COVID-19 CONTRACTS EXECUTED BY THE U.S. GOVERNMENT

KEI Webinar, Government Funding of COVID-19 Vaccines and Other Medical Technologies
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Overview of Presentation

1. Contracts KEI has obtained under the FOIA
2. Contracts entered into by Advanced Technology International (ATI)
3. Two KEI lawsuits challenging the redactions and withholding of records from our FOIA requests

KEI'S FOIA Research on the USG's COVID-19 Response

- **R&D & procurement contracts** (HHS, DOD/Army)
- **ACTIV** records & conflicts of interest forms (NIH)
- **RADx** contracts (NIH)

What KEI Has Obtained under the FOIA

Company	Type of Product	Upper Limit	Type of Agreement
Regeneron	Therapeutic	$365,610,816*	OTA
Janssen/J&J	Therapeutic	$211,693,687	OTA
Janssen/J&J	Vaccine	$689,525,867	OTA
Genentech/Roche	Therapeutic	$598,490,994	OTA
Moderna	Vaccine	$955,000,000	Standard contract
Sanofi	Vaccine	$30,775,336	Unclear
AstraZeneca	Vaccine	$1.2 billion	“Advance Agreement” pre-OTA.
Ology Bioservices	Vaccine	$148,086,484	OTA

*Regeneron was also awarded another $450 million to develop it’s treatment candidate, through ATI.

What are Other Transaction Agreements?

✅ A type of government contract

✅ Entered into for R&D and other purposes

✅ Believed by federal agencies to be ***EXEMPT*** from the Federal Acquisition Regulation and the Bayh-Dole Act

Why Use Other Transactions Agreements?

In theory: To promote US innovation by attracting nontraditional government contractors. To speed up the acquisition process.

In practice (one of the reasons): To allow contractors to exert greater control over federally-funded IP and data than they would have under a standard, Bayh-Dole contract.

The Benefits of OT Authority

The process is viewed as a win-win negotiation because OTs for Research:

- Allow for Generally Approved Accounting Procedures rather than Government cost accounting standards
- Allow cost and pricing data and certifications to be negotiable rather than mandatory
- Allow for commercially friendly intellectual property provisions
  - Handling of patents
  - Handling of technical data

Source: https://www.medicalcountermeasures.gov/BARDA/documents/Day2_GlynisFisher_John%20Ablard-OtherTransactionAuthority-508.pdf

WHY DOES THIS MATTER?

The Bayh-Dole Act, 35 U.S.C. §§ 200-212

Policy and objective: designed to both promote the commercial development of federally-funded inventions **AND** to protect against the non-use or **unreasonable use** of the inventions.

March-in rights, including the ability to march-in if the contractor fails to take steps to achieve practical application.

Practical application: ". . . to establish that the invention is being utilized **and** that its benefits are . . . **available to the public on reasonable terms."**

A **royalty-free license** to practice the invention, or have it practiced, for or on behalf of the U.S.

Rights in Technical Data under the FAR

Rights Category	Applicability	Permitted Uses within Government	Permitted Uses Outside Government
Unlimited Rights	First produced in performance of the contract or delivered under the contract regardless of how funded	Unlimited- no restrictions	Unlimited-no restrictions. Can permit others, even a competitor, to use the data
Limited Rights	Data developed at private expense & not first delivered under the contract	Unlimited, except cannot be used for manufacture	Emergency repair or overhaul; evaluation by foreign government

How Does This Apply to the C-19 OTAs?

REDEFINE “practical application” to eliminate the words “on reasonable terms.”

REMOVE two of the four grounds for march-in rights.

NARROW OR ELIMINATE the government’s royalty-free license.

ELIMINATE OR WEAKEN the government’s unlimited rights in technical data delivered under the contracts.

Practical Application under Bayh-Dole v. OTAs

Contracts that adhere to the Bayh-Dole Act	"[To practice a Subject Invention] under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations **available to the public on reasonable terms**."
Regeneron OTA	"[To practice the Subject Invention] under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, **available to the public for a regulatory approved product.**"
J&J OTA	J&J: "[To practice the Subject Invention] under such conditions so as to establish that the Subject Invention is **capable of being utilized.**"
Genentech/ Roche OTA	"[To practice the Subject Invention] so as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, **available to the public for a regulatory approved product.**"

The Moderna R&D Contract Obtained under FOIA

- NOT an OTA. Standard government contract.
- COMMITS nearly $1 billion for Moderna to perform research and development and scaling up manufacture on the Moderna-NIH vaccine candidate.
- NO COST-SHARING. The USG is funding 100% of the work.

How We Know This

H.7 Acknowledgement of Federal Funding – Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00034."

