EXHIBIT 2

Department of Defense (DoD) and Biomedical Advanced Research and Development Authority (BARDA) Roles in Manufacture and Deployment of Covid Countermeasures:

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Executive Summary

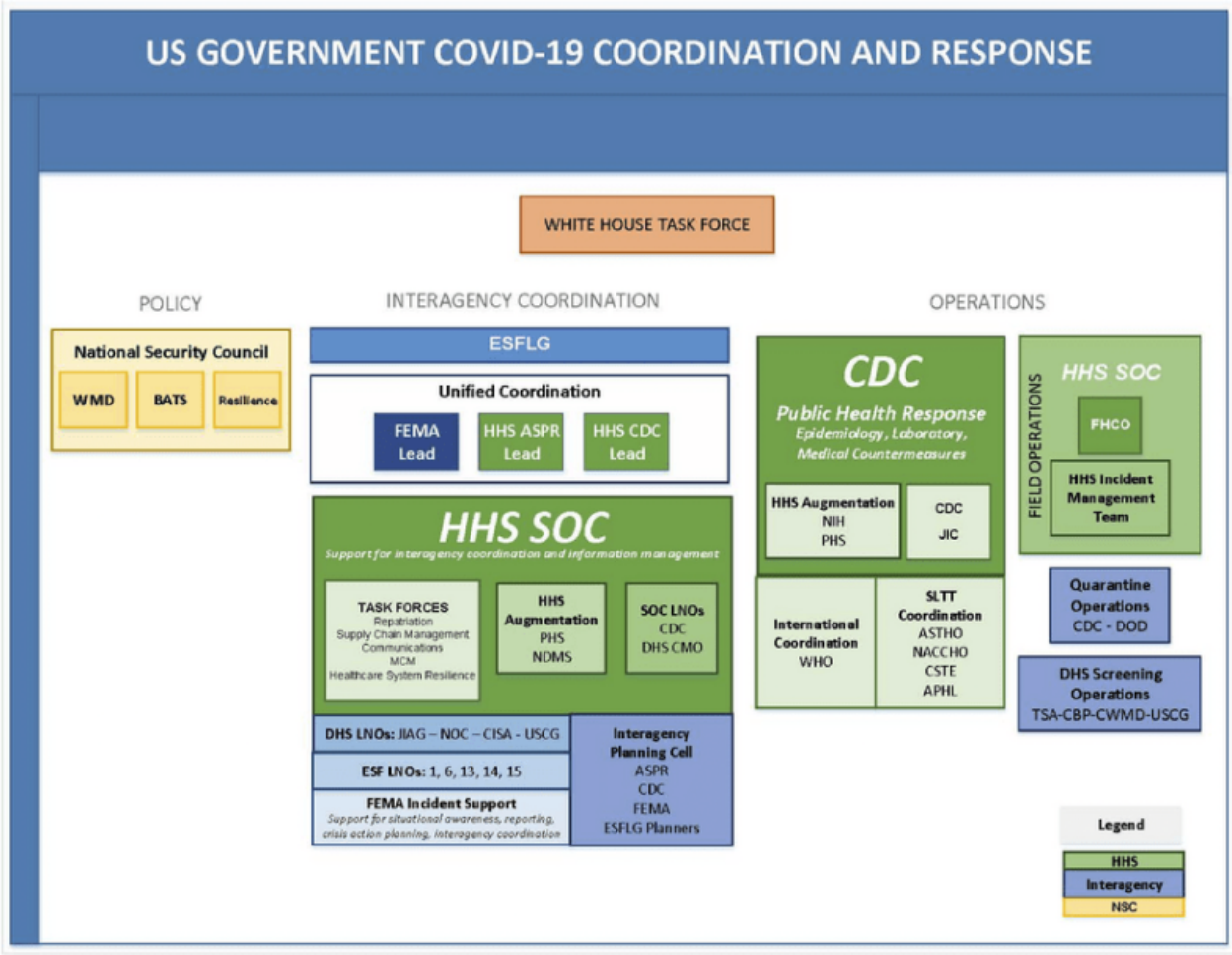
- **All Covid countermeasures, including biological materials marketed as vaccines, were ordered by the DoD as a "large scale manufacturing demonstration" via Other Transactions Authority contracts.**
- **According to Operation Warp Speed/HHS Assistant Secretary for Preparedness and Response (ASPR) reports, DoD ordered and oversaw the development, manufacture, and distribution of the countermeasures.**
- **Hundreds of contracts for Covid countermeasures became available via FOIA and SEC disclosures in partially-redacted form.**
- **Review of these contracts indicates a high degree of control by the US Government (DOD/BARDA) and specifies the scope of deliverables as "demonstrations" and "prototypes" only.**
- **The contracts include the removal of all liability for the manufacturers and any contractors along the supply and distribution chain under the 2005 PREP Act and related federal legislation.**
- **While the DOD/BARDA countermeasure contracts refer to safety and efficacy requirements for vaccines and mention current Good Manufacturing Practices (cGMP) compliance, these items are explicitly carved out as not being paid for nor ordered by the US Government.**
- **Use of Emergency Use Authorized (EUA) covered countermeasures under a declared Public Health Emergency cannot constitute a clinical investigation (21 USC 360bbb-3(k)), therefore these countermeasures could not be tested for safety or efficacy in accordance with US law (21 CFR 312 and 21 CFR 601), nor could compliance with current Good Manufacturing Practices (cGMP) or Good Distribution Practices (GxP in general) be enforced by the FDA.**
- **This legal fact was known to high-level FDA officials, to DOD and BARDA officials and to the pharmaceutical companies signing these contracts.**
- **This fact was not known to the public, clinical investigators, clinical trial subjects, or the lower-level employees of the pharmaceutical companies and the US Government.**

