

Written Testimony of

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before the

**The Senate Committee on Health, Education, Labor and Pensions**

**on**

“Preparing for the Next Public Health Emergency:  
Reauthorizing the Pandemic and All-Hazards Preparedness Act”

May 4, 2023



Mr. Chairman and Members of the Committee,

Thank you for the opportunity to testify today on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). I am Robert Weissman, president of Public Citizen. 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.

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.

This testimony has two parts. In the first section, I review the experience with government funding for Covid vaccines. That investment helped get products to market in remarkable time. But the government failed to include conditions in its grant and acquisition agreements, or to make use of other available tools, to ensure that 1) taxpayers were not ripped off; 2) there was sufficient production of mRNA vaccines to meet global need; and 3) taxpayers and patients would be protected from price gouging as the pandemic wound down.

The second section aims to learn from the lessons of the Covid vaccine experience. It recommends building into grant agreement provisions to ensure transparency, affordability and global access. It also encourages the adoption of alternative funding models, such as prize funds, to support innovation. In many cases, especially in the market segments covered by PAHPA, alternative funding models will deliver superior benefits to the patent monopoly approach.

## **I. LESSONS FROM COVID VACCINE DEVELOPMENT**

Operation Warp Speed was a great success in speeding the development of lifesaving vaccines and getting them to market. It was proof that the Biomedical Advanced Research and Development Authority (BARDA) model can work.

But it also was proof that the BARDA model needs important refinements, because taxpayers were gouged; hundreds of thousands or perhaps millions of people likely died needlessly because of avoidable vaccine shortages; and now patients and the public are poised to be ripped off further, with vaccines needlessly rationed due to high prices.

Government support underlay the entire Covid vaccine R&D project, beginning decades before Covid appeared and continuing through clinical trials and scaled up production. Covid-19 was not the first infectious disease caused by a coronavirus. NIH invested \$700 million in coronavirus research in the two decades after SARS, during which period there was very little private sector investment in the field. In 2019, before Covid, there were only six active

coronavirus clinical trials involving pharmaceutical companies. All of them depended crucially on public funding.<sup>1</sup>

The federal government's early investment in coronavirus research laid the foundation for the rapid response to Covid, helping accelerate the development of many leading vaccine candidates.<sup>2</sup>

Most of the leading first-generation Covid vaccine candidates – including those by Pfizer/BioNTech, Johnson & Johnson and Moderna – relied on the NIH's approach of “freezing” coronavirus spike proteins in their pre-fusion shape. One vaccine scientist noted that we were “very lucky, actually” that scientists had earlier developed the method for freezing coronavirus spike proteins.<sup>3</sup>

Among the vaccine makers, Moderna uniquely benefitted from federal support,<sup>4</sup> though the company consistently maneuvered to downplay federal support:

- Moderna tried to file patents on certain vaccine technologies that had been co-invented with NIH. After Public Citizen drew attention to the maneuver,<sup>5</sup> Moderna backed down.<sup>6</sup>
- BARDA gave large-scale grants to Moderna to complete clinical trials and scale up manufacturing.<sup>7</sup>
- Altogether, the U.S. government spent roughly \$2.5 billion on the vaccine that would be called –misleadingly – the Moderna vaccine. It should rightly have been called the NIH-Moderna vaccine (or perhaps simply the NIH vaccine). The U.S. government paid the entire cost of its development, save for a relatively tiny donation (\$1 million) from the singer Dolly Parton.<sup>8</sup>
- While the vaccine was developed through a four-year partnership with the National Institutes of Health (NIH), Moderna fought against naming federal scientists co-

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<sup>1</sup> Zain Rizvi, “Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma’s Monopoly Model,” Public Citizen, February 19, 2020, <https://www.citizen.org/article/blind-spot>.

<sup>2</sup> Zain Rizvi, “Leading COVID-19 Vaccine Candidates Depend on NIH Technology,” Public Citizen, November 10, 2020, <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology>.

