VACCINE CONTRACTS IN THE CONTEXT OF PANDEMICS AND EPIDEMICS

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This article explores the contractual architecture of vaccine contracts, as well as the allocation of resulting vaccines in preparation for, and in response to, pandemics and large-scale epidemics. Drawing on contracts predominantly related to COVID-19 vaccines collected through publicly available databases, the work begins by providing an overview of the relationships between the parties entering into these agreements, the bargaining processes adopted, their timeline relative to market demand for vaccines, and the substantive obligations imposed by these contracts.

The essay then briefly considers the effects of this contractual architecture on the manufacturing and distribution of vaccines across the globe, highlighting allocative disparities in access to vaccines between populations in the Global North and the Global South.

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I. Introduction

This article provides an overview of the contractual architecture of vaccine contracts used during pandemics and large-scale epidemics. The goal of this work is to outline the main features of vaccine contracts[1] used during pandemics and epidemics, as well as to provide some representative contractual language to illustrate current contractual approaches to the development, manufacturing, and allocation of vaccine-related technology.[2] The sources used in this project were pub-

1. As noted in Part II.C.1, the expression "vaccine contracts" may refer to three different types of contracts: those that fund and/or regulate vaccine R&D, those that fund/or regulate vaccine manufacturing, and those that place a purchase order for vaccine doses. Some contracts combine two or all of these dimensions. *See infra* notes 69–74 and accompanying text (providing examples of vaccine contracts). When providing examples or referring to excerpted language, the essay specifies the type of contract being used.

2. This author uses the expression "vaccine technology" across her work to encompass both vaccines as finished products and each of the individual components thereof (e.g., active ingredients, adjuvants, stabilizers). *See generally* Ana Santos Rutschman, Vaccines as Technology: Innovation, Barriers, and the Public Health [hereinafter Vaccines as Technology] (Cambridge University Press, 2022) (describing the different types of components and processes involved in the development and production of

licly available contracts, or excerpts thereof, related to COVID-19 vaccines. In addition to contractual provisions, the project also looked at policies from selected major funders of vaccine research and development (R&D), particularly in the context of pandemic and epidemic diseases. This article then categorized the findings by developing existing taxonomies in technology transfer and biotech law.

The sources were collected in the following databases: "Comparison of US COVID-19 Contracts,"[3] compiled by Knowledge Ecology International (KEI);[4] the "Master Alliance Provisions Guide: COVID-19 Contracts,"[5] compiled by the Global Health Innovation Alliance Accelerator (GHIAA);[6] and

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vaccines, as well as the varying types of laws applicable to discrete vaccine components and to vaccines as a whole).

3. *See Comparison of US COVID-19 Contracts*, KNOWLEDGE ECOLOGY INTERNATIONAL [hereinafter KEI Database], https://docs.google.com/spreadsheets/d/16QIr3flPfxHX0XQWTblRmYTXiUY7m3DSEy8rHUlIic0/edit#gid=0 [https://perma.cc/EB6Z-ZAY9] (compiling COVID-19 contacts) (last visited Nov. 6, 2022). KEI obtained these copies of selected COVID-19 vaccine contracts via requests submitted pursuant to the Freedom of Information Act (FOIA), files made available by the Department of Health and Human Services as part of the HHS Reading Room. and analysis of filings with the Securities & Exchange Commission. *COVID-19 Contracts*, KNOWLEDGE ECOLOGY INTERNATIONAL, https://www.keionline.org/covid-contracts [https://perma.cc/LKJ8-CK9C] (last visited February 4, 2023).

4. *See Knowledge Ecology International*, KNOWLEDGE ECOLOGY INTERNATIONAL, https://www.keionline.org/about [https://perma.cc/SHF6-5NV6] (providing background information about KEI) (last visited Nov. 6, 2022). KEI defines itself as a "not-for-profit, non-governmental organization" focused on issues related to "management of knowledge resources" and motivated by "social justice" goals. *Id.*

5. *See Alliance Provisions Guide (MAPGuide): COVID-19*, GLOBAL HEALTH INNOVATION ALLIANCE ACCELERATOR, *Master* [hereinafter GHIAA Database] https://ghiaa.org/mapguide-home/search-results/?qs=Covid+19 [https://perma.cc/SM4B-CQBD] (compiling COVID-19 contracts) (last visited Nov. 6, 2022). The MAPGuide is defined by these organizations as "a tool for accessing and exploring analysis of global health agreements." *MAPGuide*, GHIAA, https://ghiaa.org/mapguide-home/ [https://perma.cc/MN7F-BYGZ] (last visited No. 6, 2022).

6. *See* GLOBAL HEALTH INNOVATION ALLIANCE ACCELERATOR (GHIAA), https://ghiaa.org [https://perma.cc/K2TW-M4ZX] (providing background information on GHIAA) (last visited Mar. 5, 2023). GHIAA describes itself as "promot[ing] transparency of agreements terms that have an impact on global health" and does so by "publish[ing] new materials, curat[ing] useful information, collaborat[ing] with stakeholders, and provid[ing] consulting

"Licenses: COVID-19,"[7] compiled by the Medicines Patent Pool (MPP).[8]

At the time the research was performed, the KEI database contained 420 entries related to COVID-19 contracts, of which sixty-one were identified as having a "purpose" related to vaccines or components thereof. The terms identified as relevant for purposes of this research were "vaccine" (for which there were fifty-one results), "vaccine manufacture" (five results), "oral vaccine administration" (one result), "delivery of vaccine" (two results), "spike protein manufacturing" (one result)[9] and "vaccine component" (one result).[10]

The GHIAA database contained thirty-one entries[11] related to COVID-19 contracts, of which twenty-seven listed "vaccine" as the covered technology.[12] Of these, twenty-five entries related solely to "vaccine," while two covered both vaccine and other type of technology ("drug" or "diagnostic").

The MPP database contained fifteen entries related to COVID-19 contracts (specifically, licenses) of which three were listed as relating to a "vaccine candidate," two as a "research

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support." *Id. See supra* the star footnote for the Author's disclosure of an advisory position at the board of this organization.

7. *See Products Licensed*, MEDICINES PATENT POOL [hereinafter MPP Database], https://medicinespatentpool.org/progress-achievements/licences [https://perma.cc/P7HR-R2B6] (making available all of its licensing and sublicensing agreements) (last visited Nov. 6, 2022).

8. *See About Us*, MEDICINES PATENT POOL, https://medicinespatentpool.org [https://perma.cc/QG3R-53ZM](providing background information on Medicines Patent Pool) (last visited Nov. 6, 2022). Medicines Patent Pool defines itself as "a United Nations-backed public health organisation working to increase access to, and facilitate the development of, lifesaving medicines for low- and middle-income countries." *Id.*

9. This concept is relevant because SARS-CoV-2, the virus that causes COVID-19, has a spike protein on its surface. *See generally* Yuan Huang et al., *Structural and Functional Properties of SARS-CoV-2 Spike Protein: Potential Antivirus Drug Development for COVID-19*, 41 ACTA PHARMACOLOGICA SINICA 1141, 1141 (2020) (explaining the spike protein).

10. The database further contained several contracts covering solely "needles and syringes" and one contract covering a "vaccine microneedle." KEI Database, *supra* note 3. While these components are critical for vaccine delivery, this project did not focus on needle technology.

11. There was some overlap between the contracts listed in the KEI and GHIAA databases. For instance, the contracts cited in note 171 (contract no. 75A50122C00034 between Moderna and BARDA) appeared in both databases.

12. GHIAA Database, *supra* note 5 (last visited Nov. 6, 2022).

tool for vaccine development" and one as relating to "vaccine development."[13]

In addition to contractual provisions, the project also looked at policies from selected major funders of vaccine R&D, particularly in the context of pandemic and epidemic diseases. Specifically, it considered the "Equitable Access Policy"[14] published by the Coalition for Epidemic Preparedness Innovations (CEPI);[15] the policy on "Open Access"[16] published by the Gates Foundation;[17] and the statement on "Equitable Access to Healthcare Interventions"[18] published by the Wellcome Trust.[19]

For purposes of categorizing the types of contractual provisions commonly found in vaccine contracts, the project first relied on the taxonomy adopted by one of the leading U.S. scholars in the field of technology transfer and biotech law, Professor Jorge Contreras.[20] The project borrowed categorical

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13. MPP Database, *supra* note 7 (last visited Apr. 17, 2023).

14. *Equitable Access Policy*, Coalition for Epidemic Preparedness Innovations [hereinafter CEPI *Equitable Access Policy*], https://cepi.net/wp-content/uploads/2019/01/Equitable-Access-Policy.pdf [https://perma.cc/6HRQ-MY49] (last visited Nov. 6, 2022).

15. *See id.* (describing CEPI as "a non-profit organization established to develop vaccines to prevent and respond to future epidemics, and to secure access to such products for the populations who need them").

16. *Open Access Policy*, Bill & Melinda Gates Found., [hereinafter Gates Found.], https://openaccess.gatesfoundation.org/open-access-policy/ [https://perma.cc/3Y4X-ATEK] (last visited Nov. 6, 2022).

17. *See* Gates Found., https://www.gatesfoundation.org [https://perma.cc/D9VR-3CNY] (last visited Nov. 6, 2022) (defining the Gates Foundation as "a nonprofit fighting poverty, disease, and inequity around the world").

18. *See Wellcome's Approach to Equitable Access to Healthcare Interventions*, Wellcome Tr., https://wellcome.org/what-we-do/our-work/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions [https://perma.cc/8CAG-8WGB] (outlining Wellcome Trust's approach to equitable access to healthcare interventions) (last visited Nov. 6, 2022).

19. *See What We Do*, Wellcome Tr., https://wellcome.org/what-we-do [https://perma.cc/HCK4-J3WW] (describing Wellcome Trust as "funding research, leading policy and advocacy campaigns, and building global partnerships") (last visited Nov. 6, 2022).

20. *See generally* Jorge L. Contreras, Intellectual Property Licensing and Transactions: Theory and Practice (2022) [hereinafter IP Licensing and Transactions] (explaining comprehensively the field of intellectual property licensing).

language and concepts in the case of contractual provisions common across fields of technology (e.g., "financial terms"[21] or "foreground" and "background intellectual property").[22] It then added to the taxonomy in cases in which it was necessary to reflect the specificities of vaccine development, manufacturing, and purchase. For instance, not all types of technology require the completion of clinical trials or compliance with other types of regulatory approval criteria as a pre-condition to enter the market—hence the autonomous category of "clinical trials and regulatory provisions."[23]

Finally, a word on the scope and limitations of this project. The article does not offer an exhaustive treatment of the topic at hand but proceeds instead by highlighting the contractual features that define the relationship between parties and the dynamics of the development, manufacturing, and allocation of vaccine technology. It begins by considering the types of parties involved in these contracts and the timing of bargaining processes leading to the formation of these contracts.[24] It then turns to the main substantive obligations arising from these contracts: what the parties commit to do;[25] pricing and related financial obligations;[26] access provisions;[27] provisions related to clinical trials and regulatory approval;[28] the regulation of intellectual property,[29] data and know-how;[30] and issues related to liability and compensation for vaccine-

21. *See id.* at 196–247 (explaining different types of financial terms commonly found in contractual provisions).

22. *See id.* at 263 (introducing "foreground" and "background IP").

23. *See infra* Part II.C.3 (elaborating on the clinical trials and regulatory provisions).

24. *See infra* Parts II.B and II.A, respectively (Part II.B elaborating on types of parties involved in these contracts, and Part II.A explaining the timing of bargaining process).

25. *See infra* Part II.C.1 (elaborating on different types of contracts).

26. *See infra* Part II.C.2 (elaborating on financial terms, including pricing and financial obligations).

27. *See id.* (elaborating on equitable access provisions).