A. DoD role in manufacture and deployment of Covid countermeasures.

National Security Council (and not Department of Health and Human Services) is in charge of Covid policy in the US.

March 13, 2020: "PanCAP Adapted U.S. Government COVID-19 Response Plan" (PanCAP-A) states that United States policy in response to SARS-CoV-2 is set not by the public health agencies designated in pandemic preparedness protocols (Pandemic and All Hazards Preparedness Act,[1] PPD-44,[2] BIA), but rather by the National Security Council, or NSC. NSC does not have regular attendees from public health agencies and its focus is national security and foreign policy matters."

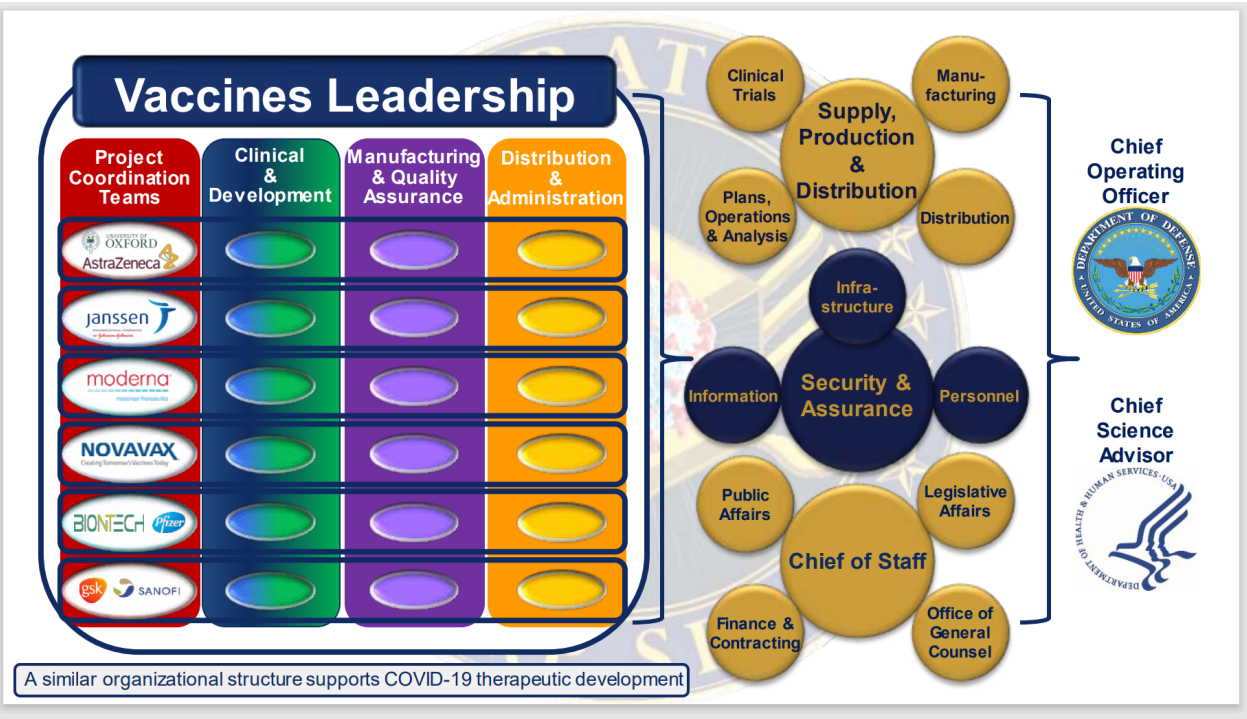
Below is the organization chart from the PanCAP-A document, p.9:



[1] https://www.govinfo.gov/content/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf
[2] https://www.in.gov/dhs/files/FEMA-Fact-Sheet-COVID-Response-3.4.20.pdf

Operation Warp Speed Organization Structure

According to the Operation Warp Speed/ASPR reports, Operation Warp Speed was declared as a "collaborative" effort of the DOD and HHS to produce "safe and effective" Covid-19 vaccines and therapeutics. However, according to the organizational chart, the DOD was formally the Chief Operating Officer, while HHS had the Chief Science Advisor position.[3]



VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf

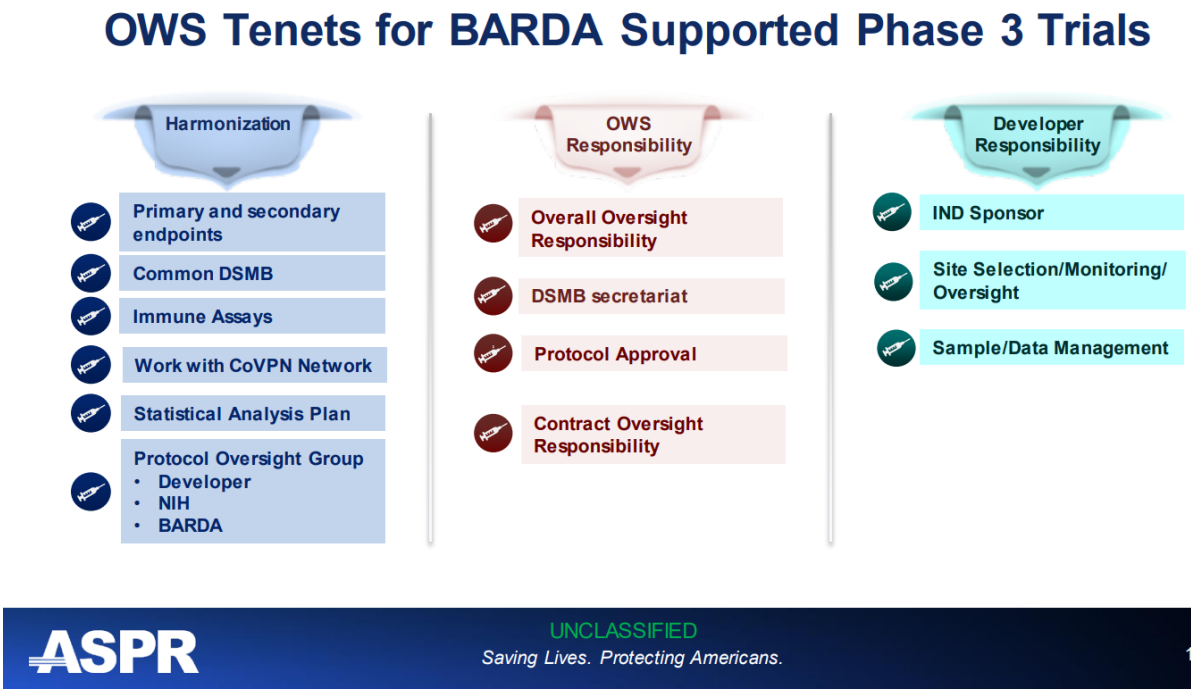
Notably, the next senior most layer of the organization is controlled by the US Government and includes all supervisory roles for manufacturing, clinical trial design and implementation, planning operations and analysis, distribution, public affairs, contracting, legal and other functions. The pharmaceutical companies are the third level down in this organization.

