U.S. Chamber of Commerce

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February 8, 2024

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 Chairman Sanders and Ranking Member Cassidy:

The U.S. Chamber of Commerce ("Chamber") and its Global Innovation Policy Center ("GIPC") appreciates the opportunity to share this statement for the record in advance of your Committee's hearing on the cost of life-saving and life-altering medicines.

The Chamber supports efforts to help ensure every American has equitable access to life-saving medicines. For that reason, we are concerned that the Biden Administration and some Members of Congress are pursuing policies that would lead to fewer life-saving drugs and less access to treatments for Americans. Further, we are concerned the Administration is advancing an agenda that would harm life-science innovation, misrepresent the respective roles of public and private funding of science, research, and development, and upend the successful legal frameworks that facilitate public-private partnerships that bring cures to market.

I. Market-restrictive policies like the IRA's price controls have a negative impact on innovation that results in limited access to new, innovative, and life-saving medications for American patients.

Reducing barriers to access has long been a health policy priority. The Chamber supports appropriate, effective efforts to help mitigate obstacles that patients might face in accessing and affording life-saving medicines. However, government price setting creates additional access challenges for Americans.

The Chamber's March 2023 *Patient Access Report, Phase 1* ("phase 1")[1] cautions that the IRA's drug pricing will harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The Report's methodology shows that in other Organization for Economic Cooperation and Development ("OECD") countries that have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines.[2]

For example, prior to the enactment of the IRA's price controls, out of 104 new oncology products released globally, 80% were FDA-approved and made available in the U.S., while only 58% of those new medicines were similarly available in Europe. Likewise, in several benchmark countries, patients often wait up to several hundred days to receive access to life-saving treatments, waiting an average of 133 days (about 4 and a half months) in Germany and up to 500 days (about 1 and a half years) in Spain.

The February 2024 *Patient Access Report Phase 2* confirms the impact that price controls will have on the ability of American patients to access new medications. Phase 2 suggests that the IRA will have a highly negative impact on the number of potential cures developed or launched in the US—in the range of 29% to 44% fewer products. Critically, these estimates are in line with other research conducted on the potential impact of the IRA on life sciences research and development ("R&D").

For example, in June 2023, the health economics research consultancy Vital Transformation estimated that the IRA could, over a 10-year period, result in a reduction of 40% in approvals from the US Food and Drug Administration ("FDA"). Similarly, a 2021 University of Chicago research paper estimating the impact of HR 5376—the draft bill that became the IRA—found that life sciences R&D spending was likely to fall by 18.5% and that this cut in investment would result in 135 fewer new medicines being developed.

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[1] *See GIPC 2023 Patient Access Report*, March 21, 2023, available at https://www.uschamber.com/intellectual-property/patient-access-report.

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

Research from the Chamber also shows that price controls decimate clinical research, particularly clinical research in cutting edge therapies. The Chamber's research, *From Groundbreaking Innovation to the Emergence of Research Deserts* ("Research Deserts"), shows that the IRA's price controls and the potential threat of march-in rights could reduce clinical research for some treatments and cures by as much as 75%.[3]

The research deserts report compares levels of clinical research between the United States and a sample of developed, major OECD economies that have historically imposed varying degrees of national price controls and other artificial cost-containment measures on the biopharmaceutical sector. Notwithstanding their comparable scientific and technological strengths, rates of clinical research and life science innovation in these economies have consistently lagged behind the United States.

As the report demonstrates, the IRA's imposition of price controls will similarly cripple U.S. leadership in clinical research and development turning the American life science innovation oasis into a research desert. The report indicates the IRA is likely to both directly and indirectly reduce the number of clinical trials by thousands across all categories of research examined. By therapeutic field, the Chamber's research shows this reduction could amount to 12.25% for cardiovascular diseases to 68.94% for obesity research. Clinical trials related to future early-phase research risk being reduced by close to 50% or more with, for example, research related to biologics and cancer reduced by 59.41% and 54.13%, respectively. Early-phase research related to obesity could be reduced by more than 75%.

