

SHARING THE NIH- MODERNA VACCINE RECIPE

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EXECUTIVE SUMMARY

"We held Moderna by the hand on a daily basis." – Moncef Slaoui, Former Scientific Head of Operation Warp Speed (2020).¹

How did a decade-old corporation that had never before sold a vaccine develop a new product targeting a novel virus within 12 months and mass produce 200 million doses? The answer lies partly in the support of the U.S. government. Moderna jointly developed the coronavirus vaccine, mRNA-1273, with the National Institutes of Health. It also benefited from a massive infusion of funding through a contract awarded by the U.S. Biomedical Advanced Research and Development Authority ("the 2020 Contract").²

In exchange for paying hundreds of millions of dollars, BARDA obtained two powerful tools that now can be used to accelerate global vaccine production. First, BARDA gained access to the entire "vaccine recipe." This includes Moderna's dossiers containing chemistry, manufacturing, and controls information, which provide manufacturing instructions in step-by-step detail. Second, BARDA obtained "unlimited rights" to data first produced by Moderna using contract funding ("Unlimited Rights Data"). These rights allow the government to share data—broadly defined as "recorded information"—for any purpose.

Moderna generated a huge amount of new information with public funding. BARDA paid Moderna to develop manufacturing processes, allowing the company to scale-up production at its existing plant and then to scale-out production by adding a manufacturing line at an external site. Indeed, the 2020 Contract identifies several critical documents, including master production records, as "contract funded."

But the 2020 Contract also places one opaque limit on BARDA's contractual power. The government cannot use its contractual rights to share certain categories of information developed at private expense, including subsequent minor modifications ("Limited Rights Data"). Those categories are redacted.

What data are Unlimited Rights Data, and what data are Limited Rights Data? A full analysis would become possible only with the entire unredacted version of the contract and access to the underlying data produced by Moderna. Nonetheless, based on public information, we can reach a high-level conclusion: **Moderna likely did not use contract funding simply to make minor modifications to its existing manufacturing process.**

¹ Karen Weintraub, Deliver a safe, effective COVID-19 vaccine in less than a year? Impossible. Meet Moncef Slaoui, USA Today (Dec 1, 2020), <https://tinyurl.com/2xnxyvdu>

² Moderna-BARDA Contract, 75A50120C00034, (Apr. 3, 2020), <https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>

Instead, Moderna learned how to commercially produce hundreds of millions of doses on the taxpayer's dime. The company went from producing fewer than 100,000 doses across all products *per year* to producing 1.3 million coronavirus vaccine doses *per batch*.³ The government thus appears to have unlimited rights in the recipe for commercial-scale mRNA vaccine production.

The Biden administration should share all the information it holds on mRNA vaccine manufacturing with the World Health Organization. This can happen in two ways. First, the Biden administration should clarify what data qualifies as Unlimited Rights Data under the 2020 Contract and share this information. Second, the Biden administration should use other legal authorities beyond the contract to share information if it finds that the Trump administration allowed Moderna to claim Limited Rights Data over important vaccine manufacturing information. For example, the Defense Production Act can allow the federal government to share Limited Rights Data in exchange for reasonable compensation.

In April, President Biden said he believed that, by the summer, the U.S. would be “in a position to be able to share vaccines, as well as know-how, with other countries who are in real need.”⁴ As part of a \$25 billion global vaccine manufacturing program, the Biden administration should release the information it holds to advance mRNA science and bolster global vaccine production. A pandemic is no time for secrets.

³ Moderna CEO Stephane Bancel Presents at Goldman Sachs' 42nd Annual Healthcare Conference Transcript, Seeking Alpha (Jun. 9, 2021), <https://tinyurl.com/52r3t7s4> (“The volumes increase are incredible to give you another magnitude in 2019, Moderna as a company across all of our products, we made less than 100,000 dose for that year.”) Statement on California Department of Public Health (CDPH) Report, Moderna Press Release (Jan. 20, 2021), <https://tinyurl.com/ycnk9cwa>. (“Moderna confirmed that a total of 1,272,200 doses were produced in batch number 041L20A”)

⁴ Novavax shares jump after Biden says focusing on its vaccine, Reuters (Apr. 27, 2021), <https://tinyurl.com/yd6b2t65>

INTRODUCTION

“We ultimately have never ... manufactured doses at this scale. So, we had a lot to learn along the way.” – Stephen Hoge, Moderna President, Testimony Before House Committee on Energy & Commerce (2020).⁵

On March 30, 2020, the Biomedical Advanced Research and Development Authority announced it would back the development and manufacturing of mRNA-1273.⁶ The coronavirus vaccine, which Moderna had jointly invented with the National Institutes of Health, was getting another boost from the federal government. As part of a \$483 million contract that eventually would be signed (“the 2020 Contract”), BARDA agreed to bankroll the vaccine’s clinical development and fund manufacturing scale-up and scale-out, aiming for a capacity of 100 million doses by 2021.⁷

In exchange for paying hundreds of millions of dollars, BARDA obtained two powerful tools that now can be used to accelerate global vaccine production.⁸ First, BARDA gained access to the entire vaccine recipe. This includes Moderna’s dossiers containing chemistry, manufacturing, and controls information, which provide manufacturing instructions in step-by-step detail. Second, BARDA obtained “unlimited rights” to data first produced by Moderna using contract funding (“Unlimited Rights Data”). These rights allow the government to use, reproduce, and share data—or recorded information—for any purpose.

⁵ Stephen Hoge, House Hearing on COVID-19 Vaccine Availability (Feb. 23, 2021): 2:35:50 – 2:36:00, <https://tinyurl.com/fjzht97u>

⁶ HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines, HHS Press Release (Mar. 30, 2020), <https://tinyurl.com/x3hjttc>. The contract award was announced publicly on April 16 but the funding was disbursed April 3. Summary of Moderna-BARDA Definitive Contract 75A50120C00034, USA Spending (Apr. 3, 2020), <https://tinyurl.com/5h6b3x5e>.

⁷ Moderna-BARDA Contract, 75A50120C00034 (Apr. 3, 2020), pg. 4, <https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf>.

⁸ Id.

Table 1: The Extraordinary Scope of the 2020 Contract⁹

Contract Item	Activities	Award	Additional Funding		Total
Pre-Award Cost (CLIN 0001)	Unknown	\$3 million ¹⁰	—	—	\$3 million
Development of mRNA vaccine to Biologics License Application (CLIN 0002)	Nonclinical work; Phase 2 and Phase 3 clinical trials; ¹¹ Regulatory submissions; and Chemistry, manufacturing, and controls, including mRNA process development for late stage clinical supply and full commercial scale.	\$427 million ¹²	Phase 3 trial expansion	\$472 million ¹³	\$1.34 billion
			Adolescent study and immunogenicity/dose finding study	\$63 million ¹⁴	
			Phase 3 adult efficacy cross over study	\$236 million ¹⁵	
			Pediatric clinical trial	\$144 million ¹⁶	
Domestic Manufacturing Scale-Out (CLIN 0003)	Enable second supply node at Lonza's New Hampshire facility. ¹⁷	\$53 million ¹⁸	—	—	\$53 million
Total		\$483 million		\$915 million	\$1.4 billion

We proceed in five parts. First, we describe the rights of the U.S. government to obtain the vaccine recipe under the contract. Second, we review the rights of the U.S. government to share the vaccine recipe under the contract. Third, we apply what we know about the contract to the specific facts of Moderna's development and manufacturing of mRNA-1273. We conclude that the government appears to retain significant Unlimited Rights Data in information related to scaling-up and scaling-out manufacturing, including the

⁹ Table data from Medical Countermeasures website unless otherwise specified. COVID-19 Medical Countermeasure Portfolio, BARDA,

<https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine>

¹⁰ Moderna-BARDA Contract, Amendment No. 7 (March 12, 2021), pg. 3.

