



**Public Citizen Comments to the Senate Health, Education, Labor, and Pensions (HELP) Committee re: Discussion Draft Legislation to Reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA)**

July 7, 2023

Chairman Sanders and Ranking Member Cassidy,

Thank you for the opportunity to comment on proposals included in the discussion draft for reauthorization of the Pandemic and All-Hazards Preparedness Act.

Public Citizen is a national public interest organization with more than 500,000 members and supporters. For more than 50 years, we have advocated with some considerable success for stronger health, safety and consumer protections; for corporate and government accountability; and for affordable access to essential medicines and biomedical technologies.

- 1) Public Citizen encourages the committee to proceed with Sen. Sanders' proposal to require companies to price medical products developed with BARDA or CDC support at levels at least as low as those available in other G7 countries and that are reasonable.**
  
- 2) Public Citizen urges the committee against proceeding with Sen. Cassidy's proposal for a renewed and expanded medical countermeasure (MCM) priority review voucher (PRV) program.**

Reasonable Pricing

Public Citizen strongly supports public investment in public health research and development (R&D), including especially for pandemics and emergency situations. But taxpayers must get a fair return on their investment. That should mean that the products that are the fruit of that investment are widely available and affordable for those who need them, on a global basis.

**In the United States, at a bare minimum, no one should have to pay more than other rich countries for medicines our country helped to develop. Instating a strengthened reasonable pricing clause in PAHPA, as proposed by Sen. Sanders, would provide a basic, commonsense protection against price gouging by drug corporations who have depended on the generosity of U.S. taxpayers for their success.**

Operation Warp Speed (OWS) provides an instructive lesson on the strengths and weaknesses of the current BARDA model and illustrates the need to require reasonable pricing of medical products developed with taxpayer support. Through OWS, taxpayers invested billions of dollars to develop lifesaving vaccines and treatments more quickly than most previously thought possible.<sup>1</sup> In addition, National Institutes of Health (NIH) infectious disease experts and academic collaborators provided instrumental scientific contributions to vaccine development.<sup>2</sup> Vaccines and treatments undergirded

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<sup>1</sup> COVID-19 Portfolio. BARDA. Accessed July 7, 2023.

<https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

<sup>2</sup> Christopher J. Morten, J.D., Ph.D., Written Statement of Christopher J. Morten, J.D., Ph.D. Before the United States Senate Committee on HELP Hearing Entitled "Taxpayers Paid Billions For It: So Why Would Moderna Consider Quadrupling the Price of

with public support saved millions of lives and many millions more from hospitalization due to COVID-19.<sup>3</sup>

But the successes of OWS in expediting research and development (R&D) must be considered alongside its failures to ensure timely global supply of medicines and protect patients and consumers against windfall profit taking by drug corporations, both during and after the pandemic.<sup>4</sup> The world went more than a year without sufficient supply of mRNA vaccines after they were first authorized for use in the United States, a humanitarian catastrophe that was both predictable and avoidable.<sup>5</sup> Particularly in the case of the NIH-Moderna vaccine, which the public paid billions of dollars to invent and develop, the United States is now scarred by the moral failing of allowing gross inequities in global access to persist for a public, lifesaving medicine – what should have been the People’s Vaccine.<sup>6</sup> Inequitable access was also irrational from a purely self-interested perspective, as low vaccination rates around the globe driven by supply inequities fueled emergence of new variants that have killed more than a million people in the United States.<sup>7</sup> The COVID-19 pandemic majorly disrupted the global economy, leading to massive reductions in global trade and long-lasting supply chain shocks.<sup>8</sup>

Additionally, despite taxpayer dollars underwriting virtually the entire development of the NIH-Moderna vaccine, at the height of the pandemic Moderna charged the United States from \$15 to \$26 per dose for a vaccine Public Citizen has estimated it costs \$3 to produce. Excessive pricing fueled Moderna’s accumulation of billions in profits and launched its executives to stratospheric levels of wealth, with several becoming newly minted billionaires. Moderna’s price going forward of \$130 per dose is completely unjustified and has no plausible explanation beyond profiteering.

The unavoidable result of Moderna’s price spike will be rationing. Uninsured and under-insured people will face a significant cost barrier to accessing vaccines, and – notwithstanding Moderna’s pledge to make vaccines available for free to uninsured and underinsured persons<sup>9</sup> -- many simply won’t take the vaccine. People will needlessly get sick and die as a result.