28. *See infra* Part II.C.3 (elaborating on clinic trials and the regulatory approval process).

29. *See infra* Part II.C.4. (elaborating on substantive contractual provisions around intellectual property).

30. *See infra* Part II.C.5 (elaborating on treatment of IP-adjacent areas, such as data and know-how, in contracts).

related injuries.[31] A final sub-section on substantive provisions provides a brief overview of categories not fully analyzed in this work, such as those relating to warranties or termination provisions.[32]

In addition to its summary nature, the research supporting this essay faced two limitations: first, while there is a substantial number of publicly available COVID-19 contracts, it is almost certain that not all contracts concerning the development, manufacturing, and allocation of COVID-19 vaccines have been made available.[33] As such, this essay has not relied on the totality of contractual provisions that have been negotiated and implemented during the COVID-19 vaccine race and the vaccine rollout. Nonetheless, the significant number of contracts that have been made available, as listed above,[34] as well as their varying typology, should provide a representative sample of the breadth and categorical commonalities within the COVID-19 vaccine contractual landscape.

The second limitation emerges from the fact that, even though they are publicly available, many of the contracts collected in the databases listed above have been redacted to remove information deemed confidential or otherwise of strategic importance.[35] The article works around this type of limitation by locating unredacted language wherever possible and by making inferences from redacted sections where permissible. For instance, in the latter case, even if the pricing terms or royalty schedule for a particular contract have been redacted, it is still possible to make the point that pricing terms have been included in that specific contract. If an example of a spe-

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31. *See infra* Part II.C.6 (elaborating on contractual provisions related to liability and compensation for vaccine-related injuries).

32. *See infra* Part II.C.7 (discussing provisions such as reporting obligations, publication requirements, and duration).

33. *See, e.g.*, *COVID-19 Contracts*, *supra* note 3 and accompanying text (noting the methodology used by KEI to obtain copies of contracts related to COVID-19 vaccines).

34. *See supra* notes 5 and 7 accompanying text (providing database of available vaccine contracts).

35. *See generally* Sydney Lupkin, *A Federal Coronavirus Vaccine Contract Released at Last, But Redactions Obscure Terms*, NPR (Oct. 24, 2020), https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t [https://perma.cc/75EQ-B27Y] (describing the limitation posed by redactions) (last visited Nov. 30, 2022).

cific price set by the parties is needed, the article relies on an unredacted pricing provision in a different contract.[36]

After providing an overview of the contractual landscape according to the parameters described above, the article concludes by briefly outlining some of the apparent implications of this landscape, with an emphasis on the allocative imbalances produced by the overuse of contractual bilateralism during pandemics and large-scale transnational epidemics.

II. The Architecture of Vaccine Contracts

A. *Timing*

Contracts may either precede the outbreak of a disease caused by an emerging pathogen or be entered into once an outbreak generates demand for a vaccine. Contracts entered into prior to an outbreak typically fund the development of a vaccine candidate (or components thereof) that can be used against a known pathogen or adapted to respond to a new one.

An example of a vaccine candidate targeting an existing pathogen is that of the first licensed Ebola vaccine.[37] The rVSV-ZEBOV vaccine[38] was developed in response to multiple outbreaks of the deadliest strain of the Ebola virus (Zaire)[39] from 1976 onwards, which primarily affected populations in African countries.[40] This vaccine candidate was developed dur-

36. *See, e.g.*, Peru-Pfizer/BioNTech Agreement, *infra* note 64 (listing the price of an order for Pfizer/BioNTech COVID-19 vaccines).

37. *Ebola Virus Disease: Vaccines*, World Health Org. (Jan. 11, 2021), https://www.who.int/news-room/questions-and-answers/item/ebola-vaccines [https://perma.cc/S6CT-ZPBU] (providing information on the two Ebola vaccines currently available); *see also* Andrea Marzi et al., *Vesicular Stomatitis Virus-Based Ebola Vaccines with Improved Cross-Protective Efficacy*, 204 J. Infectious Diseases 1066 (2011) (describing the vaccine candidate).

38. The rVSV-ZEBOV vaccine is commercialized under the trade name Ervebo. *See Ervebo*, FDA (2022), https://www.fda.gov/vaccines-blood-biologics/ervebo [https://perma.cc/2H8E-7BTD] (providing an overview of Ervebo).

39. *See* Ayten Kadanali & Gul Karagoz, *An Overview of Ebola Virus Disease*, 2 N. Clin. Istanb. 81, 82 (2015) (explaining that Zaire is the deadliest strain of Ebola virus).

40. *See History of Ebola Virus Disease (EVD) Outbreaks*, U.S. Ctrs. Disease Control & Prevention, https://www.cdc.gov/vhf/ebola/history/chronology.html [https://perma.cc/88Y9-AA9K] (describing the history of the Ebola outbreak that started in the African region) (last visited Apr. 1, 2023).

ing the early 2000s.[41] However, despite the cyclical need for an Ebola vaccine from a public health perspective, it failed to attract commercial interest until the large Ebola outbreak of 2014-16.[42] The vaccine was eventually approved to enter the market in late 2019.[43] Funding for the development of this vaccine dates back to the turn of the century,[44] while the contract (in the form of a license) transferring the rights to commercialize the vaccine from the Canadian public sector to a small U.S. pharmaceutical company (NewLink) dates back to 2007.[45] In both cases, the vaccine technology was bargained over well before the outbreak that would create market demand for the vaccine (2014-16) and that would eventually result in the completion of clinical trials and the obtainment of regulatory approval to enter the market.[46]

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41. *See* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1218–22 (2018) [hereinafter *IP Preparedness*].

42. *See* Denise Grady, *Ebola Vaccine, Ready for Test, Sat on the Shelf*, N.Y. TIMES (Oct. 23, 2014) (explaining that despite an early start to Ebola vaccine development, testing was delayed until occurrence of several outbreaks); *see also* Helen Branswell, *'Against all odds': The Inside Story of How Scientists Across Three Continents Produced an Ebola Vaccine*, STAT (Jan. 7, 2020), https://www.statnews.com/2020/01/07/inside-story-scientists-produced-world-first-ebola-vaccine/ [https://perma.cc/TP38-NM9C] (explaining the delay of Ebola vaccine development until rapid spread of disease); *see generally* Rutschman, *IP Preparedness, supra* note 41, at 1219.

43. See First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2019), https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health [https://perma.cc/VC3B-9PV9] (explaining the first FDA-approved vaccine against Ebola was approved in late 2019).

44. *See, e.g.*, Branswell, *supra* note 42 (suggests that funding prior to severe outbreaks allowed earlier vaccine development).

45. *Sole Licensing Agreement for Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers*, GOV'T OF CAN., https://perma.cc/A7VJ-AA7U. Commercialization rights were further transferred from NewLink to Merck during the 2014-16 Ebola outbreak; *see also* Rutschman, *IP Preparedness*, *supra* note 41, at 1246–47 (indicating that the vaccine was licensed to NewLink Genetics for commercialization).

46. *See* Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT'L AFF. ONLINE (July 3, 2020), https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism [https://perma.cc/B6WT-6R42] (indicating that countries had already negotiated production contracts before the outbreak occurred).

An example of vaccine technology funded prior to the emergence of a specific pathogen and later adapted to respond to that pathogen is Moderna's first mRNA vaccine against COVID-19.[47] Moderna received significant amounts of private-sector funding for the development of mRNA vaccine technology as early as 2013, long before the onset of the COVID-19.[48] Moderna also received public-sector funding for R&D on mRNA technology before the COVID-19 pandemic.[49] After the outbreak began, Moderna worked in conjunction with U.S. public-sector scientists to adapt its mRNA technology to the emerging pathogen (SARS-CoV-2) causing COVID-19.[50]

Contracts may also be entered into once an outbreak is underway. The case of the Moderna COVID-19 vaccine is again instructive. While R&D on mRNA technology was funded prior to the COVID-19 pandemic, the adaptation of existing vaccine technology to a new pathogen (in this case, SARS-CoV-2) could logically only occur after the pathogen became known.[51]

In addition to contracts focusing on the development and/or manufacturing of vaccine technology before or during an outbreak, the use of contracts to secure access to the first doses of newly developed vaccines is becoming increasingly

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47. *See generally Moderna COVID-19 Vaccines*, U.S. FOOD & DRUG ADMIN. (2022), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines [https://perma.cc/PC7H-HETX] (explaining the FDA's approval of the Moderna COVID-19 vaccine).

48. *See* Damian Garde, *Ego, Ambition, and Turmoil: Inside one of Biotech's Most Secretive Startups*, STAT (Sept. 13, 2016), https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/ [https://perma.cc/68TD-E85P] (last visited Mar. 1, 2023) (describing how the large British pharmaceutical company AstraZeneca invested $240 million in Moderna in 2013, an investment that triggered successively larger amounts of private-sector funding).

49. *See* Damian Garde, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race*, STAT (Nov. 10, 2020), https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/ [https://perma.cc/6LME-YURT] (last visited Nov. 18, 2022) (indicating various funding Moderna received even before the COVID-19 pandemic).

50. *Id.*

51. *Id.*

common.[52] As seen below,[53] a particular type of contractual framework is now often used by domestic governments negotiating bilaterally with pharmaceutical companies. These contracts are typically entered into during the early stages of large-scale, transnational public health crises, when demand for a vaccine is projected to vastly outstrip existing production capacity.[54]

B. *Parties and Bargaining Process*

Funding contracts supporting the development of new vaccines against emerging pathogens typically involve one or more funding entities and a pharmaceutical company or other R&D player in the vaccine space. The funders are highly heterogenous actors, including governments, non-profit organizations and/or philanthropists, and structures bringing together private and public funders.[55]

Certain governments have long played a prominent role in funding R&D on vaccines against emerging pathogens.[56]

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52. *See infra* notes 64–67 and 72, and accompanying text (explaining that advance purchase orders of vaccines were placed by higher-income countries); *see also Viral Sovereignty*, *infra* note 65, at 9 (indicating that vaccine nationalism is achieved through contracts procuring vaccines even before they have been authorized for the market).

53. *See infra* notes 71–73 and accompanying text (exemplifying the contractual framework).

54. *See infra* notes 64–67 and 72 and accompanying text (describing the offer-supply mismatch in the context of recent pandemics).

55. In addition to benefitting from external support, recipients of funding also invest their own money and other resources in vaccine R&D. For an illustration of how multiple streams of funding coalesce around R&D on a given vaccine candidate see *IP Preparedness*, *supra* note 41, at 1228, 1232, 1234 (summarizing the types of players involved in the funding of, and R&D on, three Ebola vaccine candidates).

56. *See, e.g.*, KAVYA SEKAR, CONG. RSCH. SERV., *Domestic Funding for COVID-19 Vaccines: An Overview* (2021) [hereinafter *Domestic Funding for COVID-19 Vaccines*], https://crsreports.congress.gov/product/pdf/IN/IN11556 [https://perma.cc/E7JC-MBZX] (describing the role of the U.S. government in funding the development of COVID-19 vaccines); *see also* Michael Safi, *Oxford/AstraZeneca Covid Vaccine Research 'Was 97% Publicly Funded,'* GUARDIAN (Apr. 15, 2021), https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded [https://perma.cc/P9HS-6VRN] (describing the role of the United Kingdom government in funding the development of the Oxford/AstraZeneca COVID-19 vaccine); *see also* Can. Inst. Health Rsch., *Government of Canada funds 49 additional COVID-19 research projects – Details of the funded projects*, GOV-

For example, the United States consistently funds vaccine R&D through its agencies operating in the public health and defense space.[57] The contracts collected in the KEI database—which focuses exclusively on contracts to which the U.S. government is one of the parties—identify the federal agencies that are repeat players in the funding of vaccine R&D. In each of the sixty-one contracts related to vaccine technology in the KEI database, the funder was the Department of Health and Human Services (HHS), the Department of Defense (DoD), or an agency or other entity within the umbrella of these two departments.[58] Of the collected contracts, thirty-three were funded by entities in the public health space, sixteen were funded by defense-related entities, and twelve received mixed funding.[59] The relevant funders in the field of public health were HHS, the Administration for Strategic Preparedness and Response (ASPR), and the Biomedical Advanced Research and Development Authority (BARDA). In the defense and national security space, the relevant funders were DoD, the Army,[60] the Defense Contract Management Agency (DCMA), and the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND).[61]

ERNMENT OF CANADA (April 2, 2020), https://www.canada.ca/en/institutes-health-research/news/2020/03/government-of-canada-funds-49-additional-covid-19-research-projects-details-of-the-funded-projects.html [https://perma.cc/6DGK-TLLW] (describing the role of the Canadian government in funding the development of COVID-19 vaccines).