<https://investors.modernatx.com/node/11866/html#exhibit102amendmentno7toba.htm>

¹¹ NIAID ran the Phase 1 trial, with Moderna receiving funding from CEPI. Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (May 18 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine>

¹² The cumulative award for CLIN 0001 and CLIN 0002 was \$430 million. The CLIN 0001 amount was later identified as \$3 million. CLIN 0002 was therefore \$427 million. See note 9 and 10.

¹³ This option was exercised July 25, 2020.

¹⁴ This option was exercised March 12, 2021.

¹⁵ This option was exercised April 18, 2021.

¹⁶ This option was exercised June 15, 2021.

¹⁷ Moderna-BARDA Contract, Amendment No. 1 (May 24, 2020), pg.3,

<https://investors.modernatx.com/node/10211/html>

¹⁸ This option was exercised May 24, 2020.

commercial-scale vaccine recipe. Fourth, we describe the legal authorities—arising from sources other than the contract—that the government could use, if needed, to share the remaining parts of the recipe. Finally, we analyze how sharing this data with the World Health Organization could help advance mRNA science and bolster global vaccine production.

Our analysis is limited by a lack of transparency. Under the 2020 Contract, the government has access to voluminous data but has limited rights in certain categories of information developed at private expense and subsequent minor modifications (“Limited Rights Data”). Those categories are redacted from the publicly accessible contract. The limited rights can restrict the government’s ability based on the contract to share some data.

The Biden administration should clarify what data qualifies as Unlimited Rights Data under the contract and share this data with the World Health Organization. Where necessary, it should use other legal authorities, including the Defense Production Act, to share Limited Rights Data in exchange for reasonable compensation.

In April, President Biden said he believed that, by the summer, the US would be “in a position to be able to share vaccines, as well as know-how, with other countries who are in real need.”¹⁹ The 2020 Contract—which has now been expanded to provide Moderna \$1.4 billion for manufacturing and development work—contains powerful tools for this purpose. As part of a \$25 billion global vaccine manufacturing program, the Biden administration can share the vaccine recipe to advance mRNA science, accelerate global vaccine production, and help end the pandemic sooner.²⁰

¹⁹ Novavax shares jump after Biden says focusing on its vaccine, Reuters (Apr. 27, 2021), <https://tinyurl.com/yd6b2t65>

²⁰ Krishnamoorthi, Merkley, Warren, And Jayapal Introduce The NOVID Act To Protect The U.S. From Risk Of New Coronavirus Strains By Defeating The Virus Abroad, Press Release by Office of Congressman Raja Krishnamoorthi (Jun. 8, 2021), <https://tinyurl.com/5x9xh9yn>

BARDA HAS THE VACCINE RECIPE

"We have invested enormous efforts and finance and technology in supporting the companies directly. And, in fact, [we work] much more closely to scale up and manufacture the vaccine doses [than for clinical development]." – Moncef Slaoui, Former Scientific Head of Operation Warp Speed (2020).²¹

While the U.S. Department of Defense eventually led negotiations for many agreements under Operation Warp Speed, it did not negotiate with Moderna. Instead, BARDA, an office within the U.S. Department of Health and Human Services, was responsible for negotiating with Moderna. BARDA's authorizing statute requires the agency to condition its funding awards on gaining access to "all data related to or resulting from countermeasure and product advanced research and development."²²

The 2020 Contract has multiple provisions that allow BARDA to gain access to vaccine data. Article H.1. states that "the government shall have physical and electronic access to all documentation and data generated under this contract."

Figure 1: BARDA's Ability to Access Vaccine Data²³

H.1 Access and Disposition of Data

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

In addition to documentation and data generated under the contract, Moderna also is required to provide BARDA with copies of submissions to the U.S. Food and Drug Administration (FDA).²⁴ These dossiers typically describe in great detail preclinical studies; clinical studies; and chemistry, manufacturing and controls (CMC) data.²⁵ CMC data contain the vaccine recipe. They include information about chemical characteristics;

²¹ Dr. Moncef Slaoui, The Science and Structure of the US Government's COVID-19 Vaccine Trial Program, John Hopkins University – University of Washington Vaccine Symposium (Oct. 6, 2020): 28:15-28:37, <https://tinyurl.com/2wnddyww>

²² Pandemic and All-Hazards Preparedness Act. 42 U.S. Code § 247d-7e ("The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.")

²³ The non-proprietary format likely refers to the software format used to deliver the data.

²⁴ Moderna-BARDA Contract, pg. 27

²⁵ Price, W. Nicholson, Arti K. Rai, and Timo Minssen, Knowledge transfer for large-scale vaccine manufacturing, *Science* 369.6506 (Aug. 21, 2020): 912-914.

methods of manufacture, including raw material sources; flow charts of the manufacturing process, complete with a list of all tests performed at each step; process controls; specifications, including identity, purity, and potency requirements; drug substance batch records and drug product master production records.²⁶ Given that the vaccine has already received emergency use authorization, BARDA likely has these files on site.

BARDA also can separately request access to additional contract-funded documents, including the standard operating procedures, master production records, and batch records.²⁷

Table 2: Overview of Key Vaccine Manufacturing Documents Available to BARDA

Document	Standard Description ²⁸
Master Production Records (Master Formula)	<p>“A document or set of documents specifying the starting materials with their quantities and the packaging, materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.” (WHO)²⁹</p> <p>Master production records should include “complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.” (FDA)³⁰</p>
Batch Records	<p>“All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.” (WHO)³¹</p> <p>Batch records should include “an accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed.” (FDA)³²</p>
Standard Operating Procedures (SOPs)	<p>“An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection).</p>

²⁶ Guidance for Industry: Content and Format of Chemistry Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product, FDA (Jan. 1999), <https://www.fda.gov/media/73614/download>

²⁷ Moderna-BARDA Contract, pg. 29

²⁸ The unredacted contract does not define these terms.

²⁹ A WHO guide to good manufacturing practice (GMP) requirements Part 1: Standard operating procedures and master formulae, World Health Organization (Jan. 1997): pg. 106, <https://tinyurl.com/jbzi2bur>

³⁰ 21 CFR §211.186 Master production and control records.

³¹ WHO guide to GMP requirements, pg 104, <https://tinyurl.com/jbzi2bur>

³² 21 CFR §211.188 Batch production and control records.

