U.S. Chamber of Commerce

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March 22, 2023

The Honorable Bernie Sanders
Chair
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chair Sanders and Ranking Member Cassidy:

The U.S. Chamber of Commerce's ("the Chamber") Global Innovation Policy Center ("GIPC") appreciates the opportunity to share concerns regarding today's hearing entitled "*Taxpayers Paid Billions For It: So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?*"

The Chamber supports efforts to help ensure every American has equitable access to life-saving medicines, including Moderna's COVID-19 vaccine. However, we are concerned this hearing is premised on a false narrative that if translated into policy would lead to fewer life-saving drugs and less access to treatments for Americans. Indeed, the title of the hearing itself suggests that premise: to pursue an agenda—based on a misconstruction of the respective roles of public and private funding of science, research, and development—that would upend the successful legal frameworks that facilitate public-private partnerships and commercialization.

The Chamber's main concerns with this hearing's scope and focus can be summarized in four main points:

1. It fails to recognize that market-restrictive policies like artificial price controls can deter future innovation and inhibit patient access;

2. The hearing title suggests the discussion will grossly misrepresent the proportion of taxpayer funding for research and development in relation to private sector partners;

3. It ignores how the legal frameworks supporting public-private partnerships, including the bipartisan Bayh-Dole Act of 1980, promote the development and commercialization of lifesaving, cost-effective innovations that benefit millions of Americans. As we cite with the Xtandi example, 99.998% of research costs were borne by the private sector; and

4. It suggests that certain members of Congress intend to push forward with so-called march-in rights or other forms of forced tech transfers to weaken the statutory intellectual property ("IP") rights of America's innovative companies.

The Chamber's additional concerns are outlined in more detail below.

I. The Chamber's Research Shows that Market Restrictive Policies Deter Innovation, Inhibit Patient Access, and Limit Patient Choice.

Today, the Chamber released its *2023 Patient Access Report (Phase One)* ("The report"). As our GIPC President and CEO David Hirschmann explained in a letter to HHS Secretary Becerra, the report confirms what proponents of a free market already know: marketplace competition and effective intellectual property protections give patients greater access to the latest medicines.[1] In contrast, the Chamber's research shows that market-restrictive policies like artificial price controls can deter future innovation, inhibit patient access, and limit patient choice.

The Chamber knows that the cost of prescription medicines is a top priority for this Administration. As indicated above, the Chamber also supports efforts to help ensure every American has equitable access to life-saving medicines, including Moderna's COVID-19 vaccine.

Unfortunately, many have accepted the failed premise that government intervention and price setting is the most effective way to provide patients with access to life-saving innovations. This approach is embodied in the drug pricing provisions of the *Inflation Reduction Act* (IRA). While the IRA claims to promote access by controlling prices through so-called "negotiation," the reality is that innovators are forced to comply with the government's arbitrary price controls or face crippling penalties.

Our report cautions that the IRA's drug pricing penalties will actually harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The report's methodology demonstrates that in other OECD countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicine.[2] For example, prior to the enactment of the IRA's price controls, out of 104 new oncology products released globally, 80% were launched in the U.S., while only 58% were launched in Europe. Similarly, in several benchmark countries, patients can wait up to several hundred days to receive access to life-saving treatments, with patients waiting an average of 133 days in Germany and up to 500 days in Spain.

Surely this outcome—less innovative medicines and longer wait times—isn't what any policymaker or advocate wants. Government intervention in price setting undermines the innovation ecosystem that empowered the U.S. to become one of the most innovative countries in the world. Decisionmakers must consider the implications of price controls on patients before proceeding with the implementation of the IRA's framework that would jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. Additionally, as the Chamber will discuss in subsequent sections, policymakers must resist new efforts to undermine the successful innovation ecosystem and impose further arbitrary price controls. The ability of American patients to access life-saving innovations in a timely manner depends on it.

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[1] Ltr from David Hirschmann, President and CEO, Global Innovation Policy Center, to Secretary Xavier Becerra, March 22, 2023.