A report by STAT News in 2020 pointed out that roughly 60 military officials, including four generals, were involved in the leadership of Operation Warp Speed, many of them without any previous healthcare experience. Out of roughly 90 leadership positions on the organizational chart, only 29 were not employed by the DoD.[4]

The unclassified October 2020 documents from Operation Warp Speed presentations at the FDA's Vaccines and Related Biological Products Advisory Committee reveal control of the US Government over nearly all product design and implementation aspects of the development and clinical trials for Covid countermeasures, with the responsibility of the Sponsor (pharmaceutical

[3] See "VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf" in Attachment
[4] https://www.statnews.com/pharmalot/2020/09/28/pharmalittle-operation-warp-speed-is-more-army-than-science-jjs-covid-19-vaccine-moves-forward/

company) being only [Investigational New Drug application] IND ownership, [clinical trial] site selection/monitoring and sample and data management[5].



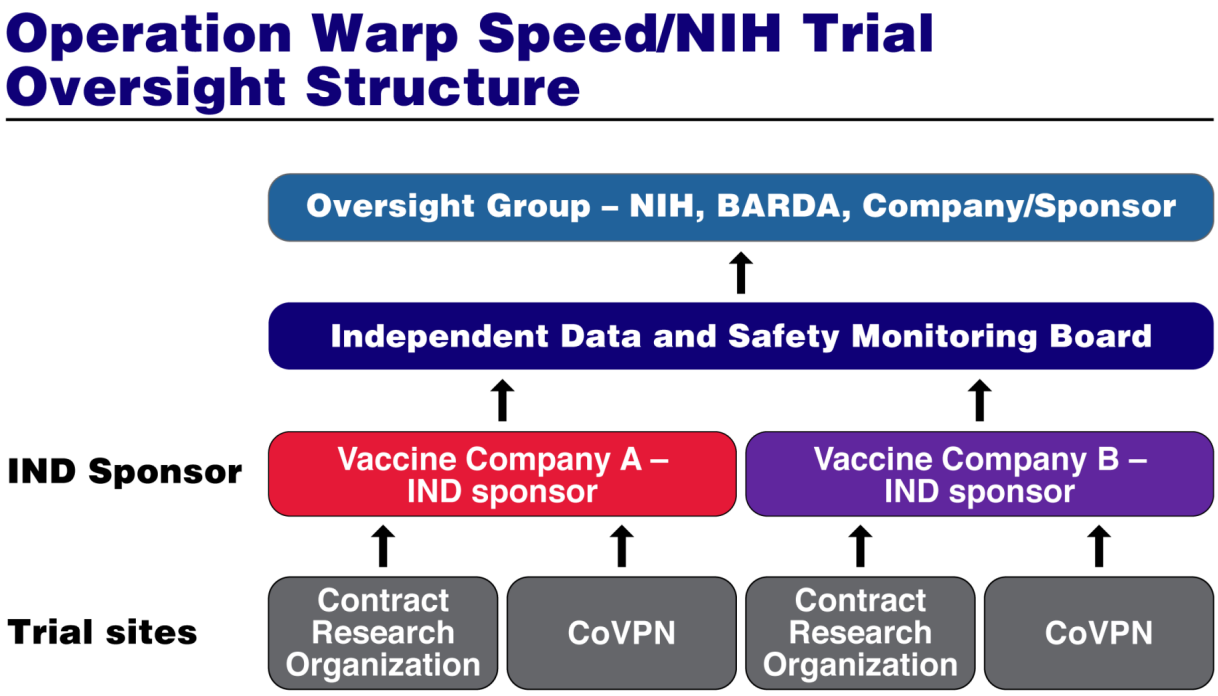
Control of the Data Safety Monitoring Board by the NIH

Operation Warp Speed also established a single Data Safety Monitoring Board (DSMB), controlled by the NIH and BARDA. This is unusual for clinical development where each pharmaceutical sponsor is responsible for establishing their own safety monitoring board and represents a highly significant degree of control as well as a potential for undue influence over the process.

The NIH/BARDA safety board was overseeing trials in the U.S. from Moderna, Johnson & Johnson and AstraZeneca, but not Pfizer, which was fully funding its clinical trial work and established its own five-member safety panel. The identities of the 10-15 experts on the safety monitoring boards were kept secret.

[5] See "VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf" in Attachment

This is illustrated by the NIH presentation at the Vaccines and Related Biologicals Advisory Committee Meeting, October 22, 2020:[6]



This tightly controlled single structure also meant that one board had an outsize influence to dictate which coronavirus vaccines eventually succeeded or came to a halt, all while most of their identities remained secret. The NIH declined to name them, saying they were "confidential" and could be identified only once a study was complete.