<sup>3</sup> Ryan Cross, “The tiny tweak behind COVID-19 vaccines,” Chemical & Engineering News, September 29, 2020, <https://tinyurl.com/yxoj472x>.

<sup>4</sup> “‘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.” Selam Gebrekidan and Matt Apuzzo, “Rich Countries Signed Away a Chance to Vaccinate the World,” New York Times, March 21, 2021, <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>.

<sup>5</sup> Peter Maybarduk to Francis Collins, November 2, 2021, <https://www.citizen.org/article/letter-urging-nih-to-reclaim-foundational-role-in-nih-moderna-vaccine>.

<sup>6</sup> Rebecca Robbins and Sheryl Gay Stolberg, “Moderna backs down in its vaccine patent fight with the N.I.H.,” New York Times, December 17, 2021, <https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html>.

<sup>7</sup> Zain Rizvi, “Sharing the NIH-Moderna Vaccine Recipe,” Public Citizen, August 10, 2021, <https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe>.

<sup>8</sup> Allie Clouse, “Fact check: Moderna vaccine funded by government spending, with notable private donation,” USA Today, November 24, 2020, <https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/639848602>.

inventors<sup>9</sup> of the vaccine sequence, as Public Citizen revealed in 2021.<sup>10</sup> Rather than credit the federal government for its role, Moderna quietly abandoned these patents in March 2023.<sup>11</sup>

- In 2020, Public Citizen revealed that Moderna and others also relied on a separate technique discovered by federal scientists and academic researchers to stabilize spike proteins and elicit an immune response.<sup>12</sup> Columbia Law School clinical professor Christopher Morten demonstrated that Moderna likely infringed the NIH-owned patent.<sup>13</sup> Moderna eventually agreed to pay NIH \$400 million plus future royalties for its use of the technique.<sup>14</sup>

All this spending and co-invention status gave the U.S. government powerful authority to condition how Moderna behaved and to share the technology. It did not do so.

Moderna generated tens of billions in Covid vaccine sales – including roughly \$10 billion in advance purchase commitments and purchases by the U.S. government<sup>15</sup> – and several of its executives became billionaires.<sup>16</sup>

Meanwhile, the world went for more than a year with an insufficient vaccine supply. Developing countries were unable to obtain enough vaccines for their people. When they could get access, it was often to lower-quality vaccines, not the high-quality mRNA vaccines of Moderna or Pfizer.

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<sup>9</sup> Sheryl Gay Stolberg and Rebecca Robbins, “Moderna and U.S. at Odds Over Vaccine Patent Rights,” New York Times, November 9, 2021, <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>.

<sup>10</sup> Public Citizen letter to NIH Director Francis Collins, November 2, 2021,

<https://www.nytimes.com/interactive/2021/11/09/us/public-citizen-nih-moderna-vaccine.html>.

<sup>11</sup> Katherine Ellen Foley and David Lim, “Moderna Quietly Abandons Some MRNA Patents,” Politico, March 7, 2023, <https://www.politico.com/newsletters/prescription-pulse/2023/03/07/eli-lilly-insulin-cost-cuts-00085724>

<sup>12</sup> Zain Rizvi, “Leading Covid-19 Vaccine Candidates Depend on NIH Technology,” Public Citizen, November 10, 2020, <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/?eType=EmailBlastContent&eId=3dbde9f7-8f59-48e0-99d8-78b49ea5e77e>.

<sup>13</sup> Christopher Morten, et. al., “U.S. 10,960,070: The U.S. Government’s Important New Coronavirus Vaccine Patent,” Technology Law and Policy Clinic, New York University School of Law, April 14, 2021, <https://www.dropbox.com/s/1om1v1kagg7j9dn/NYU%20TLP%20Clinic%20Report%20on%20NIH%27s%20070%20Patent%2020210414%20%28FINAL%29.pdf?dl=0>.

<sup>14</sup> Benjamin Mueller, “After Long Delay, Moderna Pays NIH for Covid Vaccine Technique,” New York Times, February 23, 2023, <https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html>.