57. *See* KEI Database, *supra* note 3 (detailing vaccine contracts); *see also* Table 1 (outlining sources of funding in KEI Database).

58. KEI Database, *supra* note 3; *see also Domestic Funding for COVID-19 Vaccines*, *supra* note 56 (indicating that vaccine manufacture efforts were funded by the HHS and the DoD).

59. *See* KEI Database, *supra*, note 3; *see also Domestic Funding for COVID-19 Vaccines*, *supra* note 56 (acknowledging that vaccine manufacturing efforts have been funded through appropriations made to agencies).

60. The U.S. Army has long considered vaccine R&D a strategic priority. *See, e.g.*, Kendall Hoyt, *Vaccine Innovation: Lessons from World War II*, 27 J. PUB. HEALTH POL'Y 38, 39–40 (2006) (noting that Army funding for medical research dramatically increased following the influenza outbreak during World War I, spurred by the fear that disease outbreaks in future conflicts would similarly account for the majority of American casualties).

61. *See* KEI Database, *supra* note 3 (noting that the U.S. government funds R&D via agencies); *see also* Table 1 (outlining KEI Database sources of funding).

Funding recipients are diverse R&D players, with a focus on pharmaceutical companies operating in the vaccine space. These companies range from large, long-established companies such as AstraZeneca, Pfizer, Sanofi, or Merck,[62] to emerging companies as was the case of Moderna in the United States and BioNTech in Germany at the outset of the COVID-19 pandemic.[63] Table 2 in the Appendix provides detailed information on the pharmaceutical companies listed in the KEI database and which are known to have received funding from the U.S. government for vaccine R&D, manufacturing, or procurement purposes during the COVID-19 pandemic.

In addition to funding vaccine R&D or manufacturing, contracts also regulate the purchase of resulting vaccines. In some cases, the provisions governing the sale of vaccine doses may be incorporated into larger contractual frameworks, such as a funding contract that also incorporates a purchase order. In other cases, the contract may function exclusively as a purchasing agreement. An example of this latter type of contractual framework is the binding term sheet signed between the government of Peru and Pfizer/BioNTech, through which the former placed an order for 9.9 million doses of the Pfizer/BioNTech COVID-19 vaccine during the early stages of the pandemic.[64]

The parties binding themselves to contractual frameworks governing the purchase of vaccine doses are often a country (through the appropriate governmental entity) and a pharmaceutical company.[65] This type of contractual relationship has

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62. *See* KEI Database, *supra* note 3 (noting pharmaceutical companies that are funding recipients); *see also* Table 2 (outlining KEI Database funding recipients).

63. *See* KEI Database, *supra* note 3 (indicating that Moderna and BioNTech were funding recipients who did not have contracts prior to 2020); *see also* Table 2 (outlining KEI Database funding recipients).

64. Ministry of Health of the Republic of Peru, Binding Term Sheet, EAST/176112513.3 (Sept. 2020) [hereinafter Peru-Pfizer/BioNTech Agreement]. The binding agreement is available it its entirety at https://s3.documentcloud.org/documents/20616253/covid-19-vaccine-binding-terms-sheet-pfizer-and-peru.pdf [https://perma.cc/6M6M-HMEG].

65. *See* Rutschman, *IP Preparedness*, *supra* note 41 (noting that the U.S. government negotiated H1N1 vaccine contracts with pharmaceutical companies); *see also* Sam F. Halabi & Ana S. Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, 36 EMORY INT'L L. REV. 1, 9 (2022) [hereinafter *Viral Sovereignty*] (indicating

been framed as a form of bilateralism or nationalism (defined as a situation in which a pharmaceutical company agrees to sell a pre-set or otherwise determinable number of vaccine doses to a government placing an order).[66] The contractual relationship between Peru (through its Ministry of Health) and Pfizer/BioNTech[67] referenced above constitutes an example of this type of bilateralism. Many other countries placed similar orders throughout the COVID-19 pandemic.[68]

As seen below, overuse of this type of country-by-country approach leads to problems of coordination and sub-optimal allocation, which time and again have left lower-income governments with very limited and delayed access to vaccine doses.[69]

C. *Substantive Provisions*

1. *Types of Contracts*

"Vaccine contracts" may refer to three possible contractual objects, or a combination thereof. First, contracts may fund and/or pertain to vaccine R&D.[70] Second, contracts may fund or regulate vaccine manufacturing.[71] Lastly, contracts may place a purchase order for vaccine doses.[72] Within the last category, orders may be placed when doses have been produced and are available for commercialization, or placed even before the vaccine candidate is fully developed. The latter type of contract is commonly known as an "advance purchase

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that governments contract with pharmaceutical companies for vaccine purchases).

66. *See* Rutschman, *IP Preparedness, supra* note 41 (discussing instances when governments have pre-ordered vaccine doses).

67. Peru-Pfizer/BioNTech Agreement, *supra* note 64.

68. *See* Rutschman, *IP Preparedness, supra* note 41 (indicating that Germany and the United States were among such countries placing orders); *see also Viral Sovereignty*, *supra* note 65, at 13–17 (describing various countries participating in nationalism orders).

69. *See infra* Part III (detailing the implications of the contractual landscape).

70. *See, e.g.*, Gates-Icosavax Contract, *infra* note 175 (indicating funding for COVID-19 vaccine R&D).

71. *See, e.g.*, Army-Sanofi July 2020 Contract, *infra* note 145 (detailing funding for COVID-19 vaccine manufacturing).

72. *See, e.g.*, Peru-Pfizer/BioNTech Agreement, *supra* note 64 (indicating purchase order for COVID-19 vaccine doses).

agreement."[73] This contractual framework is particularly relevant in the context of pandemics and large transnational epidemics, as the number of vaccine doses produced in the earlier stages of these public health crises has historically been vastly insufficient to meet demand.[74]

2. *Financial Terms and "Equitable Access" Provisions*

As in most other contexts, vaccine contracts include a price for the goods and/or services provided,[75] which in some cases is structured as a royalty scheme.[76] Additional financial items include provisions on sublicensing income, milestone payments, most-favored clauses, and audits.[77]

During a pandemic or large transnational epidemic, there may be a need for populations in different geo-economic areas of the globe to access the same type of vaccines. As such, there is a growing recognition of the need for differentiated pricing

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73. *See infra* Part III (explaining negotiation process for advance purchase agreements); *see also* Rutschman, *supra* note 45 (detailing that developed countries negotiated pre-production contracts for H1N1 vaccines); *see also Viral Sovereignty*, *supra* note 65, at 5 (explaining that higher-income countries used advanced purchase agreements to secure early access to vaccines).

74. *See Viral Sovereignty*, *supra* note 65, at 10 (stating that "the global vaccine manufacturing infrastructure is ill-equipped to produce enough doses to meet. . .demand").

75. By way of example, in the case of the agreement between Peru and Pfizer/BioNTech, the price agreed upon by the parties was $118,800,000 for 9,900,000 doses. Peru-Pfizer/BioNTech Agreement, *supra* note 64, at 4.

76. *See, e.g.*, CureVac-GSK Contract, *infra* note 107, at 57 (indicating that GSK will pay CureVac royalties).

77. *See* IP Licensing and Transactions, *supra* note 20, at 196 (summarizing contractual financial provisions). There are also miscellaneous types of provisions relating to the implementation and administration of funding plans. Some contracts governing the disbursement of grant funding, for example, require that a separate bank or bookkeeping accounts be kept. For instance, the contract signed by the Bill & Melinda Gates Foundation and the biotech company Icosavax in September 2020 to fund early-stage clinical trials for the Icosavax's COVID-19 vaccine candidate required grant funds to be kept in "a physically separate bank account or a separate bookkeeping account maintained as part of [the] financial records and dedicated to the Project." Gates-Icosavax Contract, *infra* 175, at 3.

provisions[78] and/or "access" provisions[79] to safeguard the interests of lower-income countries.

Pricing provisions are ubiquitous in contractual agreements governing most types of goods and have a precise meaning in contractual literature.[80] By contrast, "access" provisions have a specific set of meanings in the context of global health and are understood in varying ways by different actors in the ecosystem. As seen in the language excerpted below,[81] the idea that populations in lower-income countries should have equitable access to pandemic and epidemic vaccines is often embedded by funders into their policies. But while there is a generalized sense that the concept of "access" is inherently linked to an appropriate pricing policy,[82] there are dimensions of "access" that go beyond financial considerations. Because of the connection between notions of "access" to vaccines and pricing provisions, the remainder of this section surveys the varying uses of "access"-related language in the policies applicable to contracts funding the development of pandemic and epidemic vaccines. However, this essay reserves the treatment of non-financial terms, such as "intellectual property" and "reporting obligations", for the pertinent sections.[83]

The following examples illustrate the growing trend among funders of vaccine R&D to require some form of "equitable access" policy. For example, the Coalition for Epidemic

78. *See, e.g.*, Yee Chan et al., *Public Support in the United States for Global Equity in Vaccine Pricing*, 12 SCI. REPORTS 1, 1 (2022) (explaining that TEP was a viable vaccine pricing strategy).

79. *See infra* notes 84–98 and accompanying text (discussing "access" provisions).

80. For instance, the Organization for Economic Co-operation and Development defines "contract price" as "[a] general term referring to a written sales instrument that specifies both the price and shipment terms." Glossary of Statistic Terms: Contract Price, ORG. ECON. COOP. & DEV., https://stats.oecd.org/glossary/detail.asp?ID=5610 [https://perma.cc/3PL3-F97V] (last visited Nov. 25, 2022).

81. *See infra* notes 84–98 and accompanying text (indicating that equitable access provisions are written into the policies of funders).

82. *See infra* note 84 and accompanying text (describing an access policy including the requirement that vaccine be commercialized at "a price that does not limit equitable access.").

83. For intellectual property, *see* Part II.C.4 (explaining intellectual property); for reporting obligations, *see* Part II.C.7.a (defining reporting obligations).

Preparedness Innovations (CEPI),[84] one of the most significant funders of R&D on pandemic and epidemic vaccines,[85] defines "equitable access" to vaccines during outbreaks as situations in which "appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay."[86] CEPI further implements the following policy:

> CEPI will facilitate equitable access to epidemic vaccines by:
>
> 1. Funding the development of vaccines and maintaining investigational stockpiles, to be used free of charge when an outbreak occurs
>
> 2. Coordinating with others in the global health community to enable licensure of vaccines funded by CEPI, including by securing resources for pivotal clinical trials
>
> 3. Collaborating with others in the global health community to ensure the procurement, allocation, deployment and administration of licensed vaccines to protect global health, at a price that does not limit equitable access and is sustainable to the manufacturer.[87]

The Gates Foundation (Foundation) frames the same issue as one of "global access."[88] The Foundation states that global access "requires that (a) the knowledge and information gained from a Programmatic Investment be promptly and broadly disseminated, and (b) the Funded Developments be made available and accessible at an affordable price to our in-

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84. CEPI describes itself as a non-profit "established to develop vaccines to prevent and respond to future epidemics, and to secure access to such products for the populations who need them." CEPI *Equitable Access Policy*, *supra* note 14, at 1.