The identity of the DSMB chair Dr. Richard Whitley, an expert in pediatric infectious diseases at the University of Alabama-Birmingham was the only one publicly disclosed.[7] He was appointed as chair by Dr. Anthony Fauci.

[6] See "VRBPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-NIH-Role.pdf" in Attachment
[7] https://www.medscape.com/viewarticle/938066?reg=1&icd=login_success_email_match_norm#vp_3

B. Review of DoD/BARDA Contracts for Covid Countermeasures

Countermeasures were ordered by the DoD via Other Transaction Authority

Hundreds of Covid countermeasures contracts became available via FOIA and SEC disclosures in redacted form.[8] Review of these contracts indicates a high degree of control by the US Government (DoD/BARDA) and specifies the scope of deliverables as "demonstrations" and "prototypes" only. The contracts include the removal of all liability for the manufacturers and any contractors along the supply and distribution chain under the 2005 PREP Act and related federal legislation.

While the DoD/BARDA countermeasure contracts refer to safety and efficacy requirements for vaccines and mention current Good Manufacturing Practices (cGMP) compliance, these items are explicitly carved out as not being paid (or ordered) by the US Government.

The contracts are structured under Other Transactions Authority (OTA) - a method of contracting that was utilized by the DoD and BARDA for all Covid-related countermeasures ordered from the private industry. The OTA method of contracting allows federal agencies to order otherwise-regulated products bypassing any such regulations, as well as financial accountability mechanisms that cover standard government contracting, and other laws that regulate disclosure and Intellectual Property (IP) derived from publicly funded research.[9]

"Other" is a catchall category that is not a contract, not a research grant, not a procurement, etc.: not any normally regulated/accountable government contracting.

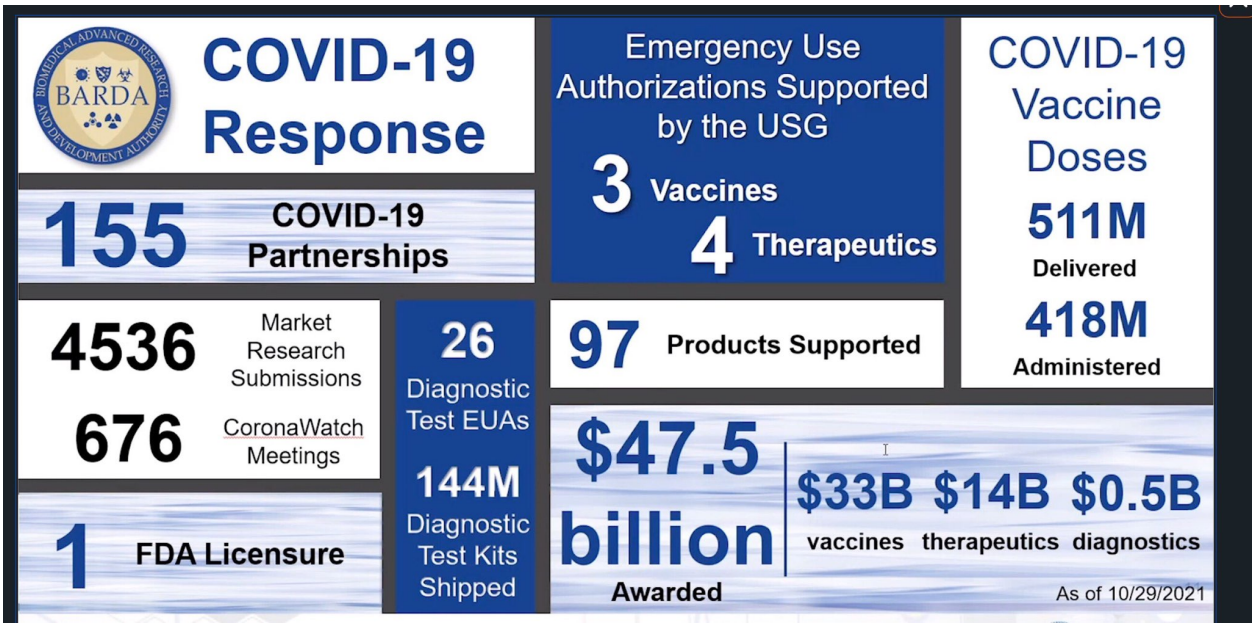
DoD used OTA to order vaguely defined "prototypes" and "demonstrations" that are not subject to regulatory scrutiny.