Certain SOPs may be used to supplement product-specific master and batch production documentation.” (WHO) ³³

Finally, under the contract with BARDA, Moderna must submit to BARDA all raw data produced as part of the contract, and BARDA explicitly retains the right to share the data outside the government, consistent with the Federal Acquisition Regulations (FAR) unlimited data rights clause described below.

Figure 2: BARDA’s Ability to Share Data Package Submitted by Moderna³⁴

02.12	Final Data Submission Package	<p>Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.</p> <p>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	<p>Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.</p>
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³³ WHO guide to GMP requirements, pg 108, <https://tinyurl.com/jbzi2bur>

³⁴ The “non-proprietary format” of the submission package likely refers to the software format used to deliver the data.

BARDA'S RIGHTS TO SHARE THE RECIPE

The 2020 Contract allocates data rights based in part on the Federal Acquisition Regulations (FAR).³⁵ Under FAR, data is defined broadly to include “recorded information, regardless of form or the media on which it may be recorded” and includes “technical data.”³⁶

The government has significant authority over publicly funded data under the contract. **Article C.2.1 provides that “the government will obtain unlimited rights to data funded under this contract pursuant to FAR Clause 52.227-14.”** Under FAR, the government has unlimited rights in data first produced in the performance of the contract.³⁷ Read together, these two provisions suggest the government retains unlimited rights in data first produced by Moderna using contract funding. Unlimited rights allow the government “to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, [data] in any manner and for any purpose, and to have or permit others to do so.”³⁸

In contrast, the government has limited rights in data generated prior to entering into or outside the scope of the contract, and data developed at private expense (“Limited Rights

³⁵ FAR applies to civilian agencies. The Defense FAR Supplement (DFARS) applies to the Department of Defense.

³⁶ FAR 52.227-14 (“Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases.”)

³⁷ In addition, FAR generally allows the government to obtain rights in data delivered, but the contract appears to explicitly limit some of these rights. FAR (“The Government shall have unlimited rights in- (i) Data first produced in the performance of this contract; (ii) Form, fit, and function data delivered under this contract; (iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and (iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.”) FAR also allows the contractor to assert copyright on the data with 1) the prior express written permission of the Contracting Officer and 2) the grant of a “nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government.”

³⁸ FAR 52.227-14, (“*Unlimited rights* means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.”)

Data”).³⁹ First, Article C.2.1 also provides that “the data generated prior to entering into or outside the scope of the agreement will, when delivered to the USG, be considered to be limited rights data subject to the restrictions covered under FAR Clause 52.227-14 Alt II paragraph (g)(3).” This clause refers to data

that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

The contract thus purports to restrict the ability of the government under the contract to share information related to items, components, or processes developed at private expense, including minor modifications, outside the government or to use that information for manufacturing.⁴⁰

Second, the contract provides

Notwithstanding . . . any contrary provision in this contract, the following categories of information developed at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in FAR 52.227-14, Alternate II. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable.⁴¹

The categories of information developed at private expense are redacted. In the version of the contract published by Moderna with its financial statements, the company justifies redacting information generally because the information “would likely cause competitive harm to the company if disclosed.”⁴² The company, however, acknowledges that its contracts with the U.S. government “include provisions that reflect the government’s

³⁹ In addition to these two clauses that prohibit the use of certain information without the consent of Moderna, the contract contains a confidentiality of information clause: “Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization. . . Confidential information. . . shall not be disclosed without the prior written consent of the individual, institution, or organization.” Moderna-BARDA Contract, pg. 45.

⁴⁰ Moderna-BARDA Contract, pg. 48

⁴¹ Id., pg. 8. The government is also prohibited from reverse engineering or otherwise evaluating materials provided under the contract to reproduce the information contained in the categories without Moderna’s prior consent.

⁴² E.g., Table B.4.13, pg 6. <https://tinyurl.com/rf6zkm6>

substantial rights and remedies” and include the powers of the government to “claim rights, including IP rights, in products and data developed under such agreements.”⁴³ In the version of the contract posted by the U.S. Department of Health & Human Services, the government justifies the redaction based on Freedom of Information Act Exemption 4, which applies to “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”⁴⁴ This lack of transparency presents a significant challenge to assessing the precise scope of the government’s rights. Nonetheless, we describe below why the government appears to hold unlimited rights in critical vaccine manufacturing information.

⁴³ *Moderna Annual Report to US Securities and Exchange Commission, Moderna (Dec. 31, 2020): pg. 137-38, <https://investors.modernatx.com/node/11166/html> (“Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government’s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: terminate agreements, in whole or in part, for any reason or no reason; reduce or modify the government’s obligations under such agreements without the consent of the other party; claim rights, including IP rights, in products and data developed under such agreements.”)*

⁴⁴ 5 U.S.C. § 552(b)(4).

BARDA APPEARS TO HAVE THE ABILITY TO SHARE SIGNIFICANT UNLIMITED RIGHTS DATA, INCLUDING THE COMMERCIAL-SCALE RECIPE

“Preparing dinner for four is not like preparing dinner for 200.” The challenges in producing medicines at large-scale with new technology are “super challenging.” – Juan Andres, Moderna Chief Technical Operations and Quality Officer (2019).⁴⁵

What data first produced by Moderna using contract funding went beyond minor modifications of data developed at private expense? The U.S. Court of Appeals for the Federal Circuit has held that general rules of contract interpretation apply in cases where the U.S. is a party to the contract.⁴⁶ Contract interpretation “begins with the plain language of the agreement.”⁴⁷ The FAR data rights clause is incorporated in the contract, but courts have rarely interpreted the provision.⁴⁸ The contract also redacts key information.

We proceed in four subparts. First, we show that Moderna likely had not developed processes for scaling-up and scaling-out manufacturing at private expense prior to the contract. Second, we demonstrate that Moderna produced significant new data about these processes using contract funding. Third, we analyze how these contract-funded contributions went far beyond minor modifications. Finally, we conclude that BARDA appears to have the ability to share significant Unlimited Rights Data, including the commercial-scale recipe, under the contract.

Our analysis is limited by a lack of transparency. First, we do not know how Limited Rights Data were defined under the contract, or how they interact with Unlimited Rights Data. The answers could limit the reach of government rights under the contract. For example, if the government explicitly allowed Moderna to retain all manufacturing know-how as Limited Rights Data, then the government may only be able under the contract to share a subset of the data first produced by Moderna, such as the manufacturing process

⁴⁵ Industrializing New Platforms, International Society for Pharmaceutical Engineering (Nov-Dec 2019) (quoting Juan Andres), <https://ispe.org/pharmaceutical-engineering/november-december-2019/industrializing-new-platforms>

⁴⁶ *Scott Timber Co. v. United States*, 333 F.3d 1358, 1366 (Fed.Cir.2003).

⁴⁷ *Gould, Inc. v. United States*, 935 F.2d 1271, 1274 (Fed.Cir.1991).