<sup>15</sup> Jennifer Kates, Cynthia Cox and Josh Michaud, “How Much Could Covid-19 Vaccines Cost After Commercialization?” KFF, March 10, 2023, <https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization>.

<sup>16</sup> Giacomo Tognini, “Surging Moderna Stock Mints The Vaccine Maker’s Fifth Billionaire,” Forbes, June 15, 2021, <https://www.forbes.com/sites/giacomotognini/2021/06/15/surging-moderna-stock-mints-the-vaccine-makers-fifth-billionaire>.

That delay in vaccination likely cost hundreds of thousands and possibly millions of lives.<sup>17</sup> It also made it more likely that new variants would emerge and that COVID would evolve into an endemic disease.<sup>18</sup>

This scenario could have been avoided, or at least mitigated. It was entirely possible to share the mRNA technology controlled by Moderna and scale up vaccine manufacturing in order to have vaccinated the world more quickly.<sup>19</sup>

Even though the development of vaccine technology depended so heavily on U.S. government support – and entirely, in the case of the NIH-Moderna vaccine – that was the road not taken.

Now, Moderna is jacking up prices further, quadrupling the price for Covid vaccines, which are expected to be needed annually. Public Citizen has estimated it costs \$3 or less per dose to manufacture the vaccine. At the height of the pandemic Moderna charged the United States from \$15 to \$26 per dose, accumulating billions in profits. Moderna’s price going forward of \$110-\$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>20</sup> -- many simply won’t take the vaccine. People will needlessly get sick and die as a result.

Moreover, because many opting for future booster shots will be over 65, Medicare stands to bear a disproportionate burden of payments. Taxpayers will once again bear the expense.

Even for people with private health insurance, price spikes that are picked up by insurance companies could lead to higher premiums.<sup>21</sup>

All of this, too, could and should have been avoided – if safeguards had been written into BARDA and NIH’s contracts with Moderna.

We must at least learn from this Covid experience and prevent a repeat with future technologies funded and developed by BARDA and PAHPA investments.

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<sup>17</sup> Chad Wells and Alison Galvani, “The global impact of disproportionate vaccination coverage on COVID-19 mortality,” The Lancet, June 23, 2022, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00417-0/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00417-0/fulltext).

<sup>18</sup> “One Million and Counting: Estimates of Deaths in the United States from Ancestral SARS-CoV-2 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>19</sup> Zoltan Kis and Zain Rizvi, “How to Make Enough Vaccine for the World in One Year,” Public Citizen, May 26, 2021, <https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year>.

<sup>20</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>.

<sup>21</sup> Jennifer Kates, Cynthia Cox and Josh Michaud, “How Much Could Covid-19 Vaccines Cost After Commercialization?” KFF, March 10, 2023, <https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization>.

## II. LEARNING FROM COVID: MEASURES TO ADVANCE TRANSPARENCY, AFFORDABILITY AND UNIVERSAL ACCESS

### Transparency

The starting point for policy around PAHPA investment in drug, vaccine, therapeutics and diagnostics research, development and acquisition should be proactive transparency. The public should know what it is financing, on what terms and the degree to which private sector partners are contributing to research and development costs.

In general, and building on existing practice,<sup>22</sup> BARDA and other government agencies should continue to aim toward standard-form provisions for R&D investments, licensing terms and acquisition contracts, to avoid wasted time with negotiation, prevent gamesmanship and ensure taxpayer interests are protected robustly. Some variation will be unavoidable, as agencies tailor terms and provisions for different needs and product markets, but the more reliance on standard provisions, the better.

Building on but going beyond what it already has in place,<sup>23</sup> BARDA should maintain a publicly available, downloadable, searchable and sortable database of all grants it has made and acquisition contracts into which it has entered, with easy public access to the contracts. Proprietary redactions should be minimized. Specific contract terms that should presumptively and proactively be made public include:

- The amount of government grants;
- The ownership and licensing terms for inventions funded directly or indirectly by government grants, not limited to instances in which the government may claim Bayh-Dole rights;
- Provisions on reasonable pricing;
- Reach-through terms to ensure reasonable pricing or other conditions for products incorporating government-funded inventions;
- International access terms; and
- The price paid and volume amount of acquisitions.

