



Issue Brief

Funding Scientific Research and Product Development For COVID-19 Innovation

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In May 2020, the U.S. government launched Operation Warp Speed (OWS) in a historic effort to accelerate the development, production, and distribution of COVID-19 vaccines and therapeutics. The joint effort between the Department of Health and Human Services (HHS) and the Department of Defense (DoD) aimed to provide a vaccine for distribution by January 2021, significantly shortening the usual vaccine development timeline.

The U.S. government committed over \$11 billion to pharmaceutical companies through OWS. Such commercialization incentives are atypical, as the government has generally funded basic research but has relied on industry to fund product development and distribution.

Funding Research & Development

Before OWS, similar programs to fund research and development of innovative technologies included the Small Business Innovation Research (SBIR) program and the Biomedical Advanced Research and Development Authority (BARDA). OWS has provided companies with greater government assistance than past SBIR or BARDA grants, potentially maintaining the US leadership of the global biomedical industry. This issue brief will describe the governance and structure of OWS and compare it to BARDA, a program that has a similar funding model focused on biomedical innovation and commercialization.

OWS was Designed to Accelerate the Process

OWS was formed “to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.”¹ To accelerate the normal vaccine development timeline that can take upwards of ten years, companies signed agreements with OWS to secure grants at developmental milestones and provide pre-purchased doses to the U.S. government, to be delivered once the treatment is proven to be safe and effective.²

The HHS & DoD: An Unusual Partnership

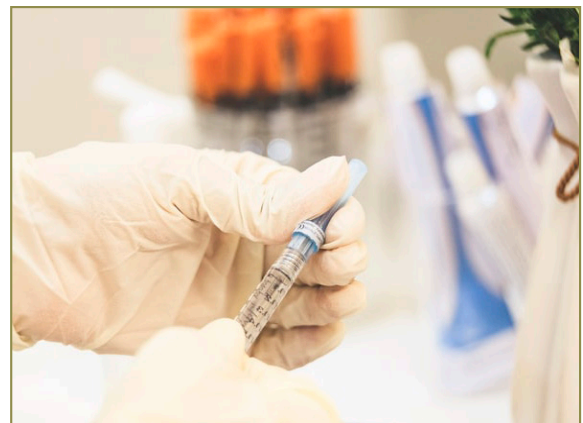
At the heart of OWS is an unusual partnership between HHS and DoD. HHS handled candidate selection while DoD has coordinated development, manufacturing, and distribution operations with participating companies. OWS was overseen by HHS secretary Alex Azar and Acting Defense Secretary Christopher Miller.³ Similarly, Moncef Slaoui, a retired Chairman of Global Vaccines at GlaxoSmithKline, served as the Chief Adviser. General Gustave Perna served as the Chief

Operating Officer. Both Slaoui and Perna are supported by HHS scientists and DoD subject matter experts, respectively. The Center for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and BARDA, all agencies within the HHS, support administrative and operational roles including distribution, diagnostics, and manufacturing.

Changes to OWS Structure & Governance

The Biden administration has made several changes to OWS structure and governance, including renaming OWS to Covid Response. David Kessler, former head of FDA, will be replacing Moncef Slaoui as the chief scientist, although Slaoui will remain on board as a consultant to OWS. The Biden administration also appointed Bechara Choucair, a former executive at Kaiser Permanente to serve as vaccine coordinator, and Tim Manning, a former FEMA official to serve as supply coordinator. The team has set a goal of vaccinating 100 million people before Biden’s 100th day in office.

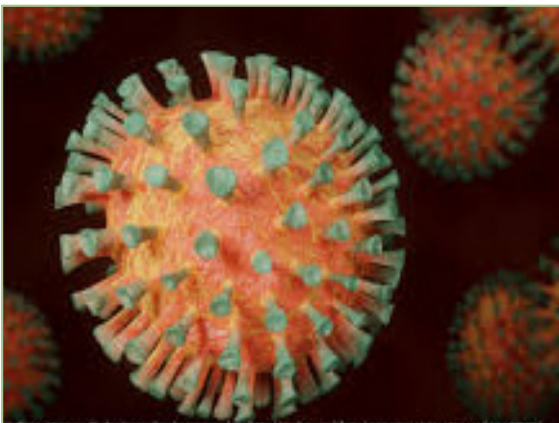
The details about the complex organizational structure of OWS funding remain confidential.



However, information released on the HHS website indicates that Congress issued \$10 billion of the CARES Act funding to the HHS, with \$6.5 billion allocated for BARDA and \$3 billion for the NIH.⁴ The NIH created its RADx (short for radical diagnostics) initiative to scale current and future diagnostics technologies, while OWS focused on vaccines and therapeutics. The RADx program has maintained independence from OWS and has a different governance culture. While the NIH is transparent in its governance and grants, OWS is secretive, primarily due to the involvement and influence of the DoD.

Funding Details: Complex & Confidential

A document leaked to STAT indicates that OWS is dominated by DoD leaders.⁵ The DoD is specialized in handling the complex logistical tasks needed for the distribution of vaccines, among which security and reliability are paramount. However, the recent mishandling of vaccine distribution has cast doubt on the necessity of the DoD partnership.⁶ States have been left to determine vaccine distribution, which has led to vaccination campaigns different from CDC recommendations.⁷



An Expanded Role for, and Confidence in, Public Investment?