⁴⁸ In *Ervin & Associates, Inc. v. US*, a contractor inputted and analyzed financial statements provided by the U.S. Department of Housing and Urban Development in an electronic database, and then challenged the government’s claim of unlimited rights in downloads of the data. As a matter of first impression, the U.S. Court of Federal Claims held that the data did not exist until the contractor performed under the contract, and thus, the data was first produced in the performance of the contract. *Ervin & Associates, Inc. v. United States*, 59 Fed. Cl. 267 (2004).

results and clinical trial data. While this data would certainly prove helpful for global vaccine manufacturers, it would likely be insufficient on its own to spur additional production in the short term. (In Part Four, we describe how the government can supplement this data by sharing Limited Rights Data using other legal authorities.) Moreover, we do not fully know the scope of the contract. Many contract activities are redacted. In addition, the 2020 Contract contains a provision for pre-award costs, meaning that Moderna was funded for work done before the agreement was finalized. It is not clear if these costs are only the cost of activities that took place between the announcement of the BARDA-Moderna collaboration (March 30) and the signing of the award (April 16) or if it extends further. Earlier BARDA funding could potentially extend the reach of government rights.

1. Moderna Likely Had Not Developed Processes for Scaling-up and Scaling-out Manufacturing at Private Expense Prior to the Contract.

Under the 2020 Contract, the government retains *unlimited* rights to data first produced by Moderna using contract funding, and *limited* rights to data developed at private expense, including minor modifications. While the FAR does not define “development,” an analogous set of regulations, the Defense FAR Supplement (DFARS), is more instructive.⁴⁹ Under DFARS, data rights are allocated based on when the item, component, or process *pertaining to the data* is developed: “Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced.”⁵⁰

How these terms were negotiated and how the categories of information developed at private expense were defined in the contract will shape the precise contours of the legal analysis. **A full analysis would become possible only with the entire unredacted version of the contract and access to the underlying data produced by Moderna. We**

⁴⁹ W. Jay DeVecchio, Taking the Mystery out of Data Rights, Reuters Briefing Papers (July 2018) Issue 18-8: pg 3, <https://media2.mofo.com/documents/180700-mystery-data-rights.pdf>. (“Although the FAR does not define “development,” there is no reason to doubt that the DOD’s concepts, long accepted, would be applied to an issue under the FAR.”)

⁵⁰ 48 CFR § 252.227-7013 Rights in technical data – Noncommercial Items. (“Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. To be considered “developed,” the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.”) 48 CFR § 27.401 Definitions. The FAR regulations also define the private expense in relation to the item, component or process. Limited rights data for example “means data . . . that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.”

currently lack this information. Nonetheless, we can draw important insights from publicly available information to help inform a high-level analysis.

Based on publicly available information, it is likely that critical parts of the vaccine recipe had not been developed prior to the contract. At the time of the BARDA award, Moderna was a biotechnology company with limited experience. Moderna had spent only three months working on mRNA-1273, and the National Institutes of Health was still enrolling participants in the Phase I trial.⁵¹ Moderna did not even have its own Investigational New Drug Application—a foundational building block of drug development.⁵² Moderna previously said it had the capability to produce mRNA at a 75 gram scale—enough for hundreds of thousands of doses—but in 2019 the company reported producing fewer than 100,000 mRNA doses for all products.⁵³ In 2020, the company warned investors that it had “limited experience manufacturing any of our vaccine candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales.”⁵⁴

We have identified two processes that likely had not been developed when Moderna entered the contract: the manufacturing scale-up that would allow Moderna to produce vaccines in larger volume equipment, and the manufacturing scale-out that would allow Moderna to expand production to additional production sites. **We use these processes to guide our analysis, but the U.S. government should confirm whether the parties**

⁵¹ Moderna Announces Award from U.S. Government Agency BARDA for up to \$483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus, Moderna Press Release (Apr. 16, 2020), <https://tinyurl.com/btjhkvbr>

⁵² Moderna Announces IND Submitted to U.S. FDA for Phase 2 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus, Moderna Press Release (Apr. 27, 2020), <https://tinyurl.com/cb6raa8> (“An open-label Phase 1 study of mRNA-1273 is being conducted by the National Institute of Allergy and Infectious Diseases under its own Investigational New Drug (IND) application.”)

⁵³ It is unclear whether this 75g capability met cGMP requirements, whether it extended to producing the mRNA itself or the formulated mRNA-LNP product, and whether it had already been achieved or was going to be done “post-2020” as one of the slides indicates. Moderna, Manufacturing & Digital Day (Mar. 4 2020), <https://investors.modernatx.com/static-files/723d73cc-97c0-4c93-ae59-ebfc7368bf90>. Moderna CEO Stephane Bancel Presents at Goldman Sachs’ 42nd Annual Healthcare Conference Transcript, Seeking Alpha (Jun. 9, 2021), <https://tinyurl.com/52r3t7s4> (“The volumes increase are incredible to give you another magnitude in 2019, Moderna as a company across all of our products, we made less than 100,000 dose for that year.”)

⁵⁴ Moderna Quarterly Report to US Securities and Exchange Commission, Moderna (Sep. 30, 2020): pg. 67, <https://investors.modernatx.com/node/10211/html> (“Completion of our clinical trials and commercialization of our vaccine candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our vaccine candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales.”)

explicitly defined items, components, or processes developed under the contract and how they categorized the types of Limited Rights Data.⁵⁵

First, Moderna had not yet developed a scaled-up manufacturing process by April. In January 2020, mRNA-1273 manufacturing was based on a small-scale process using Moderna’s personalized vaccine unit (PVU). The PVU supplied clinical trial doses for Phase I.⁵⁶ But much more was needed to produce millions of doses, let alone hundreds of millions. On March 19, Moderna began Phase II manufacturing—moving onto the next stage beyond the small-scale PVU process.⁵⁷ According to a company timeline, Moderna “started scale-up activities” on Saturday, March 28.⁵⁸ Two days later, on Monday, March 30, BARDA announced it would support Moderna’s manufacturing.⁵⁹ This helps explain why the contract contains work streams for process *development* for late-stage clinical supply and process *development* for full commercial scale. Indeed, Moderna reported in its financial statements that it had “not manufactured mRNA medicines at commercial scale” and that it “may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply.”⁶⁰ For all these reasons, the scaled-up manufacturing process—in particular, the commercial-scale process—had not been practiced and, hence, had not been developed prior to the contract.⁶¹

⁵⁵ The contract may have defined the data, item, components and processes in a different way, resulting in a different analysis, but likely reaching similar conclusions given the extensive role of the federal government, and Moderna’s lack of prior experience in manufacturing at scale.

⁵⁶ Moderna Inc Corporate Analyst Meeting Edited Transcript, Thomson Reuters Streetevents (Apr. 14, 2020): pg. 43, <https://tinyurl.com/p579rjte> (“We used the personalized vaccine unit in order to manufacture the first clinical batch that we are testing at this moment in time in Phase I” – Juan Andres, Moderna Chief Technical Operations & Quality Officer.)

