

Other Transaction Agreements: Government Contracts that May Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID-19

KEI Briefing Note 2020:3

June 24, 2020

Kathryn Ardizzone

James Love

Introduction	3
OTAs are regarded as being exempt from laws that protect taxpayers and that give the government rights in publicly-funded data and IP.	4
Other Transactions Authority was originally narrow and expanded incrementally over time, including with respect to COVID-19.	7
Legislative History of Other Transactions Authority, Department of Defense (DOD)	8
DOD's Current Other Transactions Authority	11
Research OTAs	11
Prototype OTAs	11
Follow-on Production Projects	12
Special Authorization Requirements	12
The Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) have also been granted Other Transactions Authority.	12
The Department of Health and Human Services (HHS), including Biomedical Advanced Research and Development Authority (BARDA)	12
The National Institutes of Health (NIH)	13
HHS and DOD have expressed the position that their Other Transactions Authority allows them to execute R&D contracts that modify or eliminate government rights to IP and data.	13
Federal Agencies' Positions on OTAs and Government Rights to Publicly-Funded IP and Data	17
BARDA is using Other Transactions Authority to award billions of dollars to pharmaceutical companies, including for COVID-19 R&D.	19
Like BARDA, DOD has used Other Transactions Authority to sponsor biomedical research and development in connection with COVID-19.	22
BARDA and NIH have used and are now encouraging the use of OTAs to eliminate or limit government rights in patented inventions and data.	23
Practical application has been redefined to eliminate "on reasonable terms".	24
Table 1: BARDA's definitions of "practical application" in example OTAs eliminate the requirement of availability of subject inventions "on reasonable terms."	24

Table 2: Examples of NIH efforts to change the definition of “practical application” by ignoring or eliminating “on reasonable terms” from definition of practical application	25
The NIH has, for many years, ignored the language “on reasonable terms” in the definition of “practical application.”	26
March-in rights are narrowed.	30
Table 3: March-in provisions in Bayh-Dole vs Medicines Company OTA with BARDA	30
Government rights in data are limited.	31
Table 4: BARDA OTAs eliminate unlimited government rights in data delivered under the contract.	32
Federal agencies have overstated the benefits of OTAs and used the agreements in cases where the original rationales were not met.	32
Safeguards are particularly important when corruption and political influence is possible.	35
COVID-19 OTAs should stipulate that any inventions, data and know-how arising from the funded research are “global public goods.”	37
OTAs should be required to promote access to federally funded inventions in developing countries.	38
Concluding Thoughts and Recommendations	38

1. Introduction

“Other Transactions Authority” is a term used to refer to a statutory authority granted by the U.S. Congress to 11 federal departments or agencies¹ to enter into Other Transaction Agreements (OTAs), which are legally-binding contracts² executed by the government for research and development (R&D) or other purposes.³ OTAs are defined as transactions *other than* procurement contracts, cooperative agreements, and grants.⁴ Because they are not traditional acquisition instruments, it is thought that OTAs are exempt from the laws and regulations that apply to those agreements.⁵

With the United States government awarding pharmaceutical companies hundreds of millions and even billion-dollar plus contracts to develop COVID-19 vaccines and treatments, there is considerable interest in increasing the transparency of the funding agreements and ensuring that they include provisions to protect the public interest in the affordable pricing and availability of the resulting products.

There is an expectation that public-interest safeguards in the Bayh-Dole Act,⁶ including march-in rights and the government’s royalty-free right to use federally-funded inventions, can be utilized to ensure equitable access to COVID-19 technologies.⁷ Despite these expectations, the use of OTAs by the National Institutes of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense (DOD), and other agencies to fund COVID-19 R&D suggests that such remedies may not be available.

The terms of the COVID-19 OTAs are unknown, but federal agencies take the position that OTAs are exempt from the Bayh-Dole Act, the Federal Acquisition Regulation (FAR),⁸ the Defense Federal Acquisition Regulation Supplement (DFARS),⁹ and statutes designed to preserve the integrity of the procurement process. Of particular concern for COVID-19 R&D, BARDA and NIH have used OTAs to eliminate contractors’ legal obligations to make inventions available to the public “on reasonable terms,” to narrow march-in rights, and to narrow the government’s rights in technical data.

¹ U.S. Gov’t Accountability Office, GAO-16-209, *Federal Acquisitions: Use of “Other Transaction” Agreements Limited and Mostly for Research and Development Activities* 35 (2016)[hereinafter, “GAO-16-209”].

² Heidi M. Peters, Cong. Research Serv., R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress* (2019).

³ L. Elaine Halchin, Cong. Research Serv., RL34760, *Other Transaction (OT) Authority* 1 (2011).

⁴ Nathaniel E. Castellano, “Other Transactions” Are Government Contracts, and Why It Matters, 48 Pub. Cont. L.J. 485, 490 (2019).

⁵ Victoria Dalcourt Angle, *Innovation in Government Contracting: Increasing Government Reliance on Other Transaction Agreements Mandates A Clear Path for Dispute Resolution*, 49 Pub. Cont. L.J. 87, 96 (2019).

⁶ 35 U.S.C. §§ 200-212.

⁷ Michael Liu et al., *March-In Rights And Compulsory Licensing—Safety Nets For Access To A COVID-19 Vaccine*, Health Affairs, Health Affairs Blog (May 6, 2020), DOI: 10.1377/hblog20200501.798711.

⁸ The FAR is codified at title 48 of the Code of Federal Regulations.

⁹ 48 C.F.R. pt. 201.

This Briefing Note provides a general overview and brief legislative history of Other Transactions Authority, explains how OTAs differ from traditional government funding mechanisms in terms of IP and data rights, discusses how Other Transactions Authority has been used by federal agencies, including in connection with COVID-19, and invites Congress to undertake measures to remedy the lack of transparency and restrictions on the use of public safeguards in OTAs.

2. OTAs are regarded as being exempt from laws that protect taxpayers and that give the government rights in publicly-funded data and IP.

Because OTAs are defined as transactions other than procurement contracts, grants, and cooperative agreements, a brief overview of those acquisition instruments is helpful to understanding Other Transactions Authority.

Procurement contracts, grants, and cooperative agreements are defined in the Federal Grant and Cooperative Agreement Act (FGCAA),¹⁰ which was enacted to “prescribe criteria for executive agencies in selecting appropriate legal instruments” and “promote increased discipline in selecting and using procurement contracts, grant agreements, and cooperative agreements[.]”¹¹

According to the FGCAA, procurement contracts are the legal instrument that the government uses when its main purpose is to purchase property or services for the government’s own direct benefit.¹² Grants are used when both (1) “the principal purpose of the relationship is to transfer a thing of value to [the recipient] to carry out a public purpose of support or stimulation authorized by a law of the United States”; and (2) significant participation by the government is not anticipated.¹³ Cooperative agreements, like grants, are used when “the principal purpose of the relationship is to transfer a thing of value.” For this reason, both grants and cooperative agreements are considered financial assistance mechanisms.¹⁴ Unlike grants, however, cooperative agreements are used when “substantial involvement” of the federal government is anticipated.¹⁵

Cooperative Research and Development Agreements (CRADAs) are another government contracting mechanism. They are defined as “written agreements between a federal laboratory to work on a project; typically, the project focuses on technology transfers.”¹⁶ The government may contribute personnel, services, facilities, equipment, and other resources to a CRADA but it may not contribute funds.¹⁷

¹⁰ 31 U.S.C. §§ 6301-6308.

¹¹ 31 U.S.C. § 6301.

¹² 31 U.S.C. § 6303.

¹³ 31 U.S.C. § 6304.

¹⁴ GAO-16-209 at 3-4.

¹⁵ 31 U.S.C. § 6304.

¹⁶ GAO-16-209 at 4.

¹⁷ Nancy O. Dix, Fernand A. Lavalley, Kimberly C. Welch, *Fear and Loathing of Federal Contracting: Are Commercial Companies Really Afraid to Do Business with the Federal Government? Should They Be?*, 33 Pub. Cont. L.J. 5, 30 (2003).

While OTAs are legally binding contracts, they are referred to as transactions to distinguish them from procurement contracts.¹⁸ When OTAs are defined as being other than contracts, grants, and cooperative agreements, “contracts” is synonymous with “procurement contracts.”¹⁹

Most procurement contracts are governed by the Federal Acquisition Regulation (FAR),²⁰ a set of regulations that “establishes the framework that controls the solicitation, award, and administration of government contracts.”²¹ The FAR “is the result of a 1979 statute directing the Office of Federal Procurement Policy (OFPP) within the Office of Management and Budget (OMB) to ‘issue polic[ies] ... for the purpose of promoting the development and implementation of [a] uniform procurement system.’”²² It is codified at Parts 1 through 53 of Title 48 of the Code of Federal Regulations. Many agencies have also promulgated their own regulations “that implement or supplement the FAR[,]” such as the Defense Federal Acquisition Regulation Supplement (DFARS).²³

In addition to the FAR, DFARS, and other agencies’ procurement regulations, several statutes address procurement contracts.²⁴ Because they are not procurement contracts, OTAs are widely believed to be exempt from the FAR, DFARS, and statutes that govern traditional procurements.²⁵

The idea that OTAs are exempt from certain statutes applicable to procurement contracts apparently dates back to a 1996 memorandum authored by Paul Kaminski, then Undersecretary of Defense for Acquisition and Technology, which lists statutes that apply to procurement contracts, but that “are not necessarily applicable to ‘other transactions’.”²⁶ Among the statutes on that list are the Competition in Contracting Act,²⁷ the Contracts Dispute Act,²⁸ the Anti-Kickback Act,²⁹ and the Buy American Act.^{30,31}

In 2000, an Ad Hoc Working Group of the American Bar Association’s Section of Public Contract Law issued a report about “the applicability of procurement statutes to other transactions.”³² The report, which was specific to the Department of Defense (DOD), concluded

¹⁸ Nathaniel E. Castellano, *“Other Transactions” Are Government Contracts, and Why It Matters*, 48 *Pub. Cont. L.J.* 485, 494–95 (2019).

¹⁹ *Id.*

²⁰ Kate M. Manuel et al., Cong. Research Serv., R42826, *The Federal Acquisition Regulation (FAR): Answers to Frequently Asked Questions* 3 (2015).

²¹ Surya Gablin Gunasekara, *“Other Transaction” Authority: Nasa’s Dynamic Acquisition Instrument for the Commercialization of Manned Spaceflight or Cold War Relic?*, 40 *Pub. Cont. L.J.* 893, 896 (2011).

²² Manuel et al., *supra* note 20, at 10.

²³ Armani Vadiiee and Todd M. Garland, *The Federal Government’s ‘Other Transaction’ Authority*, 18-5 Briefing Papers 1 (2018).

²⁴ *Id.*

²⁵ Peters, *supra* note 2, at 4.

²⁶ Dix et al., *supra* note 17, at 26.

²⁷ 41 U.S.C. §§ 253a-b, 416, 418 and 31 U.S.C. §§ 3551-3556.

²⁸ 41 U.S.C. §§ 601-613.

²⁹ 41 U.S.C. §§ 51-58.

³⁰ 41 U.S.C. §§ 10a-10d.

³¹ Dix et al., *supra* note 17, at 3.

³² Halchin, *supra* note 3, at 17.

that the majority of 30 statutes reviewed, including the Procurement Integrity Act,³³ the Truth in Negotiations Act,³⁴ and the Cost Accounting Standards Act,³⁵ do not apply to OTAs.³⁶ A report on Other Transactions Authority by the Congressional Research Service (CRS) quotes an excerpt from the ABA report acknowledging that “in a number of cases” some of the ABA’s “conclusions are somewhat tenuous” and that “[t]his uncertainty may lead to unnecessary litigation.”³⁷

Similarly, in 2002, DOD published an “OT[A] Guide for Prototype Projects”, which contains a list of laws that apply to procurement contracts but that do not necessarily apply to DOD OTAs,³⁸ and the Department of Homeland Security (DHS) has developed its own “list of key statutes that apply to procurement contracts that are not necessarily applicable to other transactions[.]”³⁹

A critique of those conclusions is beyond the scope of this Briefing Note. What matters, for purposes of this Note, is that despite disclaimers in the reports that they were not intended to be definitive, it is now the vast consensus that procurement-related statutes and regulations and the Bayh-Dole Act do not apply to OTAs. Indeed, OTAs’ exemption from procurement laws and regulations and the governments’ rights to federally-funded IP is the main reason for using Other Transactions Authority, from the perspective of the federal agencies and contractors who enter into OTAs, as well as other commentators.⁴⁰ According to CRS:

[T]he advantages derive from the fact that [OTAs] are not subject to the FAR and certain procurement statutes. Companies (and other entities) unwilling or unable to comply with government procurement regulations and statutes might be less likely to engage in a contract than an [OTA]. By using an [OTA] instead of a contract, an agency and its partners are able to develop a flexible arrangement tailored to the project and the needs of the participants[.]⁴¹

The Strategic Institute, which was founded by Other Transactions Authority proponent Richard Dunn,⁴² advises government contractors that the most important feature of an OTA is that the agreement “is a blank slate to be etched as far as your government customer is willing to go.”⁴³

³³ 41 U.S.C. § 423.

