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ISSUE BRIEF: DEBUNKING PHARMA'S FAIRY TALES ABOUT MARCH-IN RIGHTS

"UNDER OUR ADMINISTRATION'S NEW PROPOSAL, IF AMERICAN TAXPAYERS PAID TO HELP INVENT A DRUG – IT'S TIME FOR THAT DRUG TO BE ACCESSIBLE TO PATIENTS, INCLUDING AT A REASONABLE PRICE."

- THE WHITE HOUSE, DECEMBER 9, 2023

The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) released for public comment on December 7 draft guidance for agencies to exercise March-In Rights on federally-funded inventions.[i] March-In Rights empower federal agencies to require the owner of an agency-funded invention to grant permission to another entity to use that invention under certain conditions.[ii] Importantly, the draft guidance recognizes price can be a basis for marching-in. In the context of medicines, March-In Rights can curb price gouging on taxpayer funded medicines, as the funding agency, for example, the National Institutes of Health (NIH), can license one or more generic manufacturers to make the same drug for cheaper.

In response to the draft guidance, the pharmaceutical industry and its allies have disseminated several unfounded claims about March-In Rights to protect their excessive profits. This memo will debunk these commonly repeated myths.

CLAIM: "USING MARCH-IN RIGHTS TO LOWER PRICES IS NOT PERMITTED UNDER THE BAYH-DOLE ACT."

FACT: A PLAIN READING OF THE STATUTE AND EXPERT OPINION SUPPORT USING MARCH-IN RIGHTS TO PROTECT THE PUBLIC AGAINST PRICING ABUSES BY MANUFACTURERS EXPLOITING TAXPAYER FUNDED INVENTIONS.

The first statutory criterion for using the March-In authority allows the government to March-In when the patent holder has not achieved "practical application," which means to manufacture the invention and "establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on **reasonable terms**" (emphasis added).[iii]

It would defy the plain meaning of the statute to say that a taxpayer funded medicine that is offered only at an excessive price is available to the public on reasonable terms. This analysis of the statute is supported by dozens of academic experts in pharmaceutical and intellectual property law.[iv]

CLAIM: "LEGISLATORS THAT DRAFTED THE BAYH-DOLE ACT NEVER INTENDED FOR MARCH-IN RIGHTS TO BE USED FOR REMEDYING PRICING ABUSES."

FACT: PRICING ABUSES WERE CENTRAL TO THE BAYH-DOLE LEGISLATIVE DISCUSSION. POST-HOC CLAIMS OTHERWISE ARE REVISIONIST HISTORY.

The Congressional Record leading up to the passage of the Bayh-Dole Act reflected the understanding that March-In Rights were necessary to foster market competition and combat unreasonable profiteering on taxpayer funded inventions and federal courts have repeatedly interpreted the words "reasonable terms" to include price.[v]

More than two decades after the Bayh-Dole Act became law, former Senators Bayh and Dole wrote a letter to the Washington Post claiming that March-In Rights were not intended to address pricing abuses, but these claims should be considered with considerable scrutiny.[vi] Others have noted their letter was released at a time when the former senators were heavily involved in pharmaceutical lobbying.[vii] Bob Dole was also paid to promote Viagra in television commercials.[viii]

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CLAIM: "USING MARCH-IN RIGHTS TO LOWER DRUG PRICES WOULD CHILL INNOVATION; IT WOULD SEND US BACK TO THE DARK AGES WHEN GOVERNMENT-FUNDED INVENTIONS SAT ON THE SHELF WITHOUT BEING COMMERCIALIZED."

FACT: DRUG CORPORATIONS WOULD CONTINUE TO BE ALLOWED TO MAKE SUBSTANTIAL PROFITS, BUT NOT SUPRACOMPETITIVE PROFITS THAT HARM THE PUBLIC INTEREST IN DISREGARD OF TAXPAYERS' INVESTMENT.

A ROBUST RESEARCH INFRASTRUCTURE UNDERGIRDED BY PUBLIC INSTITUTIONS AND FUNDING AND A SLEW OF GOVERNMENT POLICIES AND PROTECTIONS WOULD CONTINUE TO FUEL ROBUST BIOMEDICAL INNOVATION.

This is not the first time, nor will it be the last, that the prescription drug industry engages in "innovation bullying," claiming that a policy to curb exorbitant profits and monopoly abuses would undermine innovation.[ix] However, the evidence shows that a drug's R&D costs bear no relationship to its price.[x]

Most recently, the drug lobby alleged lower prices would impede R&D in the context of Medicare drug price negotiation under the Inflation Reduction Act (IRA). But the Congressional Budget Office estimated 13 fewer drugs out of 1,300, or 1%, would come to market over the next 30 years as the result of the IRA. The reality is that neither using March-In Rights to rein in pricing abuses on taxpayer funded drugs, nor Medicare negotiating prices, will impede innovation.

