

With respect to establishing Pfizer's legal position on the applicability and enforceability of current Good Manufacturing Practice regulations (cGMP) as promulgated and enforced by FDA:

1. Produce signed, dated, unredacted copies of the following three (3) contract documents, pertaining to Department of Defense Other Transaction Authority project OTA W15QKN-16-9-1002:

- July 20, 2020 Medical CBRN Defense Consortium (MCDC) "**Base Agreement**" No. 2020-532, between Advanced Technology International (ATI) and Pfizer, Inc. [[Redacted copy released to public](#) through *Jackson v. Ventavia, Pfizer, ICON*];
- July 21, 2020 "**Technical Direction Letter**" for Medical CRBN Defense Consortium (MCDC) Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for COVID-19 Pandemic - Large Scale Vaccine Manufacturing Demonstration, between Advanced Technology International (ATI) and Pfizer, Inc. [[Redacted copy released to public](#) through *Jackson v. Ventavia, Pfizer, ICON*];
- ATI-DOD-Pfizer "**Project Agreement**" 2011-003 under OTA W15QKN-16-9-1002, defined at p. 9 of July 20, 2020 Base Agreement, under which Pfizer is the Project Agreement Holder ("PAH") [As of Nov. 6, 2023, not disclosed to public in any form.]

2. Identify all US federal drug manufacturing, quality control, labeling, distribution and related regulations, by Code of Federal Regulations (CFR) citation, applicable to Pfizer's development, manufacturing, quality control, labeling and distribution of the products known as "Covid-19 vaccines." Regulations that may apply include but are not limited to: 21 CFR 210, 21 CFR 211, 21 CFR 600; 21 CFR 601 and 21 CFR 820.

3. Produce signed, dated, unredacted copies of all documents Pfizer submitted to the FDA to comply with the terms of each applicable regulation between January 2020 and the present.

4. Produce signed, dated, unredacted copies of all documents Pfizer received from the FDA pertaining to compliance review and enforcement of each applicable regulation between January 2020 and the present.

5. List all contract terms and conditions, by contract title, date, section and page number, applicable to, and/or enforceable by parties, pertaining to Pfizer's manufacturing, quality control, labeling and distribution of the products known as "Covid-19 vaccines."

6. Produce signed, dated, unredacted copies of all documents Pfizer submitted to contract counterparties (ATI/US Department of Defense) documenting compliance with each applicable, enforceable contract term/condition between January 2020 and the present.

7. Produce signed, dated, unredacted copies of all documents Pfizer submitted to contract counterparties (ATI/US Department of Defense) documenting compliance with each applicable, enforceable CFR regulation governing product manufacturing, quality control, labeling and distribution between January 2020 and the present.