[2] The report found that fewer overall biopharmaceutical product launched in Canada, Japan, South Korea, Australia, and European Union member states than in the United States over the past 20 years.

II. Taxpayer Funding of R&D is Dwarfed by Private Sector R&D Investments.

This hearing's premise fails to accurately represent the true relationship between taxpayer funding and private sector expenditures on research, development, and commercialization. The U.S. government acted as a good faith partner at a crucial moment during the pandemic to ensure that private sector businesses with nearly unique capabilities were in a position to accelerate desperately needed research to fruition and produce and distribute needed countermeasures at speed and scale. Here, public funding joined the significant private resources also specifically invested into Moderna's COVID-19 research.[3] In addition, the hearing title ignores the foundational private investment that occurred in Moderna and made its mRNA research platform available prior to the pandemic and its engagement in COVID-19 research.[4]

Moderna's engagement with federal partners highlights the importance of public-private partnerships and sources of R&D funding. According to the Congressional Budget Office (CBO), the private sector invested $83 billion in pharmaceutical R&D expenditures in 2019.[5] Adjusting for inflation, that is 10 times the amount invested in the 1980s, illustrating the growing role the private sector plays in supporting the success of the America's innovation ecosystem.[6] The CBO report acknowledges that the federal government underpins biopharmaceutical R&D spending in three ways. First, the government can influence the demand for new drugs by subsidizing the purchase through federal programs, such as Medicare and Medicaid. Second, the government can help increase the supply of new drugs by funding "basic biomedical research that provides a scientific foundation for the development of new drugs by private industry."[7] Third, federal government policy can influence both the supply and demand for drugs by increasing the demand for a specific medicine while also creating incentives for the private sector to invest in the next generation of medicines.

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[3] *See* Allie Clouse, *Fact check: Moderna vaccine funded by government spending, with notable private donation*, USA TODAY November 25, 2020 (noting that claims regarding Moderna's vaccine being fully funded by the federal government are missing context and do not take into account significant private donations from other entities like Vanderbilt University and country music singer Dolly Parton); *See also* John LaMattina, *Taxpayer Funded Research And The Covid-19 Vaccine*, FORBES March 31, 2021 ("Yes, Operation Warp Speed (OWS) contributed funds to enable Moderna to build the capacity to produce its vaccine. Moderna is a small company, and its Covid-19 vaccine is its first product to make it to patients. Moderna didn't have anywhere near enough capital to build manufacturing plants. By helping to finance Moderna's efforts, as well as those of J&J, Novavax, etc., the U.S. government helped to create the situation where we will have over 600 million doses of Covid-19 vaccines by summer – enough to vaccinate every adult. Plus, more doses will be available later in the fall. Isn't this the purpose of government during a crisis.").

[4] Testimony of Tom Quaadman, Executive Vice President, GIPC, before the House Committee on Science, Space, and Technology for a hearing entitled *Building Back the U.S. Research Enterprise: COVID Impacts and Recovery* ("The Pfizer and Moderna COVD-19 vaccines both utilize a fairly novel technology called synthetic messenger RNA or mRNA. Researchers at University of Pennsylvania, Katalin Kariko and Drew Weissman, spent over a decade conducting research on synthetic mRNA and published the findings in 2005. This foundational research inspired founders of Moderna to use mRNA for medicines and raised $2 billion on the concept before going public in 2018. Soon after the world became aware of the COVID-19 virus, Moderna researchers used the mRNA technique to create a vaccine and was one of the first drugmakers to develop a vaccine suitable for clinical trials.").

[5] *Research and Development in the Pharmaceutical Industry,* Congressional Budget Office.

