

# Science Held Hostage: How Pharma is Using mRNA Vaccine Contracts With Government to Delay Future Innovation

## A PrEP4All Prevention Equity Alert – April 2023

### *Executive Summary*

Clinical trials that are crucial to future pandemic prevention and current responses to SARS CoV-2 are being delayed by pharmaceutical companies. These companies are able to use government contracts specifying when, where and how current vaccines owned by governments can be used to delay and defer access to these vaccines for research. Current SARS CoV-2 vaccines are a vital part of research for next-generation products such as nasal vaccines and pan-coronavirus vaccines. Next-generation candidates need to be tested in animals who have been vaccinated with presently available vaccines to evaluate safety and effectiveness in the context of prior immunization. However, for over two years, the terms of government contracts with industry have had the inadvertent effect of delaying sometimes effectively blocking access to these products for research purposes.

Over the course of a six-month research effort, PrEP4All spoke with US government agencies, research groups, private philanthropy and industry to better understand the causes and consequences of this challenge. The crux of the issue is language in government procurement contracts for vaccines that specifies where and how the vaccine *owned by the government* can be used. This language does not in any way restrict companies from collaborating with researchers, for example by supplying doses of

### ***A note on this report's scope and focus***

This report focuses most specifically on the US policies, laws and guidelines that contribute to challenges in obtaining current SARS CoV-2 vaccines for research purposes. While it does not provide the same level of detail for other countries, the contours of the challenge are the same worldwide: government contracts with industry do not provide for government-owned product to be used for research purposes.

The issue has impacted all of the SARS CoV-2 vaccines in use today. This report focuses most closely on Pfizer-BioNTech and Moderna because of the wide use and high efficacy of mRNA vaccines.

the vaccine held by the company, according to government sources interviewed for this report. The contractual language in question, drafted in the context of a global health crisis, has had unforeseen consequences in terms of slowing studies and adding costs and logistical burdens to research activities.

This is an eminently solvable issue that must be addressed now—before new crisis.

## Recommendations

### In the short term:

- ▶ Pharmaceutical companies including Pfizer-BioNTech and Moderna must make vaccine doses available for clinical trials without delay through a simple, transparent application process that does not require the investigator or institute to share or assign intellectual property rights for the experimental product with the company that supplied the vaccine.

### In the long term:

- ▶ World Health Organization, Gavi, COVAX, the Medicines Patent Pool and governments of countries at all income levels must develop best practices for procurement in health emergencies including consensus boilerplate language for procurement contracts that would safeguard the purchasers' ability to conduct necessary research on existing products and on next generation products. This language should be referenced in the forthcoming Pandemic Accord, relevant requests for proposals from The Pandemic Fund and in all government funding to industry partners.

## ***The Problem: Clinical and pre-clinical research is stalled or slowed by lack of timely access to today's mRNA vaccines***

PrEP4All identified three areas where barriers to access to mRNA vaccines are impeding progress:

- ▶ Pre-clinical trials of novel SARS CoV-2 and pan-coronavirus candidates
- ▶ Clinical trials of mRNA vaccines as boosters and primary series in specific populations such as PLHIV and the elderly in low and lower-middle income countries
- ▶ Validation of the WHO mRNA Hub located at Afrigen in Cape Town, South Africa

## ***Held Hostage: Pre-clinical trials of novel SARS CoV-2 and pan-coronavirus candidates***

While the sense of emergency about SARS CoV-2 has subsided, the need for next generation products has not diminished. This coronavirus will be endemic for the foreseeable future. New variants will emerge, and other novel coronaviruses could enter circulation. There is every reason to continue pursuing novel vaccines, including nasal formulations—which might allow for complete protection against infection for SARS CoV-2. Now is the time to identify effective pancoronavirus vaccines that could protect against a range of viruses in this family.

To establish whether next-generation products are effective, and before these products move to human studies, they need to be tested in animals who have been vaccinated with presently available vaccines. Currently available vaccines are also needed as reference product. A current vaccine, with known levels of efficacy, can be tested in animal or in vitro models and the results from those tests can then be used as a comparator, or point of reference, for next-generation products.

However, scientists in the United States—including those with US government grants—face enormous obstacles in obtaining the vaccines needed for animal studies. “This is a huge challenge,” one scientist told PrEP4All. “We looked everywhere and could not find a way to get Pfizer and/or Moderna mRNA vaccines.” Researchers described seeking used vials with leftover doses from health facilities and doses that were at or near expiry from hospitals and health departments. While these strategies were met with some success, the access was unstable and put clinics or health departments at risk, since the act of sharing even punctured vials for research purposes is a violation of the [CDC Provider Agreement for mRNA vaccines](#).<sup>1</sup> For a full explanation of the source of the restrictions, see the next section.