Drug manufacturers are more dependent on licensing ideas emerging from public funding than in past decades, and judicious exercise of march-in rights is very unlikely to impede translation of inventions developed by our country's brightest minds at universities into therapies.[xi] When the government invests nearly $50 billion annually in biomedical research, industry collaborators are extremely unlikely to walk away from the significant subsidization of inventions they can profit from, even if March-In Rights are exercised on the subset of taxpayer funded drugs priced excessively high.

Moreover, even with lower prices offered to U.S. patients, in line with prices paid in other high-income countries, drug corporations would still have ample resources to allocate towards R&D. Big pharma companies routinely spend more on buybacks and dividends to enrich corporate executives and shareholders than they do on R&D.[xii]

March-In Rights are designed to be used only when the owner of a government-funded invention abuses its privilege to exclude competitors in a way that harms the public interest, as defined under statute.

So long as drug corporations act as fair stewards of medical inventions developed with taxpayer dollars and do not charge U.S. patients excessive prices (including prices which are routinely multiples of those paid in other high-income countries), they need not fear these rights being exercised to remedy pricing abuses.

AS PRESIDENT BIDEN STATED IN DECEMBER:[XIII]

"IT'S A SIMPLE PRINCIPLE. YOU SHOULDN'T PAY THE HIGHEST PRICE IN THE WORLD FOR DRUGS THAT YOUR TAX DOLLARS HAVE ALREADY HELPED CREATE."

ENDNOTES

[i] NIST Releases for Public Comment Draft Guidance on March-In Rights, https://www.nist.gov/news-events/news/2023/12/nist-releases-public-comment-draft-guidance-march-rights (last visited Dec. 12, 2023).

[ii] Expanding Access and Affordability to Taxpayer Funded Drugs: The Use of March-In Rights, Public Citizen, https://www.citizen.org/article/expanding-access-and-affordability-to-taxpayer-funded-drugs-the-use-of-march-in-rights/ (last visited Jan. 16, 2024).

[iii] 35 U.S.C. §§ 201(f), 203, https://www.law.cornell.edu/uscode/text/35/203; https://www.law.cornell.edu/uscode/text/35/201#f

[iv] Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf (last accessed Dec. 12, 2023).

[v] Michael H. Davis & Peter S. Arno, Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research, 75 Tul. L. Rev. 631 (2001), https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1754&context=fac_articles

[vi] Birch Bayh & Bob Dole, Our Law Helps Patients Get New Drugs Sooner, Wash. Post Opinion (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

[vii] See James Love, Comments of James Love of Knowledge Ecology International (KEI) on the Proposal to Eliminate Unreasonable Prices as a Standalone Basis for March-in Rights (Mar. 18, 2021), https://downloads.regulations.gov/NIST-2021-0001-0023/attachment_1.pdf.

[viii]Kansaspolitics (@kansaspolitics), 1998 Bob Dole Viagra commercial, YouTube (June. 14, 2019),https://youtu.be/oMeulTWdqiY?si=nwsKy3EauCshsNqr.

[ix] Cynthia Ho & Liza Vertinsky, "Innovation Bullying" in Drug Policy, Health Aff. Forefront (Sept. 11, 2023), https://www.healthaffairs.org/content/forefront/innovation-bullying-drug-policy.

[x] Congressional Budget Office, Research and Development in the Pharmaceutical Industry (Aug. 2021) ("In CBO's assessment, current R&D spending does not influence the future prices of the drugs that result from that spending."); Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA Network 858 (2016); Vinay Prasad, Kevin De Jesus, Sham Mailankody, The high price of anticancer drugs: origins, implications, barriers, solutions, 14 Nat. Rev. Clin. Onc. 381 (2016).

[xi] Aaron Kesselheim, PORTAL, March-In Rights: Prospects & Alternatives, https://www.keionline.org/wp-content/uploads/Kesselheim-March-In.pdf (last visited Jan. 16, 2024).

[xii] William Lazonick and Öner Tulum, Sick with "Shareholder Value": US Pharma's Financialized Business Model During the Pandemic, Inst. New Econ. Thinking (Dec. 6, 2022), https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic

[xiii] Remarks by President Biden on Progress to Lower Prescription Drug Costs, Whitehouse Briefing Room: Speeches & Remarks (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/12/14/remarks-by-president-biden-on-progress-to-lower-prescription-drug-costs/.