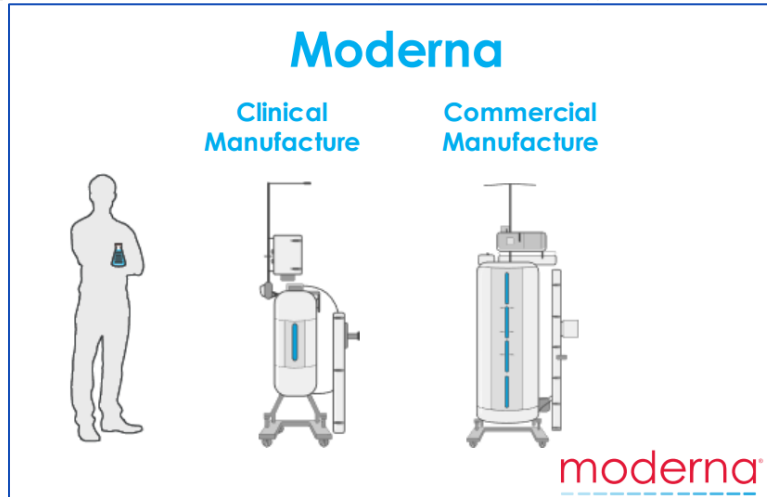
⁵⁷ Moderna First Vaccines Day Presentation (Apr. 14, 2020): Slide 217, <https://tinyurl.com/uue56bv6>. Moderna Inc Award from U.S. Government Agency BARDA to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus Edited Transcript, Thomson Reuters Streetevents (Apr. 17, 2020): pg. 6, <https://tinyurl.com/2s44fha3> (“So what we are doing is scaling up the process in addition to producing in parallel for the clinic. The scale-up that we are going to be completing, the first stage, we have already done, which is beyond what we did for Phase I. So we are going to that one, and that one is in the pocket. The next one is what we're going to be doing in the next few months with this grant.” - Stephane Bancel, Moderna CEO)

⁵⁸ Moderna Apr. 14, 2020, Presentation: Slide 217. See note 56.

⁵⁹ HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines, HHS Press Release (Mar. 30, 2020), <https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccines.html>

⁶⁰ Moderna Quarterly Report to US Securities and Exchange Commission, Moderna (Jun. 30, 2020): pg. 82, <https://investors.modernatx.com/node/9646/html>

⁶¹ There is some ambiguity about whether even the pilot scale clinical manufacturing process had been fully developed prior to BARDA funding. While Moderna said it had moved onto the next stage of manufacturing beyond the personalized vaccine unit, the contract specifically notes that “Moderna *intends to rapidly develop* a robust process for clinical manufacturing and process performance qualification. . .” (emphasis added).⁶¹ For clarity, we focus on commercial-scale manufacturing but we note the rights may extend further.

Figure 3: Excerpt from Moderna 2020 R&D Day Slide Illustrating Differences Between Scales⁶²

Second, Moderna also likely had not yet developed the scale-out and technology transfer process required to expand production to additional facilities by April. The partnership with Lonza to transfer technology and scale manufacturing was only announced on May 1.⁶³ Technology transfer was expected to begin in June.⁶⁴ Moderna may have had plans for scaling-out before entering into the 2020 Contract, but it is unlikely the process existed or was practiced before then.

Taken together, while there is some uncertainty about how particular categories of information were defined under the agreement, the processes for scaling-up and scaling-out manufacturing had likely not been developed at private expense prior to the contract.

(Although we limit our analysis to manufacturing information, we note the clinical trial data clearly did not exist. Sharing this data would help promote open science, maximize the knowledge gained from publicly funded clinical research, and remove a potential production barrier if “data exclusivity” threatens to block regulatory approval of follow-on products in the future or if bridging studies are required.)

2. Moderna Likely First Produced Significant Data About the Scaling-up and Scaling-out Processes Using the 2020 Contract Funding.

⁶² Annual R&D Day Presentation, Moderna (Sep. 17, 2020), <https://tinyurl.com/aw3m2mve>

⁶³ Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna’s Vaccine (mRNA-1273) Against Novel Coronavirus, Moderna Press Release (May 1, 2020), <https://tinyurl.com/2jttdbnh> (Partnership announced May 1)

⁶⁴ Id.

The 2020 Contract covered an extraordinarily broad scope of activities. **“For the purposes of this contract, Moderna will perform all work required to support the advanced development, scale-up manufacturing and FDA licensure of their lead SARS-CoV-2 vaccine candidate(s).”**⁶⁵ (emphasis added) Planned activities funded by BARDA include:

- Nonclinical work, including toxicology and animal studies;
- Clinical work, including Phase 2 and Phase 3 studies;
- Regulatory submissions, including preparing and filling an Investigational New Drug Application and a Biologics License Application; and
- Chemistry, manufacturing, and controls (CMC), including mRNA process development for late-stage clinical supply and full commercial scale; potency assay development and implementation; analytical method development and validation; characterization assay development and implementation.

The collaboration was extensive. Moderna was required to work “in close collaboration with BARDA” to draft a “comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA.”⁶⁶ Upon request, Moderna had to provide a host of technical manufacturing documents and, if edits were recommended, then Moderna had to address in writing concerns raised by BARDA.⁶⁷ Moderna used contract funding to generate significant new data about processes for scaling-up and scaling-out.

In terms of scaling-up, when the contract became public on April 16, Moderna said it had completed only “the first stage” of the scale-up beyond the personalized vaccine unit.⁶⁸ “The next [stage] is what we’re going to be doing in the next few months with this grant. And that will define the scale, which we will replicate in a number of different places as we install the capacity.”⁶⁹ As such, the 2020 Contract funded “process development for late-stage clinical supply” and “process development for full commercial scale.”⁷⁰

⁶⁵ See also “The project will entail pre-clinical and Phase 2 and Phase 3 clinical studies sufficient to demonstrate the safety and efficacy of the proposed vaccine(s); CMC development, scale-up, scale-out and validation of manufacturing capacities, including bulk drug substance and fill and finished drug product, with a capacity of 100 million doses by 2021 and all program management and regulatory activities necessary to achieve FDA licensure of the vaccine.” Moderna-BARDA Contract, pg. 4.

⁶⁶ Moderna-BARDA Contract, pg. 12

⁶⁷ Moderna-BARDA Contract, pg. 29

⁶⁸ See Andres and Bancel quotes from notes 56 and 57.

⁶⁹ Moderna BARDA Award Meeting Edited Transcript, pg. 6.

⁷⁰ Moderna-BARDA Contract, pg. 13 (“Process Development for Late Stage Clinical Supply”)

Table 3: Estimated mRNA-1273 Production Requirements⁷¹

Stage	Participants ⁷²	Doses ⁷³	mRNA Requirement
Phase 1 Trial ⁷⁴	15 (25 µg)	30 (25 µg)	11,250 µg
	15 (100 µg)	30 (100 µg)	(11.25 mg)
	15 (250 µg)	30 (250 µg)	
Phase 2 Trial ⁷⁵	200 (50 µg)	400 (50 µg)	60,000 µg
	200 (100 µg)	400 (100 µg)	(60 mg)
Phase 3 Trial ⁷⁶	15,210 (100 µg)	30,420 (100 µg)	3,042,000 µg (3.04 g)
Commercial Scale ⁷⁷	N/A	219 million (100 µg)	21,900,000,000 µg (21.9 kg)

In terms of scaling-out, Moderna also built at least some additional capacity and transferred technology for mRNA-1273 using contract funding.⁷⁸ In May, the government exercised an option in the 2020 Contract “to enable a second node of domestic mRNA-1273 supply at Lonza’s New Hampshire facility.”⁷⁹ The option would cover all “Kit Build-Out activities” for the facility. (The kit likely refers to the Moderna-Lonza manufacturing kit, each of which was estimated to produce 100 million doses of mRNA-1273 per year.⁸⁰) Indeed, when discussing the Moderna and Lonza collaboration, one executive noted that

⁷¹ For simplicity, we assume perfect efficiency in the production process. The real requirements are likely higher. We also do not know the amount of mRNA-1273 NIH and Moderna used for preclinical work, quality control, and stability studies.