One solution being used by some research groups, including those supported by National Institutes of Health, is purchase and validation of components that approximate Pfizer and Moderna’s mRNA vaccines. One Contract Development and Manufacturing Organization (CDMO), Helix Biotech, has formulated mRNA containing lipid nanoparticles (LNPs) using components that it describes as equivalent to the monovalent and bivalent Pfizer vaccines. One lab we spoke with was using these material as Pfizer-like vaccines for comparative purposes.

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<sup>1</sup>The Provider Agreement specifies that all COVID vaccine is US government property and can only be used by enrolled vaccination providers for immunizing humans. Specific relevant language includes:

*\*At this time, all COVID-19 vaccine in the United States has been purchased by the U.S. government (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law.”*

This lab described evaluating the immunogenicity of these “generic” vaccines in its own animal models, though as they noted, “we don’t have an authentic control [ie the Pfizer bivalent vaccine] to compare it to.” Other researchers have immunogenicity data from a precursor to the Moderna mRNA vaccine that they’re using as an approximate control for evaluation of the “generic” vaccine. Helix provides contract development support for pre-clinical research and can produce vaccine-style mRNA and LNP samples under the [US Hatch Waxman Act](#), which allows for generic production of patent-protected life-saving products to accelerate research while protecting patent holder interests. While this workaround has allowed preclinical studies to proceed that might otherwise have halted altogether, or continued without animals immunized with mono- and bivalent mRNA vaccines, it comes at an additional financial, logistic and, potentially, scientific cost—as there is no way of validating that the “generics” are equivalent to the originator products.

Both Pfizer and Moderna also offer independent investigator grants, which include financial resources and access to vaccine. However the Pfizer-BioNTech contract<sup>2</sup> reviewed by PrEP4All stipulates that the company will have non-exclusive intellectual property rights to any ‘invention’ discovered as a result of the trial where the donated vaccine was used. As one investigator told PrEP4All, these conditions meant that their university simply would not consider pursuing a grant from the company. When queried as to whether Pfizer would remove this restriction, the company stated, “The incentives provided by the patent system enabled BioNTech and Pfizer to build an infrastructure that allowed us to quickly mobilize and devote the resources, technical knowledge and know-how that is required to combat the pandemic. Maintaining that system is what will fuel the next generation of solutions and allow us to tackle any future crisis.”

Across conversations, PrEP4All heard reports of delays in research ranging from a few months to nearly a year. There are other obstacles, including shortages of components for candidates and limited clinical grade manufacturing capacity. However, the lack of easy access to mRNA vaccines was flagged by all the stakeholders we spoke to as a major barrier.

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<sup>2</sup>Pfizer-BioNTech “Key Contractual Terms and Conditions: Pfizer-BioNTech COVID-19 Investigator Sponsored Research Grants,” obtained by PrEP4All and available for viewing in full on our website states in Section 9, “Inventions,” on, page 18:

9.2. *Product-Related Inventions. Institution will grant and hereby grants to Pfizer a non-exclusive, sub-licensable, transferable, perpetual, irrevocable, worldwide, royalty-free, fully paid-up license for all purposes to each Product-Related Invention owned by it (including for avoidance of doubt any patent rights filed on such Invention). Such non-exclusive license will include the rights to: (i) sublicense to BioNTech SE and its affiliates, to a Pfizer affiliate, contractor or collaborator working for the benefit of Pfizer or in connection with a product or service of Pfizer or a Pfizer affiliate, collaborator or contractor; and (ii) sublicense or assign to a successor-in-interest some or all rights in a BioNTech or Pfizer product to which the Product-Related Invention is relevant. Institution hereby grants to Pfizer the first right to negotiate an exclusive, sub-licensable, transferable, perpetual, irrevocable, worldwide license for all purposes, with full rights to sublicense and assign, to each Product-Related Invention owned in whole or in part by it, under terms to be negotiated in good faith between the parties. Institution will promptly inform Pfizer in writing upon generation of any Product-Related Invention.*

## ***Held Hostage: Clinical trials of mRNA vaccines as boosters and primary series in specific populations such as PLHIV and the elderly in low and lower-middle income countries***