Statements made by America's most innovative companies since the IRA's enactment bear out these findings. For example, Novartis warned that the new law could discourage research in its most promising areas of study: RNA and radioligands. And Alnylam has stopped the development of a treatment for a rare eye disease due to the need "to evaluate impact of the Inflation Reduction Act."

The United States has been the global leader in all types of clinical research with particular strengths in areas of cutting-edge, early-phase trials and research related to cancer, Alzheimer's disease, diabetes, obesity, cardiovascular disease, and biologics. Additionally, American patients have also consistently benefited from having both earlier access to medications and more medications to choose from in treating their conditions. The IRA and other price control regimes would jeopardize much of our research leadership and the ability of American patients to have choices.

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[3] *From Innovation Oasis to Research Desert How Price Controls Imperil American Medical Innovation and the Search for Cures*, December 11, 2023, available at https://www.uschamber.com/intellectual-property/new-study-forecasts-devastating-impact-on-patients-and-medical-science-from-government-price-controls.

Moreover, the Chamber is pursuing litigation to block these unwarranted policies because we believe them unconstitutional.

II. If implemented, recently proposed interagency guidance on march-in rights ("proposed guidance") would radically alter America's innovation ecosystem, leading to fewer new products and technologies and seriously damaging America's global leadership, national security, and economic competitiveness.

We are deeply concerned that, if implemented, the recently proposed guidance from the Department of Commerce and NIST related to march-in rights could seriously undermine American innovation. The Bayh-Dole Act has been, since its passage, a foundational element in America's success in research and development.[4] 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.[5]

By any measure, the Bayh-Dole Act has been extraordinarily 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.[6] In addition, the Bayh-Dole Act has enabled thousands of commercial products stemming from university research to be introduced to the public.[7] 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...."[8]

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[4] *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.").

[5] 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."); *see also* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-sciences Innovation System*, ITIF, March 2019, available at https://www2.itif.org/2019-bayh-dole-exec-summary.pdf

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

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

[8] *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.).

Under the Bayh-Dole Act, Congress intended that inventions with some Federal support be developed and commercialized on an equal footing with other inventions. This part of the law also took steps to address concerns that private sector firms might fail to take reasonable steps to ***commercialize*** a partially taxpayer-funded innovation.[9] Accordingly, 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.[10]

Unfortunately, in recent years, some advocates that seek to weaken intellectual property rights have advanced a false theory that march-in rights can be used as a form of market intervention and price control. [11] The proponents of this theory wrongly claim that the government has the legal authority to "march-in" and override exclusive patent licenses at any time, for any reason, if it decides a product is too expensive. The government could then simply grant additional licenses to the patent to companies that promise to sell the product at a reduced cost.

This theory is without basis and contrary to Bayh-Dole. 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 legislative history supports such an assertion.[12] Senators Thom Tillis and Marsha Blackburn – two Members of Congress heavily engaged on issues of intellectual property law and technology transfer – have also affirmed that using march-in rights to set strict price controls "contradicts the purpose and the function of the Bayh-Dole Act."[13]

Each Administration since the law's enactment, including the Biden Administration as recently as last year, have recognized that the law is clear, confirming that price has no role to play in determining whether to exercise march-in rights.

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[9] *See Issue Brief: March-In Rights Under the Bayh-Dole Act*, Bayh-Dole Coalition, February 2023.
[10] *Id.*
[11] Ltr. from Senator Warren et. al. to Secretary Xavier Becerra, February 18, 2022.
[12] Bayh-Dole Coalition *Issue Brief*, supra note 19.
[13] 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.").

Perplexingly, the proposed guidance would cast a pallor of uncertainty over public-private collaborations. Federally supported inventions would once again be encumbered with legal risk and unpredictability, making it more difficult for universities and private sector inventors to attract the partners and capital needed to develop nascent inventions. We believe the draft guidelines are inappropriate, illegal, and should be immediately withdrawn.

The Chamber appreciates the opportunity to share comments for the record. As we have noted in this submission and in every prior submission, we stand ready and willing to work with Congress to promote free-market solutions that ensure equitable access to life-saving medication.

Sincerely,

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