³⁴ 10 U.S.C. § 2306a.

³⁵ 41 U.S.C. § 1502.

³⁶ Halchin, *supra* note 3, at 19-21.

³⁷ *Id.* at 22.

³⁸ Nikole R. Snyder, *Jurisdiction over Federal Procurement Disputes: The Puzzle of Other Transaction Agreements*, 48 Pub. Cont. L.J. 515, 522 (2019)(citing Department of Defense Acquisition, Technology, and Logistics, “*Other Transactions*” OT Guide For Prototype Projects (2002)).

³⁹ U.S. Gov’t Accountability Office, GAO-05-136, *Further Action Needed to Promote Successful Use of Special DHS Acquisition Authority* 6 (2004).

⁴⁰ Dix et al., *supra* note 17, at 26.

⁴¹ Halchin, *supra* note 3, at 1-2.

⁴² Dunn was general counsel for Defense Advanced Research Projects Agency (DARPA) and “was instrumental in the creation of DOD’s other transactions authority.” 59 No. 42 Government Contractor ¶ 350.

⁴³ Strategic Institute, *Other Transactions & Intellectual Property — an open field* (June 4, 2019), <https://www.strategicinstitute.org/other-transactions/ots-ip/>.

A majority of federal agencies surveyed by the GAO said that the flexibility provided by OTAs is their main reason for using them, “cit[ing] two areas of concern . . . protection of intellectual property rights and compliance with government cost accounting standards” that OTAs allow the agencies to overcome.⁴⁴

The freedom to deviate from the FAR is also attractive to companies because of the convenience it provides. One government contracts attorney said of OTAs: “Contractors and the government alike don’t really like the [FAR]. It costs money to comply with all of it.”⁴⁵ Likewise, the CRS has reported that “complying with government statutes and regulations constitutes, for some companies, an unacceptable administrative burden.”⁴⁶

3. Other Transactions Authority was originally narrow and expanded incrementally over time, including with respect to COVID-19.

Other Transactions Authority first appeared in the National Aeronautics and Space Act of 1958 (the “Space Act”), which created the National Aeronautics and Space Administration (NASA).⁴⁷ When the Soviet Union launched the *Sputnik* satellite into orbit, Congress became concerned that the United States was falling behind in the Space Race,⁴⁸ and it became “clear that ‘business as usual’ [was] not going to close the gap between United States and Soviet Capabilities.”⁴⁹ To enable NASA to accomplish its mission “without unnecessary delay,” the Space Act authorized the agency to “enter into and perform such contracts, leases, cooperative agreements, or *other transactions* as may be necessary[.]”⁵⁰

According to the CRS, “congressional documents from the 85th Congress do not indicate what was meant by ‘other transaction’ and do not explain why this term was included in the Space Act.”⁵¹ The term “other transaction” was devised by Paul Dembling, who drafted the relevant portion of the Space Act and later served as General Counsel of NASA.⁵² Dembling later explained that “other transactions” was a “catchall phrase” meant to cover transactions that “may not be covered under contracts, leases, and cooperative agreements.”⁵³

⁴⁴ GAO-16-209 at 12.

⁴⁵ Aaron Gregg, *Seeking an edge over geopolitical rivals, Pentagon exploits an obscure regulatory workaround*, Wash. Post (Oct. 18, 2019), <https://www.washingtonpost.com/business/2019/10/18/seeking-an-edge-over-geopolitical-rivals-pentagon-exploits-an-obscure-regulatory-workaround/>.

⁴⁶ Halchin, *supra* note 3, at 4.

⁴⁷ See *MD Helicopters Inc. v. United States*, No. CV-19-02236-PHX-JAT, 2020 WL 516469, at *1 (D. Ariz. Jan. 24, 2020).

⁴⁸ Peters, *supra* note 2, at 1.

⁴⁹ H.R. Rep. No. 85-1770, at 3163 (May 24, 1958).

⁵⁰ National Aeronautics and Space Act of 1958, Pub. L. No. 85-568, § 203(5), 72 Stat. 426, 430 (1958) (emphasis added).

⁵¹ Halchin, *supra* note 3, at 6.

⁵² Castellano, *supra* note 18, at 487.

⁵³ *Id.*

Since the passage of the Space Act, Congress extended Other Transactions Authority to 10 other federal agencies or departments within agencies.⁵⁴

Legislative History of Other Transactions Authority, Department of Defense (DOD)

Analyses of the legislative history of Other Transactions Authority often focus on that of DOD. According to CRS, “[m]ost of what is known about the rationale for, and use of, other transactions is based on DOD’s experiences with OT authority.”⁵⁵ Also, “DOD has had [Other Transactions Authority] longer than any other government agency, and NASA ‘has not developed or used the instrument in the same way that has the Department of Defense.’”⁵⁶

Other Transactions Authority was first extended to DOD with the enactment of the National Defense Authorization Act (NDAA) for FY1990 & FY1991. Section 251 of the FY1990 & FY1991 NDAA authorized DARPA⁵⁷ to enter into cooperative agreements and OTAs for “advanced research projects” but limited the use of that authority to instances “when the use of standard contracts or grants is not feasible or appropriate.”⁵⁸ The FY1990 & FY1991 NDAA also limited DARPA to using no more than \$25 million of the funds appropriated for FY 1990 and no more than \$25 million of the funds appropriated for FY 1991 for cooperative agreements and OTAs.⁵⁹ The authority was set to terminate on September 30, 1991.⁶⁰

The history of how and why DOD was first granted Other Transactions Authority often references the following narrative, retold by Richard Kuyath, counsel for 3M and a major advocate for the expansion of Other Transactions Authority:

By 1988, Dr. Raymond Colladay, then director of DARPA, concluded that DARPA needed additional flexibility in its approaches to supporting advanced R&D. The House Appropriations Committee had directed that DARPA submit a report to Congress on alternative management systems by early 1989. Among other initiatives suggested in his report, Colladay advocated the creation of a new and flexible R&D agreements authority for DARPA. The report was never sent directly to Congress. However, the biennial review of Defense Agencies required by the Goldwater-Nichols Act was performed during 1989. In October 1989 the Office of the Secretary of Defense (OSD) Study Team issued its report, which recommended that DoD prepare legislation that would give DARPA authority to enter into innovative contractual agreements.

About the same time, a group of retired flag officers and other former government officials lobbied Congress for additional authority for DARPA to enter into innovative contractual agreements so that DARPA could contract with the best and the brightest companies in the research community. This group included individuals well known to the administration

⁵⁴ GAO-16-209 at 35.

⁵⁵ Halchin, *supra* note 3, at 6.

⁵⁶ *Id.* (quoting Dix et al., *supra* note 17, at 9).

⁵⁷ Nancy K. Sumption, *Other Transactions: Meeting the Department of Defense’s Objectives*, 28 Pub. Cont. L.J. 365, 380–81 (1999) (explaining that DARPA was established in 1958, “to serve as [DOD’s] central R&D organization”).

⁵⁸ National Defense Authorization Act for Fiscal Years 1990 and 1991, Pub. L. No. 101-189, § 251, 103 Stat. 1352, 1403-04 (1989).

⁵⁹ *Id.*

⁶⁰ *Id.*

and Capitol Hill, who convinced Congress to add appropriate language to the Defense Authorization Bill for FY 1990.⁶¹

According to the DOD Office of Inspector General, Congress granted DOD Other Transactions Authority in order to increase DOD's ability to attract businesses that typically avoided entering into partnerships with the agency because "they would be subject to the FAR and [DOD] procurement regulations."⁶² Similarly, in a 2005 letter to the Secretary of the Army that discussed Other Transactions Authority, Senator John McCain explained, "Congress intended that OTAs be used for small research or limited prototype projects, especially those in which [DOD] seeks to engage nontraditional defense contractors that may be averse to the costs of regulation and red tape associated with government procurement under a FAR-type contract."⁶³

DOD's Other Transaction Authority was initially narrow and has expanded incrementally over time, through NDAs.⁶⁴ For example, as noted above, DOD's Other Transactions Authority originally was temporary, and it was only granted to DARPA for "advanced research." In 1991, Congress made DARPA's Other Transactions Authority for research purposes permanent and extended it to all military departments.⁶⁵ The NDA for FY 1994 gave DOD a new type of Other Transactions Authority, for prototype projects.⁶⁶ Congress extended this authority to all military departments in 1996.⁶⁷ In 2001, DOD was granted Other Transactions Authority for follow-on production.⁶⁸ After continued expansions, DOD may now execute prototype OTAs in excess of \$500,000,000 if the Under Secretary of Defense for Research and Engineering or the Under Secretary of Defense for Acquisition and Sustainment issue a written determination that certain conditions are met.⁶⁹

Congressional directives to DOD for how to implement OTA have similarly evolved over time. The Senate Report for the NDA for FY1990 & FY1991, for example, "enjoin[ed] [DOD] to utilize [Other Transactions Authority] only in instances in which traditional authorities are *clearly not appropriate*."⁷⁰ Similarly, the Conference Report for 1999 NDA directed DOD to use OTA

⁶¹ Richard N. Kuyath, *The Untapped Potential of the Department of Defense's "Other Transaction" Authority*, 24 Pub. Cont. L.J. 521, 527–28 (1995).

⁶² U.S. Dep't of Defense, Office of the Inspector General, Rep't No. 97-114, *Award and Administration of Contracts, Grants, and Other Transactions Issued By the Defense Advanced Research Projects Agency* 39 (1997).

⁶³ Letter from Sen. John McCain to the Hon. Francis J. Harvey, Secretary of the Army (March 31, 2005), <http://pogoarchives.org/m/dp/dp-McCain-Army-04012005.pdf>.

⁶⁴ Victoria Dalcourt Angle, *Innovation in Government Contracting: Increasing Government Reliance on Other Transaction Agreements Mandates A Clear Path for Dispute Resolution*, 49 Pub. Cont. L.J. 87, 97 (2019).

⁶⁵ National Defense Authorization Act for Fiscal Years 1992 and 1993, Pub. L. No. 102-190, § 826, 105 Stat. 1290, 1442 (1991).

⁶⁶ National Defense Authorization Act for Fiscal Year 1994, Pub. L. No. 103-160, § 845, 107 Stat. 1547, 1721, 1722 (Nov. 30, 1993).

⁶⁷ National Defense Authorization Act for Fiscal Year 1997, Pub. L. No. 104-201, § 804, 110 Stat. 2422, 2605 (1996).

⁶⁸ National Defense Authorization Act for Fiscal Year 2002, Pub. L. No. 107-107, § 822, 115 Stat. 1019, 1182 (2001).

⁶⁹ 10 U.S.C. § 2371b(a)(2)(A).

⁷⁰ S. Rep. No. 101 - 81 at 126-127 (1989)(emphasis added).

only “in the *exceptional* cases where it can be clearly demonstrated that a normal contract or grant will not allow sufficient access to affordable technologies,” adding that “[t]he conferees are especially concerned that such authority not be used to circumvent the appropriate management controls in the standard acquisition and budgeting process.”⁷¹ Senator McCain explained in a 2005 letter to the Secretary of the Army that this language reflected Congress’s “recognition of potential problems with using an OTA in lieu of a standard procurement contract[.]”⁷² In contrast, the FY 2018 NDAA states that “the Secretary of Defense *shall establish a preference*, to be applied in circumstances determined appropriate by the Secretary, for using transactions other than contracts, cooperative agreements, and grants.”⁷³

Perhaps due to Congress’s encouragement, the use of OTAs has exploded in recent years.⁷⁴ In 2018, Bloomberg Government reported that spending on OTAs doubled from 2012 to 2017.⁷⁵ A 2019 GAO report found that DOD’s use of prototype OTAs “significantly increased” both in the number of prototype OTAs and the amount of funds obligated.⁷⁶ Specifically, the report found that the number of prototype OTAs “increased five-fold,” while “obligations made on prototype other transactions nearly tripled [.]”

There were some indicators with respect to the FY2019 NDAA that the expansion of DOD’s Other Transactions Authority was beginning to face resistance from Congress. The House conference report for the FY2019 NDAA, for example, “urges [DOD] to exercise great prudence and transparency when employing OTA to prevent misuse and abuse,” and “urges [DOD] to reiterate through established guidelines that OTA is not a means for circumventing appropriate use of the [FAR], and that full and open competition should be used to the maximum extent possible to maintain a sense of integrity, fairness, and credibility in the Federal Procurement process.”⁷⁷ The FY2019 NDAA requires DOD to collect data on DOD’s use of other transactions, use that information “to update policy and guidance,” and submit an annual report to Congress on DOD’s use of OTA for the preceding fiscal year.⁷⁸

The expansion resumed with respect to COVID-19, with the enactment of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.⁷⁹ Section 13006 of the CARES Act authorizes DOD to delegate the authority necessary for DOD prototype or follow-on production OTAs in excess of \$100 million and the approval needed for OTAs over \$500 million when the OTA is

⁷¹ H.Rept. 105-736 at 590 (1998).

⁷² McCain, *supra* note 76.

⁷³ National Defense Authorization Act for Fiscal Year 2018, Pub. L. No. 115-91, § 867, 131 Stat. 1283, 1495 (2017)(emphasis added).