85. *See e.g.*, Dimitrios Gouglas et al., *CEPI: Driving Progress Toward Epidemic Preparedness and Response*, 41 EPIDEMIOLOGIC REV. 28, 28 (2019) (describing CEPI's financial support of R&D on vaccines against emerging pathogens); *see also* VACCINES AS TECHNOLOGY, *supra* note 2, at 144–48 (2022) (further describing the role of CEPI in funding vaccine R&D for pandemic and epidemic preparedness).

86. CEPI Equitable Access Policy, *supra* note 14, at 1.

87. *Id.* at 1–2.

88. GATES FOUND., *supra* note 16.

tended beneficiaries."[89] The Foundation frames global access in terms of three "requirements":

- Require a "Global Access Strategy" or "Global Access Commitments Agreement" from our partners, explaining their plans to achieve their goals and further the foundation's charitable objectives, including the identification of third party IP Rights and relationships arising in connection with the research, development, manufacturing, marketing and/or distribution of the Funded Developments, and the related IP management strategies, licensing structures, data management plans, and pricing frameworks.
- Require a humanitarian license or other IP Rights in Funded Developments and essential background technology. In those cases where the foundation does reserve a humanitarian license, it does so as necessary to ensure that either the foundation or a sub-licensee has the rights necessary for the development, manufacture and distribution of Funded Developments to achieve Global Access.
- Require periodic updates on progress and ongoing efforts to achieve Global Access.[90]

The Wellcome Trust (Wellcome) frames this problem as one of "equitable access to healthcare interventions" with a focus on access by populations in low- and middle-income countries (LMICs).[91] Wellcome's policy specifically acknowledges the role of contractual provisions in implementing policies designed to improve equitable access to medicines for populations in LMICs. The policy states, "Contractual mechanisms will be used on a case-by-case basis for those we fund," and then lists examples of requirements that may be imposed on funding recipients.[92] The first example provided in the policy is the request or requirement that "awardees have an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP

89. *Id.*
90. *Id.*
91. WELLCOME TR., *supra* note 18.
92. *Id.* at 5.

and other strategies that reflect ability to pay and ensure that economic barriers to access are low."[93] The second is that of "tailored revenue-sharing arrangements to reward organisations that help deliver our access ambitions."[94] And the third is that of "stewardship plans outlining how to achieve the optimal use of an intervention."[95]

Wellcome's policy specifically addresses the role of intellectual property in the context of equitable access. On the one hand, the policy states that Wellcome "will respect [the] awardees' and third parties' IP rights," and that "IP management will not preclude the ability to secure commercial rewards."[96] On the other hand, the policy makes it clear that the exercise of these rights must be consistent with the overarching goal of equitable access.[97] Wellcome's policy then develops a set of potential interventions that it may adopt with regard to the contracts it funds in the event that intellectual property is being used in ways that hinder Wellcome's goal of facilitating access to pharmaceuticals to populations in LMICs:

> "This might include not seeking or enforcing patents in low-income countries, voluntary licensing with broad geographic scope in middle-income countries, and patent pooling. In exceptional circumstances, such as IP being shelved or not taken forward for any reason, we will consider accessing the unexploited IP to deliver benefit in unserved countries.[98]

Finally, it is also worth considering the framing language and policy guidance offered by the World Health Organization (WHO) in this area.[99] The WHO operates under an over-

93. *Id.*

94. *Id.*

95. *Id.* Stewardship requirements are meant to "avoid the misuse, overuse or abuse of" certain types of pharmaceuticals, such as "antimicrobials and pain medicines. *Id.*

96. *Id.* at 5–6.

97. *See id.* (emphasizing the support of equitable access by the management of IP rights).

98. *Id.*

99. The Author was not involved in the development or application of any of the documents and policies referenced here.

arching "health equity" framework.[100] It defines equity as "the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality."[101] The WHO explicitly called for "equitable" responses to the COVID-19 pandemic, and COVID-19 vaccines in particular.[102]

In addition to its equity-centric framework, a contribution of the WHO worth mentioning in the context of financial provisions is its recent work on pricing guidelines, with a focus on the tailoring of pricing strategies for pharmaceuticals.[103] While an analysis of the ten-prong strategy recommend by the WHO is outside the scope of this work, it is worth noting that the WHO notes in its pricing guidance that "unaffordable prices for medicines have become one of the most pressing concerns for patients and health-care systems."[104]

As seen in Part III, in the specific case of the COVID-19 pandemic, vaccine prices have not been the main hurdle[105] to

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100. *Health Equity*, WORLD HEALTH ORG., https://www.who.int/health-topics/health-equity#tab=tab_1 [https://perma.cc/MA85-ZD9F] (last visited Feb. 23, 2023).

101. *Id.* The examples of these other dimensions provided by the WHO are "sex, gender, ethnicity, disability, or sexual orientation." *Id.*

102. *See, e.g.*, WORLD HEALTH ORG., EQUITABLE ACCESS TO COVID-19 TOOLS: ALIGNING THE PRIVATE SECTOR WITH NATIONAL RESPONSE EFFORTS (2022) (analyzing public- and private-sector responses to the COVID-19 pandemic and emphasizing the need for better governance of healthcare systems to protect consumers and vulnerable groups).

103. *See generally WHO Guideline on Country Pharmaceutical Pricing Policies*, WORLD HEALTH ORG. (2020) [hereinafter WHO GUIDELINE ON PRICING] (outlining overarching principles, specific recommendations, and implementation considerations for policy-makers and decision-makers crafting pharmaceutical pricing policies); *see also* David Tordrup et al., *Systematic Reviews for the Update of the WHO GUIDELINE on Country Pharmaceutical Pricing Policies*, *in* WEB ANNEX A *to* WHO Guideline on Pricing (2020), (analyzing the effects of ten pharmaceutical pricing policies); *see also* World Health Org., *WHO Guideline on Country Pharmaceutical Pricing Policies: Evidence-to-Decision Tables*, in WEB ANNEX B *to* WHO Guideline on Pricing (2020) (providing frameworks for panels making healthcare recommendations to utilize in moving from evidence to decisions).

104. WHO Guideline on Pricing, *supra* note 103, at vi.

105. Which is not to say that there were not some problems. For instance, South Africa ended up paying more than double the price charged to countries in the European Union for doses of the COVID-19 vaccine developed by the University of Oxford and the pharmaceutical company AstraZeneca.

vaccine access by populations in lower-income countries, which were also among the populations bearing the heaviest toll of the pandemic.[106] Rather, the inequitable use of a particular type of contractual framework—advance purchase agreements—was at the root of many of the allocative problems experienced during the pandemic, particularly by populations in the Global South.

3. *Clinical Trials and Regulatory Provisions*

The R&D actor developing a vaccine candidate typically acquires the bulk of the obligations related to the regulatory steps required to bring a vaccine to market.[107] For new vaccines, these steps require the completion of clinical trials and the submission of large amounts of data[108] to the drugs regula-

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See, e.g., Hellen Sullivan, *South Africa Paying More Than Double EU Price for Oxford Vaccine*, THE GUARDIAN (Jan. 21, 2021), https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than -double-eu-price-for-oxford-astrazeneca-vaccine [https://perma.cc/8W7M-D226] (discussing how South Africa purchased at least 1.5 million shots of Oxford-AstraZeneca's COVID-19 vaccine for $5.25 each, which is almost two and a half times the amount paid by most European countries).

106. *See, e.g.*, Nadia A. Sam-Agudu et al., *The Pandemic Is Following a Very Predictable and Depressing Pattern*, THE ATLANTIC (Mar. 22, 2022), https://www.theatlantic.com/health/archive/2022/03/pandemic-global-south-disease-health-crisis/624179/ [https://perma.cc/B7FQ-XD4Z] (noting that the Global South experienced a high death toll during the first years of the COVID-19 pandemic).

107. *See, e.g.*, GLOB. HEALTHCARE INNOVATION ALL. ACCELERATOR, *CureVac – GSK, COVID-19 Vaccine Collaboration and License Agreement* [hereinafter CureVac-GSK Contract], https://ghiaa.org/wp-content/uploads/2021/09/CureVac_GSK-COVID-Collaboration-and-License-Agreement.pdf [https://perma.cc/Q6NY-S972] (license agreement where pharmaceutical company GSK is assigned the task of preparing and filing all necessary FDA applications for the COVID-19 vaccine candidate).

108. These data are meant to establish the safety and efficacy of the vaccine candidate under review by the drug regulator. *See generally* EUR. MEDICINES AGENCY, *Clinical Efficacy and Safety Guidelines*, https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines [https://perma.cc/BEK6-HHY4] (providing guidelines on clinical efficacy and safety of human medicines for the preparation of marketing-authorization applications for EU Member States); *see also* U.S. FOOD & DRUG ADMIN., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [https://perma.cc/TD96-V38Z] (discussing the FDA's extensive drug evaluation process).

tor in the markets where the vaccine will be commercialized. The actors seeking regulatory approval to market a newly developed vaccine are usually pharmaceutical companies. The following provision, lifted from a contract assigning the British company GSK (formerly GlaxoSmithKline) the task of obtaining regulatory approval for a COVID-19 vaccine candidate, illustrates this point:

> GSK shall prepare and file all I[nvestigational] N[ew] D[rug Application]s and all new drug applications (or equivalents) for the COVID Products and shall own all Regulatory Approvals and be responsible for all decisions in connection with the Regulatory Approvals for COVID Products in the Field and in the Territory.[109]

In the case of advance purchase agreements, contracts typically impose a duty on the pharmaceutical company to obtain authorization or approval from the relevant drug regulator(s) to commercialize the vaccine.[110] Consider the following provision, excerpted from the contract between the Geneva-based vaccine procurement partnership Gavi[111] and the American pharmaceutical company Novavax:

> Novavax shall use Commercially Reasonable Endeavours to obtain such regulatory approvals as are required to enable the Vaccine to be used in each COVAX [structure developed specifically for the international procurement of COVID-19 vaccines] Participant country where allocated COVAX Doses are intended to be sold pursuant to this Agreement, taking into account cost, complexity of obtaining ap-

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109. CureVac-GSK Contract, *supra* note 107, at art. 4.8.1.

110. *See, e.g.*, *Gavi Alliance – Novavax, COVID-19 Vaccine Advance Purchase Agreement*, GLOB. HEALTHCARE INNOVATION ALL. ACCELERATOR [hereinafter Gavi-Novavax Contract], https://ghiaa.org/provision_document/gavi-alliance-novavax-covid-19-vaccine-advance-purchase-agreement-14/ [https://perma.cc/SW7P-KJMZ] (showcasing a purchase agreement where pharmaceutical company Novavax must seek regulatory approvals required to commercialize the vaccine candidate).

111. *See About our Alliance*, GAVI, THE VACCINE ALLIANCE, https://www.gavi.org/our-alliance/about [https://perma.cc/ZU39-3XZA] (last updated Jan. 5, 2023) (explaining Gavi's mission and goals).

> proval in such COVAX Participant country and the benefit of such regulatory approval.[112]

In addition to illustrating the requirement of seeking regulatory approval for a vaccine candidate, this provision also shows how the obligation is framed according to a standard of commercial reasonableness.