⁷² Excluding participants who received placebo (Phase 2 and Phase 3).

⁷³ A course of mRNA-1273 requires two doses.

⁷⁴ These are estimates for initial trial design. The results were announced May 18—after the BARDA grant—and the Phase 1 study was later amended. Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (May 18 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine>; Lisa Jackson et al., An mRNA Vaccine against SARS-CoV-2 — Preliminary Report, 383 NEJM (2020), <https://www.nejm.org/doi/full/10.1056/nejmoa2022483> (“On the basis of the results obtained in patients at these dose levels, additional groups were added to the protocol”).

⁷⁵ Laurence Chau et al., A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine, 39 Vaccine 20 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7871769/>

⁷⁶ Lindsey Baden et al., Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine, 384 NEJM (2021), <https://www.nejm.org/doi/full/10.1056/nejmoa2035389>

⁷⁷ Global Commission for Post-Pandemic Policy, Covid-19 Vaccine Production to June 30th, <https://globalcommissionforpostpandemicpolicy.org/covid-19-vaccine-production-to-june-30th-2021/>

⁷⁸ While Moderna did raise and invest its own money in building additional capacity, some of the earliest work was likely funded by BARDA, since it helped enable the second node of domestic supply at Lonza. Moderna, Prospectus, <https://investors.modernatx.com/node/9031/html> (May 18, 2020); Moderna-BARDA Contract, Amendment No. 1 (May 24, 2020), pg.3, <https://investors.modernatx.com/node/10211/html>

⁷⁹ Moderna Quarterly Report to US Securities and Exchange Commission, Moderna (Sep. 30, 2020), <https://investors.modernatx.com/node/10211/html>

⁸⁰ Rick Mullin, “Pfizer, Moderna ready vaccine manufacturing networks”, C&EN (Nov. 25, 2020), <https://cen.acs.org/business/outsourcing/Pfizer-Moderna-ready-vaccine-manufacturing/98/i46>

he “would be remiss not to mention BARDA's role in [technology transfer]. The BARDA award is allowing for us to move as quickly as we are with scale-up, both internally and with Lonza.”⁸¹

Both scaling-up and scaling-out surely resulted in significant new data. Indeed, the contract identifies a number of documents as “contract funded” (Table 4).

Table 4: Description of Select Documents Funded by the 2020 Contract

Document	Standard Description ⁸²
Assay Qualification Plan/Report Assay Validation Plan/Report Assay Technology Transfer Report	Documents that describe how analytical methods were shown to be suitable for their intended purpose and transferred to different sites. ⁸³
Batch Records	<p>“All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.” (WHO)⁸⁴</p> <p>Batch records should include “an accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed.” (FDA)⁸⁵</p>
Certificate of Analysis	Document that includes “the established specifications and specific results for each quality control test performed on the final drug product lot.” (FDA) ⁸⁶
Master Production Records (Master Formula)	<p>“A document or set of documents specifying the starting materials with their quantities and the packaging, materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.” (WHO)⁸⁷</p> <p>Master production records should include “complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.” (FDA)⁸⁸</p>

⁸¹ Q1 2020 Moderna Inc Earnings Call Edited Transcript, Thomson Reuters StreetEvents (May 7, 2020): pg. 5, <https://investors.modernatx.com/static-files/58002d52-da4d-4c9d-a884-be700224a15c>

⁸² The unredacted contract does not define these terms.

⁸³ Analytical Procedures and Methods Validation for Drugs and Biologics, FDA (Jul. 2015), <https://www.fda.gov/media/87801/download>

⁸⁴ A WHO guide to GMP requirements, pg. 104, <https://tinyurl.com/jbzi2bur>

⁸⁵ 21 CFR §211.188 Batch production and control records.

⁸⁶ Moderna COVID-19 Vaccine EUA Letter of Authorization, FDA (Jul. 7, 2020): pg. 7, <https://www.fda.gov/media/144636/download>

⁸⁷ A WHO guide to GMP requirements, pg. 106, <https://tinyurl.com/jbzi2bur>

⁸⁸ 21 CFR §211.186 Master production and control records.

Process Development Reports	Documents that describe the experiments and results associated with process development. ⁸⁹
Standard Operating Procedures (SOPs)	"An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation." (WHO) ⁹⁰

For example, master production records contain the manufacturing template for producing the vaccine. Moderna likely first created master production records for the commercial-scale manufacturing process using the contract funding, generating significant new information. Similarly, batch records contain step-by-step manufacturing instructions—and a verification that those steps were followed—for production of specific batches of vaccine.⁹¹ Moderna likely produced many new batches, and hence batch records, under the 2020 Contract for the new process, generating significant information.⁹² Finally, the Assay Technology Transfer report likely contains information about how the process was scaled-out. Moderna thus very likely first produced significant data about scaling-up and scaling-out using the 2020 Contract funding.

3. The 2020 Contract-Funded Contributions Went Far Beyond Minor Modifications.

Moderna went from producing fewer than 100,000 doses across all products in 2019 to producing 1.3 million coronavirus vaccine doses *per batch* in January 2020.⁹³ Although Moderna clearly produced a significant amount of new clinical and manufacturing data under the 2020 Contract, the company nonetheless might characterize the changes as minor modifications and, as such, subject to limited rights. After all, Moderna had spent a decade working on mRNA technology and invested in small-scale processes for making mRNA vaccines. Additionally, the government itself seemingly acknowledged the

⁸⁹ See e.g. BARDA contract with BioCryst:

https://www.sec.gov/Archives/edgar/data/882796/000117184316011576/exh_102.htm

⁹⁰ A WHO guide to GMP requirements, pg. 108, <https://tinyurl.com/jbzj2bur>

⁹¹ 21 CFR 211.188 Batch production and control records.

⁹² Vaccine manufacturing was included as a workstream under the contract.

⁹³ Moderna, Inc. (MRNA) CEO Stephane Bancel Presents at Goldman Sachs' 42nd Annual Healthcare Conference Transcript, Seeking Alpha (Jun. 9, 2021), <https://tinyurl.com/52r3t7s4> ("The volumes increase are incredible to give you another magnitude in 2019, Moderna as a company across all of our products, we made less than 100,000 dose for that year.") Statement on California Department of Public Health (CDPH) Report, Moderna Press Release (Jan. 20, 2021), <https://tinyurl.com/ycnk9cwa>. ("Moderna confirmed that a total of 1,272,200 doses were produced in batch number 041L20A")

existence of “proprietary”—apparently Moderna-owned—data in the contract. For example, in requesting technical documents, the government retained the ability to request “non-proprietary” versions of those documents for distribution within the government.

