

March 14, 2022

The Honorable Patty Murray  
Chair, Committee on Health, Education,  
Labor and Pensions  
United States Senate  
Washington, D.C. 20510

The Honorable Richard Burr  
Ranking Member, Committee on Health,  
Education, Labor and Pensions  
United States Senate  
Washington, D.C. 20510

**RE: Comments Regarding S. 3799 — the PREVENT Pandemics Act**

Dear Chairperson Murray and Ranking Member Burr:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully submits the following comments regarding S. 3799, the PREVENT Pandemics Act (the Act).

**Objectionable provisions**

Although Public Citizen supports many of the provisions included in the Act, we find the following sections of the legislation to be objectionable and urge that they be excluded or substantially revised before the legislation is finalized:

- *Section 504. Third party test evaluation during emergencies:* This section would clarify the Food and Drug Administration's (FDA's) authority to consult with third parties to evaluate and make recommendations with respect to the validity, accuracy, and reliability of *in vitro* diagnostic tests for use during a public health emergency. Public Citizen has long opposed such third-party review programs for medical devices because the third-party reviewers authorized under such programs have inherent, irreconcilable conflicts of interest. Congress should roll back, rather than expand, the FDA's authority to use third-party review programs for medical devices.
- *Section 505. Facilitating the use of real world evidence:* This section would further erode the FDA's evidentiary standards for ensuring that new drugs and high-risk medical devices are safe and effective by opening the door to greater FDA reliance on evidence from observational studies that are less rigorous than randomized, controlled clinical trials to establish the safety and effectiveness of the new drugs and high-risk medical devices. Evidence from observational studies may supplement but must not supplant data from well-designed randomized, controlled clinical trials as the primary evidence for establishing that a drug or high-risk medical device is safe and effective.

**Areas to strengthen:**

Additionally, the following provisions of the Act, which Public Citizen supports, would benefit from amendment and agency discretion to strengthen their impact:

- *Section 302. Research centers for pathogens of pandemic concern:* This section would direct the National Institute of Allergy and Infectious Diseases to establish or continue a multidisciplinary research program to provide funds to support the discovery and preclinical development of medical products for priority virus families and other viral pathogens with significant pandemic potential, through grants, contracts, and cooperative agreements. This section would be improved by including global access, licensing, and pricing requirements to ensure that any medicines invented or developed with support from taxpayer dollars under this program are accessible where they are needed and are priced in a manner that reflects public investments.
- *Section 401. Warm base manufacturing capacity for medical countermeasures:* This section would authorize and direct the Biomedical Advanced Research and Development Authority (BARDA) to support, maintain, and improve domestic manufacturing surge capacity and capabilities for medical countermeasures, such as vaccines and treatments, needed in a public health emergency. Although we are largely supportive of this section, to be most impactful and avoid pitfalls of past attempts at public-private partnerships to surge capacity for public health emergency medicines, authority under the BARDA statute and this section should be used to support a public, government-owned, contractor-operated pandemic production facility (see the Appendix, which provides Annex I from Public Citizen’s report, “A Plan for the People’s Vaccine,” that outlines details around a proposal for such a facility).

Pandemic threats do not recognize national borders. The U.S. Government can and must do much more through cooperative global initiatives to improve global pandemic preparedness, as it has in the past (see the Appendix, which provides Annex II from Public Citizen’s report, “A Plan for the People’s Vaccine”).

In any legislation Congress advances to bolster pandemic preparedness, it should support creation and enhancement of U.S. Government programs and resources to augment global production capacity for vaccines and treatments.

Thank you for considering our views on this important legislation.

Sincerely,



Michael Carome, M.D.  
Director  
Public Citizen’s Health Research Group



Peter Maybarduk  
Director  
Public Citizen’s Access to Medicines Program

cc: Members, U.S. Senate Health, Education, Labor and Pensions Committee

**Appendix**  
**Annexes I and II from Public Citizen’s report, “A Plan for the People’s Vaccine”**

**Annex I: “Deploying the Government Owned, Contractor Operated (GOCO) Model: How the U.S. Government Can Stand Up a Billion Dose mRNA Vaccine Facility Within Six Months” (PrEP4All, Public Citizen, Partners in Health)**

**1. General overview of the GOCO model**

What is a GOCO?