⁷⁴ Halchin, *supra* note 3 (“[T]he use of OTs is expected to grow at a rapid pace, due in part to recent statutory changes expanding Other Transaction authorities.”).

⁷⁵ Bloomberg Government Announcement, *OTA Spending on the Rise* (June 19, 2018), <https://platform.cinchcast.com/ses/eXdvbvAoZOMD6XFNens-BQ~~>.

⁷⁶ U.S. Gov’t Accountability Office, GAO-20-84, DOD’s Use of Other Transactions for Prototype Projects Has Increased 8 (2019)(hereinafter, “GAO-20-84”).

⁷⁷ H. Rep. No. 115-676, at 75-76 (2018).

⁷⁸ John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, § 873, 132 Stat. 1636, 1905 (2018).

⁷⁹ Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 13006, 134 Stat. 281, 552 (2020).

executed in connection with COVID-19.⁸⁰ In addition, Section 13006 removes the requirement for advance notice for OTAs in excess of \$500 million, instead requiring such notice “as soon as is practicable after the commencement of the carrying out of such transaction.”⁸¹

In an April 5, 2020 memorandum, Ellen Lord, the current Under Secretary of Defense for Acquisition and Sustainment, delegated the special approval authority for prototype and follow-on production OTAs in excess of \$100 million “to the Directors of the Defense Agencies/Field Activities with contracting authority, Commanding Officers of Combatant Commands with contracting authority, and the Director of the Defense Innovation Unit.”⁸² She delegated approval for prototype and follow-on production OTAs in excess of \$500 million to “the Senior Procurement Executives [] of the Military Departments, the Director of [DARPA], and the Director of the Missile Defense Agency [].”⁸³

DOD’s Current Other Transactions Authority

DOD’s Other Transaction Authority is codified at 10 U.S.C. § 2371 for “basic, applied, and advanced research projects” and 10 U.S.C. § 2371b for “prototype project[s]” and “follow-on production.”

Research OTAs

There are three conditions on DOD’s use of Other Transaction Authority for research projects. First, “to the maximum extent practicable[,]” DOD research OTAs may not “provide[] for research that duplicates research[.]”⁸⁴ Second, the government must share costs equally with the contractor.⁸⁵ Third, OTAs for research projects are only an option when traditional procurement mechanisms are “not feasible or appropriate.”⁸⁶

Prototype OTAs

The rules for DOD prototype OTAs are somewhat more relaxed than they are for DOD research OTAs. Only one of the following four conditions must be satisfied before the authority may be exercised:

1. “[A]t least one nontraditional defense contractor or nonprofit research institution participat[es] to a significant extent”;
2. “All significant participants . . . are small businesses . . . or nontraditional defense contractors”;
3. Non-government sources contribute at least one third of the total cost; or

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Memorandum of Ellen M. Lord, Under Sec’y of Def. for Acquisition and Sustainment, to Sec’y of the Military Dep’ts (April 5, 2020), <https://www.acq.osd.mil/dpap/policy/policyvault/USA000752-20-DPC.pdf>

⁸³ *Id.*

⁸⁴ 10 U.S.C. § 2371(e)(1)(A).

⁸⁵ 10 U.S.C. § 2371(e)(1)(B).

⁸⁶ 10 U.S.C. § 2371(e)(2).

4. “The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of [an OTA].”⁸⁷

A “nontraditional defense contractor” is one that has not performed “a contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section” for at least one year before the solicitation of the OTA.⁸⁸

Follow-on Production Projects

DOD prototype OTAs “may provide for the award of a follow-on production contract or transaction to the participants in the transaction.”⁸⁹ Follow-on production OTAs may be awarded without using competitive procedures if competition was used for the original OTA, and the original OTA was successfully completed.⁹⁰

Special Authorization Requirements

Special authorization from “a senior procurement executive” or the director of DARPA is required for prototype projects and follow-on OTAs “expected to cost the Department of Defense in excess of \$100,000,000 but not in excess of \$500,000,000.”⁹¹ Prototype and follow-on production OTAs in excess of \$500,000 million may not be executed unless either the Under Secretary of Defense for Research and Engineering or the Under Secretary of Defense for Acquisition and Sustainment issues a written determination and “the congressional defense committees are notified in writing at least 30 days before such authority is exercised.”⁹² The authority to approve such OTAs may not be delegated (except as provided under the CARES Act).⁹³

4. The Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) have also been granted Other Transactions Authority.

As noted above, 11 federal agencies or departments have been granted the authority to enter into OTAs. Following is an explanation of the Other Transactions Authority of HHS and the NIH.

The Department of Health and Human Services (HHS), including Biomedical Advanced Research and Development Authority (BARDA)

Other Transaction Authority was extended to HHS with the passage of the Pandemic and All Hazards Preparedness Act of 2006 (the “PAHPA”), the statute that created the Biomedical

⁸⁷ 10 U.S.C. § 2371b(d)(1).

⁸⁸ See 10 U.S.C. § 2302(9).

⁸⁹ 10 U.S.C. § 2371b(f)(1).

⁹⁰ 10 U.S.C. § 2371b(f)(2).

⁹¹ 10 U.S.C. § 2371b(a)(2)(A).

⁹² 10 U.S.C. § 2371b(a)(2)(B).

⁹³ 10 U.S.C. § 2371b(a)(3).

Advanced Research and Development Authority (BARDA).⁹⁴ Located within the HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR), BARDA was established to support the advanced research and development of medical countermeasures.⁹⁵ HHS exercises its Other Transactions Authority under the PAHPA through ASPR/BARDA.

There are two limitations on HHS's Other Transaction Authority—(1) HHS is required, to the maximum extent practicable, to use competitive procedures when entering into OTAs, and (2) the Assistant Secretary for Financial Resources generally must first issue a written determination “that the use of [Other Transaction Authority] is essential to promoting the success of the project” before HHS may enter into an OTA “in excess of \$100 million.”⁹⁶ The CARES Act eliminated the special approval requirement for OTAs in excess of \$100 million in public health emergencies.⁹⁷ Cost sharing is not required for HHS OTAs.

The National Institutes of Health (NIH)

Although the NIH falls under HHS, it was granted Other Transactions Authority separately from HHS. The NIH's Other Transactions Authority is codified at three sections of the United States Code: 42 U.S.C. § 285b-3 (for the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program), 42 U.S.C. § 284n (for “certain demonstration projects”), and 42 U.S.C. § 287a (for the Cures Acceleration Network).

Like that of DOD, the use of OTAs by the NIH has greatly expanded in recent years. Knowledge Ecology International (KEI)'s review of OTAs executed by the National Institutes of Health (NIH) from 2016 to 2019 disclosed at NIH's Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER)⁹⁸ found that the number of OTAs executed by the NIH and disclosed at RePORTER increased by 385 percent in that time frame.

5. HHS and DOD have expressed the position that their Other Transactions Authority allows them to execute R&D contracts that modify or eliminate government rights to IP and data.

When the government funds R&D using a traditional procurement contract, it retains certain rights to any IP and data arising from the funded research. Given how agencies interpret their Other Transactions Authority, OTAs may alter or eliminate those rights, which could be instrumental to ensuring widespread access to COVID-19 health products.

⁹⁴ Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417 § 401, 120 Stat. 2831, 2865-72 (2006).

⁹⁵ U.S. Dep't of Health and Human Servs., Biomedical Advanced Research and Development Authority, <https://www.phe.gov/about/barda/Pages/default.aspx>.

⁹⁶ 42 U.S.C. § 247d-7e(c)(5)(A)(ii).

⁹⁷ Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 3301, 134 Stat. 281, 383-84 (2020).

⁹⁸ RePORTER is an online database maintained by the NIH of information about NIH-funded projects. NIH Office of Extramural Research Pub. No. 11-7702, *Research Portfolio Online Reporting Tools (RePORT)* (2010).

The ability of contractors to exert greater control over their IP and data is a main draw of OTAs.

The GAO conducted a survey of the federal agencies that have been granted Other Transactions Authority for a “Report to the Ranking Member, Committee on Science, Space, and Technology, of the House of Representatives.” According to the report, federal agencies use their Other Transactions Authority to address contractors’ concerns about “protection of intellectual property rights”, among other purposes.⁹⁹ Specifically, agencies told the GAO that OTAs allow them to attract companies that “wished to secure greater protection of intellectual property rights than would be possible under traditional contracting mechanisms.”¹⁰⁰ Likewise, the Strategic Institute advises government contractors that, “for IP matters particularly, OT[A]s are an open field. Neither contractors nor agencies should be hidebound by traditional FAR and DFARS IP rules.”¹⁰¹

Following is a summary of the government’s rights to IP and data developed under procurement contracts, grants, and cooperative agreements that federal agencies believe Other Transactions Authority allows them to sidestep.

Government Rights to IP Arising from Federally-Funded R&D

The Bayh-Dole Act was enacted in order to promote the commercialization of federally-funded inventions and “ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions,” among other policies and objectives.¹⁰² It allows contractors to elect to retain title to subject inventions,¹⁰³ i.e., “one[s] conceived or first actually reduced to practice in the performance of work under a funding agreement”,¹⁰⁴ and authorizes federal agencies to license the rights to inventions developed by federal employees in federal laboratories on an exclusive basis.¹⁰⁵

The Bayh-Dole Act sets forth different rules for federally-owned inventions, and inventions in which a contractor or grant recipient takes ownership of inventions that arise from federally-supported research.¹⁰⁶ In both cases, there are a number of safeguards to protect the public interest in federally-funded inventions.¹⁰⁷ For example, regardless of whether a subject invention is owned by the federal government or a contractor, the government retains a “nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.”¹⁰⁸ In addition, the Bayh-Dole Act

⁹⁹ GAO-16-209, *supra* note 1, at 12.

¹⁰⁰ *Id.*

¹⁰¹ Strategic Institute, *supra* note 43.

¹⁰² 35 U.S.C. § 200.

¹⁰³ 35 U.S.C. § 202(a)

¹⁰⁴ 35 U.S.C. § 201(e).

¹⁰⁵ 35 U.S.C. § 207.

¹⁰⁶ Section 202 of the Bayh-Dole Act sets forth the rules governing federally-supported research. See 35 U.S.C. § 202. Section 209 governs federally-owned inventions. See 35 U.S.C. § 209.

¹⁰⁷ U.S. Gov’t Accountability Office, GAO-09-742, Information on the Government’s Right to Assert Ownership of Federally Funded Inventions 9 (2009).

¹⁰⁸ 35 U.S.C. §§ 202(c)(4), 209(d)(1).

authorizes the government to “march-in” and require the contractor to issue a compulsory license to a subject invention (or the government may issue the license itself) when any of four circumstances are present.¹⁰⁹ The first two criteria, and the ones most frequently cited, are that the contractor “has not achieved, and is not taking reasonable steps to achieve, practical application of the subject invention,” and that marching-in “is necessary to alleviate health or safety needs.”¹¹⁰ Achieving “practical application of the subject invention” requires “establish[ing] 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*.”¹¹¹

The obligation to make inventions “available to the public on reasonable terms” includes, among other things, an obligation that a product or service has a reasonable price,¹¹² although there is a vocal contingent of opponents of any restraints on pricing who have argued otherwise.¹¹³ Such arguments ignore the fact that “the public” includes consumers of products or services, and that “protect[ing] the public against nonuse *or unreasonable* use of inventions”,¹¹⁴ from the “Policy and objective[s]” of the Act, requires more than selling a good at any price.

Other public interest provisions of the Bayh-Dole Act include the obligation to disclose subject inventions to the federal government¹¹⁵ and the requirement to “manufacture[] substantially” products derived from federally-funded inventions in the United States.¹¹⁶

Procurement contracts subject to the Bayh-Dole Act must incorporate “Standard Patent Rights” clauses¹¹⁷ which memorialize these public-interest safeguards.¹¹⁸ FAR 52.227-11, “Patent Rights—Ownership by the Contractor” requires that government procurement contracts incorporate march-in rights, the royalty-free license, and other public-interest provisions in the Bayh-Dole Act.¹¹⁹ For DOD procurement contracts with small businesses and nonprofits, FAR 52.227-11 applies.¹²⁰ DOD procurement contracts with large businesses must use the clauses at DFARS 252.227–7038 Patent Rights—Ownership by the Contractor (Large Business).¹²¹

¹⁰⁹ 35 U.S.C. § 203(a).

¹¹⁰ 35 U.S.C. § 203(a)(1)-(2).

¹¹¹ 35 U.S.C. § 201(f).

¹¹² See generally, Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirement Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631 (2001).

¹¹³ See, e.g., Christopher Rowland, *A rare deterrent to limitless drug price increases may die under Trump*, Wash. Post (April 18, 2019), https://www.washingtonpost.com/business/economy/a-rare-deterrent-to-limitless-drug-price-increases-may-die-under-trump/2019/04/17/7578e5e0-5bcd-11e9-a00e-050dc7b82693_story.html?noredirect=on; Joseph Allen, *The Washington Post Misses the Mark on March-in Rights*, IP Watchdog (April 22, 2019), <https://www.ipwatchdog.com/2019/04/22/washington-post-misses-mark-march-rights/id=108499/>.

¹¹⁴ 35 U.S.C. § 200 (emphasis added).