Building on existing practice, BARDA contracts should also require affirmative disclosures from contracting parties. These disclosures should include:

- The documented dollar amount of co-funding that contractors and third parties provide for research projects;
- The terms, if any, by which the contractor licenses inventions arising from a government-funded project to third parties; and
- The price that contractors charge third parties for products developed with substantial government support.

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<sup>22</sup> <https://www.phe.gov/about/amcg/BARDA-BAA/Documents/otar-consortium.pdf>

<sup>23</sup> <https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

The issue of contractor co-funding requires special attention. Rather than accepting just a single claim of total contractor investment, the government should require disaggregated information. Drawing on expert reviews<sup>24</sup> and prior legislative proposals,<sup>25</sup> we recommend that contractors' total expenditures on R&D be itemized by direct and indirect costs, including for:

- Basic and preclinical research; and
- Clinical research, reported separately for each clinical trial, per patient, per year, comprising:
  - Personnel costs (including salary and benefits)
    - Administrative staff
    - Clinical staff
  - Materials and supplies
  - Clinical procedures
  - Site management
    - Site monitoring costs
    - Site retention
    - Other
  - Central laboratory
  - Equipment
  - Other direct costs
    - Publication Costs
    - Subawards/Consortium/Contractual Costs
    - Other;
  - Development of alternative delivery systems, dosage forms, strengths or combinations; and
  - Other development activities, such as post-approval testing and record and report maintenance.

### **Affordability and Reasonable Pricing**

In funding new drugs, vaccines, therapeutics and diagnostic tools to address emergency or potential emergency solutions, taxpayers aim to bring to market products that otherwise would not be developed or to speed their development. Getting the product to market is essential, but so is ensuring reasonable pricing. If products are going to be purchased by taxpayers, not only is there a taxpayer interest in prudently conserving public funds, but high prices may drain public funds at the expense of other public health benefits or may limit the size of government acquisition and distribution plans. If products are going to be purchased by private insurers and/or directly by individuals, then high prices will unavoidably limit access.

This latter point cannot be emphasized enough: access to essential medical technologies necessarily must take into account affordability, not mere provision in the market. A high-priced medical product is as inaccessible to those who cannot afford it as one that does not exist.

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<sup>24</sup> NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), <https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH>

<sup>25</sup> S.909 – Prescription Drug Price Relief Act of 2021, <https://www.congress.gov/bill/117th-congress/senate-bill/909/text>

Moreover, in public health crises, it will often be the case that price-based rationing has broader, multiplier impacts beyond the direct impact on those who cannot obtain a product. Rationing due to price or for other reasons may permit pandemics to spread or allow viruses to mutate, for example.

In short, reasonable pricing provisions are vital for PAHPA-related investments.

The first starting point for reasonable pricing is that the United States should not pay more for drugs and products it helped develop than other high-income countries pay. This should be non-controversial. If the U.S. government helped pay for the invention and development of a drug or biomedical product, then surely it should not be charged prices higher than other rich countries which did not support development of the product.

The government has, episodically, included “Most Favored Nation” (MFN) clauses in procurement contracts, including in its contract with Pfizer for purchases of the antiviral Paxlovid.<sup>26</sup> The operative MFN provision in that contract reads:

If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.<sup>27</sup>

But MFN provisions are just a bare minimum starting point for thinking about affordability and reasonable pricing. The overarching point to understand about reasonable pricing for biomedical products is that manufacturing costs are generally very low relative to overall development costs. The main costs that drug, vaccine and other biomedical corporations must recover are research and development, including cost of failure in pursuing many different ideas.

From this overarching point follows two key principles that should define reasonable pricing. First, a reasonable price should correlate to a manufacturers’ development expense and acceptance of risk. If a drug maker can show that it incurred large R&D costs, or that it invested heavily in the riskier, earlier stages of development, then, all other things equal, the reasonable price of a resultant drug should be higher. On the other hand, if the government incurred most of the expense and the manufacturers’ actual outlay was small, or if the government primarily funded the early-stage work, then a reasonable price should be lower.