[6] *Id.*

[7] *Id.*

As industry experts and thought leaders have noted, the CBO's report can only lead to one conclusion: our public-private partnerships are working, allowing innovative private sector actors and the federal government to contribute through their unique areas of specialization, which improves the efficiency of the innovation ecosystem overall. In other words, the data indicates that our system is working, and not because taxpayers are bearing a burden and companies are simply free-riders. On the contrary, the private sector pays market rates to license rights to intellectual property when useful discoveries emerge from government-funded research. The system works because the private sector assumes the risk of actual drug development and testing, a process of sunk investment that more often than not results in failure and significant financial loss.[8]

The role of the private sector in bringing publicly funded basic research to market is even more pronounced in the context of life-saving treatments. According to a recent paper published by several scholars, of the tens of thousands of National Institutes of Health ("NIH") funded grants from 2000, only 18 treatments were approved by the Food and Drug Administration ("FDA").[9] Of these 18 approved treatments, taxpayer funding totaled only $670 million. In contrast, private-sector funding totaled $44.3 billion. When applying these facts in a logistic regression analysis, they found a "positive and significant relationship between private sector funding and the likelihood of FDA approval…[while] [t]he relationship between public funding and the likelihood of FDA approval is….negative and not statistically significant."[10] In other words, compared to the significant resources invested by private enterprises, public funding had almost no impact on the product's ultimate approval and availability to the public.[11]

This evidence makes clear what proponents of strong public-private partnerships have known all along: that the private sector, subject to inherent market risks and potential economic failure, plays a significant and vital role in bringing new discoveries to patients, i.e., the private sector and private resources play the indispensable role in turning a discovery into a medicine and making it widely available for public consumption and use. This Committee's leadership must recognize this basic fact and, instead of perpetuating a false narrative about the exaggerated role of taxpayer funding in research and development, should promote and advocate for the continued growth of public-private partnerships.

III. Legal Frameworks that Promote Successful Public-Private Partnerships have Delivered Lifesaving, Cost-Effective Innovations to the Public and Must be Protected.

The Chamber is also concerned that this hearing serves as a proxy for attacks on the successful statutory framework which promotes public-private research and development partnerships. This framework is otherwise known as the Bayh-Dole Act, which, since its passage, has

[8] *Id.*

[9] Schulthess, D., Bowen, H.P., Popovian, R. et al.,*The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals*, Ther Innov Regul Sci 57, 160–169 (2023)

[10] *Id.*

[11] *The US Ecosystem for Medicines. How new drug innovations get to patients*, Vital Transformations (Showing that the private sector is responsible for inventing 90% of all medicines (45% pharma companies, 45% biotech), academia 8% and the government around 1%.).

been a foundational element in America's success in research and development.[12] The Bayh-Dole Act enables public-private collaborations and allows expanded access to new, life-changing innovations that help make the U.S. the global innovation leader.[13]

By any measure, the Bayh-Dole Act has been highly successful. According to some estimates, since its passage the Bayh-Dole Act has contributed $1.9 trillion to the U.S. economy, supported 6.5 million jobs, and helped lead to more than 15,000 start-up companies.[14] In addition, the Bayh-Dole Act has allowed thousands of commercial products stemming from university research to be introduced to the public.[15] As The Economist put it, the Bayh-Dole Act "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States…."[16]

The Bayh-Dole Act's success is even more pronounced in the case of life-science innovations, and its legal framework is considered foundational for biopharmaceuticals.[17] Prior to the enactment of Bayh-Dole, not a single pharmaceutical product had been created from federally funded inventions. In contrast, since Bayh-Dole's implementation, more than 200 new life-saving treatments and vaccines have been developed and brought to market.[18] This includes some of the technologies, therapeutics, and treatments which drove the development of COVID-19 vaccines, illustrating that both the public and private sectors play critical roles.[19]

One product that reflects the remarkable success of the Bayh-Dole Act in life-sciences innovation is Xtandi (enzalutamide), the only novel hormone therapy approved by the FDA to treat three types of advanced prostate cancer. UCLA, as the patentee, received less than $500,000 in taxpayer funding to support early-stage research that directly contributed to the initial discovery of Xtandi. In contrast, Astellas and its partners contributed almost $2.2 billion in pre-clinical studies and clinical trials to bring Xtandi to market. As a result of this collaborative public-private partnership, which proportionally cost taxpayers less than 0.023 percent of Xtandi's overall development cost, hundreds of thousands of patients have received a life-saving treatment that

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[12] *See Quaadman*, *supra* note 3 ("Bayh-Dole established a fair, appropriate, and pragmatic system for the federal government to transfer proprietary rights in research. It has been critical to the success of the United States in bridging the "valley of death" and ensuring that scientific knowledge translates into usable products, services, and technologies that both serve end-users and advance national strategic priorities.").