A GOCO facility is a model used by the federal government in which the government pays a privately owned company to operate a facility that the government owns. The GOCO approach has been utilized extensively and successfully since the Manhattan Project by the Departments of Energy and Defense for both cutting edge scientific research and the widespread production of critical, high-technology national security assets.

GOCOs have historically been used to manufacture some of the most complex technology ever produced. For example, America’s arsenal of nuclear weapons are produced completely by GOCOs, with the plutonium pits being manufactured at Los Alamos National Lab (owned by the U.S. Government, operated by a consortium of partners led by Batelle), non-nuclear components being manufactured at the Kansas City National Security Campus (owned by the U.S. Government, operated by Honeywell), and final warhead assembly being performed at Pantex Plant in Amarillo, TX (owned by the U.S. Government, operated by a consortium of manufacturing partners led by Bechtel).<sup>1</sup>

The U.S. Government even uses the GOCO model already to produce vaccines — the National Institute of Allergy and Infectious Diseases (NIAID)’s Vaccine Research Center (VRC) Vaccine Pilot Plant (VPP) in Frederick, MD produces cGMP doses for clinical trials, and is owned by the U.S. Government and operated by Leidos Biomedical Research, Inc.<sup>2</sup> Sixteen of the seventeen U.S. Department of Energy National Laboratories utilize the GOCO model, as well as all of the 49 federally funded research and development centers (including the national labs).<sup>3</sup>

The widespread use of the GOCO model across the federal government reflects its inherent structural advantages over other models of public-private cooperation, especially in the context of manufacturing technologies. Scale-up of manufacturing for complex technologies is necessarily capital intensive and requires hundreds of millions of taxpayer dollars. Often, the federal government does not have the skills required to operate manufacturing facilities. However, simply giving away taxpayer money to a private corporation to build a capital asset that the government does not own or control necessarily leaves the government in a vulnerable position. In such a scenario, the private corporation then owns the asset funded with taxpayer dollars, and can use this asset for other purposes or even leave the business entirely. Such vulnerabilities are precisely what the GOCO model was designed to eliminate. The GOCO model ensures that the taxpayer funded capital asset will be operated for the purposes the government intends while simultaneously leveraging skillsets of private industry to ensure rapid, efficient, and cost-effective achievement of the government’s goals.

Six inherent vulnerabilities to the COCO model that are solved by the GOCO model

The GOCO model solves for at least six inherent structural vulnerabilities of the contractor ownership aspect of the COCO model, none of which can be remedied by contract. These six vulnerabilities are listed below. While these vulnerabilities can be derived theoretically via simple economic reasoning, each vulnerability has also been empirically demonstrated in USG funded-COCOs that failed to meet the medical countermeasure needs they were designed for.

COCO vulnerabilities that are resolved with a GOCO model include:

1. The asset is wedded to the technologies or platforms the owner of the facility has expertise in making (originator lock-in)  
E.g. Novartis in Holly Springs;<sup>4</sup> Merck/J&J partnership<sup>5</sup>
2. If a contractor owns an asset, it can sell the asset directly and/or leave the market  
E.g. Novartis in Holly Springs;<sup>4</sup> DoD ADM in Alachua<sup>4</sup>
3. If the owner is not able to fulfill the medical countermeasure mission (e.g. lack of competence in producing vaccines) the U.S. loses its ability to use the asset  
E.g. Emergent BioSolutions<sup>6</sup>
4. Contractor ownership eliminates competition for operating the facility, dramatically reducing incentive for high performance  
E.g. Emergent BioSolutions;<sup>6</sup> DoD ADM in Alachua<sup>4</sup>
5. Contractors will use the assets to produce other life-saving technologies, leaving the assets inflexible during existing or potential emergencies (stranded asset problem)  
Texas A&M;<sup>4</sup> Novartis in Holly Springs<sup>4</sup>
6. COCOs have required massive investment during the COVID pandemic to *reserve* capacity in the facilities the U.S. government built with public dollars. Ironically, none of these reservations worked to produce usable medical countermeasures.  
E.g. Emergent Biosolutions;<sup>7</sup> DoD ADM in Alachua<sup>8</sup>

