

**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**

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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).¹

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.² 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).³

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;⁴ Merck/J&J partnership⁵
2. If a contractor owns an asset, it can sell the asset directly and/or leave the market
E.g. Novartis in Holly Springs;⁴ DoD ADM in Alachua⁴
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 BioSolutions⁶
4. Contractor ownership eliminates competition for operating the facility, dramatically reducing incentive for high performance
E.g. Emergent BioSolutions;⁶ DoD ADM in Alachua⁴
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;⁴ Novartis in Holly Springs⁴
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;⁷ DoD ADM in Alachua⁸

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.⁹ 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).¹⁰ Lonza is investing ~\$200 million to add a new facility (32,000 ft²) to the Portsmouth site that will be completed by 2023.¹¹ 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.¹² These kits can be placed in industrial buildings with the necessary utilities (e.g., electricity, water for injection).¹³ 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.¹⁴ 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 capacity¹⁵

Dose	Lines Required ¹⁶	Total Line Cost ¹⁷	Facility Cost	Average Total Cost
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.¹⁸ 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.¹⁹

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
- [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
- [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.COVID.S 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
- [8] 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%20operational.>