PhD1,2,3; Matthew J. Jackson, PhD1,4; Edward W. Zhou, PharmD1,4; et al. New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378>

³ See Robert Weissman, Public Citizen, ‘Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act,’ <https://www.citizen.org/wp-content/uploads/Weissman-Senate-HELP-testimony-5.4.23.pdf>

⁴ Senate Health, Education, Labor, and Pensions Committee, Majority Staff, ‘Public Investment, Private Greed,’ <https://www.sanders.senate.gov/wp-content/uploads/Sanders-Public-Medicines-Report.pdf>

⁵ Zain Rizvi, Public Citizen, ‘Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma’s Monopoly Model,’ <https://www.citizen.org/article/blind-spot/>

⁶ Zain Rizvi, Public Citizen, ‘Leading COVID-19 Vaccine Candidates Depend on NIH Technology,’ <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology>

⁷ ‘Rich Countries Signed Away a Chance to Vaccinate the World,’ <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>; Zain Rizvi, Public Citizen, ‘Sharing the NIH-Moderna Vaccine Recipe,’ <https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/>

Despite significant taxpayer investment in the NIH-Moderna vaccine, the U.S. government failed to include safeguards for global access in its contracts with Moderna. The manufacturer went on to generate tens of billions in Covid vaccine sales while leaving the world with insufficient vaccine supply for more than a year. In a [Public Citizen report](#), researchers showed that it was possible to manufacture enough vaccine for the world much more quickly – if the technology was shared by Moderna.⁸

Now Moderna is quadrupling the price of its Covid vaccines, which are expected to be needed annually.⁹ This exceptional cost to U.S. consumers should have been avoidable. One approach would have been to include reasonable pricing provisions in the licenses NIH gave Moderna for use of government technology.

We appreciate the steps that the U.S. government and NIH have since taken to improve access to medicines globally. In 2022, President Biden announced licenses for 11 publicly owned medical technologies to the World Health Organization’s (WHO) COVID-19 Technology Access Pool (C-TAP).¹⁰ We [commended](#) this, noting that, “The announcement is a turn toward sharing not only doses, but knowledge, which is the difference between charity and justice. This path, if pursued with seriousness of purpose, can improve resilience to future pandemics and bring a measure of justice to a terribly unjust time.” The collaborative research agreement between the National Institutes of Allergy and Infectious Diseases and South African manufacturer Afrigen is another positive step forward towards equitable access through sharing the latest science and technology.¹¹

We call on NIH to shepherd global access and commit its full resources to this path of technology sharing by adopting licensing policies and R&D contract standards that proactively support medicines access. We believe it is both within NIH’s power and responsibility to help ensure that taxpayers get a fair return on their investment while maximizing the impact of NIH’s critical health technologies by making them available

⁸ Public Citizen, ‘How to Make Enough Vaccine for the World in One Year,’ <https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/>

⁹ Robert Weissman, Public Citizen, ‘Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act,’ <https://www.citizen.org/wp-content/uploads/Weissman-Senate-HELP-testimony-5.4.23.pdf>

¹⁰ NIH Makes COVID-19 Technologies Available to Global Manufacturers Through WHO Program, <https://www.techtransfer.nih.gov/policy/ctap>; <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses>

¹¹ Public Citizen, ‘NIH-Afrigen Agreement Will Help WHO’s Fight Against Pandemics,’ <https://www.citizen.org/news/nih-afrigen-agreement-will-help-whos-fight-against-pandemics/>

equitably and globally.¹²

In a June 2022 [letter](#) to President Biden, Public Citizen and 20 other civil society organizations called for the nomination of an NIH Director who will “prioritize patient access and public health in their role as the world’s premier steward of biomedical research.” We noted that, “the NIH Director is empowered to remedy price gouging and access constraints through licensing competition using march-in and worldwide royalty-free rights. The NIH can also proactively support access by adopting upstream policies that build transparency and reasonable pricing conditions into funding and cooperative research and development agreements.”

NIH’s licensing policies, research and development contract conditions, and rights under the Bayh-Dole Act are powerful tools to improve access to the medicines the agency helps develop.

Licensing NIH-owned inventions

NIH can increasingly use licensing agreements to support global and equitable access to NIH technologies, including through reasonable pricing provisions and non-exclusive licensing practices.