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the COVID Vaccine?” March 20, 2023. <https://www.help.senate.gov/imo/media/doc/Morten%20-%20Full%20written%20statement.pdf>

<sup>3</sup> “Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths,” Commonwealth Fund, December 13, 2022. <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>

<sup>4</sup> “Three Things to Know Before Sen. Sanders’ Hearing on Moderna’s ‘Corporate Greed,’” Public Citizen, March 2023. <https://www.citizen.org/article/hearing-on-moderna-corporate-greed/>

<sup>5</sup> COVID-19: Principles for Global Access, Innovation and Cooperation. <https://www.citizen.org/article/covid-19-principles-for-global-access-innovation-and-cooperation/>

<sup>6</sup> “Three Things to Know Before Sen. Sanders’ Hearing on Moderna’s ‘Corporate Greed,’” Public Citizen, March 2023. <https://www.citizen.org/article/hearing-on-moderna-corporate-greed/>

<sup>7</sup> “Briefing Note: One Million and Counting: Estimates of Deaths in the United States from Ancestral SARS-CoV2 and Variants,” Public Citizen, June 1, 2022. <https://www.citizen.org/article/one-million-and-counting-estimates-of-deaths-in-the-united-states-from-ancestral-sars-cov-2-and-variants/>

<sup>8</sup> “Study Shows Vaccine Nationalism Could Cost Rich Countries US\$4.5 Trillion,” International Chamber of Commerce, January 25, 2021, <https://iccwbo.org/news-publications/news/study-shows-vaccine-nationalism-could-cost-rich-countries-us4-5-trillion/>; Eleanor Bell, et. al., “Estimates of the Global Burden of Covid-19 and the Value of Access to Covid-19 Vaccines,” Vaccines, August 15, 2022, <https://www.mdpi.com/2076-393X/10/8/1320>.

<sup>9</sup> Alexander Tin, “Moderna to Offer Free Covid Vaccines to Uninsured After Emergency Ends,” CBS News, February 18, 2023, <https://www.cbsnews.com/news/free-covid-vaccine-moderna-uninsured-after-public-health-emergency-ends>

OWS episodically used Most Favored Nations (MFN) clauses allowing the government to purchase medicines at the lowest price available in “covered nations.”<sup>10</sup> 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.

**Had Sen. Sanders’ proposed policy been in place, obligating BARDA to include reasonable pricing conditions in its contracts with Moderna supporting clinical development of the NIH-Moderna vaccine, Americans would have been protected against this price gouging and its inevitable associated negative impacts on health.**

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.”<sup>11</sup> 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:<sup>12,13</sup>

*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.<sup>14</sup> 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 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*

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<sup>10</sup> See discussion of the MFN provision at: Claire Cassidy, “Pfizer Agrees to International Reference Pricing in Government Contract for Covid-19 Therapeutic,” Knowledge Ecology International, February 2, 2022, <https://www.keionline.org/37294>.

<sup>11</sup> 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/>

<sup>12</sup> *Ibid.*

<sup>13</sup> 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>

<sup>14</sup> “Cooperative Research and Development Agreements (CRADAs),” Drug Database. <http://drugdatabase.info/cradas/>

*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?*

Lower prices and expanded access could be further enhanced through incorporating requirements for manufacturers that have already obtained generous returns on their original investments to license patents and access to needed materials and testing data to all qualified manufacturers to facilitate pricing competition. Additionally, we encourage the committee to consider including in PAHPA an obligation for manufacturers to price medicines affordably in developing countries. Nonexclusive licenses to qualified manufacturers to supply LMICs can help to satisfy this requirement. Reach-through terms could be included to ensure that reasonable pricing and other obligations apply to follow-on medical inventions that build on those supported by BARDA and CDC.

**Public Citizen applauds Sen. Sanders for his proposal to include reasonable pricing requirements in PAHPA reauthorization. We encourage all members of the committee to support this commonsense protection against price gouging for the medical products we pay to develop.**

#### Priority Review Vouchers

In addition to empowering drug corporations to price drugs at levels that are unaffordable for patients and strain health budgets, the current monopoly-driven business model often fails to provide incentive for pharmaceutical corporations to research and develop medicines for some types of diseases or conditions, such as those for neglected tropical diseases, rare pediatric diseases, and medical countermeasures. Priority review voucher programs have been advanced by policymakers in an attempt to spur development of products in these categories to serve unmet health needs.