Speed: the GOCO model vs the COCO (contractor owned, contractor operated) model

There is a misconception that a COCO model can produce mRNA vaccines faster than a GOCO model. This is grounded in the false assumption that the federal government *itself* would have to build the COVID vaccine manufacturing facility under a GOCO model.

Rather, in *either* model (GOCO or COCO), the federal government would: 1) pay a private contractor to locate and purchase an existing facility and then retrofit that facility to produce COVID vaccines (or simply build a new facility from scratch, which is more time-intensive); and 2) pay a private contractor to manufacture COVID vaccine drug substance in this facility. The only *difference* between the COCO and GOCO models is that in a COCO model, the entirety of the USG's investments in these new assets become the private property of the contractor and thus outside of the control of the USG, leaving the assets subject to numerous vulnerabilities discussed in the following section. In a GOCO model, the USG retains ownership of the assets it paid its private sector partner to construct.

**2. Realizing mRNA vaccine production via the GOCO model**

The U.S. government can stand up an mRNA vaccine production facility capable of producing a billion doses within six months. By investing approximately \$550 million, the Biden administration can build three to seven production lines in a GOCO facility. The U.S. government

can pay a private sector partner to either 1) acquire a pharmaceutical facility with cleanroom capabilities; or 2) build modular cleanroom facilities within an existing industrial building.

### 1. Purchasing a pharmaceutical facility, with built-in cleanroom capability

Working with an experienced contractor like Lonza—which is responsible for the vast majority of global mRNA-1273 production—can expedite timelines.<sup>9</sup> Lonza has ten U.S. production sites, at least two of which are registered with FDA and have commercial biological production capabilities (Houston, TX and Portsmouth, NH).<sup>10</sup> Lonza is investing ~\$200 million to add a new facility (32,000 ft<sup>2</sup>) to the Portsmouth site that will be completed by 2023.<sup>11</sup> If Lonza or other contractors have cleanroom capacity available for sale, the production process can be set up in existing rooms—similar to what BioNTech did at Marburg.

### 2. Building new cleanroom capabilities using prefabricated modules within an industrial building

Moderna has employed modular “kits” to stand up production. A modular ISO class 7 cleanroom facility can be built in under three months, from initial order to commercial operation at the production facility.<sup>12</sup> These kits can be placed in industrial buildings with the necessary utilities (e.g., electricity, water for injection).<sup>13</sup> In addition to the Lonza Portsmouth site that already houses a kit, the U.S. government can explore using a pharmaceutical manufacturing plant that recently closed in West Virginia.<sup>14</sup> Based on public disclosures, we estimate that between 3 to 7 kits—and production lines—would be needed.

**Table 1 – Estimated resource requirements for 1 billion dose mRNA-1273 capacity<sup>15</sup>**

<b>Dose</b>	<b>Lines Required<sup>16</sup></b>	<b>Total Line Cost<sup>17</sup></b>	<b>Facility Cost</b>	<b>Average Total Cost</b>
mRNA-1273 (50 ug)	3 to 4	240-320 million	100 million	\$380 million
mRNA-1273 (100 ug)	6 to 7	480-560 million	200 million	\$720 million

### 3. Standing up an mRNA vaccine manufacturing GOCO in six months

In September 2020, a biotechnology company bought a manufacturing plant in a small German city for \$90 million.<sup>18</sup> The 300 staff at the facility had never worked with the new vaccine technology used by the company. But, in less than six months, the team switched from making cancer medicines to pumping out vaccines. Today, BioNTech’s Marburg facility is producing millions of mRNA vaccine doses a week, with an expected annual capacity of up to one billion doses.<sup>19</sup>

A GOCO facility can similarly offer a rapid pathway to mRNA production while preventing the repeated failures associated with private ownership of key national security infrastructure. It would give the government the flexibility, oversight and control needed to address the coronavirus pandemic and future biological threats.