¹¹⁵ 35 U.S.C. § 202(c)(1).

¹¹⁶ 35 U.S.C. § 204.

¹¹⁷ 37 C.F.R. § 401.3.

¹¹⁸ 37 C.F.R. § 401.14.

¹¹⁹ FAR § 52.227–11.

¹²⁰ FAR § 227.303(1).

¹²¹ FAR § 252.227–7038.

Government Rights to Technical Data Arising from Federally Funded R&D

The government also has certain rights in technical data (including trade secrets) arising from procurement contracts.

FAR Clause 52.227-14 “Rights in Data--General” governs data rights for civilian agency procurement contracts. It generally creates two categories of rights in technical data: unlimited rights and limited rights.

The government generally has unlimited rights in data delivered or produced under a civilian procurement contract.¹²² Unlimited rights allow the government “to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, *in any manner and for any purpose*, and to have or permit others to do so.”¹²³ This, according to the ABA, means that the government can even allow a contractor’s competitor to “practice the technical data *for any reason, including commercial gain.*”¹²⁴

¹²⁵

Limited rights apply to “data, other than computer software . . . that embody trade secrets or are commercial or financial and confidential or privileged” if the data was “developed at private expense.”¹²⁶ Limited rights data “may be reproduced and used by the Government,” but they may not “be used for purposes of manufacture nor disclosed outside the Government[.]”¹²⁷

The DFARS create three categories of government rights in data related to procurement contracts. Generally, DOD has “unlimited rights” in data “[c]reated exclusively with Government funds”, “government purpose rights” in data “developed with mixed funding”, and “limited rights” in data “developed exclusively at private expense.”¹²⁸

Similar to the FAR, “unlimited rights” under the DFARs include the “rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.”¹²⁹ “Government purpose rights” authorize the government to use “technical data within the Government without restriction”, and to “[r]elease or disclose technical data outside the Government . . . for United States government purposes.”¹³⁰ “Government purposes” encompass “any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by

¹²² FAR § 52.227-14(b)(1).

¹²³ FAR § 52.227-14(a)(2)(emphasis added).

¹²⁴ Susan B. Cassidy, Alexander B. Hastings, and Jennifer L. Plitsch, *What Every Company Should Know about IP Rights When Selling to the US Government*, American Bar Association (July/August 2017), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2016-17/july-august/what-every-company-should-know-about-ip-rights-when-selling-us-government/ (emphasis added).

¹²⁵ *Id.*

¹²⁶ FAR § 52.227-14(a).

¹²⁷ FAR § 52.227-14 alt II.

¹²⁸ DFAR § 252.227-7013(b).

¹²⁹ DFAR § 252.227-7013(a)(15).

¹³⁰ DFAR § 252.227-7013(a)(13).

the United States Government to foreign governments or international organizations.”¹³¹ They “include competitive procurement, but do not include . . . commercial purposes[.]” “Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government.”¹³² Use of limited rights data outside the government is restricted.¹³³

Federal Agencies’ Positions on OTAs and Government Rights to Publicly-Funded IP and Data

As shown below, it is the position of HHS, NIH, and DOD that OTAs are not subject to the Bayh-Dole Act or the government’s rights to data under the FAR and DFARS.

An HHS presentation on Other Transaction Authority states that “OTA is not subject to Bayh-Dole Act. However, OTA Contracting Officer may still include Limited-Rights Data clause . . . if appropriate[.]”¹³⁴ In addition, HHS publishes an “Other Transaction for Advanced Research (OTAR) Template” on its website, which states that IP and data rights are “fluid and negotiable[.]” and that “[t]he government will consider present and future government and industry needs in exercising good business judgment in negotiating IP.”¹³⁵

Similarly, NIH asserts that OTAs enable “[f]lexibility in [the] allocation of [IP] rights”¹³⁶ and that “[c]ost savings are possible by limiting the government’s need for data license rights in OTs.”¹³⁷ Past NIH OTAs have modified the standard Bayh-Dole Act standard patent rights clauses as follows:

- “Waiv[ing] [the] government [royalty-free] license for a period of years”;
- “Allow[ing] protection of materials as trade secrets”; and
- “Negotiat[ing] [] a new definition to “Practical Application[.]”¹³⁸

As noted previously, the term “practical application” refers to the obligation to make federally-funded inventions “available to the public *on reasonable terms*.” In declining to exercise march-in rights to address unreasonable prices, the NIH has employed an erroneous definition of practical application, ignoring the phrase “on reasonable terms” and asserting that

¹³¹ DFAR § 252.227-7013(a)(12).

¹³² DFAR § 252.227-7013(a)(14).

¹³³ *Id.*

¹³⁴ Glynis Fisher, John Ablard, U.S. Dep’t of Health and Human Servs. Office of the Assistant Sec’y for Preparedness and Response, *Other Transaction Authority at HHS* (June 8, 2011)(on file with author).

¹³⁵ U.S. Dep’t of Health and Human Servs. Office of the Assistant Secretary for Preparedness and Response, *Other Transaction for Advanced Research (OTAR)*, <https://www.phe.gov/about/amcg/otar/Documents/otar-consortium.pdf> (hereinafter, “BARDA OTAR Template”).

¹³⁶ Nat’l Insts. of Health, *Other Transaction Authority Training Participant Guide 1/2018v2* 103, 214 <https://oamp.od.nih.gov/sites/default/files/DSAPS/NPI-3000%20NIH%20NOTAB%20Participant%20Guide%2001-18v2.pdf> [hereinafter, “NIH OTA Participant Guide”].

¹³⁷ *Id.* at 214.

¹³⁸ *Id.*

practical application of an invention is satisfied whenever an invention is manufactured and made available, regardless of the terms of availability.¹³⁹

The definition of practical application in certain OTAs incorporates the definition that the NIH has insisted on using, even though it does not comport with the plain language of the Bayh-Dole Act: a sample OTA in the NIH Other Transaction Authority Participant Guide defines “Practical Application” identically to the definition supplied by the Bayh-Dole Act at 35 U.S.C. § 201(f), except that it removes the phrase “on reasonable terms.”¹⁴⁰

DOD goes even further than HHS with regard to intellectual property rights in OTAs, by encouraging DOD contracting officials to deviate from the normal allocation of rights between the government and contractors. According to the DOD OTA Guide:

It is important that the [Agreement Officer] be familiar with IP rights under the Bayh-Dole Act (35 U.S.C. §201-204) for patents and 10 U.S.C. §2320-21 for technical data; however, these statutes do not apply to OTs and ***negotiation of rights of a different scope is permissible and encouraged.***¹⁴¹

DOD has executed OTAs that deviate from the Bayh-Dole Act safeguards in the following ways:

- “Delay[ing] exercising [the] government purpose license rights until 5 years after the agreement was completed”;
- Allowing contractors “to maintain inventions and data as trade secrets for an unspecified period of time under certain conditions”;
- Not providing the government its rights in “technical data produced under the agreement unless the agency invoked ‘march-in’ rights”;
- Declining government patent rights; and
- Declining rights to data.¹⁴²

¹³⁹ See, e.g., Elias A. Zerhouni, Director, NIH, *In the case of Xalatan, Manufactured by Pfizer, Inc.*, (Sept. 17, 2004), <https://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf> (finding that an “invention has reached practical application because it is being utilized and has been made widely available for use by glaucoma patients for at least eight years”); Francis S. Collins, Director, NIH, *Determination in the Case of Norvir® Manufactured by AbbVie* 4 (Nov. 1 2013), <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf> (“AbbVie’s record of manufacture and ritonavir’s availability and use around the world demonstrate that AbbVie has achieved practical application of the Subject Patents as required under Bayh-Dole.”).

¹⁴⁰ NIH OTA Participant Guide at 413.

¹⁴¹ U.S. Dep’t of Defense, Office of the Under Sec’y of Defense for Acquisition and Sustainment, *Other Transactions Guide* 50 (2018), [https://www.dau.edu/guidebooks/Shared%20Documents/Other%20Transactions%20\(OT\)%20Guide.pdf](https://www.dau.edu/guidebooks/Shared%20Documents/Other%20Transactions%20(OT)%20Guide.pdf) [hereinafter, “DOD OTA Guide”](emphasis in original).

¹⁴² U.S. Gov’t Accountability Office, GAO-01-980T, *Information on the Federal Framework and DOD’s Other Transaction Authority* 6-8 (2001).

6. BARDA is using Other Transactions Authority to award billions of dollars to pharmaceutical companies, including for COVID-19 R&D.

HHS has exercised its Other Transactions Authority through BARDA, which, as noted, is part of the ASPR.

BARDA, which was allocated \$3.5 billion by the CARES Act,¹⁴³ has used Other Transactions Authority to award hundreds of millions, if not billions of dollars, to large pharmaceutical companies, including with respect to COVID-19.

KEI is awaiting the results of a Freedom of Information Act (FOIA) request submitted in March of 2020 for all contracts listed in BARDA's COVID-19 Medical Countermeasure Portfolio.¹⁴⁴ KEI will update this Briefing Note once it obtains responsive records.

Below is a summary of what KEI learned about BARDA's use of Other Transactions Authority from publicly-available sources, including Federal Procurement Data System—Next Generation (FPDS-NG, <https://www.fpds.gov/>).

BARDA's first OTA, HHSO100201300011C, was executed in May of 2013 with GlaxoSmithKline (GSK), for the development of "[d]rugs to combat bioterrorism and antibiotic resistance."¹⁴⁵ The GSK OTA had a term of up to five years and a ceiling of \$200 million.¹⁴⁶ BARDA executed a similar OTA with AstraZeneca in 2015 (HHSO100201500029C), the Medicines Company (HHSO100201600026C) in 2016, and Hoffman-La Roche in 2016 (HHSO100201600038C).

These OTAs are part of BARDA's Broad Spectrum Antimicrobial Program,¹⁴⁷ which "uses novel public-private partnerships to incentivize research and development of novel antimicrobial drug candidates primarily through advanced development of drug candidates toward FDA approval."¹⁴⁸

Since the outbreak of COVID-19, BARDA has expanded its existing OTAs and entered into new ones, to fund the development of COVID-19 treatments and vaccines.

¹⁴³Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, tit. VIII, 134 Stat. 281, 561 (2020).

¹⁴⁴ U.S. Dep't of Health and Human Servs. Pub. Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, <https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>.

¹⁴⁵ U.S. Dep't of Health and Human Servs. News Division, *HHS forms strategic alliance to develop new antibiotics Approach provides a pipeline of new drugs rather than a single medical countermeasure* (May 22, 2013), <https://www.phe.gov/Preparedness/news/Pages/strategic-alliance-130522.aspx>.

¹⁴⁶ *Id.*

¹⁴⁷ Christopher Houchens & Joseph Larsen, *The Role of the Biomedical Advanced Research and Development Authority (BARDA) in Promoting Innovation in Antibacterial Product Development*, AMR Control (Aug. 2, 2017), <http://resistancecontrol.info/2017/the-role-of-the-biomedical-advanced-research-and-development-authority-barda-in-promoting-innovation-in-antibacterial-product-development>.

¹⁴⁸ U.S. Dep't of Health and Human Servs., *Broad Spectrum Antimicrobials*, <https://www.medicalcountermeasures.gov/barda/cbrn/broad-spectrum-antimicrobials/>.

For example, on February 4, 2020, HHS announced that it had expanded upon an existing OTA with Regeneron Pharmaceutical “to develop new treatments combating the novel coronavirus.”¹⁴⁹ This OTA was HHSO100201700020C, which was first entered into by BARDA and Regeneron in 2017 “to discover, research, develop, and manufacture a portfolio of antibodies targeting up to 10 pathogens that pose significant risk to public health, starting with Influenza virus.”¹⁵⁰ The Regeneron OTA has a term of 10 years, and BARDA is obligated to cover 80 percent of the costs.¹⁵¹ The amended Regeneron OTA has a ceiling of \$220,703,360.60.¹⁵²

HHS expanded two pre-existing OTAs with Janssen Pharmaceutical Companies (the pharmaceutical component of Johnson and Johnson) to conduct COVID-19 R&D. On February 11, 2020, Johnson and Johnson announced that it had expanded an OTA between Janssen and BARDA to develop a COVID-19 vaccine.¹⁵³ That OTA was HHSO100201700018C, which was first announced by BARDA on September 15, 2017.¹⁵⁴ It originally had a \$43 million contribution from BARDA and a ceiling of \$237 million.¹⁵⁵ The initial purpose of this OTA was to promote the advanced development of a portfolio of products to treat or prevent “emerging infectious diseases, including influenza viruses with pandemic potential.”¹⁵⁶

On February 11, 2020, the 2017 J&J OTA was amended to reflect an “[a]ddition of new asset for 2019 Novel Corona Virus[.]”¹⁵⁷ On March 27, 2020, the J&J OTA obligated \$456,237,081 to the company for the development of a COVID-19 vaccine, and the contract was given an upper limit of \$689,525,867.¹⁵⁸

On February 18, 2020, Johnson & Johnson announced that it had expanded a different OTA with BARDA, HHSO100201800012C.¹⁵⁹ The goal of this expanded OTAs is to identify a

¹⁴⁹ U.S. Dep’t of Health and Human Servs. Press Office, *HHS, Regeneron Collaborate to Develop 2019-nCoV Treatment* (Feb. 4, 2020), hhs.gov/about/news/2020/02/04/hhs-regeneron-collaborate-to-develop-2019-ncov-treatment.html.