DoD/BARDA exerted overwhelming control over the pharmaceutical industry

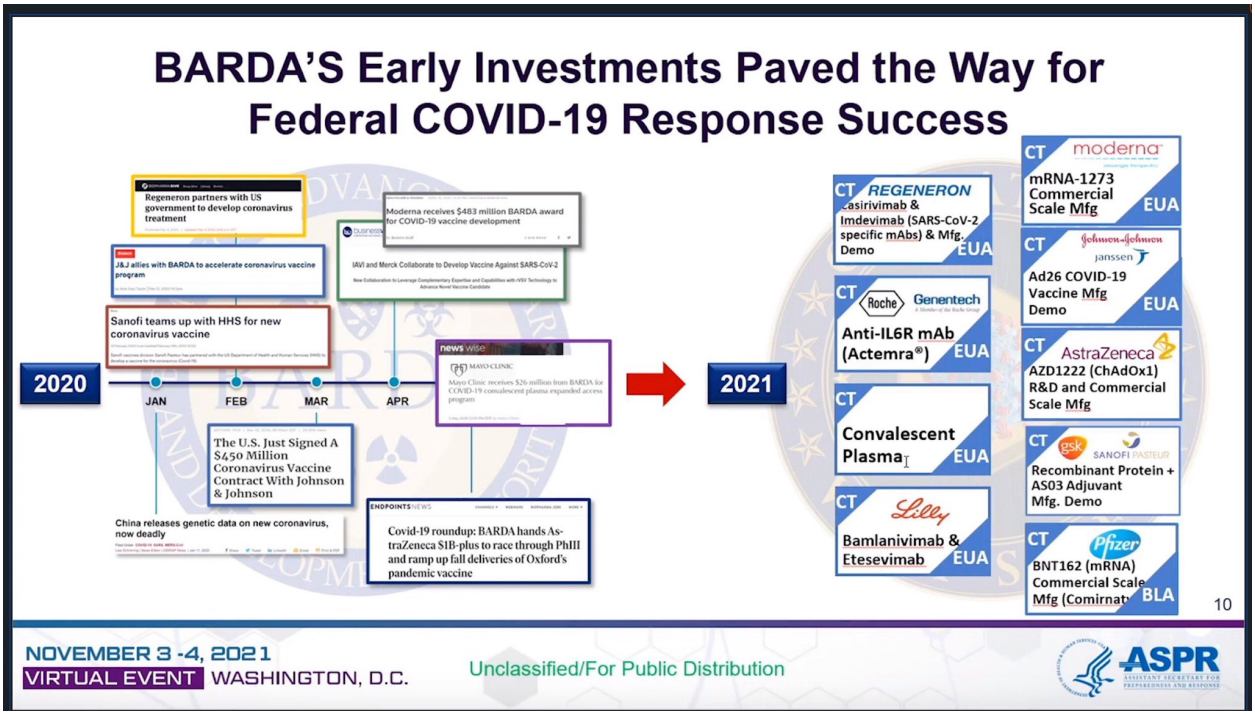
BARDA recently reported that in 2020-2021 they distributed $47.5 billion in Research and Development (R&D) funding for "Covid countermeasures," including $33 billion of it for the Covid-19 vaccines.

For perspective, the entire US pharmaceutical industry R&D spend is roughly $100 billion per year. This represents an overwhelming degree of control exerted by BARDA alone over the entire private pharmaceutical industry in the United States.

[8] https://www.keionline.org/covid-contracts
[9] https://www.keionline.org/bn-2020-3