**Public Citizen urges members of the HELP committee to oppose inclusion of the PRV proposal because existing PRV programs have been demonstrated to be ineffective at meeting program goals and risk facilitating product approvals based on weak evidence, posing increased safety risks.**

Alongside the creation of the medical countermeasure PRV program, the 21<sup>st</sup> Century Cures Act tasked the Government Accountability Office (GAO) with analyzing the impacts of it and two previous PRV programs.<sup>15</sup> After reviewing academic literature analyzing the neglected disease, rare pediatric disease, and MCM PRV programs, GAO stated that PRV program studies “found little to no effect on drug development.”<sup>16</sup> Regarding the MCM PRV program specifically, study “[a]uthors stated that, given the extent to which development of medical countermeasures already occurs via direct or indirect federal funding, alternatives other than the PRV program could better stimulate development of medical countermeasures.”<sup>17</sup>

A 2021 study examining the MCM PRV program found that all five medical countermeasures that were initially awarded a PRV were initially developed through public funding – four out of five were

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<sup>15</sup> “Drug Development: FDA's Priority Review Voucher Programs,” GAO, January 31, 2020. <https://www.gao.gov/products/gao-20-251>

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.; M.S. Sinha, N. Jain, T. Hwang, and A.S. Kesselheim, “Expansion of the Priority Review Voucher Program under the 21st Century Cures Act: Implications for Innovation and Public Health,” *American Journal of Law and Medicine*, vol. 44 (2018).

underwritten by the U.S. government and the fifth by the German government.<sup>18</sup> All five products additionally had clinical trials sponsored by the U.S. government, three of which were designed and conducted by federal agencies.<sup>19</sup> This direct support was further supplemented by the federal government with expedited review at FDA, special exclusivity periods barring generic competition and advanced purchase commitments, often secured at risk – before the product received FDA approval.<sup>20</sup>

Additionally, studies have noted that expedited review designations have been associated with lower evidentiary standards, fewer pivotal trials and pivotal trial participants, and increased risks of safety after approval.<sup>21</sup> Dr. Ramachandran noted in her testimony before the committee that “this incentive has failed to effectively promote the development of medical countermeasures and may instead lead to the hasty approval of potentially unsafe medical products of uncertain benefit, legislators should reconsider and even sunset this program altogether.”<sup>22</sup> Public Citizen agrees.

Thank you again for the opportunity to provide comment on the discussion draft for reauthorization of PAHPA. We look forward to working with you to promote biomedical R&D that meets public health needs while preserving access and preventing price gouging. Please contact Steven Knievel, access to medicines advocate at Public Citizen, at [sknievel@citizen.org](mailto:sknievel@citizen.org) with any questions or for further discussion.

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<sup>18</sup> Reshma Ramachandran, Ravi Gupta, and Jing Luo, “An Unnecessary Gift for COVID-19 Vaccines and Therapeutics: The Medical Countermeasure Priority Review Voucher,” *American Journal of Public Health*, October 14, 2021, e1–4, <https://doi.org/10.2105/AJPH.2021.306495>; Reshma Ramachandran, M.D., M.P.P., M.H.S., “Written Testimony of Reshma Ramachandran, M.D., M.P.P., M.H.S. of Yale School of Medicine, Hearing on ‘Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act,’” May 4, 2023, [https://www.help.senate.gov/imo/media/doc/Ramachandran\\_Written%20Testimony\\_PAHPA%20Reauthorization\\_4May2023\\_Senate%20HELP.pdf](https://www.help.senate.gov/imo/media/doc/Ramachandran_Written%20Testimony_PAHPA%20Reauthorization_4May2023_Senate%20HELP.pdf)

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

<sup>21</sup> Nicholas S. Downing et al., “Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010,” *JAMA* 317, no. 18 (May 9, 2017): 1854–63, <https://doi.org/10.1001/jama.2017.5150>.

<sup>22</sup> Ramachandran, Written Testimony before the Senate HELP Hearing on PAHPA reauthorization, May 4, 2023.