Endnotes

- [1] *The U.S. Nuclear Weapons Complex: Overview of Department of Energy Sites*. Congressional Research Service. 2020. [https://www.everycrsreport.com/files/2021-03-31\\_R45306\\_01d628c405d0a16b2c9225268c46adecff8b936b.pdf](https://www.everycrsreport.com/files/2021-03-31_R45306_01d628c405d0a16b2c9225268c46adecff8b936b.pdf)
- [2] See: <https://www.niaid.nih.gov/research/marybeth-daucher-phd>
- [3] *Value of the DoE National Laboratories*. National Laboratory Directors' Council. 2020. [https://nationallabs.org/site/wp-content/uploads/2021/01/NLDC\\_Value-of-DOE-Labs\\_15Oct2020-PUB.pdf](https://nationallabs.org/site/wp-content/uploads/2021/01/NLDC_Value-of-DOE-Labs_15Oct2020-PUB.pdf)
- [4] *Additional Information That Congress May Find Useful as It Considers DOD's Advanced Development and Manufacturing Capability*. United States Government Accountability Office. 2017. <https://www.gao.gov/assets/gao-17-701.pdf>
- [5] The Merck plant in North Carolina dedicated to producing the J&J vaccine has yet to produce usable drug substance, despite the \$268.8 million deal being announced by the Biden administration in March 2021. This is the slowest scale-up of Ad26.COVS drug substance production to date. See: <https://www.nytimes.com/2022/02/08/business/johnson-johnson-covid-vaccine.html>
- [6] "U.S. cancels multimillion-dollar deal with coronavirus vaccine maker whose plant ruined Johnson & Johnson doses." *The Washington Post*. 2021. <https://www.washingtonpost.com/business/2021/11/05/coronavirus-vaccine-emergent-biosolutions-cancel/>
- [7] [https://www.usaspending.gov/award/CONT\\_AWD\\_75A50120F33007\\_7505\\_HHSO100201200004I\\_7505](https://www.usaspending.gov/award/CONT_AWD_75A50120F33007_7505_HHSO100201200004I_7505)
- [8] [https://www.usaspending.gov/award/CONT\\_AWD\\_W911QY20C0101\\_9700\\_-NONE\\_-NONE-](https://www.usaspending.gov/award/CONT_AWD_W911QY20C0101_9700_-NONE_-NONE-)
- [9] Our estimate of planned production lines: Moderna, Norwood, Mass (~2 to 5); Lonza, Portsmouth, New Hampshire (1); Lonza, Visp, Switzerland (6); Lonza, Netherlands (1); ROVI, Spain (1).
- [10] The other sites (e.g., Hayward, CA) could also potentially be retrofitted given the smaller scale of mRNA production. <https://pharma.lonza.com/about/locations/portsmouth-newhampshire-usa> <https://pharma.lonza.com/about/locations/pearland-texas-usa>
- [11] <https://www.lonza.com/news/2021-05-06-07-02>
- [12] PrEP4All, Hit Hard, Hit Fast, Hit Globally. <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>
- [13] Beyond modular units, a pharmaceutical engineering firm, with U.S. army assistance, was able to design and build a facility that began GMP manufacturing in just eight months <https://themedicinemaker.com/discovery-development/giving-it-all-weve-got-lessons-learned-from-operation-warp-speed>
- [14] "Feds throw lifeline to shuttered Viatrix plant in West Virginia, but its fate remains uncertain," <https://www.fiercepharma.com/manufacturing/feds-throw-lifeline-to-recently-shuttered-viatrix-plant-where-more-than-1-400-jobs>
- [15] This table is drawn from modeling by mRNA process engineers and public information about mRNA production from current manufacturers.
- [16] Lonza, for example, has stated that each production line is capable of producing 300 million doses of mRNA-1273 at 50ug annually. <https://www.businesswire.com/news/home/20210601006111/en/Moderna-Announces-New-Drug-Substance-Production-Agreement-with-Lonza-in-the-Netherlands>
- [17] We used estimates from Lonza's public statements (\$79 million per line), but this may reflect higher costs associated with working in Switzerland. Process modeling suggests the lines could be constructed for \$60 million per line. <https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/>
- [18] €77,853. <https://biontechse.gcs-web.com/node/9571/html>
- [19] <https://investors.biontech.de/news-releases/news-release-details/biontech-provides-update-vaccine-production-status-marburg#:~:text=The%20approvals%20make%20BioNTech's%20Marburg,19%20vaccine%2C%20once%20fully%20operationa>