The current SARS CoV-2 vaccines were evaluated rapidly, in limited geographies and without structured studies looking at vaccine efficacy in specific subpopulations. Information about how mono- and bivalent vaccines as primary series and boosters can reduce the risk of morbidity and mortality in elderly and immunocompromised people, particularly in low- and lower-middle income countries where vaccine roll out was initially delayed, remains limited. The trials that could have provided this information were delayed due to challenges in obtaining vaccines for the research. High income countries with vaccine supplies cannot donate for research purposes without permission from the manufacturer. One entity involved in funding trials called the situation “exceedingly frustrating,” and stated that trials in low- and lower-middle income countries designed to learn more about how primary immunization and boosters impact disease severity and mortality in people living with HIV, the elderly and other populations have been slowed down by delays in company decisions about whether to authorize use of the product for these trials. The entity estimated that a trial looking at the impact of boosters on disease severity in people living with HIV was delayed for a year. Because the virus is changing all the time, research questions also evolve. The delays mean that when company approval comes, the question is often obsolete.

## ***Held Hostage: Validation of the WHO mRNA Hub located at Afrigen in Cape Town, South Africa***

In 2021, the French government, with assistance from the Medicines Patent Pool, sought permission from Pfizer-BioNTech and Moderna to ship French-government owned doses of mRNA vaccine to Afrigen, in South Africa, which needed them as reference material to establish the quality of vaccines produced by the mRNA hub. Moderna agreed to the request; according to the MPP, and as [reported in the press](#),<sup>3</sup> Pfizer did not, reportedly stating that there was adequate global supply of mRNA vaccines for SARS CoV-2 and therefore no emergency to justify Afrigen’s request. The French government later asked Moderna for permission to use additional doses in human clinical trials. As this report went to press, the company had not yet replied. If the Hub does not validate its manufacturing capabilities at this moment—when global mRNA vaccine supply is not an issue—then it will not be able to meet global needs when the next crisis emerges. This is an emergency situation, and all relevant companies should expedite permissions and share supplies as needed.

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<sup>3</sup> Anthony Sguazzin, 2022. “Moderna Gives WHO’s mRNA Hub Some Help, Pfizer Snubs Request,” September 19, 2022, Bloomberg News. <https://www.bloomberg.com/news/articles/2022-09-19/moderna-gives-who-s-mrna-hub-some-help-pfizer-snubs-request?leadSource=uverify%20wall> (Accessed 13 January, 2023)

## ***The Cause: Industry is invoking clauses in procurement contract language—instead of providing a solution***

The current situation stems from the contracts that the US government, COVAX and all other governments purchasing mRNA vaccines signed with industry to obtain doses. The contractual language restricts where the vaccine can be used and limits usage to the scope defined in the regulatory authorization for the immunization. In the US, this is the Food and Drug Administration's [Emergency Use Authorization](#) issued for each vaccine, specifying that it can be used for for primary (monovalent) and booster (mono- and bivalent) immunization in children and adults. In the United States, the EUA-defined scope of use is stipulated in the [Public Readiness and Emergency Response \(PREP\) Act](#)<sup>4</sup>, which protects manufacturers, providers, program managers and many other responders in a public health emergency from liability for things that might happen in the midst of the emergency response. The Act existed prior to SARS CoV-2 and has been updated several times since the start of the pandemic to cover providers, manufacturers and other entities involved in the SARS CoV-2 response.

Through the PREP Act, the US government provides pharmaceutical companies with the assurance that they will not be held responsible for anything that happens with products made available as part of a response to a public health emergency. For SARS CoV-2 vaccines, this indemnification only holds as long as the product is used in accordance with the Emergency Use Authorization for the vaccine. These EUAs restrict the use to immunization of the US population in the geographies where the company is protected from liability by the PREP Act.

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<sup>4</sup>The PREP Act update, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 issued by the Department of Health and Human Services on March 17, 2020, states that, "To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act." Liability is waived only if the product is used in accordance with the EUA. <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures> (Accessed January 13, 2023)

For example, in the Moderna contract, the section titled Public Readiness and Emergency Preparedness (PREP) ACT in every contract<sup>5</sup> states:

Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the “Disputes Clause” (52.233-1) .

Government representatives familiar with these issues who spoke to PrEP4All for this report stated that, “The primary objective of including the PREP Act language is to provide vaccine developers with clarity on who will be receiving the vaccine. This in turn allows them to better understand their requirements for execution of the contract deliverables – things like labeling, pharmacovigilance, liability that are influenced by receiving population. Secondly, the PREP Act language, along with other language in the contract around scope, deliverables, terms and conditions, etc., further defines the contract/agreement objectives.”

When governments want to use SARS CoV-2 vaccines for purposes other than those in the original contract, they query industry partners. This step occurred as part of vaccine donations from the US and other high income countries to low and lower middle income countries. A donation for an immunization campaign could not be used for research purposes, including research in humans, without additional negotiation.