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<sup>26</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>27</sup> The MFN provision is H.7 in the full contract, which is available here: <https://www.keionline.org/misc-docs/COVID19/Pfizer-Contract-Paxlovid-W58P0522C0001-17Nov2021.pdf>.



Second, at a certain point, a manufacturer has obtained a reasonable return on its original investment and should no longer be entitled to supra-competitive profits. Although we support reasonable pricing conditions and revenue caps for products that are completely developed in the private sector, the situation is qualitatively different with government funding. In the pure private case, the patent monopoly and the possibility of a bonanza payout is, at least in theory, the incentive for undertaking the up-front risky investment. However, where the government has assumed a substantial portion of the risk – including by directly funding the manufacturer to undertake R&D -- and where the government guarantees purchases, the manufacturers’ risk is greatly lessened. In these circumstances, after a manufacturer secures a certain return on its investment, it should no longer be entitled to supra-competitive profits and an automatic license to manufacture the patented invention (and gain access to needed materials and make use of testing data) should be available to all qualified manufacturers.

Price terms are obviously a central subject of any purchase agreement, but reasonable pricing terms should be included in R&D contracts, covering both later government purchases and provision of products in the private market. As regards government purchases, including reasonable pricing terms will establish market norms and expectations. Not only does this leverage the government’s unique power at the point it is making grants and investments in new products, it orients drug maker and market understandings and forecasts. No manufacturer should be blindsided by a government demand for reasonable prices; and no manufacturer should feel empowered to challenge the rule that it is entitled to a reasonable reward, but no more.

It is even more important that reasonable pricing provisions apply to the private market. In the absence of price restraints, Big Pharma pricing models regularly deny people access to necessary treatments, therapies and preventative services. When Big Pharma corporations price drugs to maximize profits, they are necessarily setting prices out of reach for many people, especially those with no insurance, limited insurance or insurance with high co-pays. The median launch price of a new drug in the United States jumped from \$2,115 in 2008 to \$180,007 in 2021, a 20 percent annual inflation rate, according to researchers at Brigham and Women’s Hospital in Boston.<sup>28</sup>

As a result of these soaring prices, non-adherence to drug regimens due to price – the cost of drugs, co-pays and deductibles – is at epidemic levels. Thirty percent of Americans report that they have skipped drug treatments or otherwise haven’t taken medicines as prescribed because of cost.<sup>29</sup>

Forced rationing based on excessive pricing is morally appalling and antithetical to good public health policy in any circumstance. The idea that high prices would deny access to care for vital medicines, vaccines or treatments in a time of public health emergency – *for products invented and/or developed with support from U.S. taxpayers* – should be unthinkable. It certainly

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<sup>28</sup> Robert Langreth, “New Drug Prices Soar to \$180,000 a Year on 20% Annual Inflation,” Bloomberg, June 7, 2022, <https://www.bloomberg.com/news/articles/2022-06-07/new-drug-prices-soar-to-180-000-a-year-on-20-annual-inflation>.

<sup>29</sup> Liz Hamel, Lunna Lopes, Ashley Kirzinger, et al., “Public Opinion on Prescription Drugs and Their Prices,” Kaiser Family Foundation, April 5, 2022, <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices>

shouldn't be tolerated. And it is completely avoidable if BARDA and other relevant agencies operate proactively to ensure reasonable pricing.

Nor should reasonable pricing obligations end with the wind-down of a public health emergency. In cases where the public has made substantial contributions to the development of a product, then the public has every reason to demand that the resultant products remain affordable. The case of the Moderna vaccine is illustrative. Moderna has generated enormous profits during the pandemic and is quadrupling Covid vaccine prices now that the acute phase of the pandemic is over. People will continue to need updated Covid vaccines; Moderna has already generated more than fair returns on its modest investment; and yet the company aims to price gouge consumers. BARDA and other agencies should ensure this scenario never repeats.