The long-dominant paradigm of innovation funding has assigned to the public sector the role of supporting scientific research and to the private sector the role of supporting product development and commercialization. In short, the taxpayer funded the R and private investors funded the D in R&D (Research and Development). The imperatives of the moment changed all this, at least for the moment.

The COVID-19 pandemic imposed on society health and economic burdens so swift and so large as to overwhelm the capabilities of the private sector. In particular, vaccine R&D needed large and immediate investments in product development, clinical testing, manufacturing capacity, and distribution networks. No one gave serious attention to the traditional preference for private investment, funded by the pharmaceutical industry based on profits from previous innovations or by venture capitalists in anticipation of future innovation. Certainly, private investments did play a role, but the heavy lifting was done by the federal government, coming the resources and the organizational capabilities of the Department of Health and Human Services and the Department of Defense.

And lo and behold, it worked. The traditional paradigm was based on a suspicion that the government would do a poor job of 'picking winners,' of deciding which firms were likely to generate successful products if allocated taxpayer funds. But most of the firms selected by the government did produce successful vaccines. Other nations also supported their domestic vaccine industries, and many of them also were successful. Vaccine candidates in China, Britain, Russia, and elsewhere mostly used public funds, and many successfully participated in the innovation race with US firms.

The question now becomes: what will happen after COVID-19 recedes. Will the traditional division of labor between the public and private sectors reassert itself, or will the public sector retain a broader mandate in the life sciences?



BARDA was originally designed to fund research and development of technologies and infrastructure through public-private partnerships in response to perceived biological threats that are traditionally underfunded by the biopharmaceutical industry.⁸ Conceived in 2011, BARDA has partnered with over 300 companies to address these concerns. Its partnerships have led to the FDA approval of over 50 products, ranging from influenza vaccines to diagnostics for anthrax and Zika virus.⁹ BARDA has been used to fund a large portion of OWS' contracts with additional "flexible funding" sources that have yet to be disclosed.¹⁰

OWS Committed up to \$11 Billion

OWS has committed up to \$11 billion¹¹ to seven vaccine and two therapeutics companies, substantially more than BARDA's 2019 budget of \$1.27 billion. Vaccine criteria developed by OWS included robust preclinical data, ability to enter phase 3 clinical trials during the summer or fall of 2020, and the capacity to reliably produce a vaccine or therapeutic at scale.¹² OWS funding contributed directly to five of the six vaccines developed by major western nations including the US. The Pfizer BioNTech partnership received no direct R&D funding from OWS but did sign major pre purchase contracts.

Johnson & Johnson (Janssen) and Moderna signed contracts for funding early clinical trials with HHS in March and April of 2020 respectively. Following the advent of OWS, contracts were then signed by AstraZeneca, Regeneron,

Novavax, Pfizer, Sanofi, GSK, and Eli Lilly. Janssen and Moderna extended their agreements with OWS to include phase 3 trials and vaccine procurement, bringing them in line with the other agreements signed. While many of the details of these contracts were kept secret, the US government was often promised the first 100 million doses produced. If every vaccine candidate is successful, the US will be guaranteed 800 million vaccine doses.

Pressure for Contract Transparency

Bowing to public and congressional pressure, OWS recently released heavily redacted contracts with a few of their portfolio companies¹³. OWS contracts are not subject to the regulatory oversight and transparency guidelines that typically accompany government funding.¹⁴ OWS funds routed to a defense contract management firm, Advances Technologies International (ATI), which provides partner companies with the agreed funding. This approach is common for defense projects where security and agility are prioritized over transparency. The defense department has cited the national security risks involved with vaccine procurement but has been criticized for weakening taxpayer protections.¹⁵

Milestone Grants & Pre-Purchase Agreements

The published contracts contain milestone grants and pre-purchase agreements.¹⁶ The milestone grants (a variant of push funding that is supplied if a candidate reaches regulatory milestones) need not be repaid if the vaccine candidate is unsuccessful. In a recent interview with

BioCentury, Slaoui remarked that “if phase III trials had failed, all the monies would have come from the U.S. Government,” signaling the vast extent of government support in development.¹⁷ Pre-purchase agreements function as pull incentives for successful candidates that are FDA approved. This is in contrast with the current drug development paradigm where the government funds basic research and science, with promising technologies being developed, manufactured, and distributed by private firms.¹⁸ These private firms are given a patent on their technology in order to charge above-market prices for a period of time to regain their development costs.

Conclusion

OWS upsets the paradigm as the government is now investing in every stage of the drug’s development, including commercialization. In return for subsidizing development, manufacturing, and distribution, OWS requested priority treatment of their citizens. The redacted OWS contracts reveal little about milestone payment quantities and global access although they assure that the US government will receive the vast majority of initial supply. Despite the billions of dollars committed by OWS, the US is expected to pay more per dose than the European Union.¹⁹

The FDA approved the Pfizer and Moderna vaccine candidates for emergency use in December with vaccine distribution following shortly thereafter. These results show promise for government funding of biomedical development in the future. Whether or not the OWS model will be copied in the future remains undetermined.

Citations

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