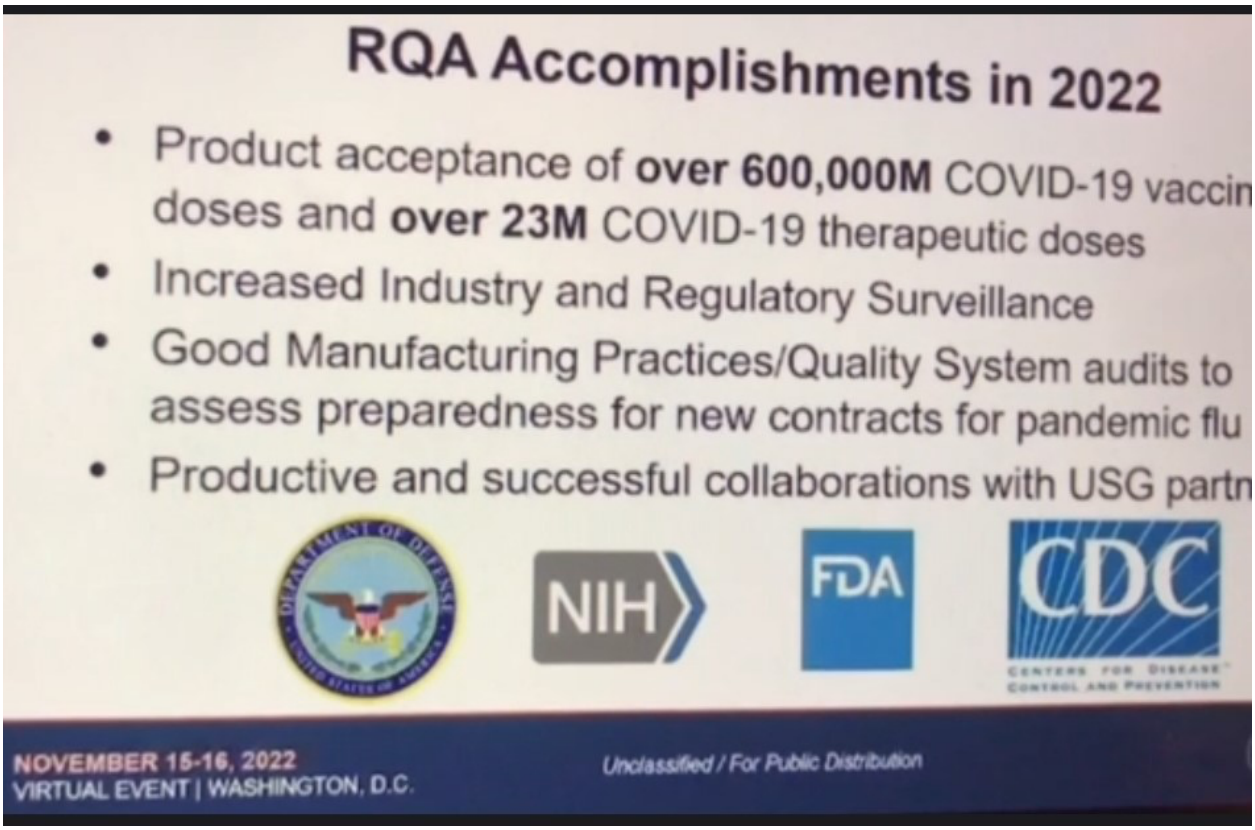


Furthermore, in BARDA's own report, all this spending was for "demonstrations" or at best "large scale manufacturing" only (as contracts specify) – see language on the right-hand side of this chart, which is also reflected in the DoD/BARDA contracts.



While the FDA regulates pharmaceutical products in the United States, it appears that for the Covid countermeasures, BARDA assumed the role of the regulator. Recently, on BARDA Industry Day, November 15-16, 2022, BARDA representative Tremel Faison, Director of Regulatory and Quality Assurance, claimed that the Regulatory and Quality Affairs (RQA) department tested and released 600 million Covid vaccine doses and 23 million therapeutic doses in the US, as well as increased "regulatory industry surveillance" and performed quality audits of the manufacturers.[10]

It is not clear why BARDA and not the FDA performed these activities.



[10] See video clip from the presentation in Attachment.

DoD/BARDA countermeasures produced by established network of defense contractors

The DoD/BARDA contracts for "countermeasures" are managed by Advanced Technology International (ATI).[11] ATI mostly manages R&D consortia for the Department of Defense for things like weapons manufacturing, metal casting and forging, ship production and technology aimed at "countering Weapons of Mass Destruction (WMDs)." Two of these consortia related to biomedical projects.

The Medical Technology Enterprise Consortium (MTEC), operating on behalf of the U.S. Army Medical Research and Development Command, includes technology for gene-editing, nanotechnology, "telehealth solutions," artificial limbs and brain implants. MTEC is currently developing a wearable device to diagnose Covid-19 before symptoms appear.

The Medical CBRN Defense Consortium (MCDC)[12] currently includes 318 large and small businesses and academic entities that "support the Department of Defense's (DoD) medical pharmaceutical and diagnostic requirements to counter Chemical, Biological, Radiological and Nuclear (CBRN) threat agents" and enable "prototype technologies for therapeutic medical countermeasures targeting viral, bacterial and biological toxin targets of interest to the DoD," including the development of vaccines.