### **International Access**

PAHPA support for R&D should be contingent on ensuring that U.S.-supported inventions are available globally on reasonable terms. To be clear, this access need not come at the expense of Americans. The objective should be to expand affordable supply to meet the needs of people around the world.

Guarantees of global accessibility will advance a diverse range of U.S. interests:

First, the United States has a humanitarian interest in ensuring everyone has access to needed drugs, vaccines, therapies and diagnostics. The market alone will not ensure universal access; in fact, relying on the market alone ensures massive disparities in global access. Monopolistic manufacturers of new products may not have capacity on their own to scale up production to meet global needs. Beyond production capacity, Big Pharma routinely overlooks low-income and lower-middle-income countries, which do not have the ability to pay high-income prices for products. Especially for U.S. taxpayer-funded products, the United States has a humanitarian duty to ensure global access.

Second, the United States has a public health interest in ensuring global access. As the waves of Covid variants reminded us, failing to control a highly transmissible virus in one part of the world invites mutations that will inevitably impact the United States. Ensuring people around the world have access to vaccines, drugs, treatments and diagnostics directly assists public health in the United States.

Third, sharing biomedical technology can afford enormous global economic benefits. The Covid pandemic massively disrupted the global economy. Major government intervention in the United States offset the impacts, but the pandemic led to massive reductions in global trade and long-lasting supply chain shocks.<sup>30</sup> To whatever extent sharing of biomedical technology could reduce comparable impacts in the future, the economic benefits would be extraordinary – just shaving

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<sup>30</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-10 and the Value of Access to Covid-19 Vaccines,” Vaccines, August 15, 2022, <https://www.mdpi.com/2076-393X/10/8/1320>.

months off the period of a pandemic could save hundreds of billions of dollars for the U.S. economy.

Last, sharing technology and ensuring global availability of important biomedical advances would secure tremendous diplomatic gains for the United States. It would evidence not only our technological prowess but our beneficence.

Ensuring affordable global access to new biomedical inventions requires establishing sufficient global manufacturing capacity and taking measures to promote affordability, including especially in lower-income countries. Both these components are crucial. In the case of the pandemic, once the mRNA vaccines were developed, there was very little supply available for poor countries. To a very considerable degree, the shortage was artificial, a result of Moderna and Pfizer refusing to share their technology with other manufacturers. But adequate supply by itself is not enough. Products must be affordable for low- and middle-income countries, otherwise they will remain as inaccessible as if they did not exist.

To this end, PAHPA-related R&D contracts should include the following provisions:

- An automatic license to the World Health Organization (WHO) and efforts such as the WHO's mRNA Technology Transfer Program.<sup>31</sup> Along with a license for relevant intellectual property and testing data, U.S. research and development contracts should require grantees to engage affirmatively in technology transfer, including the sharing of biomaterials, product recipes and manufacturing methods. The affirmative objective should be to build up manufacturing and development capacity in developing countries.
- A duty for manufacturers to make best efforts to scale up production to meet global need and to license with low and fixed royalties to qualified third parties to manufacture for developing country markets. Licensing for developing countries can be easily arranged through the Medicines Patent Pool, an international institution established for exactly this purpose.<sup>32</sup>
- An obligation for affordable pricing for developing countries. Generally, this should be marginal pricing for low- and middle-income countries and substantially discounted pricing for upper-middle-income nations. Companies should be able to satisfy the pricing obligation by providing non-exclusive licenses, if they prefer. It is important that affordability and licensing arrangements cover middle-income countries to ensure rapid, worldwide availability of critical new products. By way of example, Public Citizen has estimated that the need for the Covid treatment Paxlovid (Nirmatrelvir/ritonavir) in non-high income countries is at least 10 times what has been purchased.<sup>33</sup>

### **Other pro-access, pro-innovation contract terms**

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<sup>31</sup> "mRNA Technology Transfer Programme Moves to the Next Phase of its Development," World Health Organization, April 20, 2023, <https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development>