The Bayh-Dole Act requires NIH and other government agencies granting partially-exclusive or exclusive licenses to U.S. government-owned inventions to ensure that the scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.¹³ We urge NIH to take seriously this requirement and rigorously and transparently assess whether a license should be nonexclusive or have its exclusivity limited, for example, by omitting low- and middle-income countries from the geographic scope of exclusivity or by providing that a licensee will have its exclusivity curtailed or eliminated after certain revenue benchmarks have been achieved. Exclusive licenses grant corporations monopoly power, leading to high drug prices and in many cases rationing of essential medicines, where individuals or state programs cannot pay. As a result of monopoly pricing, Americans pay more than two-and-a-half times as much for prescription drugs than people in other countries.¹⁴ One-in-

¹² Public Citizen, Letter to President Biden calling for a pro-access to medicines NIH Director, <https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf>

¹³ 35 U.S.C. § 209, Licensing Federally Owned Inventions. Knowledge Ecology International, Joint Comments by KEI, UACT, Social Security Watch and Health Gap on the proposed NIH Exclusive License in CAR Therapy to Lyell Immunopharma (Sept. 19 2019), <https://www.keionline.org/31713>; Zain Rizvi, Public Citizen, ‘Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma’s Monopoly Model,’ <https://www.citizen.org/article/blind-spot/>

¹⁴ RAND, Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries,

four Americans report they have been unable to afford their medicines.¹⁵ Exclusivities can also throttle supply and allow companies to profiteer from taxpayer funded technologies.¹⁶ If the government nonetheless grants an exclusive license, it should ensure that the exclusivity is appropriately limited as required under law.

Nonexclusive licenses should be the norm and leverage must be exercised at the outset to induce manufacturers to share technology, price reasonably, deliver transparently, and otherwise contribute to ensuring access. We appreciate NIH's nonexclusive licensing of the proline-substituted coronavirus spike protein. Nonetheless, NIH could have gone further to facilitate vaccine access, given its essential contribution. In a March 2021 [letter](#) to the Department of Health and Human Services and NIH, Public Citizen and other civil society organizations specified that the licensing agreement should “1. Empower the U.S. government to authorize manufacturing of mRNA-1273 – including by government-owned production facilities, 2. Require technology sharing with the World Health Organization to help ramp up global production, and 3. Include requirements for accessible pricing universally.” These safeguards could have ensured that NIH technology maximized its impact on protecting public health in the United States and globally.

Additionally, NIH should work to identify qualified international licensees, and work closely on licensing and access strategies for key technologies with WHO and the Medicines Patent Pool. The Covid technologies recently licensed to WHO through C-TAP should set a precedent for NIH sharing technology globally. This would allow manufacturers from around the world to help scale-up production and prevent rationing.¹⁷ The [Medicines Patent Pool](#) (MPP) aims to help solve the challenges faced by developing countries in accessing medical technologies by negotiating deals that are acceptable to both patent holders and generics firms. The U.S. licensed government-owned patents related to the HIV medicine darunavir to MPP in 2010, the first license

<https://www.rand.org/news/press/2021/01/28.html>; <https://www.citizen.org/wp-content/uploads/Becerra-antimonopoly-letter-for-sign-on-1.pdf>

¹⁵ Gallup, Medication Insecurity by Race and Political Identity, <https://news.gallup.com/poll/316052/large-racial-divide-covid-cost-concerns.aspx>; <https://www.citizen.org/wp-content/uploads/Becerra-antimonopoly-letter-for-sign-on-1.pdf>

¹⁶ Public Citizen, Letter to NIH Director Francis Collins: Ensure Access, Affordability and Open Science in COVID-19 Treatments and Vaccines, <https://www.citizen.org/wp-content/uploads/Public-Citizen-letter-to-Francis-Collins-re-COVID-19-treatment-plans.pdf>

¹⁷ Zain Rizvi, 'The NIH Vaccine,' <https://www.citizen.org/article/the-nih-vaccine/>

granted to MPP.¹⁸ This forward-looking contribution helped establish MPP and encourage subsequent licenses from the pharmaceutical industry. We hope NIH will build on this precedent and work increasingly closely with WHO and MPP.