This level of attention to where and how the vaccine will be used and to reducing industry liability is warranted and appropriate, especially in a crisis situation. Operation Warp Speed compressed normal product development timelines to a fraction of the yearslong process of development and data collection that usually precedes introduction of a new vaccine. The Operation Warp Speed timeline was short because of immense investment, political will, and pressing need.

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<sup>5</sup>All of the procurement contracts issued under Operation Warp Speed can be found online at the US Department of Health and Human Services Freedom of information Act Reading Room. The <https://www.hhs.gov/foia/electronic-reading-room/index.html>



However, industry is using the conditions in contracts that apply to government-owned vaccine as the rationale for restricted access, on the part of research groups, to the vaccines that it owns. As representatives from Pfizer told PrEP4All, “We’re limited in so many ways because the vaccines are being purchased only by governments around the world.” However, the US government groups PrEP4All spoke to affirmed that the companies were not constrained by government contracts, and that companies would not need to seek government approval to use vials not needed to fulfil the contractual requirements.

The companies that made first generation vaccines could readily make those vaccines available for preclinical research. Several stakeholders PrEP4All interviewed ascribed traced industry reluctance to make reference product available to the concerns that the research would identify superior or equivalent products that might become competitors or, in the case of human trials, that side effects or adverse events not previously reported might be observed. The concern about competition would appear to be substantiated by the previously-cited Pfizer-BioNTech agreement which provides the company with non-exclusive rights to products developed in trials it supports.

### ***The Solutions: Resolve uncertainty, remove IP provisions in pharma contracts, and develop new language to prevent the problem in the future***

The barriers to access to mRNA vaccines that are delaying scientific progress are readily solvable. Industry partners could immediately make vaccine available for next generation studies with limited or no restrictions with regard to intellectual property rights. Government purchasers could request vaccine supplies for preclinical trials. In the near term, as vaccines enter the marketplace—meaning they can be bought by non-governmental entities—the barrier to research use might also be reduced, if not removed. In theory, a laboratory could budget for and procure the vaccines they need as reference product. However it is not clear for how long and how readily monovalent vaccines will be available or what research groups would be charged.



Now is the time to take steps to remove this barrier to scientific progress. Here's how:

**In the short term:**

- ▶ **Pharmaceutical companies including Pfizer-BioNTech and Moderna must make vaccine doses available for clinical trials without delay through a simple, transparent independent investigator application process that does not require the investigator or institute to share or assign intellectual property rights for the experimental product with the company that supplied the vaccine<sup>6</sup>. Governments must use all possible leverage to expedite permissions to use mRNA vaccines for research, especially in instances where the government has patent rights or provided significant funding for the vaccine.**

**In the long term:**

- ▶ **World Health Organization, Gavi, COVAX, the Medicines Patent Pool and governments of countries at all income levels must develop best practices for procurement in health emergencies including consensus boilerplate language for procurement contracts that would safeguard the purchasers' ability to conduct necessary research on existing products and on next generation products. This language should be referenced in the forthcoming Pandemic Accord, relevant requests for proposals from The Pandemic Fund and in all government funding to industry partners.**

Activists can hold all of these bodies accountable through direct action, lobbying elected officials and engaging in the Accord and Fund processes where decisions about provisions for research and research funding are made. Together, we can remove a barrier that is holding scientific progress hostage.

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<sup>6</sup> In March 2023, in response to queries from PrEP4All, Pfizer's US Vaccines Policy and Public Affairs Lead stated that a "specific GMG [Global Medical Grant] process is being set up to provide vaccine to non-government organizations as a comparator for trials in vaccine development of other vaccines." Pfizer stated that this competitive grant program would involve a publicly posted request for proposal, followed by review and approval by the company. As this report went to press, the RFP had not been posted. It is not clear whether this grant contract would have the same terms with regard to granting of a non-exclusive license to Pfizer as the independent investigator grant previously cited. Given Pfizer's response to the query about removing the clause, cited in the body of this report, it seems likely that the language would be retained. The program as described leaves decisions about the scientific merit of the proposed research with the company, an arrangement that could lead to conflicts of interest.

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## About PrEP4All

PrEP4All is a nonprofit advocacy organization that uses AIDS activist tactics to address the ongoing HIV epidemic as well as emerging outbreaks and pandemics, such as MPOX and COVID-19. Our goal is ensuring equitable access to urgently needed biomedical prevention, diagnostics, and therapeutics. To learn more about our work, please visit [www.prep4all.org](http://www.prep4all.org).