<sup>32</sup> <https://medicinespatentpool.org/>

<sup>33</sup> Letter to Katherine Hiner, Acting Secretary to the U.S. International Trade Commission, Public Citizen, April 12, 2023, <https://www.citizen.org/article/post-hearing-brief-for-investigation-no-332-596-covid-19-diagnostics-and-therapeutics-and-flexibilities-under-the-trips-agreement/>

PAHPA contract terms should include other pro-access, pro-innovation measures, including:

- “Reach-through” provisions, ensuring that any party using a licensed technology must apply the same access and affordability provisions as included in the original contract terms. Reach-through provisions prevent gaming of the affordability and accessibility obligations, for example, through modest alterations of the original product. They also extend the affordability and accessibility benefits to follow-on and combination products, re-paying the taxpayers for their initial investments.
- Duties to license to other qualified drug researchers and manufacturers to facilitate more innovation. The licensing obligation should include intellectual property and data rights for the end product, but also materials needed for conducting research. Additionally, BARDA procurement contracts should include boilerplate language safeguarding the ability to conduct necessary research on existing and next generation products. There is evidence to suggest that companies are restricting access to Covid vaccine that would be used for research purposes, for example, imposing potentially severe impediments to important research.<sup>34</sup>

### **Prizes and other models to support biomedical innovation**

The work of BARDA and related agencies is so important because they address market failures. These failures trace to familiar sources and have nothing to do with the behavior or ethics of any individual corporation or researcher. The core problem is that Americans need to support innovation in products that we hope will never be used, or for which market demand is very uncertain. We need biomedical products for pandemics that we hope never occur, and we need to be prepared to scale up for pandemics with a profile different than what we have planned for. We need new antibiotics that we may hold in reserve to prevent resistance. We need countermeasures for biological and chemical weapons that we hope will never be deployed. In such circumstances, the traditional model of incentivizing R&D by the grant of limited term patent monopolies breaks down. PAHPA and BARDA are direct responses to that market failure.

In addition to the contractual measures sketched above, a reauthorized PAHPA should also authorize different approaches to supporting R&D -- that is, to move beyond research grants grafted on to the patent monopoly model. PAHPA in fact contemplates such alternative approaches,<sup>35</sup> but these should be more affirmatively supported and required.

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<sup>34</sup> “Science Held Hostage: How Pharma is Using mRNA Vaccine Contracts with Government to Delay Future Innovation,” PrEP4All, April 2023, <https://static1.squarespace.com/static/5e937afb7a75746167b39c/t/643ee03ce3538e2bb5d925bf/1681842236736/PrEP4All+Prevention+Equity+Alert+-+4-2023.pdf>

<sup>35</sup> (42 U.S.C 247d-7e(c)(4)(D)). Perversely, BARDA has used this authority to circumvent the modest existing rules in existing law to promote affordability. A reauthorized PAHPA should explicitly prevent this misuse of “other transition” authority. See Christopher Rowland, “Trump Administration Makes it Easier for Drugmakers to Profit from Publicly Funded Coronavirus Drugs, Advocates Say,” Washington Post, July 1, 2020, <https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/>.

One model is to offer prizes in place of patents.<sup>36</sup> Instead of offering a patent monopoly as an incentive for innovation, BARDA and other agencies may offer prizes. Developers may be awarded dollar awards from a prize fund, with all intellectual property and related rights vested in the federal government. There are numerous potential benefits to a prize fund. First, it can offer sufficient incentive for research and development work for products for which there may be no apparent market, as described in the cases above. Thus prizes can be used to induce *more* innovation than patents might. Second, the prize fund can be reasonably calibrated to the public health value of the product or products being developed. This is very different than patents, which are calibrated not to public health value, but market demand. Third, prizes can eliminate price gouging. Innovators are rewarded by prizes, not monopolies, so the resultant products can be licensed broadly to manufacturers and sold as generics. Fourth, prizes can be adjusted to avoid the winner-takes-all problem of patents. Portions of a prize fund may be shared with innovators whose research assisted the development process but did not ultimately lead to a patented invention, an approach proposed in Senator Sanders' Medical Innovation Prize Fund Act as an "open-source dividend." Fifth, prizes can incentivize collaboration, with diverse research centers pooling efforts and sharing the prize, rather than trying to lay claim to a singular patent. Similarly, prizes can overcome the problem of patent thickets.

