**Government Contracts with COVID Vaccine Makers Let Federal Agencies Bypass Normal Regulatory Process, FOIA Documents Show.**

A video recording from a public seminar from November 2022 shows a BARDA employee Tremel Faison stating that BARDA accepted, and quality checked all covid-19 vaccine doses in the US[[1]](#footnote-1).

The mission of the Biomedical Advanced Research and Development Authority (BARDA) is to develop medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases[[2]](#footnote-2).

BARDA is neither a regulated pharmaceutical manufacturer, nor a licensed distributor, nor a regulatory agency with a mandate to enforce consumer protection laws with respect to pharmaceuticals and medical devices. However, BARDA currently claims to have 77 products on the market[[3]](#footnote-3).

For pharmaceutical products, in addition to the regulations of clinical trials and manufacturing processes, a critical part of consumer safety monitoring comes from the regulated licensed pharmacy distribution system.

Pharmacy distribution is licensed by each state. For example, the State of California publishes applicable laws and regulations in an 800-page book[[4]](#footnote-4). NONE OF IT applies to BARDA, a federal agency who now admits that it the distributor of all covid vaccines.

Childrens Health Defense filed a FOIA requesting an explanation of how BARDA handles the quality control of the covid vaccines. The HHS produced a Standard Operating Procedure[[5]](#footnote-5), which states that:

Covid-19 "vaccines" are not regulated by normal pharmacy distribution laws as they are handled by the federal agency using non-transparent federal warehousing, and not by the state licensed pharmacy distributor.

These products were ordered by BARDA (and DOD via Other Transaction Authority contracts[[6]](#footnote-6)) and are handled through BARDA’s own protocols (not FDA).

The SOP produced by BARDA states that:

1. The vials are shipped outside of the regulated pharmacy distribution chain. Note that they may contract with regulated pharmacy distributors like McKesson, but the distributor is not governed by the same regulations as when they are working with the properly regulated pharmacy products.
2. The product is shipped from the manufacturer to the Strategic National Stockpile.  Presumably it is then shipped from NSS to the vaccinators.  This is totally separate from the normal pharmacy distribution, which is licensed by state and subject to FDA regulations for traceability, adverse event monitoring, recalls, etc.  None of it applies.
3. The SOP itself simply describes that BARDA receives sealed trucks, checks accompanying documentation, checks that the temperature was controlled and not much else. There is no testing/verification of the contents of the vials.  We already know that since lot-release testing by the FDA does not apply to EUA Countermeasures. This was confirmed by Peter Marks (Director of CBER FDA) in [his declaration in court](https://sashalatypova.substack.com/p/declaration-of-peter-pretzel-marks).
4. It says that the manufacturers are supposed to provide cGMP certification letter with the product.  However, even if they put in a letter stating they are compliant, there is no enforcement mechanism by which the compliance can be verified and assured, therefore there is no real requirement to be compliant.  Remember that there is also no statutory requirement as EUA-Countermeasures are deployed based on "maybe effective" criterion only (21USC 360(bbb)).

Therefore, no consumer safeguards for pharmaceutical product distribution are being followed, as expected by the public and repeatedly advertised by the health officials and media. This represents a dishonest “bait and switch” policy utilized by the health administration in collusion with the pharmaceutical companies to push these dangerous products onto unaware public.

Additionally, it is expected that by 2023 all pharmas must become compliant with:

The Drug Quality and Security Act (DQSA), was enacted by Congress on November 27, 2013. [Title II of DQSA, the Drug Supply Chain Security Act (DSCSA)](https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. These requirements will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Covid countermeasures do not have this requirement. [They are exempt](https://www.fda.gov/media/168035/download), and thus should be deemed automatically mislabeled, counterfeit and falsified.

Note that vaccination doses are primarily administered in retail pharmacies:

According to CDC, as of June 8, 2023, 303.7 million doses had been administered at 41,000 retail pharmacy locations according to CDC: <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/>

Out of a total of 677.7 million doses CDC claims have been administered: <https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions>

More information in an HHS-OIG report from Jan. 2023,

<https://oig.hhs.gov/oei/reports/OEI-05-22-00010.pdf>

stating that as of Dec. 2022, DoD had injected 7.5 million, VA had injected 7.4 million, and Indian Health Services (IHS) had injected 2.2 million, while the neighborhood pharm techs at retail pharmacies had injected 234.9 million.

Adding pharmacies and pharmacy technicians to the PREP Act "covered persons" list was an important part of PREP Act declarations and amendments.

1. See video file in the Attachment folder [↑](#footnote-ref-1)
2. https://medicalcountermeasures.gov/ [↑](#footnote-ref-2)
3. https://medicalcountermeasures.gov/barda/fdaapprovals [↑](#footnote-ref-3)
4. https://www.pharmacy.ca.gov/laws\_regs/lawbook.pdf [↑](#footnote-ref-4)
5. See “BARDA FOIA from CHD” in the Attachment folder [↑](#footnote-ref-5)
6. https://www.keionline.org/covid-contracts [↑](#footnote-ref-6)