[13] Tom Wilbur, *IP Explained: Four things to know about the Bayh-Dole Act*, September 13, 2019 ("Adopted by Congress in 1980, the bipartisan Bayh-Dole Act allows institutions and grant recipients, such as universities, to hold the title to patents on inventions stemming from government-funded research and to license the rights to those inventions to private sector partners who further develop them for commercialization. These private sector partners, including biopharmaceutical companies, assume the full risk of developing and commercializing the technologies that may eventually prove to be viable products. This can generate royalties for the research institution, paid by the commercial developer, once a product is brought to market.").

[14] Home - The Bayh-Dole Coalition (bayhdolecoalition.org).

[15] *See* https://autm.net/surveys-and-tools/databases/statt.

[16] *Innovation's golden goose*, The Economist, December 14, 2002 (Describing how the Bayh-Dole Act was perhaps the most inspired piece of legislation enacted in the last half century.).

[17] Lou Berneman, *A plan to cut the price of some medicines could end up hurting more than it helps, The Morning Call*, October 19, 2022.

[18] Wilbur, *supra* note 12.

[19] Joseph Allen, *Lawmakers Aim a Triple Whammy at American Innovation*, IP Watchdog, November 7, 2022.

otherwise would not exist. Notwithstanding these freely available facts affirming the outstanding success of the Bayh-Dole mechanism, biopharmaceutical industry critics have targeted Xtandi in their attempts to support the false notion that the government pays twice. In truth, it would be fair to say the private sector paid four thousand four hundred times.

The Bayh-Dole Act works well and provides countless benefits to the American public. At a time when America is engaged in a global competition for innovation leadership, we cannot risk upending highly successful legal frameworks based upon false narratives which misrepresent the role of taxpayer funding in the commercialization of products. The documented and growing effort of the Chinese government to outpace U.S. innovation, particularly in the biopharmaceutical sector, would be supported and enhanced by efforts to weaken our current, successful framework. The Chamber urges this Committee to resist any legislative actions which would weaken the tech transfer frameworks established under the Bayh-Dole Act and instead do anything and everything it can to support its continued success.

IV. The Federal Government Must Not Engage in Actions that Will Degrade and Undermine Successful Statutory Frameworks.

Separate and independent from preventing any legislative changes to the Bayh-Dole Act's successful framework, this Committee must resist any efforts to turn to tech transfer using "march-in" rights. As this Committee is well aware, during the Bayh-Dole Act's drafting process, lawmakers were concerned about private sector startups and market-dominant enterprises who failed to ***commercialize*** a partially taxpayer-funded innovation on reasonable terms.[20] Because of that, Congress included a ***very limited*** march-in provision which allows the government to force the patent owner to grant additional licenses if, for example, good faith efforts are not being made to bring the product to market.[21]

Unfortunately, in recent years, advocates for weakened intellectual property rights have advanced a false theory that march-in rights can be used as a form of price control. These advocates, including several Members of Congress, have asked the federal government to force march-in rights as a blunt tool to reduce the price of certain life science products.[22] The proponents of this theory claim that the government has the legal authority to "march-in" and revoke exclusive patent licenses at any time, for any reason, if it decides a product is too expensive. The government could then simply re-license the patent to companies that promise to sell the product at a reduced cost.