Prizes are an important alternative to the monopoly incentive model in all circumstances, but they are particularly important – and especially deserving of much more widespread usage – in the PAHPA context, where the temporary monopoly model definitionally fails.

A second model is to lean in more heavily to the research contracting model. This would involve contracting with research centers at universities and corporations to undertake research in service of the U.S. government, rather than making grants but allowing the grantees to control the fruits of the research. The government would maintain ownership and control of all intellectual property and associated rights; coordinate product development; and license final products on a non-exclusive basis to all qualified manufacturers. In the case of the NIH-Moderna vaccine, where essentially the entire enterprise was funded by the U.S. government, this is practically what occurred – with the crucial caveat that Moderna was permitted to control the fruits of the research.

A third model is patent and/or know-how buyouts: In a case of a chemical weapon countermeasure, for example, the government would negotiate with the patent holder a fair agreement to purchase all intellectual property and related rights – a one-time payment – and then license multiple manufacturers to produce the countermeasure on a contractual basis. If the U.S. government is the only purchaser, this is what will effectively happen in any case, but it converts the price negotiation into a more rational process to determine fair compensation to the innovator for the value of their innovation.

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<sup>36</sup> Senator Sanders has previously introduced legislation to create a prize fund for biomedical research. See the Medical Innovation Prize Fund Act, introduced as S495 in the 115<sup>th</sup> Congress. <https://www.congress.gov/bill/115th-congress/senate-bill/495/text?s=2&r=1&q=%7B%22search%22%3A%5B%22Medical+Innovation+Prize+Fund+Act%22%5D%7D>. For a detailed discussion of innovation prizes, see the work of Knowledge Ecology International, here: <https://www.keionline.org/book/prizes-to-stimulate-innovation>.

These varied approaches may be combined. For example, a prize system can be supplemented with direct grants, with the size of the prize awards effectively adjusted. In a case of patent or know-how buyouts, the payment to the grantee should be adjusted to reflect the grant contributions from the government and the amount of capital risked by the patent holder.

These models, especially combining prize funds and direct grants, are especially appealing to prepare for future threats. The public health imperative is to investigate and prepare for a wide range of threats and to position the country (and the world) to have products already identified and in far-along or completed development stage if any of those threats emerge. Researchers at NIH have identified 20 virus families for which they propose a series of steps that would lead to prototype vaccines.<sup>37</sup> This is not work that will receive drug and vaccine maker investment with a temporary monopoly incentive, because the problems are too speculative and the likelihood of payout too uncertain. But it is exactly the kind of work that PAHPA should be supporting through prize funds and direct research contracting.

## CONCLUSION

The underlying theory of PAHPA was validated by the Covid pandemic, which showed the crucial importance of a real public health infrastructure to prepare for pandemics and emergencies and to make significant investments in biomedical innovation. But so too did the pandemic illustrate the very real costs – in dollars and lives – of failing to act proactively to ensure an adequate supply and affordability of key biomedical products. The reauthorization of PAHPA must be the moment to make our pandemic and emergency preparedness more robust. First, a reauthorized PAHPA should require BARDA and other agencies to build transparency, affordability, production and licensing terms into R&D and acquisition contracts. Second, it should require BARDA and other agencies to adopt prize funds and other creative measures to more efficiently fund biomedical R&D and advance public health objectives.

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<sup>37</sup> Gina Kolata, “Fauci Wants to Make Vaccines for the Next Pandemic Before it Hits,” New York Times, July 25, 2021, <https://www.nytimes.com/2021/07/25/health/fauci-prototype-vaccines.html>; Barney S. Graham and Nancy J. Sullivan, “Emerging Viral Diseases from a Vaccinology Perspective: Preparing for the Next Pandemic,” Nature Immunology, 19, 20-28 (2018), <https://www.nature.com/articles/s41590-017-0007-9>.