4. *Intellectual Property*

(a) *"Background" and "Foreground" Intellectual Property*

In his book about intellectual property licensing, Professor Jorge Contreras defines "background" intellectual property as intellectual property "that one party controlled prior to the commencement of the joint development project."[113] He further notes that actors bringing background intellectual property to a project typically do so by using nonexclusive licenses that last only for the duration of the project.[114]

"Foreground" intellectual property is described as intellectual property "developed by one party or by both parties together" during an R&D collaboration.[115] Foreground intellectual property may be owned solely by one of the parties to the project or by both, depending on the contributions of each party (and the intellectual property rules governing those contributions).[116] In some cases, the parties may own some intellectual property jointly while other intellectual property rights are owned individually by one of the parties.[117] In the case of jointly owned intellectual property, one of the parties may elect to assign its rights to the other for efficiency or economic reasons.[118]

Even though parties to a contract governing vaccine R&D or technology transfer typically maintain control over the intellectual property they bring to the project, it is common for a cross-licensure scheme to be implemented in order to facilitate the use of that intellectual property by the other party or parties.

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112. Gavi-Novavax Contract, *supra* note 110, at art. 7.1.3.
113. IP Licensing and Transactions, *supra* note 20, at 263.
114. *Id.*
115. *Id.*
116. *Id.*
117. *Id.*
118. *Id.*

The contract completed in 2020 by the U.S. government[119] and the U.S. pharmaceutical company Novavax illustrates these cross-licensure dynamics and involved multiple deliverables, including "vaccine-manufacturing platforms that offer early-stage manufacturing flexibility."[120] Before entering into this contract with the U.S. government in June 2020, Novavax had funded the development of a COVID-19 vaccine candidate called NVX-CoV2373.[121] The company owned the intellectual property covering NVX-CoV2373, as well as other vaccine technology that would be relevant for the project funded by the U.S. government—specifically, a manufacturing platform using a certain type of virus (sf9/baculovirus).[122] The parties to this contract determined that the intellectual property rights over NVX-CoV2373 and the sf9/baculovirus manufacturing platform constituted "background IP" brought by Novavax to the project.[123] As discussed in greater detail below,[124] this particular contract also considered manufacturing know-how, data, and proprietary manufacturing materials (e.g. cell banks and viral stock) as part of the "background IP."[125]

Novavax then licensed this background intellectual property to the government through insertion of the following provision into the contract:

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119. Specifically, the United States Army through Advanced Technology International (ATI), a non-profit organization often used by the Department of Defense. *See About Us*, ADVANCED TECH. INT'L, https://www.ati.org/about-us/ [https://perma.cc/V2WM-CL8J] (explaining how ATI is the contractor for the Department of Defense) (last visited Apr. 1, 2023).

120. GHIAA, *US Department of Defense - Novavax, COVID-19 Vaccine Development Agreement*, at 12 [hereinafter U.S. DoD-Novavax Contract], https://ghiaa.org/wp-content/uploads/2021/03/Novavax-—US-Army-Agreement-for-Research-Development-of-Covid-19-Vaccine_BaseSOW.pdf [https://perma.cc/32XK-2VZU].

121. *Id.* at 63; *see also* NOVAVAX, *Novavax Investigational COVID-19 Vaccine (NVX-CoV2373),* https://www.novavax.com/science-technology/vaccine-pipeline/covid-19-investigational-vaccine [https://perma.cc/QTH9-FQ2G] (stating that "NVX-CoV2373 is a protein-based vaccine targeting SARS-CoV-2, the virus that causes COVID-19").

122. *See* Novavax, *supra* note 121 (explaining that the vaccine design utilized the sf9/baculovirus virus).

123. U.S. DoD-Novavax Contract, *supra* note 120, at 63.

124. *See infra* Part II.C.4–5 (discussing different provisions in the NVX-CoV2373 contract).

125. U.S. DoD-Novavax Contract, *supra* note 120, at 63–64.

> Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicensable license to use the Background IP to the limited extent necessary for the U.S.[126]

The following provision established a similar license flowing from the government to the company:

> Background IP License to Novavax. [. . .] [T]he U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.[127]

The same contract can be used to illustrate the principle that foreground intellectual property belongs to the party who develops it:

> [. . .] Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing.[128]

Lastly, regarding the foreground intellectual property, funders—particularly governmental ones—typically also guarantee a license that enables them to practice (or have a designed entity practice) the foreground intellectual property:

> Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up li-

126. *Id.* at 64.

127. *Id.*

128. *Id.*

> cense to practice or have practiced the Foreground IP for or on behalf of the U.S. Government.[129]

(b) *Sub-Licensure*

In the context of vaccine R&D and/or manufacturing, contracts typically regulate the possibility of sub-licensure[130] of technology covered by intellectual property rights. Moreover, they typically impose some form of restriction on sub-licensure both at the formal and material levels.[131] The formal restrictions typically consist of a requirement for a written agreement, while the material restrictions may range from mandatory review on part of the original licensor of any sub-licensure request to limitations imposed on the sub-licensees, such as prohibitions on the grant of further sub-license rights. An example of a common sub-licensure framework can be found in the patent license agreement completed between the U.S. National Institutes of Health and the Medicines Patent Pool Foundation (MPP) in May 2022:

> Upon written approval, which shall include prior review of any sublicense agreement by NIAID, and which shall not be unreasonably withheld, the Licensee may enter into sublicensing agreements under the Licensed Patent Rights. These sublicenses will not have a further right of sublicense.[132]

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129. *Id.*

130. Legal scholar Jorge Contreras has defined a sub-license as follows: "a grant of rights by a licensee to a third party (the sublicensee) which encompasses some or all of the rights that have been granted to the licensee under a primary license agreement. Unlike an assignment of a license, the licensee that grants a sublicense generally remains bound by the terms of the original license. By the same token, the sublicense only exists so long as the underlying license remains in force." IP LICENSING AND TRANSACTIONS, *supra* note 20, at 165.

131. *See* Patent License-Non-Exclusive, Agreement A-258-2022, National Institutes of Health, § 4.1, https://medicinespatentpool.org/licence-post/structure-based-design-of-spike-immunogens-research-tool-for-vaccine-development [https://perma.cc/Z9MM-6S3E] (detailing sub-licensure limitations).

132. *Id.*

5. *IP-Adjacent Areas: Data and Know-How*

Contracts governing the development, manufacturing and/or transfer of vaccine technology also establish[133] mechanisms for the protection of information qualifying as "data," typically by assigning property-like rights[134] over this subject matter to one or both of the parties.[135] Data are usually understood as "recorded information"[136] that is generated and collected according to set criteria.[137]

In addition to data, which is usually aggregated in discernible ways and transferable with relative ease from a logistical perspective, there are informational units relevant for the development or transfer of vaccine technology that may only be partially codified.[138] Particularly in the context of vaccine

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133. All contracts covering vaccine development and/or manufacturing collected in the databases utilized as a basis for this work contained data-related provisions. *See infra* notes 140–49 and accompanying text for an example of a contract establishing such a data protection regime.

134. *See generally Data and Intellectual Property*, WORLD INTELL. PROP. ORG., https://www.wipo.int/about-ip/en/frontier_technologies/data.html [https://perma.cc/D34V-P7NW] (noting the fourth session of the WIPO Conversation on IP and Frontier Technologies, which discussed the interaction between intellectual property and data in the context of artificial intelligence) (last visited Nov. 30, 2022); *see generally* J. H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 49 (1997) (tracing the emergence of hybrid intellectual property regimes protecting certain types of data).

135. *See supra* notes 151–153 and accompanying text (discussing provisions in vaccine contracts related to assignment of intellectual property rights).

136. *See supra* note 150 and accompanying text (describing data as recorded information in the context of contracts to which the U.S. government is a party as a funder of scientific R&D).

137. For instance, the United States National Academies of Sciences, Engineering, and Medicine have described data as follows: "Data are facts, numbers, letters, and symbols that describe an object, idea, condition, situation, or other factors. A data element is the smallest unit of information to which reference is made." NAT'L RSCH. COUNCIL, A QUESTION OF BALANCE: PRIVATE RIGHTS AND THE PUBLIC INTEREST IN SCIENTIFIC AND TECHNICAL DATABASES, 15 (1999); *see also* IP LICENSING AND TRANSACTIONS, *supra* note 20, at 556–61 (further discussing data licensing and its historical development).

138. For a contrast between data and different types of information gleaned from data or obtained through other processes, *see, e.g.*, Olaf Dammann, *Data, Information, Evidence, and Knowledge: A Proposal for Health Informatics and Data Science,* 10 ONLINE J. PUB. HEALTH INFORMATICS e224 (2018) (explaining the contrast between data and other forms of knowledge).

manufacturing, non-explicit information—that is, knowledge that cannot be derived from the goods and/or the data themselves—is critical to enable the production of new vaccines, as well as the scaling up of production through the addition of additional manufacturers.[139] This type of knowledge is often described as "know-how."[140]

Increasingly, both data and know-how are governed by proprietary frameworks. Some contracts treat data and know-how as forms of intellectual property. For example, the Novavax contract described in the previous section considered both data and "manufacturing know-how" as part of the "background IP."[141] Article 7.1 and enclosure 4 of the contract listed patents and patent applications that were to be considered "background IP."[142] The same provision established that "[b]ackground IP also consists of (a) manufacturing know-how."[143] In addition to know-how, the contract further enlarged the concept of intellectual property to encompass data by stating that "background IP" also covered "data from preclinical and clinical research studies, analytical and process development research, and data related to, or generated using, the [b]ackground [k]now-[h]ow."[144]

Other contracts treat data and know-how as distinct from intellectual property.[145] However, even under this type of ap-

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139. *See, e.g.*, Priti Krishtel & Fatima Hassan, *Share Vaccine Know-How*, 374 SCI. 379 (2021) (noting that "[p]harmaceutical companies will also need to share knowledge, including the "secret sauce," to accelerate vaccine production by other manufacturers" in the context of the COVID-19 pandemic).

140. *Id.*; s*ee also* IP LICENSING AND TRANSACTIONS, *supra* note 20, at 118–19 (further discussing the particular challenges of establishing licensure frameworks for know-how).

141. *See* U.S. DoD-Novavax Contract, *supra* note 120, at 63–64.

142. *Id.* at 64.

143. *Id.* at 63–64 (defining "background know-how" as "including, without limitation, the [vaccine] manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes").

144. *Id.*

145. *See, e.g.*, *Contract W15QKN-16-9-1002 between U.S. Army Contracting Command-New Jersey (ACC-NJ) and Sanofi Pasteur, Inc.*, at 29 [hereinafter U.S. Army-Sanofi July 2020 Contract], https://www.keionline.org/misc-docs/DOD-ATI-Sanofi-Technical-Direction-Letter-W15QKN1691002-30July2020-HHSRR.pdf [https://perma.cc/847S-FLKQ] (treating patent rights and technical data rights separately).

proach, there is usually some degree of propertization of information. For instance, the contract completed in 2020 by the U.S. Army Contracting Command and the French pharmaceutical company Sanofi for the development of a COVID-19 vaccine addressed "patent rights"[146] and "technical data rights"[147] as distinct categorical constructions and through separate provisions.[148] "Technical data" is defined in the Defense Federal Acquisition Regulation Supplement (which applied to the contractual relationship since the funding party was the U.S. government) as "recorded information, regardless of the form or method of recording, of a scientific or technical nature (including computer software documentation)."[149] The contract then established that the company would grant the U.S. government "unlimited rights" in a wide array of technical data.[150] "Unlimited rights" are defined in the Defense Federal Acquisition Regulation Supplement as the "rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so."[151] In the case of the contract between the U.S. Army and Sanofi, the company granted the government unlimited rights over data emanating from several sources, such as non-clinical study reports (e.g. reports on the mechanism of action and on antibody persistence), clinical trial activities, the manufacturing and development plan and the documentation submitted to the U.S. Food and Drug Administration as part of the application to market the vaccine, among many others.[152]

The propertization of data and know-how has significant consequences from a scientific perspective.[153] While this falls outside the scope of this essay, it is nonetheless worth noting

146. *Id.*
147. *Id.*
148. *Id.*
149. *See* 48 C.F.R. § 252.227-7015(a)(4) (2023) (further defining "Technical data" as a term that "does not include computer software or data incidental to contract administration, such as financial and/or management information").
150. U.S. Army-Sanofi July 2020 Contract, *supra* note 145, at 21–22 and 29.
151. DFARS, 252.227-7013(16) (2023).
152. U.S. Army-Sanofi July 2020 Contract, *supra* note 145, at 21–22.
153. *See, e.g.*, J. H. Reichman & Paul F. Uhlir, A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment, 66 LAW & CONTEMP. PROBS. 315, 319–20

that some funders of vaccine R&D now ask that that awardees implement "open data" models as a condition of funding.[154] This does not mean that data generated during vaccine R&D and manufacturing will be made available to the public at large. In fact, a significant amount of data is treated as confidential not just by the parties to these contracts, but also by third parties, such as drug regulators like the FDA.[155]

6. *Liability and Compensation for Vaccine-Related Injuries*

One area of particular salience in the field of vaccine law and policy relates to the question of which actor(s) in the vaccine ecosystem will support the compensation of potential injuries resulting from vaccine administration. This question, which pervades both the negotiation of vaccine contracts and the structuring of compensation schemes through domestic laws,[156] does not stem from the existence of particularly heightened risks associated with the administration of newly developed vaccines as opposed to other types of pharmaceuticals.[157] Rather, it is tied to the idiosyncratic history of public perceptions of vaccination,[158] as well as the evolution of incen-

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(2003) (explaining that the legal privatization and commercialization of scientific data pose risks of interfering with the norms of public science).