## **Annex II: "Helping Countries Help Themselves": BARDA's Influenza Program (excerpt from "A Plan for the People's Vaccine")**

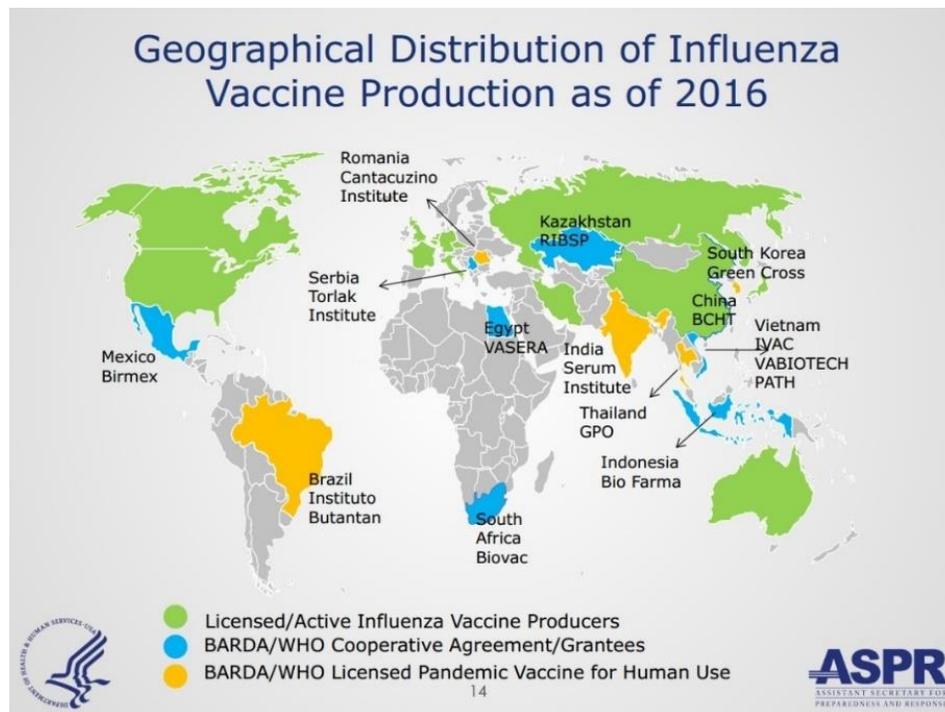
"Diseases do not respect borders so increasing the ability to make flu vaccine in any country helps every country reduce the spread of flu," explained Robin Robinson, then director of the U.S. Biomedical Advanced Research and Development Authority, in 2010.[25] "While we continue to build vaccine manufacturing capacity in the United States, and develop new, faster technologies for producing vaccine domestically, we can increase pandemic preparedness worldwide by helping other countries take advantage of technology."