Neither the public text of the contract nor the FAR data rights clause defines “minor modification.” But federal procurement policy tends to weigh the relative contribution of public and private funding in allocating rights.⁹⁴ A minor modification to a process would thus represent a small relative financial contribution by the federal government to the existing processes.

While a lack of transparency precludes a detailed analysis, we believe the scaled-up and scaled-out processes likely go far beyond a minor modification to small-scale processes based on the significant investment of the federal government. First, given the early intervention of the federal government and other foundations, Moderna likely made only modest investments in the manufacturing process for mRNA-1273 itself prior to entering into the contract.⁹⁵ Second, while Moderna has spent millions of dollars developing platform capabilities, the federal government’s initial investment on clinical development and manufacturing scale-up for mRNA-1273 (\$430 million) was more than double what Moderna reported spending on platform research—including mRNA science, delivery science, and manufacturing process design, and technical development and unallocated manufacturing expenses—in the year before (\$176 million).⁹⁶ The BARDA award was thus a significant sum. For these reasons, the contract-funded manufacturing scale-up and scale-out processes likely went beyond a minor modification.

This conclusion is consistent with the risk incurred by the federal government. Moderna itself acknowledged in financial statements the general challenges associated with manufacturing scale-up: “CMC activities for a new class of medicines such as mRNA require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing have occurred and may continue to occur.”⁹⁷ While not specifically naming a company candidate, a senior Operation Warp Speed official also acknowledged that “The biology

⁹⁴ 41 USC 2302: Rights in technical data. (“(d) Factors To Be Considered in Prescribing Regulations. — The following factors shall be considered in prescribing regulations under subsection (a): (1) Whether the item or process to which the technical data pertains was developed — (A) exclusively with Federal funds; (B) exclusively at private expense; or (C) in part with Federal funds and in part at private expense.”)

⁹⁵ Moderna repurposed the personalized vaccine unit used in cancer vaccines. CEPI funded the manufacturing of Phase I trial material.

⁹⁶ *Moderna Annual Report to US Securities and Exchange Commission (10-K), Moderna (Feb. 26, 2021)*, <https://investors.modernatx.com/node/11166/html>

⁹⁷ *Id.*, pg. 62.

of scaling manufacturing is a very temperamental activity, and there were many, many different attempts over the months until we cracked it.”⁹⁸ The code that was “cracked” using government dollars should be subject to unlimited rights.

4. BARDA Appears to Have the Ability to Share Significant Unlimited Rights Data, Including the Commercial-Scale Recipe.

Under the 2020 Contract, the government retains unlimited rights to data first produced by Moderna using contract funding, and has limited rights to data developed at private expense, including minor modifications. Those categories are redacted, restricting our ability to precisely assess the scope of government rights.

Nonetheless, based on public information, we can develop a high-level analysis: Since the data Moderna first produced about the processes for scaling-up and scaling-out manufacturing using contract funding went beyond minor modifications of data developed at private expense, BARDA appears to have unlimited rights. Unlimited rights allow the government “to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.”⁹⁹ BARDA thus appears to have the ability to share new information about the processes for scaling-up and scaling-out manufacturing. In particular, since the master production records likely had to be newly written (i.e., data was first produced) for the commercial-scale process using contract funding, BARDA would seem free to share the commercial-scale vaccine recipe.

This data could help manufacturers around the world ramp up production. It could also answer important questions about mRNA vaccine production, including but not limited to:

- What is the scale of commercial production? What equipment, materials, and in-process controls are used? What is the design of the facilities? What are the labor requirements?
- What are the differences between the small-scale process and the commercial-scale process? What results did these changes produce?
- How can mRNA companies mix the mRNA and lipids to formulate a lipid nanoparticle at scale?
- How is the process controlled to reduce variability and assure product quality?

⁹⁸ Katie Thomas, “The Vaccines Will Probably Work. Making them Fast Will Be the Hard Part.”, NYT (Nov. 17, 2020), <https://www.nytimes.com/2020/11/17/health/coronavirus-vaccine-operation-warp-speed.html>

⁹⁹ FAR 52.227-14 <https://www.acquisition.gov/far/52.227-14>

- What analytical methods are required and how are these analytical methods used throughout the process to assess the quality of process intermediates and of the finished product?
- What specifications should mRNA companies aim to meet when producing at scale?

Finally, this data could advance mRNA science by allowing scientists to rapidly build on existing research.

SHARING THE REST OF THE RECIPE

What if the federal government does not maintain unlimited rights under this contract to some parts of the vaccine recipe? For example, the government may have broadly conceded during contract negotiations that certain important data had been developed by Moderna at private expense and were Limited Rights Data. If the government's ability to share some of the information under the contract is limited, the government should clarify these restrictions for the public.

Even if key information is Limited Rights Data, the government nonetheless has other legal authority to share this information. Where necessary, the government should use these other authorities, including the Defense Production Act, to share Limited Rights Data in exchange for reasonable compensation to Moderna.

At least four tools may be available.

First, the government may have additional data rights beyond the 2020 Contract. This contract is only one among several major federal government agreements with Moderna. The federal government first invested in Moderna when the company had three employees.¹⁰⁰ Moderna entered into additional agreements with the U.S. Department of Defense in 2013; the National Institutes of Health in 2016; and BARDA for a Zika vaccine in 2016.¹⁰¹ Those contracts may contain additional useful rights in the underlying platform. Moderna, for example, has acknowledged that it used the same mRNA technology and lipid technology in both the Zika vaccine and the coronavirus vaccine, mRNA-1273.¹⁰²

¹⁰⁰ Regina Dugan, How DARPA seeded the ground for a rapid COVID-19 cure, Interview with Yahoo Finance (Dec. 17, 2020), <https://finance.yahoo.com/video/darpa-seeded-ground-rapid-covid-214655580.html>

¹⁰¹ mRNA Strategic Collaborators: Government Organizations, Moderna, <https://tinyurl.com/j7m96a42>. Arthur Allen, Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines, Kaiser Health News (Nov. 18, 2020), <https://tinyurl.com/wbd6s83y>

¹⁰² Moderna, Inc. (MRNA) Presents at BMO Growth and ESG Conference Call Transcript, Seeking Alpha (Dec. 9, 2020). CEO Stephane Bancel Presents at Goldman Sachs' 42nd Annual Healthcare Conference Transcript, Seeking Alpha (Jun. 9, 2021), <https://tinyurl.com/52r3t7s4> ("What's important to note here, and I'll remind everyone, because I know that we did probably mention this earlier, but the technologies, the mRNA technologies and the lipid nanoparticle technologies that are used in all of those vaccines that I just mentioned, are exactly the same as that that's being used in our mRNA-1273 COVID-19 vaccine." – Lavina Talukdar, Moderna Senior VP)

Table 5: Direct Federal R&D Support to Moderna

Government Agency	Award Year	Project Scope	Amount
Defense Advanced Research Projects Agency (DARPA)	2013	Development of mRNA platform ¹⁰³	\$25 million
	2020	Development of a mobile manufacturing prototype ¹⁰⁴	\$56 million
Biomedical Advanced Research and Development Authority (BARDA)	2016	Development and large-scale manufacturing of Zika vaccine ¹⁰⁵	\$117 million
	2020	Development and large-scale manufacturing of mRNA-1273.	\$1.4 billion
National Institutes of Health (NIH)	2016	Vaccine research and development for infectious diseases. ¹⁰⁶ NIH helped run clinical trials for mRNA-1273. ¹⁰⁷	N/A; Collaboration with federal scientists.