154. *See infra* notes 181–183 and accompanying text.

155. *See generally* Ana Santos Rutschman, *Vaccine Clinical Trials and Data Infrastructure*, UTAH L. REV. 771, 797–99 (2021) (finding that the FDA has treated most vaccine data as part of legal frameworks regulating trade secrecy and other confidential information); *see also* 21 U.S.C. § 331(j) (2020) (prohibiting the FDA to disclose methods and processes that qualify as trade secrets); 39 Fed. Reg. 44,602, 44,633 (Dec. 24, 1974); 42 Fed. Reg. 3,094, 3,106 (Jan. 14, 1977) (collectively showing how the FDA has long interpreted the prohibition set forth in 21 U.S.C. § 331(j) to encompass "safety and effectiveness data for new drugs," including vaccines).

156. *See* Halabi & Omer, *infra* note 157, at 471.

157. *See* Sam Halabi & Saad Omer, *A Global Vaccine Injury Compensation System*, 317 J. AM. MED. ASS'N 471, 471 (2017) ("[v]accines are extremely safe and harm is rare"); *see also* Matthew Z. Dudley et al., *The State of Vaccine Safety Science: Systematic Reviews of the Evidence*, 20 LANCET INFECT. DIS. e80, e87 (2020) (concluding that vaccines overall have "an excellent safety profile overall").

158. *See* Halabi & Omer, *supra* note 157 (explaining that "the specter of vaccine injury plays a central role in vaccine access and will continue to do so as vaccine technologies evolve"); *see also* Sarah Geoghegan et al., *Vaccine Safety: Myths and Misinformation*, 11 FRONTIERS IN MICROBIOLOGY 372 (2020) (summarizing the long and complicated history of common vaccine safety controversies); *see also* Laura Conklin et al., *Vaccine Safety Issues at the Turn of*

tives provided to vaccine manufacturers. For instance, the United States and several other jurisdictions—nineteen countries in total at the time of writing[159]—have domestic laws implementing a "no-fault" compensation system, in which the government assumes the role of compensating individuals who suffer an injury related to the administration of certain vaccines.[160] Unlike the approach taken under standard product liability laws, in which an injured party brings a negligence claim against a manufacturer, a "no-fault" compensation regime requires no proof of negligence; the injured party only has to demonstrate that the injury was caused by the administration of the vaccine.[161] In countries like the United States, upon such a demonstration, the government—not the manufacturer—then compensates the injured individual.[162]

A similar legal framework exists in some countries for vaccines developed in the context of a severe public health crisis. In the United States, for example, a declaration of a public health emergency—such as the one issued by the Department of Health and Human Services with regard to COVID-19[163]—triggers the application of the Public Readiness and Emergency Preparedness Act (PREP Act).[164] This law establishes a

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the 21st Century, 6 BMJ GLOB. HEALTH e004898 (2021) (explaining the six key discussions of vaccine safety in the 21st century with the emergence of antivaccination groups); *see also* Matthew Hornsey et al., *The Psychological Roots of Anti-Vaccination Attitudes: A 24-Nation Investigation*, 37 HEALTH PSYCHOL. 307 (2018) (finding the different psychological factors that may motivate people to reject scientific findings regarding vaccines and vaccination).

159. Halabi & Omer, *supra* note 157, at 471.

160. *See* 42 U.S.C. §§ 300aa-10 (implementing the National Childhood Vaccine Injury Act of 1986).

161. Halabi & Omer, *supra* note 157, at 471*; see also* Kimberly M. Thompson, Walter A. Orenstin & Alan R. Hinman, *Performance of the United States Vaccine Injury Compensation Program (VICP): 1988-2019*, 38 VACCINE 2136 (2020) (outlining the main features of the no-fault compensation regime in the United States).

162. This compensation is funded through a tax imposed on selected vaccines. *See* Thompson et al., *supra* note 161, at 2137.

163. *Determination That A Public Health Emergency Exists*, DEP'T OF HEALTH AND HUM. SERV. (Jan. 31, 2020), https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx [https://perma.cc/MAY3-SANU].

164. Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat 2680 (2005).

similar compensatory regime[165] for injuries caused by products qualifying as "countermeasures,"—that is, drugs, vaccines, and other products developed in connection with the crisis at the root of a given emergency declaration.[166] As an incentive to R&D and manufacturing, the companies producing these vaccines are immunized from liability for harms caused by the administration of a vaccine dose, as injured individuals are required to bring claims under the Countermeasures Injury Compensation Program (CICP),[167] which is funded and administered separately from the no-fault compensation regime applicable to vaccines developed outside the context of public health crises.[168]

Contracts entered into during pandemics and epidemics reflect the particular dynamics that surround issues of liability and compensation in connection with the administration of vaccines. For instance, the advance purchase agreement during COVID-19 between the European Union and CureVac, a German pharmaceutical company,[169] immunized vaccine manufacturers from liability and assigned national governments the task of indemnifying harms linked to vaccine administration, among other costs:

> [E]ach participating Member State shall indemnify and hold harmless the contractor, its Affiliates, subcontractors and sub-licensees, . . . for liability in-

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165. *But see* Katharine Van Tassel et al., *Covid-19 Vaccine Injuries — Preventing Inequities in Compensation*, 384 NEW ENG. J. MED. e34(1), e34(2) (2021) (noting the financial limitations of the program).

166. *See* 42 U.S.C. § 247d-6d(i)(1) (listing pandemic and epidemic products, security countermeasures, drugs and biologics authorized for emergency use by the FDA as countermeasures for purposes of the application of the PREP Act).

167. 42 U.S.C. §§ 247d-6d, 247d-6e; s*ee also Countermeasures Injury Compensation Program (CICP)*, HEALTH RES. AND SERV. ADMIN., https://www.hrsa.gov/cicp [https://perma.cc/H2SX-AZPY] (providing an overview of the program) (last visited Dec. 3, 2022).

168. *See generally* Allison M. Whelan, *The Prep Act and the Countermeasures Injury Compensation Program: Past, Present, and Future*, 71 DEPAUL L. REV. 689 (2022) (examining the PREP Act and the Countermeasures Injury Compensation Program).

169. CureVac's vaccine candidate ultimately did not move past efficacy trials. *See* Jon Cohen, *What Went Wrong With CureVac's Highly Anticipated New mRNA Vaccine for COVID-19?*, SCI. (June 18, 2021), https://www.science.org/content/article/what-went-wrong-curevac-s-highly-anticipated-new-mrna-vaccine-covid-19 [https://perma.cc/E2E7-2KM9].

> curred and normally borne by them relating to harm, damages and losses . . . arising from the use and deployment of the Products [vaccines] supplied to the participating Member State.[170]

Contracts between vaccine manufacturers and the U.S. government applied similar principles, implementing the PREP Act as described above. For example, the contract entered into between the pharmaceutical company Moderna and the Biomedical Advanced Research and Development Authority (BARDA) in April 2020, which provided funding for the development of Moderna's COVID-19 vaccine candidate,[171] included the following provision:

> The Federal Government may not use, or authorize the use of, any products or materials provided under either this agreement or any future purchase from Recipient's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.[172]

7. *Other Types of Provisions*

(a) *Reporting Obligations*

Reporting obligations typically include requirements for conferences between the parties during the performance of the contract, as well as the submission of periodic reports documenting both progress and financial benchmarks. For example, the contract between the U.S. pharmaceutical company Inovio and the U.S. government for the development of

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170. Advance Purchase Agreement (*"APA"*) for the Development, Production, Advance Purchase and Supply of a COVID-19 Vaccine for EU Member States, SANTE/2020/C3/049, European Commission Directorate-General for Health and Food Safety, https://ghiaa.org/wp-content/uploads/2021/01/Curevac_-_redacted_advance_purchase_agreement.pdf [https://perma.cc/KWE6-VSJZ], at 1.23.3.

171. Contract No. 75A50120C00034 [hereinafter Moderna-BARDA April 2020 Contract], https://www.keionline.org/misc-docs/FOIA/BARDA-ModernaTX-Contract-75A50120C00034-16Apr2020.pdf [https://perma.cc/L6H9-ZAR2].

172. *Id.* § B.4.4 ("Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage").

COVID-19 vaccine-related technology[173] required weekly teleconferences with the U.S. government, ad hoc meetings, quarterly submission of progress and financial reports, the submission of an expenditure forecast within thirty calendar days of the receipt of funding and, lastly, the submission of a final report.[174]

(b) *Publication Requirements*

Funding contracts often require the publication of results and/or data. For instance, the Gates Foundation establishes in its contracts the principle that publication of data or results (or both) may be required.[175] The language found in the contract between the Foundation and the American pharmaceutical company Icosavax[176] is representative of this requirement: "If the Project description specifies Publication or Publication is otherwise requested by the Foundation, You [the funding recipient] will seek prompt Publication of any Funded Developments consisting of data and results."[177]

The contract further defines "publication" as a "publication in a peer-reviewed journal or other method of public dissemination specified in the Project description or otherwise approved by the Foundation in writing."[178]

Some funders further qualify publication requirements by adding an obligation that published articles be made available

173. Specifically, the contract funded the "development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery." *Other Transaction Authority for Prototype Agreement between Inovio Pharmaceuticals, Inc. and Natick Contracting Division (Government)* (June 2020) at 2 [hereinafter Inovio-U.S. Government Contract], https://www.keionline.org/misc-docs/DoD-Inovio-OTA-22June2020.pdf [https://perma.cc/3YNV-ZTZQ].

174. *Id.* at 14–16.

175. *See Global Access and Price Agreement Commitment Between the Gates Foundation and Icosavax*, GHIAA, (Sept. 2020), at 3 [hereinafter Gates-Icosavax Contract] https://ghiaa.org/wp-content/uploads/2022/08/COVID-vaccine-grant-agreement.pdf [https://perma.cc/G2SH-M72F] (mentioning publication requirements).

176. *See* ICOSAVAX, *About*, https://icosavax.com/about/ [https://perma.cc/CB3A-V9CR] (providing background information on Icosavax) (last visited Mar. 3, 2023).