Through the mechanism of Other Transactions Authority, MCDC contracted with hundreds of companies to deliver Covid-related "countermeasures." Pfizer doses were ordered on July 20, 2020, through Base Agreement between Advanced Technologies Inc (ATI, a DOD vendor management company) and Pfizer, Inc., identified as MCDC Base Agreement No. 2020-532:

- July 21, 2020, MCDC Technical Direction Letter or Statement of Work (SOW) for **"COVID-19 Pandemic - Large Scale Vaccine Manufacturing Demonstration"** between Pfizer and DOD/Advanced Technologies Inc.[13]

Other vaccine contracts have similarly-worded scope of work provisions describing them as "demonstrations."

The contracts also have clauses that specify that the Government is not paying the pharmaceutical companies for Research and Development or regulatory approval activities, and that those are undertaken by the company on their own.

[11] https://www.ati.org/
[12] https://www.medcbrn.org/current-members/
[13] https://www.keionline.org/misc-docs/DOD-ATI-Pfizer-Technical-Direction-Letter-OTA-W15QKN-16-9-1002-21July2020.pdf

DoD/BARDA contracts for countermeasures are not "arms-length" deals

The review of Pfizer and Moderna contracts by which the DoD/BARDA ordered hundreds of millions of Covid-19 vaccine doses revealed a lack of any real accountability for product safety, efficacy, or manufacturing quality from the pharma manufacturers, combined with a high degree of micromanagement and control from the contracting entity (DoD/BARDA).

While the contracts state that the contractor is acting independently and not as an agent of the government, they are not "arms-length" deals due to the substantial control exerted by the DoD. Specifically, the contracts are for sums of money that dwarf any existing product produced by a pharma company, even a large one. Pfizer's contract was for ~$2 billion but extended to ~$10 billion, or up to 500 million doses. There is no real accountability other than "reasonable effort" standard applied to the manufacturer and no real measurable criteria for quality or safety of the delivered product.

However, several aspects of the contracts are tightly micro-managed, including operational details, data, FDA interactions and communications. The manufacturers are supposed to have daily calls/meetings with the DoD/BARDA on the status of the project. Additionally, the communications of the pharmaceutical manufacturers with the FDA are under tight control of BARDA. There is no possibility for independent dialogue between pharma and the FDA (something all pharma companies are typically very sensitive about). Under these contracts, all communications with the FDA are reviewed and approved by BARDA, and any in-person meetings with the FDA are accompanied by up to four BARDA personnel.

Finally, the product is shipped to DoD as sole purchaser. The delivered product is not serialized – i.e., unit doses are not barcoded and thus not traceable under normal pharmaceutical distribution rules which exist to flag any safety or quality issue in the supply chain. The product thus is open to both falsification/mislabeling and adulteration. The product is shipped to DoD and handled through a "black box" DoD distribution system, ostensibly due to the cold chain storage requirements. The product is deemed "US Government property"[14] until it is injected into a person. All persons performing any tasks along manufacturing, supply chain, distribution and administration of the shots are "covered persons" under PREP Act liability shields, as long as they follow US Government orders. Regardless of place of employment, they are deemed to be US Government employees for purposes of this work.

Furthermore, the DOD contracts describe Covid countermeasures as intended for "civil and military application."

[14] https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#6-23-22

Use of EUA covered medical countermeasures under Public Health Emergency does not constitute a clinical investigation

Use of EUA covered countermeasures under Public Health Emergency cannot constitute a clinical investigation (21 USC 360bbb-3(k)). Therefore, these countermeasures could not be tested for safety and efficacy in accordance with US law (CFR 21), nor could compliance with current Good Manufacturing Practices (cGMP) or cGxP in general be enforced by the FDA.

This legal fact was known to high-level FDA officials, DoD, BARDA and HHS officials and to the pharmaceutical companies signing these contracts. However, all these parties, including the FDA officials proceeded to play their roles by pretend-"authorizing" the products. The FDA cited 21 USC 360bbb in a briefing document for Covid-19 Vaccine Development they produced in 2020.[15]

These facts was not disclosed to the American public, clinical investigators, clinical trial subjects, and the lower-level employees of the pharmaceutical companies and the US Government who were told that these were authentic clinical investigations and that the results were showing the products to be "safe and effective."

[15] See "FDA briefing on development of C-19 vaccines" in Attachment.