This unfounded theory is false and nothing could be further from the original intent of the legal authority. March-in rights were never intended to be a mechanism whereby the government could dictate the price of a commercialized product. The late Senators Birch Bayh and Bob Dole—the lead sponsors and negotiators of the Act—both confirmed march-in rights were never intended to be a mechanism to control prices. Senators Bayh and Dole noted that nothing in the text or

[20] *See Issue Brief: March-In Rights Under the Bayh-Dole Act*, Bayh-Dole Coalition, February 2023.
[21] *Id.*
[22] Ltr. from Senator Warren et. al. to Secretary Xavier Becerra, February 18, 2022.

legislative history supports such an assertion.[23] Senators Thom Tillis and Marsha Blackburn, your colleagues and two recognized experts on intellectual property law and tech transfer, have also recognized that using march-in rights to set strict price controls "contradicts the purpose and the function of the Bayh-Dole Act."[24]

If utilized, this false theory of march-in rights, which has unfortunately gained mainstream traction, would deter private sector partnerships thereby decimating America's life sciences innovation ecosystem and directly result in fewer life-saving products entering the market.[25] As our comments previously noted, the Bayh-Dole Act's overwhelming success has allowed universities and research institutes to partner with the private sector, which has the expertise, capacity, and resources to commercialize technologies. Using march-in rights on available products would destroy the Bayh-Dole Act's delicate balance and harm future innovation.[26]

If anything, lawmakers should want private industry to save American taxpayers money by commercializing academic research and bringing products to market. Bayh-Dole's successful commercialization framework ultimately benefits the public and delivers taxpayers the benefits of the basic research that their government marginally funded. This framework works because private sector actors believe it will operate as it has done the past 40 years: without the threat of forced tech transfer. If private companies were to become subjected to forced march-in rights, these innovators would lose faith in the system and would no longer take the necessary risks needed to translate promising scientific discoveries into testable products, and ultimately deliver them to market. Again, as cited earlier, a change of policy could have taken 99.998% of research funding off the table with the development of Xtandi.

This Committee must reject calls for utilizing march-in rights and should stand firm in defense of the Bayh-Dole Act's successful statutory frameworks. Anything short of that would represent a failure to protect America's innovation and tech transfer ecosystem.

V. Conclusion.

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[23] Bayh-Dole Coalition *Issue Brief*, supra note 19.

[24] Ltr. from Senators Thom Tillis and Marsha Blackburn to Secretary Xavier Becerra, February 24, 2022 ("Stripping intellectual property rights for private actors simply because they are commercializing their applied research on terms opponents dislike contradicts the very purpose and function of the Bayh Dole Act. March-in rights were never intended to function as price controls nor does the statute allow it. The authors of the statute – Senators Bayh and Dole – have said as much. Every Republican and Democratic Administration dating back to President Clinton has agreed. The statute clearly doesn't sanction marching in to control prices of successfully commercialized products.").

[25] Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, Information Technology and Innovation Foundation, March 14, 2019; *See also* Ltr. from Senators Tillis & Blackburn, *supra* note 23 ("March-in rights, exercised inappropriately, would destroy the development of new, innovative, and life-saving medications.").

[26] Bayh-Dole Coalition, *supra* note 19 ("If the government ever chose to misapply march-in rights for price control, confidence in universities or federal laboratories as reliable research partners would collapse. No company would agree to license a university or federal laboratory invention under these circumstances. No venture capitalist would fund a startup company with that sword hanging over its head.").

The Chamber appreciates the opportunity to submit these comments for the record. We stand ready and willing to work with this Committee to find ways to ensure that life-saving medications are both available and accessible to all Americans. However, the Chamber cannot and will not support misguided, market-restrictive efforts that limit patient access and choice and fail to recognize and appropriately consider the private sector's chief role in bringing new, innovative, and life-changing products to market. The Chamber urges this Committee to continue to support the wildly successful statutory frameworks which support public-private partnerships and to resist all efforts to undermine support and confidence in their protections.

Sincerely,

Patrick J. Kilbride
Senior Vice President
Global Innovation Policy Center
U.S. Chamber of Commerce

cc: Members of the Senate Committee on Health, Education, Labor, and Pensions