Conditions in R&D funding agreements

Conditions in NIH research and development contracts are another powerful policy tool that NIH can use to support affordable access to the medicines and technologies that the agency helps fund. It should be a requirement that the corporations benefiting from public funding and public science act in the public interest.¹⁹ This should include standard clauses ensuring federally funded inventions are priced reasonably. Reasonable pricing clauses were first introduced in 1989 and routinely used by the NIH in the early 1990s, and their reintroduction has been called for today by Senate HELP Committee Chair Bernie Sanders (I-VT).²⁰

Most Favored Nations (MFN) clauses are one example of reasonable pricing that should be routine in any NIH R&D funding agreement. The Senate HELP Majority Staff recently found that “U.S. taxpayers virtually always pay more than people in other countries for treatments that NIH scientists helped invent.”²¹ At a bare minimum, Americans should not have to pay more than people in other rich countries for medicines our country helped to develop.²² The MFN clause included in the United States’ agreement for Pfizer’s Paxlovid ensured that the U.S. received the lowest price for the drug among the G7 countries + Switzerland.²³

Public Citizen’s [comments](#) recently submitted to the Senate HELP Committee state: “[Operation Warp Speed] episodically used Most Favored Nations (MFN) clauses

¹⁸ US National Institutes of Health (NIH) First to Share Patents with Medicines Patent Pool As it Opens for Business, <https://medicinespatentpool.org/news-publications-post/us-national-institutes-of-health-nih-first-to-share-patents-with-medicines-patent-pool-as-it-opens-for-business>

¹⁹ Zain Rizvi, Public Citizen, ‘Leading COVID-19 Vaccine Candidates Depend on NIH Technology,’ <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology>

²⁰ New Report Shows How Badly Big Pharma Is Ripping Off American People With Publicly Funded Medications, <https://www.sanders.senate.gov/press-releases/news-new-report-shows-how-badly-big-pharma-is-ripping-off-american-people-with-publicly-funded-medications/>

²¹ Senate Health, Education, Labor, and Pensions Committee, Majority Staff, ‘Public Investment, Private Greed,’ <https://www.sanders.senate.gov/wp-content/uploads/Sanders-Public-Medicines-Report.pdf>

²² Public Citizen Comments to the Senate HELP Committee re: Discussion Draft Legislation to Reauthorize the Pandemic and All-Hazards Preparedness Act, <https://www.citizen.org/article/public-citizen-comments-to-the-senate-help-committee-on-the-pandemic-and-all-hazards-preparedness-act/>

²³ Knowledge Ecology International, ‘Pfizer Agrees to International Reference Pricing in US Government Contract for COVID-19 Therapeutic,’ <https://www.keionline.org/37294>

allowing the government to purchase medicines at the lowest price available in ‘covered nations.’ When the government substantially subsidizes and de-risks R&D for a drug or vaccine, then a reasonable price should be substantially lower and reflect that public investment, rather than future supra-competitive profits, is the primary driver of innovation...Drug corporations and other opponents of reasonable pricing requirements often claim that when a version of reasonable pricing policy was in place in the early 1990s, that it chilled collaborations between the U.S. government and private collaborators, and that when the policy was lifted, that the number of cooperative agreements ‘increased significantly and quickly.’²⁴ However, opponents’ narrative of historical experience with reasonable pricing fails to withstand examination.” Knowledge Ecology International’s James Love has repeatedly debunked this argument before:^{25,26}

This claim, made frequently by the technology transfer community, bears some scrutiny. KEI obtained data from the NIH on CRADAs under the Freedom of Information Act (FOIA), which is available [here](#).²⁷ Until 1996, the NIH only reported what are now called “Standard” CRADAs. Beginning in 1996, the NIH added a new category, “Materials” CRADAs. All of the CRADAs involving the reasonable pricing clause were standard CRADAs.

From 1990 to 1994, the calendar years when the reasonable pricing clause was used for the whole year, the average number of standard CRADAs executed was 33. There was also a significant biotech stock market crash in 1992 and 1993. From 1996 to 2000, the number of standard CRADAs increased, to an average of 46 per year. But a lot was happening that had nothing to do with the reasonable pricing clause.