177. Gates-Icosavax Contract, *supra* note 175.

178. *Id.*

on an "open access" basis.[179] An article (or data) is deemed to have been published under an open access model when "there are no financial, legal or technical barriers to accessing it - that is to say when anyone can read, download, copy, distribute, print, search for and search within the information, or use it in education or in any other way . . ."[180] CEPI's equitable access policy, for instance, illustrates this approach by stating that "CEPI will also ensure open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development."[181]

While publication requirements have typically been designed with scientific publications in mind, some pharmaceutical companies now favor a different approach. Moderna, for instance, has repeatedly elected not to publish results in traditional scientific publications[182]—highly regarded, peer-reviewed journals such as *Nature*—while publicizing the company's work through journalistic media outlets.[183]

In cases in which the publication discloses information about intellectual property, contracts often require that the publication be delayed for a specified period of time.[184] For

179. *See supra* note 175 and accompanying text (noting that the Gates Foundation requires publications to be made under "open access" terms).

180. *What is Open Access?*, OPEN ACCESS, https://www.openaccess.nl/en/what-is-open-access [https://perma.cc/3GVQ-VCYK]; *see also* PETER SUBER, OPEN ACCESS 4 (MIT Press 2012) (defining open access as publications that are "digital, online, free of charge, and free of most copyright and licensing restrictions"); *see generally* Jorge Contreras, *Open Access Scientific Publishing and the Developing World*, 8 ST. ANTONY'S INT'L L. REV. 43, 45-46 (2012) (summarizing the emergence of open access publishing models). *But see also* Carol Brayne et al., *The Challenges of Open Access Data*, 399 LANCET 517 (2022) (listing problems affecting open access data in particular, including inadequate treatment and misuse of data).

181. CEPI, *supra* note 14.

182. *See* Garde, *supra* note 48 (describing Moderna's choice to not publish in traditional science journals and instead doing so in mainstream media outlets).

183. *Id.*

184. The contract between the Gates Foundation and Icosavax contains such a requirement: "Publication may be delayed for a reasonable period for the sole purpose of seeking patent protection, provided the patent application is drafted, filed, and managed in a manner that best furthers Global Access." Gates-Icosavax Contract, *supra* note 175.

example, the contract[185] between by the Oswaldo Cruz Foundation, a large funder of scientific and technological R&D in Brazil,[186] and the British-Swedish pharmaceutical company AstraZeneca, for the production of COVID-19 vaccines, established that "[i]n case the publication contains patentable information, Licensees will delay the publication for an additional period of ninety (90) days (or more, if mutually agreed between the Parties) with the purpose of preparing and filing the appropriate patents."[187]

(c) *Term*

With regard to term, contracts tend to establish a definite or identifiable duration.[188] For example, the contract between by the Oswaldo Cruz Foundation, a large funder of scientific and technological R&D in Brazil,[189] and AstraZeneca for the production of COVID-19 vaccines stated that the duration of the contract was the amount of time "necessary for the completion of [the contract's] object" adding that the estimated period of time would be twelve months.[190]

Moreover, contracts also incorporate language enabling (but not mandating) the extension of the term. For instance, the same contract between the Oswaldo Cruz Foundation and AstraZeneca used permissive language ("the Term may be extended") tied to a requirement of a written agreement between the parties ("an addendum to be signed by the Parties . . .").[191]

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185. *Fiocruz - AstraZeneca, Technological Transfer Agreement*, GHIAA [hereinafter Fiocruz-AstraZeneca Contract], https://ghiaa.org/wp-content/uploads/2021/11/Fiocruz_AZ-COVID19-Vaccine-Technology-Transfer-Agreement.pdf [https://perma.cc/32DV-THDP].

186. *The Foundation*, OSWALDO CRUZ FOUNDATION, https://portal.fiocruz.br/en/foundation [https://perma.cc/836E-UERN].

187. Fiocruz-AstraZeneca Contract, *supra* note 185, at 69.

188. *See generally* IP LICENSING AND TRANSACTIONS, *supra* note 20, at 362–74 (discussing the main features of term and duration of licenses).

189. *The Foundation*, OSWALDO CRUZ FOUNDATION, https://portal.fiocruz.br/en/foundation [https://perma.cc/DA99-YGLM] (last visited Apr. 1, 2023).

190. *Fiocruz - AstraZeneca, COVID-19 Technological Order Agreement*, GHIAA, cl. 2.1, https://ghiaa.org/wp-content/uploads/2021/07/Fiocruz_AstraZeneca-Technical-Order-Agreement.pdf [https://perma.cc/CM34-3GQF].

191. *Id.* cl. 2.2–2.3.

(d) *Miscellaneous*

Other types of provisions found in the surveyed contracts included terms regulating milestones;[192] confidentiality;[193] representations and warranties;[194] and provisions regulating termination of the contract.[195]

III. Implications of the Contractual Landscape

While seemingly balancing the interests of all parties involved—funders, pharmaceutical companies and, indirectly, the populations accessing the resulting vaccines—the contractual framework described above enables the creation and maintenance of deep allocative disparities.[196] In practice, the

192. Due to heavy redactions in publicly available contracts, this article does not address specific issues related to milestones in the context of the development of COVID-19 vaccines.

193. For example, the contract between the U.S. government and Novavax established that "[u]pon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media." U.S. DoD-Novavax Contract, *supra* note 120 and accompanying text, at 26.

194. For example, the contract between the U.S. government and Novavax included a clause stating that "[e]ach Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement." *Id.* at 43.

195. For example, the contract between the U.S. government and Novavax established a procedure for termination of the contract by mutual agreement, as well as by unilateral decision of the government, provided that there was a "reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources. . ." *Id.* at 14.

196. To be sure, the contractual architecture surveyed above is not the only contributing factor towards these problems. Failure to use other legal mechanisms (e.g., binding international agreements governing the allocation of certain resources during large transnational crises), as well as longstanding limitations affecting the role of international governance organizations such as the World Health Organization, also contribute to the allocative disparities highlighted here. An analysis of these other types of problems is, however, outside the scope of this article. As such, the goal of this part is to emphasize how the uncoordinated deployment of commonly used and perfectly lawful frameworks nonetheless perpetuates and drives a further

vast majority of the (limited) supply of drugs and vaccines needed during a pandemic or epidemic is captured by repeat players in the Global North. For instance, a study published in late 2020—as the first COVID-19 vaccines were being made available in the United States and Europe—found that, at the pace higher-income countries were ordering vaccine doses, populations indicated for these vaccines in most lower-income countries would have to wait until 2024 to have similar access COVID-19 vaccines.[197]

This facet of transnational exclusion is rooted in the extensive use of a particular type of contract surveyed above: advance purchase agreements.[198] These agreements are negotiated even before a pharmaceutical is fully developed and au-

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wedge into allocative disparities at the transnational level, and in particular across the Global South and Global North divide. For a discussion of the limitation of transnational governance in public health, *see generally* Lawrence O. Gostin & Emily A. Mok, *Grand Challenges in Global Health Governance*, 90 BRIT. MED. BULL. 7 (2009) (asserting that political, legal, social, and economic contours of the international regime are inhibiting progress in global health); *see generally* Gian Luca Burci, *The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations*, 2 J. INT'L HUM. L. STUD. 204 (2020) (discussing challenges to the WHO's authority and weaknesses of the IHR 205); *see generally* Lawrence O. Gostin, Roojin Habibi & Benjamin Mason Meier, *Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats*, 48 J. L. MED. & ETHICS 376 (2020) (exploring the promises and limitations of the WHO framework and describing how these limitations led to the contemporary revision of the IHR); *see generally* Moosa Tatar et al., *The Role of Good Governance in the Race for Global Vaccination During the COVID-19 Pandemic*, 11 SCI. REP. 22440 (2021) (suggesting that the WHO and wealthier nations should assist in the distribution of vaccines to nations with less global governance).

197. DUKE GLOBAL HEALTH INSTITUTE, *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?* (Nov. 9, 2020), https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive [https://perma.cc/HQ8R-Q37J].

198. *See generally* Rutschman, *supra* note 45 (criticizing the effect of "vaccine nationalism" on the allocation of vaccines globally); *see also Viral Sovereignty*, *supra* note 65 (discussing the use of advanced purchase agreements to secure vaccines for the highest-income countries and leaving lower-income countries at risk); *see also* Mark Turner, *Vaccine Procurement During an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons From 2009-H1N1*, 11 GLOB. PUB. HEALTH 322 (2016) (explaining the process of procurement of vaccines during 2009-H1N1 and expectations for the future of vaccine procurement).

thorized to enter the market.[199] Purchasers commit to buying a set amount of product, often with an option for the purchase of additional doses at later date.[200] This commitment provides pharmaceutical companies with an economic incentive to bring the product to market as quickly as possible, and the obligations of both parties become active once regulators authorize the product to be commercialized.[201]

In theory, this contractual equilibrium is beneficial to both sides of the bargain: buyers in need of a pharmaceutical product queue up early on, helping finance the later stages of R&D and regulatory review, thus benefiting suppliers (from an economic perspective) and society at large (from a public health perspective, as the pronounced spike demand is triggered by an infectious disease outbreak).[202] In practice too, this legal framework has been shown to work in some instances: since 2000, the Geneva-based public-private partnership Gavi has been using this model to procure childhood vaccines.[203]

However, during large-scale transnational public health crises, this equilibrium collapses. Without a centralized mechanism to coordinate concurrent purchases, the law of the strongest prevails.[204] Wealthier players—who are also repeat players when negotiating with large pharmaceutical companies—always capture the most doses available early on. This

199. *See generally* VACCINES AS TECHNOLOGY, *supra* note 2, at 99–100 (discussing the process of "vaccine nationalism" and the global allocation issues that stem from it); *see also supra* notes 109–11 and accompanying text (including an example of an advance purchase agreement for doses of a COVID-19 vaccine).

200. *See* VACCINES AS TECHNOLOGY, *supra* note 2, at 100–01 (indicating that there is a minimum demand for product, even if conditions change in the future).

201. *Id.* at 99–100.

202. *Id.*

203. *See generally* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 763 (explaining that Gavi uses a partnership procurement model). It should be noted that the procurement model used by Gavi applies to pharmaceutical products that present significant differences from the ones addressed in this chapter: routine childhood vaccines are needed beyond the short-lived spike brought about by pandemic and epidemics.

204. *See* VACCINES AS TECHNOLOGY, *supra* note 2, at 100–05 (illustrating how advance purchase orders placed by higher-income countries prevail over the public health needs of lower-income countries).

happened most recently during the 2009 swine flu and COVID-19 pandemics. In 2009, even before the WHO declared the outbreak of a new strain of the H1N1 virus a pandemic, multiple higher-income countries placed orders that virtually captured all the projected vaccine supply, leaving lower-income countries with no access to vaccines.[205] A similar pattern emerged during COVID-19, with thirty-two higher-income countries (representing roughly 13% of the global population) ordering more than half of the projected global supply of vaccines.[206]

This particular form of contractual bilateralism further drives a wedge into allocative disparities between populations in the Global North and the Global South. It invariably undermines public health goals, as it relies almost exclusively on geopolitical and economic criteria, which seldom align with the geographical distribution of pandemic and epidemic diseases, and the toll they take on human health.

IV. Conclusion

This article has reviewed some of the main features of vaccine contracts, with a particular focus on those governing the development and sale of vaccines needed during large transnational public health crises. It has then connected these legal frameworks to the allocative disparities in access to vaccines that have long disadvantaged populations in the Global South. While current contractual practices support the speedy development of new vaccines against emerging pathogens, they also contribute to the deepening of these allocative imbalances, which in turn imperils theesponse to future transnational outbreaks of emerging pathogens.

205. *Id.* at 101–02.
206. *Id.* at 103.