¹⁵⁰ Regeneron Pharmaceuticals, Inc., Quarterly Report (Form 10-Q)(Nov. 8, 2017).

¹⁵¹ *Id.*

¹⁵² HHSO100201700020C (P00007), https://beta.sam.gov/awards/89973786%2BAWARD?keywords=HHSO100201700020C&sort=-relevance&index=&is_active=true&page=1.

¹⁵³ Johnson & Johnson, *Johnson & Johnson Announces Collaboration with U.S. Department of Health & Human Services to Accelerate Development of a Potential Novel Coronavirus Vaccine* (Feb. 11, 2020), <https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine>.

¹⁵⁴ U.S. Dep’t of Health and Human Servs. Office of the Assistant Secretary for Preparedness and Response, *HHS, Janssen Research & Development join forces on innovative influenza products* (Sept. 15, 2017), <https://www.phe.gov/Preparedness/news/Pages/janssen-flu.aspx>.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ HHSO100201700018C (P00006), https://beta.sam.gov/awards/88171845%2BIDV?keywords=HHSO100201700018C&sort=-relevance&index=&is_active=true&page=1.

¹⁵⁸ HHSO100201700018C (P00008), <https://beta.sam.gov/awards/89139853%2BIDV>.

¹⁵⁹ Johnson & Johnson, *Johnson & Johnson to Expand Partnership with U.S. Department of Health & Human Services to Accelerate the Discovery of Potential COVID-19 Treatments*, (Feb. 18, 2020),

compound from a library of existing antiviral molecules that is effective against SARS-CoV-2.”¹⁶⁰ The original OTA appears to be identified as procurement no. 75A50118C00012 on government contract reporting websites such as FPDS-NG and beta.SAM.gov. The solicitation ID for 75A50118C00012 is BAA18100SOL00003, which was amended by HHS in March of 2020 to “to focus specifically on products to diagnose, prevent, or treat coronavirus infections.”¹⁶¹ Records reflect that 75A50118C00012 was first executed on September 21, 2018, and amended several times since the outset of COVID-19.¹⁶² The description for a February 14, 2020 amendment is as follows: “In response to the current novel coronavirus (?COVID-19?) outbreak, a.”¹⁶³ The OTA now has an upper limit of \$211,693,687.¹⁶⁴

Yet another BARDA contract related to COVID-19 is a possible OTA. On May 21, 2020, HHS announced that it had entered into an agreement with AstraZeneca for “up to \$1.2 billion in support, in parallel, advanced clinical studies, vaccine manufacturing technology transfer, process development, scaled-up manufacturing, and other development activities.”¹⁶⁵ As of the date of this publication, the most recent government contract involving AstraZeneca, 75A50120C00114, was executed by AstraZeneca and the ASPR on May 20, 2020.¹⁶⁶ The description for the May 20, 2020 AstraZeneca contract states: “Issue Advanced Agreement prior to award of an Other Transaction Agreement (OTA) for the COVID19 Vaccine Development and Manufacturing.”¹⁶⁷ It thus appears that this agreement contemplates the future issuance of a related OTA. The agreement obligates \$413,200,000.

The benefits of using Other Transactions Authority, according to the ASPR, are that OTAs are flexible, allowing the funding of a portfolio of product candidates, rather than requiring asset-based funding; they “allow the company and the government to enter into consortia”; they

<https://www.jnj.com/johnson-johnson-to-expand-partnership-with-u-s-department-of-health-human-services-to-accelerate-the-discovery-of-potential-covid-19-treatments>.

¹⁶⁰ *Id.*

¹⁶¹ U.S. Dep’t of Health and Human Servs., *HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus* (March 6, 2020), <https://www.hhs.gov/about/news/2020/03/06/hhs-solicits-proposals-for-development-of-medical-products-for-novel-coronavirus.html>.

¹⁶² The author searched “75A50118C00012” at beta.SAM.gov.

¹⁶³ 75A50118C00012 (P00004),

https://beta.sam.gov/awards/88796845%2BAWARD?keywords=75A50118C00012%20&sort=-relevance&index=&is_active=true&page=1.

¹⁶⁴ 75A50118C00012 (P00006),

https://beta.sam.gov/awards/90574274%2BAWARD?keywords=75A50118C00012%20&sort=-relevance&index=&is_active=true&page=1.

¹⁶⁵ U.S. Dep’t of Health and Human Servs. Office of the Assistant Secretary for Preparedness and Response, *Trump Administration’s Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to be Available Beginning in October*, (May 21, 2020), <https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html>.

¹⁶⁶ The author searched “Astrazeneca” in the search engine at fpds.gov and sorted the results by “Date Signed.”

¹⁶⁷ 75A50120C00114 (0),

https://beta.sam.gov/awards/90205157%2BAWARD?keywords=75A50120C00114&sort=-relevance&index=&is_active=true&page=1.

allow “[t]ime and cost savings” because they enable “the government and its industry partner to decide jointly to replace an underperforming candidate” rather than having to terminate a contract and award a new one; they reduce the costs of drug development; and that OTAs permit a “[t]rue collaboration” because “both partners are represented on joint scientific or technical oversight committees.”¹⁶⁸

7. Like BARDA, DOD has used Other Transactions Authority to sponsor biomedical research and development in connection with COVID-19.

DOD has used Other Transactions Authority for a collaboration with Gilead Sciences (“Gilead”) that appears to be connected with the antiviral drug Remdesivir, which has been granted experimental use as a treatment for COVID-19.¹⁶⁹ The OTA, W911QY1690001, was executed on August 17, 2016 by Gilead and the Army.¹⁷⁰ The description of the OTA is “OTA for prototype, Ebola virus.”¹⁷¹ The Army collaborated with Gilead around this same time period to test Remdesivir against the Ebola virus.¹⁷² When tested against Ebola and other coronaviruses, Remdesivir was shown to be effective against coronaviruses.¹⁷³ The Gilead OTA has an upper limit of nearly \$50 million.¹⁷⁴

Another example of a COVID-related DOD OTA is the Medical Technology Enterprise Consortium (MTEC). MTEC is a “biomedical technology consortium.”¹⁷⁵ It was established by an OTA with U.S. Army Medical Research and Development Command.¹⁷⁶ MTEC’s members include large and small companies and universities.¹⁷⁷ The purpose of MTEC is to support “the health and performance of U.S. military personnel.”¹⁷⁸ MTEC publishes a list of active and closed solicitations on its websites. On the list of closed solicitations are

¹⁶⁸ Elizabeth Jarrett, *Innovative partnerships support antibiotic development*, ASPR Blog (Sept. 23, 2015), <https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=157>.

¹⁶⁹ U.S. Food and Drug Admin., *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment* (May 1, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>.

¹⁷⁰ W911QY1690001 (0), https://beta.sam.gov/awards/68110444%2BAWARD?keywords=W911QY1690001&sort=-relevance&index=&is_active=true&page=2.

¹⁷¹ *Id.*

¹⁷² U.S. Army Medical Research Inst. of Infectious Diseases, *Antiviral Compound Provides Full Protection from Ebola Virus in Nonhuman Primates* (Oct. 9, 2015), http://www.usamriid.army.mil/press_releases/Travis_ID_Week_FINAL.pdf. Remdesivir was identified as GS-5734 at the time.

¹⁷³ Timothy P. Sheahan et al., *Broad-spectrum Antiviral GS-5734 Inhibits Both Epidemic and Zoonotic Coronaviruses*, *Science Translational Medicine* vol. 9, 396 (2017), doi:10.1126/scitranslmed.aal3653.

¹⁷⁴ W911QY1690001 (P00013), https://beta.sam.gov/awards/85565339%2BAWARD?keywords=W911QY1690001&sort=-relevance&index=&is_active=true&page=2.

¹⁷⁵ *About MTEC*, MTEC, <https://www.mtec-sc.org/about-us/>.

¹⁷⁶ *Id.*

¹⁷⁷ *Current Members*, MTEC, <https://www.mtec-sc.org/current-members/>.

¹⁷⁸ *Request for Project Proposals, Solicitation Number: MTEC-20-12-COVID-19_Diagnostics “Wearable Diagnostic for Detection of COVID-19 Infection” 3* (May 1, 2020), https://www.mtec-sc.org/wp-content/uploads/2020/05/20-12-COVID19_Diagnostics-RPP-1.pdf.

20-12-COVID-19_Diagnostics, regarding “Wearable Diagnostic for Detection of COVID-19 Infection,” and 20-09-COVID-19, “Development of Treatments for COVID-19.”¹⁷⁹

Another example is the Medical CBRN Defense Consortium (MCDC), which is sponsored by the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense and managed by Advanced Technology International, a “Collaboration Management Firm.”¹⁸⁰ Like MTEC, MCDC’s website publishes a list of open and closed solicitations. Related to COVID-19 are RPP-20-07, “Development of Diagnostic Tests for the Rapid and Accurate Diagnosis of Human SARS-CoV-2,” awarded to New Horizons Diagnostics on May 28, 2020 and RPP-20-04, “Advance Treatment Based on Polyclonal Antibodies to Treat Coronavirus Disease 2019 (COVID-19) Response,” awarded to Grifols Shared Services North America, Inc. on April 9, 2020.¹⁸¹ Notably, Ology Bioservices, Inc. (“Ology”) and Inovio Pharmaceuticals (“Inovio”) are members of the MCDC.¹⁸² On March 24, 2020, Inovio announced that DOD had awarded Ology “a contract valued at \$11.9 million to work with Inovio” “to manufacture Inovio’s DNA vaccine (INO-4800) for prevention of infection with the COVID-19 virus.”¹⁸³

8. BARDA and NIH have used and are now encouraging the use of OTAs to eliminate or limit government rights in patented inventions and data.

Both BARDA and the NIH are using OTAs to eliminate or limit certain government’s rights in patents and data.

KEI submitted FOIA requests for all OTAs executed by BARDA and NIH, and they are still pending. KEI reviewed three BARDA OTA documents that are available online, however. One is a flow-down agreement for subcontractors regarding the 2015 AstraZeneca OTA,¹⁸⁴ the second is what appears to be the actual 2015 AstraZeneca OTA itself, included as a “BARDA OT[A] Sample” in an NIH OTA training document,¹⁸⁵ and the third is an SEC exhibit of an OTA between BARDA and the Medicines Company.

Some departures from the default government rights to IP and data developed pursuant to a procurement contract are present in the documents. Among these changes are a redefinition of the term “practical application,” to eliminate the obligation to provide the benefits of an invention to the public “on reasonable terms,” a narrowing of the grounds for march-in rights, and a narrowing of the government’s rights in technical data.

¹⁷⁹ *Solicitations*, <https://www.mtec-sc.org/solicitations/>.

¹⁸⁰ *Accelerating DoD’s Fielding of Prototypes for Medical Countermeasures*, <https://www.medcbrn.org/>.

¹⁸¹ *Solicitations*, <https://www.medcbrn.org/solicitations/#1547817555427-f9628bb4-f0b9>.

¹⁸² *Current Members*, <https://www.medcbrn.org/current-members/>.

¹⁸³ Inovio, *Ology Bioservices, Inovio Partner To Manufacture COVID-19 DNA Vaccine With \$11.9 Million Department of Defense Grant* (March 24, 2020), <http://ir.inovio.com/news-releases/news-releases-details/2020/Ology-Bioservices-Inovio-Partner-To-Manufacture-COVID-19-DNA-Vaccine-With-119-Million-Department-of-Defense-Grant/default.aspx>.

¹⁸⁴ Contract No. HHSO100201500029C Flowdown Requirements for Subcontracts (Appendix A), <https://www.astrazeneca.com/content/dam/az/Government%20Contract%20T%26Cs/ATM-AVI%20Flowdown%20Requirements%20for%20Subcontracts.pdf>.

¹⁸⁵ NIH OTA Participant Guide, *supra* note 136, at 405 - 461.

Practical application has been redefined to eliminate “on reasonable terms”.

Both the AstraZeneca and the Medicines Company OTAs define “Practical Application” as follows:

With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, 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.¹⁸⁶

The primary and intended consequence of the new definition is to modify the obligation in the Bayh-Dole Act of making the products embodying federally-funded inventions “available to the public on reasonable terms,”¹⁸⁷ to the shorter, “available to the public.” These three words, “on reasonable terms,” are not a minor issue. “On reasonable terms” is a central if under-used safeguard in the Bayh-Dole Act, to protect the public against “unreasonable use of inventions”—a stated purpose of the statute.¹⁸⁸

Table 1 illustrates the difference between the definitions of “practical application” in the Bayh-Dole Act and BARDA OTAs .

Table 1: BARDA’s definitions of “practical application” in example OTAs eliminate the requirement of availability of subject inventions “on reasonable terms.”