Second, the government also holds a patent as leverage to require information sharing. As Public Citizen has previously described, the National Institutes of Health spent years working on coronaviruses, eventually obtaining U.S. Patent No. 10,960,070, which claimed a technology used to stabilize coronavirus spike proteins in their prefusion conformation.¹⁰⁸ Moderna uses this spike protein technology in mRNA-1273. However, Moderna does not have a license to use the technology.¹⁰⁹ Scholars at New York University estimate that the government could demand over a billion dollars in compensation from Moderna based on its 2021 U.S. sales projections alone.¹¹⁰ That gives significant leverage.

Third, the government could draw on the president's authority under the Defense Production Act.¹¹¹ The law contains several provisions to promote the national defense.

¹⁰³ mRNA Strategic Collaborators: Government Organizations, Moderna, <https://tinyurl.com/j7m96a42>

¹⁰⁴ DARPA Awards Moderna up to \$56 Million to Enable Small-Scale, Rapid Mobile Manufacturing of Nucleic Acid Vaccines and Therapeutics, Moderna Press Release (Oct. 8, 2020), <https://tinyurl.com/yeshjv6j>

¹⁰⁵ mRNA Strategic Collaborators: Government Organizations, Moderna, <https://tinyurl.com/j7m96a42>

¹⁰⁶ NIH-Moderna Confidential Cooperative Research and Development Agreement No. 2016-0005, Provided by Bob Herman from Axios (Aug. 2016), <https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html>

¹⁰⁷ Statement from NIH and BARDA on the FDA Emergency Use Authorization of the Moderna COVID-19 Vaccine, NIH Press Release (Dec. 18, 2020), <https://tinyurl.com/u8hu96fr>

¹⁰⁸ Zain Rizvi, Leading COVID-19 Vaccine Candidates Depend on NIH Technology (Nov 10, 2020), <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/>

¹⁰⁹ Selam Gebrekidan and Matt Apuzzo, Rich Countries Signed Away a Chance to vaccinate the World, NYT (Mar. 21, 2021), <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>

¹¹⁰ Christopher Morten et al, "U.S. 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent", NYU Law Technology Law & Policy Clinic (Apr. 14, 2021), <https://tinyurl.com/4rhfvu96>

¹¹¹ Zain Rizvi, Jishian Ravinthiran, Amy Kapczynski, Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide, Health Affairs Blog (August 6, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210804.101816/full/>

Given the threat posed by emerging variants due to uncontrolled spread of the virus, the president could require Moderna to share technology to expand vaccine production under the DPA. Specifically, Title I of the DPA allows the president to require corporations to prioritize and accept contracts. The government could use the authority to require Moderna to accept contracts for technology transfer. And the DPA allows the president to allocate “materials, services, and facilities.” The Act defines “materials” to include “commodities,” “products,” “articles,” and “products,” and, crucially, “any technical information or services ancillary to the use of any such materials.” Vaccine know-how would clearly constitute such technical information. The DPA also contains a broad information disclosure authority that the president could use to require sharing.¹¹²

Fourth, the government could share the manufacturing data that it has on file. Federal agencies have sweeping power to share information within their possession.¹¹³ Sharing the data obtained under the contract could give rise to a legal challenge, but these need not necessarily stop the governmental action.¹¹⁴ Although trade secrets may be protected under the Fifth Amendment,¹¹⁵ a takings claim against the government would not prevent data sharing, notwithstanding BARDA’s explicit assurance in the contract that certain data would be treated as confidential.¹¹⁶ Rather, the government could pursue this course of action so long did so for a public use and provided “just compensation.”¹¹⁷ In this case, sharing the recipe could help expand vaccine production and protect public health,

¹¹² Zain Rizvi and Peter Maybarduk, *A Plan for the People’s Vaccine*, Public Citizen (Dec. 8, 2020).

¹¹³ Christopher Morten, *Publicizing Corporate Secrets for Public Good* (unpublished, on file). 5 U.S.C. § 301.

¹¹⁴ David Vogel, *Government Agencies Can Misuse Your Trade Secret and You Can't Stop Them*, *Public Contract Law Journal* (1999) (“If the Government’s use of a trade secret is a taking for public use under the Fifth Amendment, then injunctive relief should never be available, even if the use also violates the [Trade Secrets Act] and the [Economic Espionage Act].”)

¹¹⁵ The Takings Clause of the Fifth Amendment prohibits the government from taking private property for public use, without just compensation. U.S. Constitution, amend. V. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (“We therefore hold that to the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment.”)

¹¹⁶ *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (U.S. 1984) (holding that a federal agency releasing trade secrets could constitute a taking because it interfered with reasonable investment-backed expectation that the data would be not disclosed). In addition to the limited rights clause that prohibits use of certain information without the consent of Moderna, the Moderna-BARDA contract contains a confidentiality of information clause: “Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization. . . Confidential information. . . shall not be disclosed without the prior written consent of the individual, institution, or organization.”) pg. 45

¹¹⁷ *Knick v. Tp. of Scott, Penn.*, 139 S. Ct. 2162, 2179 (2019) (“As long as just compensation remedies are available . . . injunctive relief will be foreclosed.”). *See John Echeverria, Eschewing Anticipatory Remedies for Takings*, 128 *HARV. L. REV. F.* 202 (“The Supreme Court has repeatedly stated that the Takings Clause “is designed not to limit the governmental interference with property rights per se, but rather to secure compensation in the event of . . . a taking.”).

satisfying the public use criteria. With appropriate disclosure around research and development costs, the government could provide reasonable and just compensation to Moderna, accounting for the full extent of risk-adjusted federal investments. In this way, the government could ensure that knowledge needed to end the pandemic quickly is not kept secret.

CONCLUSION

How did a decade-old corporation that had never before sold a vaccine develop a new product targeting a novel virus within 12 months and mass produce 200 million doses? The answer lies partly in the support of the U.S. government. The National Institutes of Health jointly invented mRNA-1273. BARDA helped shepherd its development and manufacturing. The U.S. government now has the singular ability to help others benefit from this publicly funded work.

There is enormous interest in ramping up global mRNA vaccine production. Indeed, according to the World Health Organization, 19 manufacturers from more than a dozen countries in Africa, Asia, and Latin America have expressed interest in scaling mRNA vaccine production.¹¹⁸ As part of a \$25 billion global manufacturing program, the Biden administration should release the data it holds to advance mRNA science and bolster global mRNA vaccine production. A pandemic is no time for secrets.

¹¹⁸ World Health Organization, 6th Access to COVID-19 Tools (ACT) Accelerator Facilitation Council meeting (May 12, 2021): 45:23-45:51, <https://tinyurl.com/wephf47>



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