V. Appendix

Table 1: Sources of Funding in the KEI Database

Federal Agency / Agencies	Company	Contract Number	Date (M/D/Y)	Purpose
DOD/ Army	AstraZeneca	W15QKN2191003	10/28/ 2020	Vaccine
DOD/ Army	Novavax	W911QY20C0077	6/4/ 2020	Vaccine
DOD/ Army	Novavax	W911QY20C0077 P0001	6/4/ 2020	Vaccine
DOD/ Army	Novavax	W911QY20C0077 P0002	6/4/ 2020	Vaccine
DOD/ Army	Novavax	W911QY20C0077 P0003	6/4/ 2020	Vaccine
DOD/ Army	Ology Bioservices (previously Nanotherapeutics, Inc.)	W911QY2090003	2/21/ 2020	Vaccine
DOD/ Army	Ology Bioservices (previously Nanotherapeutics, Inc.)	W911QY2090003 Mods 1-5,8-10,12,14,15,17,23-25.	Through 3/2/ 2021	Vaccine
DOD/ Army	Ology Bioservices (previously Nanotherapeutics, Inc.)	W911QY2090003-Appendix-A-4	3/20/ 2020	Vaccine
DOD/ Army	Pfizer	W15QKN1691002; MCDC2011-003	7/21/ 2020	Vaccine
DOD/ Army	Pfizer	W15QKN1690012	12/22/ 2020	Vaccine
DOD/ Army	Pfizer	W58P0521C0002	7/30/ 2021	Vaccine
DOD/ Army	Sanofi	W15QKN1691002; MCDC2011-005	7/30/ 2020	Vaccine
DOD/ Army/ DCMA	Grand River Aseptic Manufacturing (GRAM)	W3110Y2OCC086R1033	8/4/ 2020	Vaccine and Therapeutics
DOD/ Army/ JPEO-CBRND/ DCMA	Janssen (Johnson&Johnson) - ATI	W15QKN1691002-P00081; MCDC2011-004	8/5/ 2020	Vaccine
DOD/ Army/ Natick	Inovio Pharmaceuticals	W911QY2090016	6/22/ 2020	Delivery of vaccine
DOD/ Army/ Natick	Inovio Pharmaceuticals	Redacted, but W911QY20C0084	6/18/ 2020	Delivery of vaccine (Cellectra 2000)

Federal Agency / Agencies	Company	Contract Number	Date (M/D/Y)	Purpose
HHS/ ASPR/ BARDA	Esperovax	75A50120C00154	7/26/ 2020	Oral Vaccine Administration
HHS/ ASPR/ BARDA	Vaxess	75A50120C00160	8/6/ 2020	Spike Protein Manufacturing
HHS/ ASPR/ BARDA	AstraZeneca	75A501-20-C-00114	5/20/ 2020	Vaccine
HHS/ ASPR/ BARDA	AstraZeneca	75A501-20-C-00114 MODP00001	7/31/ 2020	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C	8/15/ 2017	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00001	Redacted	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00002	Redacted	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00003	Redacted	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00004	Not disclosed	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00005	12/19/ 2019	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00006	2/11/ 2020	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00007	3/20/ 2020	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00008	3/27/ 2020	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00009	Not disclosed	Vaccine
HHS/ ASPR/ BARDA	Janssen (Johnson&Johnson)	HHSO100201700018C-P00010	8/21/ 2020	Vaccine
HHS/ ASPR/ BARDA	Merck Sharp & Dohme	HHSO100201600031C	9/29/ 2016	Vaccine

Federal Agency / Agencies	Company	Contract Number	Date (M/D/Y)	Purpose
HHS/ ASPR/ BARDA	Merck Sharp & Dohme	HHSO100201600031C-P00001	5/27/ 2017	Vaccine
HHS/ ASPR/ BARDA	Merck Sharp & Dohme	HHSO100201600031C-P00002	9/6/ 2017	Vaccine
HHS/ ASPR/ BARDA	Merck Sharp & Dohme	HHSO100201600031C-P00003	5/23/ 2018	Vaccine
HHS/ ASPR/ BARDA	Merck Sharp & Dohme	HHSO100201600031C-P00004	5/9/ 2019	Vaccine
HHS/ ASPR/ BARDA	Moderna	75A50120C00034	4/16/ 2020	Vaccine
HHS/ ASPR/ BARDA	Moderna	75A50120C00034-P00003	Redacted	Vaccine
HHS/ ASPR/ BARDA	Protein Sciences Corporation (Sanofi)	HHSO100201600005I	2/14/ 2020	Vaccine
HHS/ ASPR/ BARDA	Texas A&M University System	75A50120F33007-P00001	8/27/ 2020	Vaccine
HHS/ ASPR/ BARDA	Texas A&M University System	75A50120F33007-P00002	10/9/ 2020	Vaccine
HHS/ ASPR/ BARDA	Texas A&M University System	HHSO100201200002I/ 75A50120F33007	7/23/ 2020	Vaccine
HHS/ ASPR/ BARDA	Moderna	HHS0100201600029C	9/1/ 2016	Vaccine (ZIKA)
HHS/ ASPR/ BARDA	Sanofi/Protein Sciences Corporation	HHSO100201600005I_ base_contract	8/16/ 2016	Vaccine Component Manufacturing and R&D
HHS/ ASPR/ BARDA	Emergent Biosolutions	HHSO100201200004I	6/15/ 2012	Vaccine Manufacture
HHS/ ASPR/ BARDA	Emergent Biosolutions	HHSO100201200004I task order 75A50120F33007	5/24/ 2020	Vaccine Manufacture
HHS/ ASPR/ BARDA	Emergent Biosolutions	75A50120F33007 P00001	8/24/ 2020	Vaccine Manufacture
HHS/ ASPR/ BARDA	Emergent Biosolutions	75A50120F33007 P00002	9/24/ 2020	Vaccine Manufacture

Federal Agency / Agencies	Company	Contract Number	Date (M/D/Y)	Purpose
HHS/ ASPR/ BARDA	Emergent Biosolutions	75A50120F33007 P00003	10/7/ 2020	Vaccine Manufacture
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND	Novavax - ATI	W15QKN1691002, MCDC2011-001	6/25/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND	Novavax - ATI	W15QKN1691002, MCDC2011-001 (Revised)	7/6/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND	Novavax - ATI	W15QKN1691002, MCDC2011-001	12/21/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100	8/9/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00001	8/9/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00002	9/11/ 2020	Vaccine

Federal Agency / Agencies	Company	Contract Number	Date (M/D/Y)	Purpose
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00003	12/11/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00004	2/11/ 2020	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00007	6/15/ 2021	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00008	6/16/ 2021	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00009	6/16/ 2021	Vaccine
HHS/ ASPR/ BARDA; DOD/ Army/ JPEO-CBRND/ DCMA	Moderna	W911QY20C0100-P00010	6/17/ 2021	Vaccine

TABLE 2: LIST OF FUNDING RECIPIENTS IN THE KEI DATABASE

Pharmaceutical Company	**Number of Contracts in KEI Database**
AstraZeneca	3
Emergent Biosolutions	5
Esperovax	1
Grand River Aseptic Manufacturing (GRAM)	1
Inovio Pharmaceuticals	2
Janssen (Johnson&Johnson)	11
Janssen (Johnson&Johnson) - ATI	1
Merck Sharp & Dohme	5
Moderna	12
Novavax	4
Novavax – ATI	3
Ology Bioservices (previously Nanotherapeutics, Inc.)	3
Pfizer	3
Protein Sciences Corporation (Sanofi)	1
Sanofi	1
Sanofi/Protein Sciences Corporation	1
Texas A&M University System	3
Vaxess	1

TABLE 3: TYPE OF CONTRACT BY R&D, MANUFACTURE OR PROCUREMENT

Company	Federal Agency or Agencies	Contract Number
AstraZeneca	HHS/ASPR/ BARDA	75A501-20-C-00114
AstraZeneca	HHS/ASPR/ BARDA	75A501-20-C-00114 MODP00001
AstraZeneca	DOD/Army	W15QKN2191003
Emergent Biosolutions	HHS/ASPR/ BARDA	HHSO100201200004I
Emergent Biosolutions	HHS/ASPR/ BARDA	HHSO100201200004I task order 75A50120F33007
Emergent Biosolutions	HHS/ASPR/ BARDA	75A50120F33007 P00001
Emergent Biosolutions	HHS/ASPR/ BARDA	75A50120F33007 P00002
Emergent Biosolutions	HHS/ASPR/ BARDA	75A50120F33007 P00003
Esperovax	HHS/ASPR/ BARDA	75A50120C00154
Grand River Aseptic Manufacturing (GRAM)	DOD/Army/ DCMA	W3110Y2OCC086R1033
Inovio Pharmaceuticals	DOD/Army/ Natick	W911QY2090016
Inovio Pharmaceuticals	DOD/Army/ Natick	Redacted, but W911QY20C0084
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00001
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00002
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00003
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00004
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00005
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00006
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00007
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00008

Company	Federal Agency or Agencies	Contract Number
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00009
Janssen (Johnson&Johnson)	HHS/ASPR/ BARDA	HHSO100201700018C-P00010
Janssen (Johnson&Johnson) - ATI	DOD/Army/ JPEO-CBRND/ DCMA	W15QKN1691002-P00081; MCDC2011-004
Merck Sharp & Dohme	HHS/ASPR/ BARDA	HHSO100201600031C
Merck Sharp & Dohme	HHS/ASPR/ BARDA	HHSO100201600031C-P00001
Merck Sharp & Dohme	HHS/ASPR/ BARDA	HHSO100201600031C-P00002
Merck Sharp & Dohme	HHS/ASPR/ BARDA	HHSO100201600031C-P00003
Merck Sharp & Dohme	HHS/ASPR/ BARDA	HHSO100201600031C-P00004
Moderna	HHS/ASPR/ BARDA	75A50120C00034
Moderna	HHS/ASPR/ BARDA	75A50120C00034-P00003
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00001
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00002
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00003
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00004

Company	Federal Agency or Agencies	Contract Number
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00007
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00008
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00009
Moderna	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND/DCMA	W911QY20C0100-P00010
Moderna	HHS/ASPR/ BARDA	HHS0100201600029C
Novavax	DOD/Army	W911QY20C0077
Novavax	DOD/Army	W911QY20C0077 P0001
Novavax	DOD/Army	W911QY20C0077 P0002
Novavax	DOD/Army	W911QY20C0077 P0003
Novavax - ATI	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND	W15QKN1691002, MCDC2011-001
Novavax - ATI	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND	W15QKN1691002, MCDC2011-001 (Revised)
Novavax - ATI	HHS/ASPR/ BARDA; DOD/ Army/JPEO-CBRND	W15QKN1691002, MCDC2011-001
Ology Bioservices (previously Nanotherapeutics, Inc.)	DOD/Army	W911QY2090003
Ology Bioservices (previously Nanotherapeutics, Inc.)	DOD/Army	W911QY2090003 Mods 1-5,8-10,12,14,15,17,23-25.
Ology Bioservices (previously Nanotherapeutics, Inc.)	DOD/Army	W911QY2090003-Appendix-A-4

Company	Federal Agency or Agencies	Contract Number
Pfizer	DOD/Army	W15QKN1691002; MCDC2011-003
Pfizer	DOD/Army	W15QKN1690012
Pfizer	DOD/Army	W58P0521C0002
Protein Sciences Corporation (Sanofi)	HHS/ASPR/ BARDA	HHSO100201600005I
Sanofi	DOD/Army	W15QKN1691002; MCDC2011-005
Sanofi/Protein Sciences Corporation	HHS/ASPR/ BARDA	HHSO100201600005I_ base_contract
Texas A&M University System	HHS/ASPR/ BARDA	75A50120F33007-P00001
Texas A&M University System	HHS/ASPR/ BARDA	75A50120F33007-P00002
Texas A&M University System	HHS/ASPR/ BARDA	HHSO100201200002I/ 75A50120F33007
Vaxess	HHS/ASPR/ BARDA	75A50120C00160