<u>Source</u>	<u>Definition of Practical Application</u>
Bayh-Dole Act “funding agreements” ¹⁸⁹	“The term ‘practical application’ means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, 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. ” ¹⁹⁰

¹⁸⁶ The Medicines Company, Exhibit 10.1, *Other Transaction Agreement (OTA) between The Medicines Company 8 Sylvan Way Parsippany, New Jersey, 07054 and the United States of America Department of Health and Human Services Assistant Secretary for Preparedness and Response 330 Independence Avenue, SW G640 Washington, DC 20201 (the “Parties”) CONCERNING The research and development to advance the development of a portfolio of antibacterial programs* (Sept. 15, 2016), <https://www.sec.gov/Archives/edgar/data/1113481/000111348116000094/mdcoex101093016-q32016.htm> (hereinafter, “The Medicines Company OTA”).

¹⁸⁷ See 35 U.S.C. § 203(a)(1)(authorizing march-in for failure to achieve practical application) and 35 U.S.C. § 201(f)(defining practical application to require the availability of subject inventions to the public “on reasonable terms”).

¹⁸⁸ 35 U.S.C. § 200.

¹⁸⁹ Funding agreements are defined at 35 U.S.C. § 201(b).

¹⁹⁰ 35 U.S.C. § 201(f).

<p>AstraZeneca OTA, Agreement No.: HHS0100201500029C PR No.: 05162378</p> <p>Medicines Company OTA, Agreement No.: HHSO100201600026C PR No.: OS182081</p>	<p>“Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, 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.”¹⁹¹</p>
---	--

Table 2 provides two examples from NIH march-in cases in which the NIH rejected the petitioners’ argument that drug companies failed to achieve practical application because they were charging U.S. residents far more for drugs developed with U.S. taxpayers’ dollars than they did residents of high-income countries. In rejecting the march-in petitions, the NIH stated that practical application had been achieved because the drugs were available to the public. To so conclude, the NIH supplied a definition of practical application that defies the text of the Bayh-Dole Act because it eliminates a major component of the definition—the “on reasonable terms” language. This is the same definition the NIH recommends using for OTAs.

Table 2: Examples of NIH efforts to change the definition of “practical application” by ignoring or eliminating “on reasonable terms” from definition of practical application

<u>Examples</u>	<u>NIH efforts to redefine practical application</u>
<p>2004 Norvir/Ritonavir March-in Case. Decision by Elias A. Zerhouni, MD, then Director of NIH (subsequently head of R&D for Sanofi). July 29, 2004. http://ott.od.nih.gov/Reports/March-In-Norvir.pdf.</p>	<p>“[T]he record in this instance demonstrates that Abbott has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of ritonavir and the drug’s availability and use by the public.”</p>
<p>2016 Xtandi/Enzalutamide March-in Case. Decision by Francis S. Collins, MD, PhD, NIH Director. June 20, 2016. https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf.</p>	<p>“Practical application is evidenced by the ‘manufacture, practice, and operation’ of the invention and the invention’s ‘availability to and use by the public . . .’ Xtandi® is broadly available as a prescription drug.”</p>
<p>Other Transaction Authority Training, Participant Guide. 2018. Sample OTA, page 228. https://oamp.od.nih.gov/sites/default/files/DSAPS/NPI-3000%20NIH%20OTAB%20Participant%20Guide%2001-18v2.pdf</p>	<p>Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, 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.</p>

¹⁹¹ NIH OTA Participant Guide, *supra* note 136, at 413.

9. The NIH has, for many years, ignored the language “on reasonable terms” in the definition of “practical application.”

Attempts by the NIH to bypass the plain language of the Bayh-Dole Act are not a new occurrence.

In the 2004 Norvir/ritonavir case, Abbott increased the price of the NIH-funded HIV drug by 400 percent, with the price increase only applying to U.S. residents and not to customers in any other country.¹⁹² In the 2016 Xtandi case, Astellas Pharmaceutical charged \$129 thousand per year in the United States, and only \$39,000 thousand to \$30 thousand per year in other high income countries, for a prostate cancer drug that was developed with grants from the NIH and U.S. Army.¹⁹³ In both cases, the petitioners argued that the NIH should exercise march-in rights because the holder of rights to the inventions failed to achieve practical application of the inventions by not making them available on reasonable terms,¹⁹⁴ and in both cases, the NIH determined that making a product available to the public at any price achieved practical application, on the grounds that the product was “available to the public,” and for sale in the United States.¹⁹⁵

The NIH's position on the Bayh-Dole Act and the pricing of federally funded inventions is controversial, particularly in light of the plain language in the Bayh-Dole statute that practical application requires the inventions being “available to the public on reasonable terms.” The NIH advocates for using OTAs to eliminate the words “on reasonable terms” so that companies are not subject to any government constraints on pricing.

¹⁹² See Essential Inventions, *Petition To Use Authority Under Bayh-Dole Act To Promote Access To Ritonavir, Supported By National Institute Of Allergy And Infectious Diseases Contract No. AI27220* (Jan. 29, 2004),

<http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf>. In 2012, under President Obama, a new case was filed by the American Medical Students Association (AMSA), KEI, U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM). *Request For March-In On Abbott Patents For Ritonavir On Grounds That Abbott Private Sector Prices For Ritonavir Are Higher In Usa Than In Other High Income Countries, And Abbott's Refusal To License Patents For Non-Abbott Fixed Dose Combinations Of Hiv Drugs*, October 25, 2012, https://www.keionline.org/wp-content/uploads/2012_Oct25_Ritonavir_march_in_complaint.pdf

¹⁹³ See Letter from Knowledge Ecology International and the Union for Affordable Cancer Treatment to the Hon. Sylvia Mary Mathews Burwell, Sec'y, Dep't of Health and Human Servs., et al. (January 14, 2016), <https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf>

¹⁹⁴ See Essential Inventions, *supra* note 190, and Knowledge Ecology International and the Union for Affordable Cancer Treatment, *supra* note 191.

¹⁹⁵ Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004, <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf>; Francis S. Collins, Director, NIH, *Determination in the Case of Xtandi Manufactured by Astellas Pharmaceuticals*, June 20, 2016, https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf

New efforts to require the NIH to enforce the requirements that inventions be made available to the public “on reasonable terms” were highlighted in a 2001 article by professors Peter Arno and Michael Davis, titled “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research,”¹⁹⁶ in the *Tulane Law Review*.¹⁹⁷ Arno and Davis focused attention on the definition of “practical application” at 35 U.S.C. § 201(f). Greater attention was drawn to the issue when Arno and Davis published the op-ed, “Paying Twice for the Same Drugs,” in the March 27, 2002 issue of the *Washington Post*.¹⁹⁸ The *Post* op-ed prompted Senators Birch Bayh and Bob Dole—the sponsors of the Bayh-Dole Act—to submit a letter to the editor to the *Washington Post*, that was published with the title “Our Law Helps Patients Get New Drugs Sooner.” In the letter, Bayh and Dole claimed that Arno and Davis “mischaracterized the rights retained by the government under Bayh-Dole”, stating that “Bayh-Dole did not intend that the government set prices on resulting products.”¹⁹⁹

At the time of the letter, which was more than two decades after the law was enacted, Dole was starring in television commercials for Viagra on behalf of Pfizer,²⁰⁰ and both Dole and Bayh had been working in a series of lobbying jobs for a variety of clients.

In 2002, Dole was working for Verner Liipfert,²⁰¹ a firm with clients such as Eli Lilly and the Intellectual Property Owners Association,²⁰² and he created the lobbying firm Bob Dole Enterprises, to sign up clients such as Johnson and Johnson.²⁰³ He also worked for Alston & Bird, another firm with a powerful lobbying practice, where Dole represented companies such as Celgene.²⁰⁴

¹⁹⁶See Peter Arno and Michael Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631 (2001).

¹⁹⁷ See *id.*

¹⁹⁸ Peter Arno and Michael Davis, *Paying Twice for the Same Drugs*, Wash. Post (March 27, 2002), <https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/>

¹⁹⁹ Birch Bayh and Bob Dole, *Our Laws Help Patients Get New Drugs Sooner*, Wash. Post (April 11, 2002), <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>.

²⁰⁰ Associated Press, *Pfizer Hires Bob Dole for TV Ad Campaign*, L.A. Times, (December 12, 1998), <https://www.latimes.com/archives/la-xpm-1998-dec-12-fi-53139-story.html>.

²⁰¹ Center for Responsive Politics, Bob Dole Employment Timeline, OpenSecrets.org, https://www.opensecrets.org/federal-lobbying/firms/summary?id=D000000183&cycle=2002https://www.opensecrets.org/revolving/rev_summary.php?id=14067 (hereinafter, “Bob Dole Employment Timeline”).

²⁰² Center for Responsive Politics, *Lobbying Firm Profile: Verner, Liipfert et al*, OpenSecrets.org, <https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=1998&id=D000000183>.

²⁰³ Center for Responsive Politics, *Lobbying Firm Profile: Bob Dole Enterprises*, OpenSecrets.Org, <https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2001&id=F220982&year=2003>.

²⁰⁴ Bob Dole Employment Timeline, *supra* note 201.

Birch Bayh left the Senate in 1981, after his defeat by Dan Quayle in the 1980 election. He founded a law firm with D.C. offices, joined other law D.C. law practices, before joining Venable in June 2001.²⁰⁵

In 1997, Bayh and Lloyd Cutler represented the Seattle based firm Cellpro in the NIH's first march-in case, requesting a compulsory license on a patent held by Johns Hopkins University (JHU).²⁰⁶ JHU had licensed its patent to a company called Becton Dickinson, which relicensed them to the medical device maker Baxter.²⁰⁷

Bayh took the position, in 1997, when hired by Cellpro, that regulations implementing the Bayh-Dole Act should take into account the impact of licensing practices on the prices of medical care. The March 3, 1997 march-in petition submitted by Lloyd Cutler and Birch Bayh on behalf of Cellpro states, in pertinent part:

[I]nvestigation may be needed to determine whether the royalty layering that plainly exists in the present case . . . is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation.²⁰⁸

Later, Bayh had different clients, and embraced different views. In 2004, the year of the ritonavir march-in case, Venable described Bayh's role as follows:

Pharmaceutical industry clients' interaction with public research and academic institutions presents challenging issues in licensing, ownership, and confidentiality, requiring diplomacy and ingenuity. The firm for many years has represented academic and research institutions, including Princeton, Johns Hopkins, Yale, McGill, the University of Maryland, the University of California, the Smithsonian Institution, and the British Royal Botanical Gardens. Venable understands the financial dimensions of the bioscience industry from its representation of numerous companies in complex transactions around the globe, both in public-private arrangements with research institutions and in private-private deals with other companies.

Venable has extensive experience with federally funded research and technology transfer. Indeed, the Bayh-Dole Act (Federal Technology Transfer Act), was authored and sponsored by Senator Birch Bayh, now a partner in Venable's legislative group, who continues to actively promote federal research and technology transfer.²⁰⁹

Bayh spoke at the 2004 NIH hearing on the 2004 ritonavir march-in request. He repeated his assertion that the words "on reasonable terms" had nothing to do with the price of products and

²⁰⁵ <https://www.venable.com/about/news/2001/06/former-us-senator-birch-bayh-joins-venable>.

²⁰⁶ Letter from Lloyd N. Cutler and Birch Bayh to the Hon. Donna E. Shalala, Sec'y of Health and Human Servs. (March 3, 1997), <https://www.keionline.org/wp-content/uploads/cellpro-request.pdf> (hereinafter, "Cellpro Petition").

²⁰⁷ *Id.* at 6-7.

²⁰⁸ *Id.* at 15-16.

²⁰⁹ https://web.archive.org/web/20040323092744/http://www.venable.com/pharm_licensing.cfm.

stated that “I should emphasize that I am not being compensated to appear here today.”²¹⁰ What Bayh did not mention was that Abbott (the subject of the march-in request) was a client of Venable,²¹¹ his employer, or that his work at Venable, advocating for technology transfer, was listed as part of Venable’s pharmaceutical practice.²¹²

Aside from the obvious fact that two former members of Congress, speaking more than two decades after a law was enacted, after both had engaged in lucrative lobbying careers, and worked at firms with drug company clients, raises issues about the reliability of their representations, it is also well established that a bill sponsors’ subjective view of what Congress intended, after the law was enacted, is not a legitimate method of statutory interpretation, particularly for the unambiguous definition of practical application.

The U.S. Supreme Court has observed that a statement written by legislators who sponsored a bill, years after it comes law “does not qualify as legislative ‘history’” and is of “scant or no value” in construing the statute.²¹³ Further evidence that post enactment statements by former legislators as to the intent of a law they sponsored are not taken seriously by courts is the Supreme Court’s decision in *Stanford v Roche*.²¹⁴ Bayh filed an amicus brief with the Court, regarding the intent of the provision of the Bayh-Dole Act addressing contractors’ right to retain title to subject inventions.²¹⁵ The Court not only ruled contrary to Bayh’s position, but it did not even bother to cite his brief.²¹⁶

The former Senators’ statements, decades after enactment of the Bayh-Dole Act, on what they think the statute intended, clearly have no place in the debate over the meaning of the Act and should be cast aside. Unlike the Senators’ subjective opinions on what the law intended, it was the text of the statute that was voted on by both houses of Congress and signed into law.