Robinson was referring to BARDA's international program, launched years earlier, to help developing countries build influenza vaccine manufacturing capacity. The spread of the deadly

H5N1 influenza strain had raised alarm bells in 2004. After a global call for action at the World Health Assembly, the Bush Administration launched a new program.[26]

The impact was significant. In 2005, vaccine producers in the countries involved could collectively produce less than 1 million doses of pandemic influenza vaccine. In 2014, they could produce nearly 300 million doses. In 2018, they could produce over 500 million doses.[27]

FIGURE 2: BARDA GLOBAL INFLUENZA VACCINE PARTNERS (BLUE/YELLOW) (2016)[28]



Behind the success lay a novel partnership with the World Health Organization (WHO), which was implementing a global influenza plan, and developing country manufacturers. Alongside the WHO, BARDA helped build facilities, train personnel, provide technical assistance, and transfer technology for scalable manufacturing.[29] WHO obtained an intellectual property license from a Russian institute on a vaccine strain so that manufacturers could more easily begin production, and created a vaccine technology hub.[30] BARDA and WHO supported 14 manufacturers in 13 countries.[31] While funding data is not publicly available, the U.S. government reported investing \$72 million by 2013.[32] Every dollar invested by BARDA leveraged seventeen dollars of local investment.[33] Congress expressed strong support. In 2013, the Senate Committee on Appropriations pushed back against proposed funding cuts and noted that “The capability of developing countries to produce influenza vaccine within their borders is crucial to reducing the threat of a global pandemic.”[34]

In a sense, the BARDA program was merely a pilot for what is needed now: a U.S. government initiative to rapidly increase vaccine supply by sharing technology, building capacity, and mobilizing the global community. There are important differences. The leading coronavirus

vaccine candidates rely on newer technology as compared to traditional egg-based approaches used in many influenza vaccines, raising the prospect of more complex technical processes and intellectual property claims. But the BARDA international program offers an important vision. “We are helping countries help themselves,” said Robin Robinson, BARDA’s former director.

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Excerpt footnotes:

[35] Now, the U.S. government should rise to meet the needs of this moment, and inject American ambition into the global response.

[25] BARDA Grants Help Build Global Flu Vaccine Manufacturing Capacity, Business Wire (Sep. 30, 2010), <https://tinyurl.com/y2hcl72r>

[26] Michael L. Perdue and Rick A. Bright, United States of America Department of Health and Human Services support for advancing influenza vaccine manufacturing in the developing world, *Vaccine* 29 (Jul. 1, 2011): A48-A50, <https://tinyurl.com/y3sbjzmz> In 2005, the World Health Assembly passed a resolution calling for increased developing country vaccine capacity. The U.S. Homeland Security Council then echoed this call in its National Strategy for Pandemic Influenza Implementation Plan, urging international cooperation to develop vaccine manufacturing capacity.

[27] Changing the Landscape for Global Pandemic Influenza Vaccine Manufacturing, ASPR (Feb. 13, 2014), <https://tinyurl.com/y4nn23dk>. (BARDA projected they would be able to produce up to 500 million doses by end of 2016.) Global Partnerships and International Preparedness: Challenges and Innovative Partnering, ASPR (Oct. 2016), <https://tinyurl.com/y23ub6y3> .The head of the program, Rick Bright, noted in 2018 that “Pandemic vaccine manufacturing capacity in developing countries has expanded to over 500 million doses from this program.”

[28] Id.

[29] International Influenza Vaccine Manufacturing Capacity Building Program, Medical Countermeasures, <https://tinyurl.com/y23ub6y3>

[30] Friede, Martin, et al, WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing country production capacity through technology transfer, *Vaccine* 29 (Jul. 1, 2011): A2-A7, <https://tinyurl.com/y218x5j>

[31] Id.

[32] Julie Schafer, BARDA International Influenza Vaccine Manufacturing Capacity Building Program, ASPR, <https://tinyurl.com/y2hwpjxp>

[33] International Influenza Vaccine Manufacturing Capacity Building Program, Medical Countermeasures, <https://tinyurl.com/y23ub6y3>

[34] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, U.S. Senate (2013), <https://tinyurl.com/y2cbbth6>

[35] Jason deBruyn, NCSU’s B TEC moves to front lines in bio education, *Business Journals* (Apr. 15, 2011), <https://tinyurl.com/y39kg7je>