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

Response from BARDA

Dear Ms. Ardizzone and Mr Rizvi:

Thank you for your recent letter addressing your concerns with transparency and oversight around the Biomedical Advanced Research and Development Authority's (BARDA) contract with Moderna. The trust of the American people is vital in the all-of-America response to the ongoing COVID-19 pandemic. In recognizing this important relationship, the leadership of BARDA and Operation Warp Speed are committed to remaining transparent with the American people. Accordingly, as products are brought under the BARDA OWS portfolio, we will ensure that public announcements are made in a transparent manner.

The contracting officer responsible for the Moderna contract has been in touch with the company and will ensure their compliance with their contractual requirements.

Response from Moderna

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), supported the research and development of mRNA-1273 with $955 million in federal funding under Contract no. 75A50120C00034. BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the company for conducting the program described in the BARDA contract. The U.S. government is providing up to $1.525 billion in funding for the supply of mRNA-

Source: *Moderna Announces Supply Agreement with U.S. Government for Initial 100 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273)*, https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-supply-agreement-us-government-initial-100

Regeneron OTA Cost-Sharing

*“In the first quarter of 2020, we announced an expansion of our Other Transaction Agreement (**"OTA"**) with BARDA, pursuant to which **U.S. Department of Health and Human Services** ("HHS") is obligated to fund **80% of our costs** incurred for certain research and development activities related to **COVID-19 treatments**.”*

Source: Regeneron Pharmaceutical 10-Q, August 5, 2020.

AstraZeneca Advanced Agreement/OTA 75A50120C00114

D. INTELLECTUAL PROPERTY RIGHTS

(b)(4)

Advanced Agreement is in anticipation of Other Transaction Agreement No: 75A501-20-C-00114 between the Department of Health and Human Services and AstraZeneca.

(b)(4)

What We Still Don’t Know

❌ Total + proportionate contributions by the U.S. government in other contracts.

❌ Existence (or not) of any reasonable pricing clauses or other terms that would promote affordability and access.

COVID-19 Procurement Contracts

- $1 -2 billion contracts.
- Advance purchase doses of vaccine candidates, before proven safe & effective.
- Described by HHS press releases as a partnership between HHS, DOD, and the contractors.
- We have not YET obtained any of these agreements under the FOIA, but we have FOIA'd all agreements.

Advanced Technology International/the MCDC

1. Some procurement contracts are not contracts directly with the USG.
2. Instead, **the Army** has a **$16 billion OTA** with ATI, and ATI enters into “sub-OTAs” with pharmaceutical companies.

An Awarded Solicitation for the MCDC/ATI

RPP-20-11 (6/9/2020)	20-11: COVID-19 Pandemic Vaccine Rapid Advanced Research and Development (ARD) to Large Scale Manufacturing	BARDA/JPM-CBRN-Medical	Received: 11 Selected: 4 Basket: 2	Novavax, Inc. Pfizer Sanofi Janssen Research & Development	7/6/2020 7/21/2020 7/31/2020 8/5/2020	$1,600,434,522 $1,950,000,000 $1,789,013,740 $1,001,650,000

Source: https://www.medcbrn.org/solicitations/#1547817555427-f9628bb4-f0b9

KEI v. National Insts. of Health, 8:20-cv-2927

- Filed 10/9/2020 in the District Court of Maryland
- Remdesivir grants and clinical trial costs
- ACTIV contracts and communications
- RADx contracts
- EIDD-2801 grants and contracts
- ACTIV conflict of interest disclosures

KEI v. Department of Health and Human Services & Department of the Army, 1:20-cv-02986

- Filed 10/16 in the United States District Court of the District of Columbia
- The six R&D contracts obtained with redactions (BARDA)
- Phlow Corporation contract ($354,256,000)(BARDA)
- Novavax contract ($1.6 billion)(BARDA & Army)
- CIADM at Emergent Biosolution contract ($22 million)(BARDA)
- SAb Biotherapeutics contract ($7.2 million)(BARDA)
- Grifols Shared Services North America, Inc. contract ($12.7 million)(BARDA)
- Moderna contract extension ($471,596,459)(Army)
- Pfizer purchase agreement ($2 billion)(BARDA & Army)
- Moderna purchase agreement ($1.5 billion)(BARDA & Army)

Concluding Thoughts: Why This Matters

- **Affordability of and access to** COVID-19 technologies are critical to ending the pandemic.
- Relevant to those factors are (1) the **relative contributions** of **government funders** (2) the **rights** that the U.S. government has retained in the **IP and data underlying the technologies**, etc. **TRANSPARENCY IS KEY.**