Bayh’s and Dole’s positions about the Bayh-Dole Act’s intent are contrary to the plain meaning rule, *i.e.*, that “[s]tatutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.”²¹⁷ It is also contrary to the “rule against surplusage”—that “words cannot be

²¹⁰ Nat’l Insts. of Health, *NIH Public Meeting on Norvir/Ritonavir March-in Request, Statement of Senator Birch Bayh to the National Institutes of Health* (May 24, 2004), <https://www.otc.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>.

²¹¹ *See, e.g., Campbell v. Purdue Pharma, L.P.*, No. 1:02CV00163 TCM, 2004 WL 5840206 (E.D. Mo. June 25, 2004)(noting that Venable represented the defendants, which included Abbott Laboratories).

²¹² https://web.archive.org/web/20040323092744/http://www.venable.com/pharm_licensing.cfm.

²¹³ *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, (2010).

²¹⁴ 563 U.S. 776 (2011)

²¹⁵ Brief Amicus Curiae of Birch Bayh in Support of Pet’r, *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776 (2011)(hereinafter, “Bayh Amicus Brief”).

²¹⁶ *Compare* 563 U.S. 776 (“Section 202(a), which states that contractors may “elect to retain title,” confirms that the Act **does not vest title**”)(emphasis added) *with* Bayh Amicus Brief at 11 (“The Bayh–Dole Act, by operation of law, presumptively and automatically vests ownership rights in inventions arising from federally-funded research in the universities, small businesses, and nonprofit organizations responsible for their creation.”).

²¹⁷ *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 175-76 (2009)(quoting *Engine Mfrs. Assn. v. South Coast Air Quality Management Dist.*, 541 U. S. 246, 252 (2004)).

meaningless, else they would not have been used.”²¹⁸ For availability to the public alone to be sufficient, regardless of the terms on which an invention is available, would be to render the words “on reasonable terms” mere surplusage.

Since the Arno/Davis articles and the 2004 Norvir/ritonavir case, opponents of pricing constraints on federally funded inventions have published dozens of blogs and articles claiming that “available to the public on reasonable terms” means anything but a reasonable price to the public. In 2018, NIST proposed new regulations to define “practical application” as not addressing the prices paid by consumers of products and proposed narrowing the federal royalty free right,²¹⁹ but this effort was blocked by opposition from members of Congress and patient advocacy groups.²²⁰ A 2019 report in the *Washington Post* on the NIST proposal included this quote from Georgetown Law Professor John R. Thomas.

We have march-in rights for a reason, as a safety valve, and pricing is one of just many issues that could make something not reasonably available[.] The idea that the price is too high fits pretty comfortably in the wording of the statute.²²¹

Groups such as Bayh-Dole 40 continue to wage a battle against any efforts to enforce the “on reasonable terms” language or more generally the use of march-in rights or the federal government royalty free right in inventions to address prices for biomedical inventions.²²²

The NIH and BARDA redefinitions on “practical application” appear to be a continuation of this lobbying effort by rightsholders.

10. March-in rights are narrowed.

Earlier OTA contracts we have reviewed provide for march-in rights, but with changes. For example, the Medicines Company/BARDA OTA eliminates two of the four circumstances in which the federal government may march in, as illustrated in Table 3.

Table 3: March-in provisions in Bayh-Dole vs Medicines Company OTA with BARDA

Bayh-Dole Act	Medicines Company/BARDA OTA in 2016 ²²³
Federal agency determines that such—	HHS determines that:

²¹⁸ See *United States v. Butler*, 297 U.S. 1, 65 (1936).

²¹⁹ Draft NIST Special Publication 1234, *Return on Investment Initiative for Unleashing American Innovation* 33,58 2018, <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>. KEI’s commentary is published at <https://www.keionline.org/29518>.

²²⁰ James Love, *KEI Comment on the NIST Green Paper on Bayh-Dole technology transfer recommendations regarding march-in and government use rights* (April 24, 2019), <https://www.keionline.org/30451>.

²²¹ Christopher Rowland, *A rare deterrent to limitless drug price increases may die under Trump*, *Wash. Post* (April 18, 2019), https://www.washingtonpost.com/business/economy/a-rare-deterrent-to-limitless-drug-price-increases-may-die-under-trump/2019/04/17/7578e5e0-5bcd-11e9-a00e-050dc7b82693_story.html.

²²² See, e.g., <https://bayhdole40.org/category/news/march-in-rights/>.

²²³ The Medicines Company OTA, *supra* note 184.

<p>(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;</p> <p>(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;</p> <p>(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or</p> <p>(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.</p>	<p>1. Such action is necessary because Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or</p> <p>2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by Recipient, assignee, or their licensees.</p>
---	---

One comment on the revised OTA provision for march-in is that grounds (1) on a failure to achieve practical application is effectively weakened by the changes in the OTA definition of practical application, as is discussed above.

Ground (2) has been retained, but grounds (3) and (4) were eliminated in the Medicines Company OTA.

Grounds (4) involves Section 204 of the Bayh-Dole Act which is titled “Preference for United States industry.” Note that in 2019, the Medicines Company was acquired by Novartis, a Swiss firm.²²⁴

More significantly, the actual language in the Medicines Company OTA is different from the NIH OTA Participant Guide text²²⁵ or the BARDA Template for Other Transaction for Advanced Research.²²⁶ The fact that a core provision, such a march-in rights, can be modified from the agency template illustrates the importance of reviewing the actual as opposed to the model contracts.

11. Government rights in data are limited.

²²⁴ *Novartis to acquire The Medicines Company for USD 9.7 bn, adding inclisiran, a potentially transformational investigational cholesterol-lowering therapy to address leading global cause of death*, Novartis (Nov. 24, 2019), <https://www.novartis.com/news/media-releases/novartis-acquire-medicines-company-usd-97-bn-adding-inclisiran-potentially-transformational-investigational-cholesterol-lowering-therapy-address-leading-global>.

²²⁵ NIH OTA Participant Guide, *supra* note 136, at 254.

²²⁶ BARDA OTAR Template, *supra* note 135, at 20-21.

Unlimited rights in data are not provided in the agreements KEI has reviewed. Because HHS is a civilian agency, if the OTAs were instead FAR-based contracts, the government would have unlimited rights in any data developed through the funded research.

Table 4 provides examples of BARDA OTA provisions which eliminate government rights in data.

Table 4: BARDA OTAs eliminate unlimited government rights in data delivered under the contract.

Procurement contracts under the FAR	The government has unlimited rights in data delivered under the contract, giving the government the ability “to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so. ” ²²⁷
Medicines Company OTA, Agreement No.: HHSO100201600026C PR No.: OS182081	“For Data delivered under this Agreement, other than computer software and Limited Rights Data, the Recipient grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, nontransferable, nonsublicensable, irrevocable, worldwide license in such Data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government, except as expressly provided elsewhere in this Agreement.” ²²⁸
AstraZeneca OTA, Agreement No.: HHS0100201500029C PR No.: 05162378	For Data other than computer software, the Recipient grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, nontransferable, nonsublicensable, irrevocable, worldwide license in such Data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government, subject to the limitations applicable to the Government’s use of Limited Rights Data and except as expressly provided elsewhere in this Agreement. ²²⁹

12. Federal agencies have overstated the benefits of OTAs and used the agreements in cases where the original rationales were not met.

According to CRS, the benefits of OTAs include “providing a mechanism to pool R&D resources,” attracting non traditional contractors,” “lowering costs by eliminating requirements associated with the [FAR],” and “Speeding up’ the acquisition process.”²³⁰

²²⁷ FAR 52.227-14(a)(emphasis added).

²²⁸ The Medicines Company OTA, *supra* note 184 (emphasis added).

²²⁹ NIH OTA Participant Guide, *supra* note 136, at 424-425 (emphasis added).

²³⁰ Peters, *supra* note 2, at 6.

The GAO and others have warned, however, that OTAs “carr[y] the risk of reduced accountability and transparency, in part because such agreements may not require compliance with federal requirements, such as government cost accounting standards.”²³¹ Similarly, the CRS notes that “[a] number of analysts warn that along with the potential benefits come significant risks, including potentially diminished oversight and exemption from laws and regulations designed to protect government and taxpayer interests.”²³²

Two large OTAs executed by DOD were modified after facing scrutiny. One involved Future Combat Systems (FCS), an OTA for “a networked ‘system-of-systems,’ which link[ed] soldiers with both manned and unmanned ground and air vehicles, sensors, and munitions.”²³³ In April of 2004, the GAO reported that FCS was “at significant risk for not delivering required capability within budgeted resources[.]”²³⁴ During a Senate hearing discussing the FCS OTA on March 16, 2005, Senator John McCain was skeptical of the use of Other Transactions Authority for the program; particularly, the omission of the Procurement Integrity Act.²³⁵ McCain stated as follows:

Now, what you are saying is we do not need those laws. You can do the job yourself better than enforcing laws that were passed by the Congress of the United States to preserve the integrity of the taxpayer. You can do a better job. My point is if you want to come back and say, change the procurement laws, Congress, so that I can do a better job than these laws are having any beneficial effect, then I would be certainly open to it. I know this committee would be and so would all of Congress But to just make a decision on your own that laws that were enacted because of previous scandals to try to prevent future scandals are being exempted from a huge \$100 billion and-some contract, you are going to have to give me a better reason than the fact that you have great judgment.²³⁶

Shortly thereafter, on March 31, 2005, McCain sent a letter to the Secretary of the Army reiterating his concerns about the use of Other Transactions Authority for the program.²³⁷ Specifically, he highlighted the involvement of Boeing, a large, traditional government contractor, and a restructuring of the FCS that delayed completion of the program and added to its cost.²³⁸ McCain also noted that the Army had not explained why the FCS OTA omitted the protections of the Truth in Negotiations Act, Procurement Integrity Act, and Cost Accounting Standards.²³⁹ He called upon the Army to “provide an estimate as to what additional costs the

²³¹ GAO-16-209 at 1.

²³² Peters, *supra* note 2.

²³³ 47 No. 12 Gov't Contractor ¶ 134.

²³⁴ U.S. Gov't Accountability Office, GAO-04-635T, *The Army's Future Combat Systems' Features, Risks, and Alternatives, Statement of Paul L. Francis, Director, Acquisition and Sourcing Management 2* (2004).

²³⁵ See generally *Department of Defense Authorization for Appropriations for Fiscal Year 2006 Hearings before the Comm. on Armed Servs. U.S. Sen., S. Hrg. 109-22, Pt 4, 109th Cong.* (2005).

²³⁶ *Id.* at 414-15.

²³⁷ McCain, *supra* note 62.

²³⁸ *Id.*

²³⁹ *Id.*

program would incur if the current OTA were converted to [a FAR-based contract].²⁴⁰ The 2006 NDAA ordered the Army to convert the FCS OTA to a FAR-based contract.²⁴¹

Another incident involving OTA occurred in 2018, when the DOD faced criticism concerning an OTA with a \$950 million ceiling that was awarded to Rean Cloud to “move computer systems to the Internet cloud.”²⁴² After facing criticism “that the procurement wasn’t handled properly,” and that DOD “show[ed] favoritism to a partner of Amazon Web Services[,]” DOD lowered the upper limit for the contract to \$65 million.²⁴³ According to FPDS, the most recent action for the Rean Cloud OTA occurred on February 14, 2019, with the description “[d]eobligation of excess funds following termination of production agreement.”²⁴⁴

In addition to concerns about how OTAs are being used, there is reason to question whether they are accomplishing the objectives for which they were authorized.

A 2002 report by the DOD Office of Inspector General found that OTAs “ha[d] not attracted a significant number of nontraditional Defense contractors to do business with the Government” because “Traditional Defense contractors have received 94.5 percent of the \$5.7 billion in funds for 209 prototype other transactions.”²⁴⁵ The report added:

We find this trend disturbing, as other transactions do not provide the government a number of significant protections, ensure the prudent expenditure of taxpayer dollars, or prevent fraud. Procurement statutes and the FAR provide contracting officers the tools to negotiate fair and reasonable prices, and to ensure that taxpayer dollars are expended for costs which are allowable and consistent with federal procurement policies. TINA, CAS, and the various audit provisions are among the tools that have provided contracting officers’ visibility into contractor costs and help the government ensure that prices negotiated and eventually paid are reasonable. These provisions have served the interests of the government and the taxpayer for many decades.²⁴⁶

According to CRS, “DOD documents” demonstrate that traditional contractors participate more than nontraditional contractors in OTAs.²⁴⁷ Federal News Network recently reported that only

²⁴⁰ *Id.*

²⁴¹ National Defense Authorization Act for Fiscal Year 2006, Pub. L. No. 109-163, § 212, 199 Stat. 3136, 3167 (2006).

²⁴² Christian Davenport and Aaron Gregg, *Faced with increased criticism, Pentagon slashes cloud computing contract award to an Amazon partner*, Wash. Post (March 5, 2018), <https://www.washingtonpost.com/news/the-switch/wp/2018/03/05/faced-with-increased-criticism-pentagon-slashes-cloud-computing-contract-awarded-to-an-amazon-partner/>.

²⁴³ *Id.*

²⁴⁴ 0001 (2), https://beta.sam.gov/awards/81393114%2BAWARD?keywords=W15QKN189P001&sort=-relevance&index=&is_active=true&page=1.