The average NIH budget was 55% higher in 1996 to 2000 than in 1990 to 1994. Probably more consequential, from year end 1992 to year end 1994, the NASDAQ

²⁴ James Love. “Jamie Love Responds to Criticism of Knowledge Ecology International Letter,” IP Watchdog, May 15, 2019. <https://ipwatchdog.com/2019/05/15/jamie-love-responds-criticism-knowledge-ecology-international-letter/id=109239/>

²⁵ KEI Comments on:

KEN23378 1T draft of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), <https://www.keionline.org/wp-content/uploads/KEI-comments-2023-pahpa.pdf>

²⁶ Ibid.; James Love. “The number of standard and material CRADAs executed by the NIH from 1985 to 2020 and the relationship to NIH reasonable pricing clause,” Knowledge Ecology International. April 5, 2021. <https://www.keionline.org/wp-content/uploads/KEI-BN-2021-3.pdf>

²⁷ “Cooperative Research and Development Agreements (CRADAs),” Drug Database. <http://drugdatabase.info/cradas/>

biotech index declined from 170.64 to 81.54, a decline of 48%, whereas from year end 1995 to year end 2000, the same index increased from 133.77 to 634.32, an increase of 374%.

More significantly, regarding the CRADA data, the number of standard CRADAs fell to 28 by 2005, and was relatively flat from 2000 to 2013, despite a massive 17-fold increase in the NASDAQ biotech index, and a 64% increase in the NIH budget. Are we supposed to conclude that increases in the NIH budget or rising share prices and new private investments aren't good for innovation because the number of CRADAs did not increase from 2000 to 2013?

March-in and paid-up rights under the Bayh-Dole Act

In addition to proactively establishing pro-access licensing policies and contract conditions, NIH should march-in and use its worldwide paid-up rights under Bayh-Dole to support access at home and abroad.²⁸ Publicly funded and publicly owned inventions developed through federal funding are governed through rules under the Bayh-Dole Act. These rules afford funding agencies, like NIH, certain rights over inventions developed with taxpayer funding to protect the public interest, including:

- 1) the right to “march-in” and license competition when a drug corporation is failing to make a medicine available on reasonable terms, or to alleviate health or safety needs not being met by the manufacturer;²⁹ and
- 2) a nontransferable, irrevocable, paid-up license to practice or have practiced the invention for or on behalf of the United States throughout the world.³⁰

Patients and activists have long fought for the Department of Health and Human Services to use these rights to lower the price of the prostate cancer medicine enzalutamide (brand-name Xtandi), a medicine invented at University of California Los Angeles with NIH funding.³¹ The Average Wholesale Price of Xtandi in the United States is six times the price of Xtandi in Japan.³² More than 40 civil society organizations, in a [letter](#) to Secretary

²⁸ Public Citizen, Letter to President Biden calling for a pro-access to medicines NIH Director, <https://www.citizen.org/wp-content/uploads/cso-letter-to-biden-re-nih-director.pdf>

²⁹ 35 USC 203(a)(1) & (2)

³⁰ 35 USC 202(c)(4)

³¹ Public Citizen & Partners Urge President Biden to Lower Price of Xtandi, https://www.citizen.org/wp-content/uploads/xtandi-march-in-request-cso-support-letter-2022.10_final-1.pdf

³² Letter to Secretary Becerra and Acting Director Tabak on Xtandi March-in Petition and Most Favored Nation Clause in Pfizer Contract, Clare M. Love, Eric L. Sawyer, Robert Sachs, Universities Allied for

Becerra, have also called on the Department of Health and Human Services to use its march-in authority under the Bayh-Dole Act as a key policy option to combat excessive drug prices:

The federal government has the power under existing law to increase competition and lower drug prices...the Bayh–Dole Act allows the federal government to “march-in” on drug patents developed with federal funding, or to use such patents royalty-free on behalf of the United States.³³ These actions can help introduce additional producers. Generic competition, the Food and Drug Administration has found, can lead to price reductions of 95 percent.³⁴

We appreciate the opportunity to comment. Thank you.

Essential Medicines, February 3, 2022, <https://www.keionline.org/wp-content/uploads/Love-Sachs-Sawyer-UAEM-Letter-Xtandi-PfizerContract-3Feb2022.pdf>

³³ KEI, KEI Briefing Note 2017:1. Bayh-Dole Act and difference between March-In Rights and the world wide royalty free rights in patents, <https://www.keionline.org/24132>

³⁴ FDA, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, <https://tinyurl.com/uxdc9>