²⁴⁵ U.S. Dep’t of Defense Office of Inspector General, Rept. No. D-2002-064, *Statement for the Record Robert J. Lieberman, Deputy Inspector General Department Defense to the Subcommittee on Technology and Procurement Policy House Committee on Government Reform on The Services Acquisition Reform Act (SARA) of 2002* 11 (March 12, 2002), <https://media.defense.gov/2002/Mar/12/2001712299/-1/-1/1/02-064.pdf>.

²⁴⁶ *Id.* at 11-12.

²⁴⁷ Peters, *supra* note 2, at 24.

\$7.4 billion of the nearly \$21 billion spent by DOD on OTAs from 2015 to 2017 went to traditional contractors.²⁴⁸ Lockheed Martin, Northrop Grumman, and Boeing, were among the top five recipients of DOD OTA funds as of August 7, 2018.²⁴⁹

HHS's Other Transactions Authority does not require the participation of nontraditional contractors, does not require cost sharing, and does not even require competition.

It is not even clear that OTAs speed up contracting time. Because all terms of an OTA are negotiable, they may take longer to execute traditional contracts with standard clauses.²⁵⁰ DOD does not maintain a record of the "time it takes to execute [OTAs] vs. traditional contracts."²⁵¹

Regarding the possible benefits of a consortium, CRS notes that "[s]ome analysts . . . have argued that many of today's consortia do not operate as collaborative organizations, but function more like managed multiple award task order contracts."²⁵² CRS also reports that "[s]ome analysts have argued that consortia reduce competition", because only consortium members can apply for a bid.²⁵³

Overall, there is insufficient information to assess the usefulness of Other Transactions Authority. CRS reported in February of 2019 that "DOD lacks authoritative data that can be used to assess [OTAs] effectiveness and better understand broader trends associated with these agreements."²⁵⁴ According to the CRS, the main source of information about OTAs is the FPDS-NG, but that data is not "fully reliable."²⁵⁵ Similarly, in 2012, the GAO found that the Department of Homeland Security was not keeping a record of its reasons for using Other Transactions Authority and was not maintaining "information to measure the benefits of other transaction authority, which include reaching nontraditional contractors."²⁵⁶

13. Safeguards are particularly important when corruption and political influence is possible.

Government contracts for biomedical research can involve political influence. Dr. Rick Bright was, until recently, Director of BARDA. His 2020 whistleblower complaint contains a section

²⁴⁸ Scott Maucione, *As OTAs grow, traditional contractors are reaping the benefits*, Federal News Network (July 17, 2018), <https://federalnewsnetwork.com/contracting/2018/07/as-otas-grow-prime-contractors-are-reaping-the-benefits/>.

²⁴⁹ Chris Cornillie, *A Closer Look at the Pentagon's \$2 Billion a Year OTA Pipeline*, Federal News Network (January 22, 2019), <https://federalnewsnetwork.com/fiscal-2019-federal-contracting-playbook/2019/01/a-closer-look-at-the-pentagons-2-billion-a-year-ota-pipeline-2/>.

²⁵⁰ Peters, *supra* note 2, at 16.

²⁵¹ *Id.*

²⁵² *Id.* at 4.

²⁵³ *Id.*

²⁵⁴ Halchin, *supra* note 3, at 10.

²⁵⁵ *Id.* at 10-11.

²⁵⁶ U.S. Gov't Accountability Office, GAO-12-557, *Department of Homeland Security: Further Action Needed to Improve Management of Special Acquisition Authority* 11 (2012).

titled, "Since 2017, Dr. Bright Has Objected to HHS Leadership's Cronyism and Award of Contracts to Companies with Political Connections to the Administration,"²⁵⁷ which included the following passage:

[F]rom approximately the spring of 2017 through the date of his involuntary removal as Director of BARDA, HHS leadership pressured Dr. Bright and BARDA to ignore expert recommendations and instead to award lucrative contracts based on political connections and cronyism. Dr. Bright repeatedly clashed with Dr. Kadlec and other HHS leaders about the outsized role played by John Clerici, an industry consultant to pharmaceutical companies with a longstanding connection to Dr. Kadlec, in the award of government contracts.

As described in Section A, below, in the summer of 2017, Dr. Bright objected to the efforts of ASPR staff and Mr. Clerici to pressure Dr. Bright to extend a contract with Mr. Clerici's client, Aeolus Pharmaceuticals ("Aeolus"), which an IPR had concluded should be allowed to expire without further funding. In attempting to justify the extension of this failed contract, Mr. Clerici emphasized that Aeolus's Chief Executive Officer was a "wildcard" and a friend of Jared Kushner, President Trump's son-in-law and a Senior Advisor to the President. Dr. Bright stood his ground on this contract, which led to some discord between him and HHS leadership. As discussed in Section B, below, Dr. Bright's relationship with Dr. Kadlec and other HHS leaders became further strained in late 2018 after Dr. Bright objected to directions from Dr. Kadlec and his Chief of Staff, Christopher Meekins, to transfer \$40 million from BARDA to the SNS to allow it to purchase generic Oseltamivir, a drug which a task force of experts had concluded was an inferior choice, in terms of scientific merit and public health preparedness, for the SNS compared to a competing drug developed and recently approved by the FDA. Dr. Kadlec ignored the objections of Dr. Bright and other experts and used BARDA funds to award a lucrative contract to purchase the inferior option, Oseltamivir, from the pharmaceutical company Alvogen, which was one of Mr. Clerici's clients. As discussed in Section C, below, Dr. Bright also clashed with Dr. Kadlec and other members of HHS leadership when BARDA recommended awarding a task order on a contract only to Amgen to supply a drug for the SNS to treat radiation exposure rather than to both Amgen and Partner Therapeutics. Partner Therapeutics hired Mr. Clerici to manage its bid protest. Dr. Bright became so concerned about the improper role consultants such as Mr. Clerici played in promoting Partner Therapeutics's drug and their improper influence on Dr. Kadlec and HHS leaders that he requested that the HHS Office of General Counsel ("OGC") initiate a procurement integrity violation investigation into the matter, and further that the OGC request an investigation by the Inspector General ("IG") into outside influence on this contract. Dr. Bright subsequently learned that ASPR awarded a \$55 million sole source contract to Partner Therapeutics, contrary to the original TEP decision.

As discussed in Section D, below, the pressure on Dr. Bright escalated in the fall of 2019, after he rejected pressure by Dr. Kadlec to invest millions of dollars in EIDD-2801, a drug developed at Emory University by a longtime friend of Dr. Kadlec. EIDD-2081 was presented as a "miracle cure" for influenza, Ebola and nearly every other virus, even

²⁵⁷ <https://assets.documentcloud.org/documents/6882607/OSC-Complaint-Redacted.pdf>

though the developer had not yet conducted clinical trials and no data had been compiled to demonstrate either the efficacy or safety of the drug in humans. Dr. Bright's reluctance to fund EIDD-2801, which had already receiving \$30 million of government funding through NIH and DOD to conduct Phase 1 clinical trials, clearly frustrated Dr. Kadlec and further strained their relationship. Finally, as discussed in Section E below, Dr. Kadlec's frustration with and animus towards Dr. Bright reached its breaking point when, after the emergence of COVID-19, Dr. Bright resisted efforts to fall into line with the Administration's directive to promote the broad use of chloroquine and hydroxychloroquine and to award lucrative contracts for these and other drugs even though they lacked scientific merit and had not received prior scientific vetting. Dr. Bright's refusal to do so, along with his communication with members of Congress, the White House, and the press about these issues, which revealed HHS leadership to be disengaged and dismissive of the emerging threat, proved to be Dr. Bright's undoing.²⁵⁸

Dr. Bright's allegations of corruption in the procurement process at BARDA highlight the importance of transparency and oversight in government contracts. It is difficult to conceive of any legitimate reason for excluding the requirements of the Procurement Integrity Act, Truth in Negotiations Act, Cost Accounting Standards, and other statutes designed to ensure the integrity of government procurements and to prevent the scenarios outlined by Dr. Bright. As noted above with respect to FCS, McCain requested from DOD an explanation for excluding these protections from the FCS OTA, and Congress thereafter ordered the FCS OTA to be converted to a FAR-based contract, conceivably because DOD failed to produce an adequate justification.

Because OTAs inherently entail reduced accountability and oversight, it is critical that Congress requires all agencies with Other Transactions Authority to maintain detailed and accurate accounts of their use of the Authority, including the time it takes to execute the agreements relative to the time it takes to execute traditional contracts, the extent to which a nontraditional contractor participates, the competitive procedures used, the nature of cost sharing between the contractor and the federal government, and the justifications for departing from the allocation of rights in data and IP between the government and contractors under traditional mechanisms.

14. COVID-19 OTAs should stipulate that any inventions, data and know-how arising from the funded research are "global public goods."

In some cases, the U.S. government will have an interest in inventions, data and know-how becoming global public goods. For example, in the context of COVID-19 vaccines, it is clearly in the interest of the United States that vaccines for COVID-19 be available and accessible globally, both for humanitarian and self interested health and economic reasons. In this regard, the funding agency should ensure the contracts have sufficient rights to permit rights in patents, data, know-how and other intellectual property rights to be shared freely or licensed globally on reasonable and affordable terms. Under the Bayh-Dole Act, in some cases, this requires the

²⁵⁸ Addendum to the complaint of prohibited personnel practice and other prohibited activity by the department of health and human services submitted by Dr. Rick Bright, p. 6-7, <https://assets.documentcloud.org/documents/6882560/Rick-Bright-Whistleblower-Complaint.pdf>.

existence of an agreement with a foreign government or other party to be in existence prior to the signing of a funding agreement.²⁵⁹ An OTA involving biomedical inventions should ensure that the funding agency has sufficient rights to assign rights in inventions, data and know-how as full or quasi global public goods.²⁶⁰

15. OTAs should be required to promote access to federally funded inventions in developing countries.

Chapter No. 300 of the Public Health Services Technology Transfer Policy Manual, titled “PHS Licensing Policy,” states that “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”²⁶¹ This policy should be reflected in all OTAs, with measures to ensure that this policy is actually implemented. There is currently almost no evidence that the NIH or BARDA has sought to include measures in exclusive patent licenses that give effect to this policy.

16. Concluding Thoughts and Recommendations

As Congress, the GAO, and others have recognized, Other Transactions Authority carries the potential for misuse by contractors and federal agencies desiring an end-road around laws and regulations that were designed to protect the public.

Business firms acting in their self interest will always prefer the ability to avoid those restrictions, but that does not mean that they should be able to do so—particularly when enormous amounts of taxpayers’ dollars are awarded, for contracts of great importance to public health or national security, such as awards involving hundred of millions of dollars in public funds to develop and manufacture COVID-19 vaccines.

Policymakers should protect the public interest in federally-funded R&D by ensuring the following measures are implemented.

1. Agencies should be required to publish in an online repository the text of OTAs they execute, including, without redactions, all provisions regarding the allocation of rights in patents, know-how, data and other intellectual property.
2. Departures from rights in data and inventions from in federal FAR or DFAR regulations, the Bayh-Dole Act and other norms must be justified in a document, made publicly available, which sets out the factors and analysis that justified the modifications.

²⁵⁹ 35 U.S.C. § 202(c)(4).

²⁶⁰ A quasi-public good has some but not all of the characteristics of a Samuelson public good, and in the case of biomedical inventions like vaccines, could refer to licenses to use inventions, data or know-how that are subject to modest and affordable royalties.

²⁶¹ United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, *PHS Licensing Policy* (Dec. 8, 2010), <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300-policy.pdf>.

3. All agencies with Other Transactions Authority must be required to establish and maintain accurate systems for maintaining detailed information about their use of OTAs, including, but not limited to, the original basis for using an OTA and subsequent evaluations of the outcomes, including those associated with reductions in public rights in inventions and data.
4. For projects involving R&D for biomedical inventions, the funding agency should be required to publish information on the costs of each clinical trial funded by the OTA and the specific contributions from the federal government and other parties.
5. For projects involving biomedical inventions and products, the OTA should require transparency of prices and units sold, consistent with World Health Assembly resolution WHA72.8, adopted May 28, 2019, with support from the United States.
6. Federal agencies including, but not limited to, NIH and BARDA should not be allowed to redefine practical application to exclude the obligation to make the benefits of inventions “available to the public on reasonable terms,” particularly in the context of COVID-19 diagnostics, drugs or vaccines.
7. For projects involving biomedical inventions and products, federal agencies should retain sufficient rights in data to transfer manufacturing know-how and register competing products.
8. At a minimum, as regards pricing for biomedical inventions and products, all OTAs should require that products be available in the United States at prices no higher than the median price in the seven largest economies as measured by GDP that have at least half the per-capita income of the United States, as measured by the World Bank Atlas method for Gross National Income per capita.
9. An OTA involving biomedical inventions should ensure that the funding agency has sufficient rights to assign rights in inventions, data and know-how as full or quasi global public goods.
10. OTA agreements should include measures to implement the PHS Licensing Policy to ensure broad accessibility for developing countries.
11. Congress should legislate that all OTAs are subject to the Procurement Integrity Act and the Truth in Negotiations Act.
12. The GAO should conduct a review of the use of Other Transactions Authority in funding biomedical diagnostics, drugs and vaccines.