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

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1. Introduction

"Other Transactions Authority" is a term used to refer to the authority granted by the U.S. Congress to 11 federal departments or agencies[1] to enter into Other Transaction Agreements (OTAs), which are legally-binding contracts,[2] executed by the government for research and development (R&D) or other purposes, that do not guarantee the same government rights and protections for the public as do traditional funding agreements.[3] OTAs are often 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 license to use federally-funded inventions, can be utilized to ensure equitable access to COVID-19 technologies.[7] Despite these expectations, such remedies are either limited or eliminated, in four COVID-19 related OTAs (three executed by the Biomedical Advanced Research and Development Authority (BARDA)[8] and one executed by the Department of Defense (DOD)) obtained by Knowledge Ecology International (KEI) under the Freedom of Information Act (FOIA).[9]

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[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] BARDA is a component of the Assistant Secretary for Preparedness and Response (ASPR). *See* U.S. Dep't of Health & Human Servs., *Office of the Assistant Secretary for Preparedness and Response Organization Chart*, https://www.hhs.gov/about/agencies/orgchart/aspr/index.html. Although the contracting agency is identified as ASPR in the title of the OTAs, the agreements are part of BARDA's COVID-19 Medical Countermeasures Portfolio. *See* U.S. Dep't of Health & Human Servs. Public. Health Emergency, *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.
[9] The four OTAs are: Other Transaction Agreement (OTA) Other Transaction for Advanced Research (OTAR) between Regeneron Pharmaceuticals, Inc. and the United States of America Department of Health and Human Services Assistant Secretary for Preparedness and Response, Agreement No.

Stated otherwise, when awarding contracts worth hundreds of millions of taxpayers' dollars to fund the development of COVID-19 therapeutics and vaccines, the U.S. government has chosen to contractually limit the safeguards available under federal law to protect the public. If the pharmaceutical companies that received the funds take advantage of the current public health crisis to charge unreasonable prices for the resulting COVID-19 treatments or vaccines, the government cannot rely on those measures to ensure access or to control costs.

Federal agencies that have been granted Other Transactions Authority take the position that OTAs are exempt from the Bayh-Dole Act, the Federal Acquisition Regulation (FAR),[10] the Defense Federal Acquisition Regulation Supplement (DFARS),[11] and statutes designed to preserve the integrity of the procurement process. The OTAs that KEI reviewed reflect the attitude that Bayh-Dole Act legal safeguards are optional. Three of the OTAs eliminate contractors' legal obligations to make inventions available to the public "on reasonable terms", narrow the grounds for march-in rights, and limit the government's rights in technical data developed under the agreements.[12] An OTA between BARDA and Johnson & Johnson completely eliminates the government's royalty-free license to use the invention or have it utilized on the government's behalf, and an OTA between DOD and Ology Bioservices circumvents the Bayh-Dole Act altogether.[13]

Among other protections, the OTAs eliminate a safeguard that allows the government to grant a compulsory license to a federally-funded medical product and permit generic manufacture if a pharmaceutical company that developed the product with federal funding charges an unreasonable price for it.

HHSO100201700020C (Jan. 31, 2020)(on file with author)(hereinafter, "Regeneron OTA"); Other Transaction Agreement (OTA) Other Transaction for Advanced Research (OTAR) between Genentech, Inc. and the United States of America Department of Health and Human Services Assistant Secretary for Preparedness and Response Concerning Genentech Umbrella Agreement, Agreement No. HHSO100201800036C (Sept. 27, 2018)(on file with author)(hereinafter, "Genentech OTA"); Other Transaction for Advanced Research (OTAR) between Janssen Research & Development, LLC and the United States of America Department of Health and Human Services Biomedical Advanced Research and Development Authority, Agreement No.:HHSO100201800012C (Sept. 21, 2018)(on file with author)(hereinafter, "Johnson & Johnson OTA"); 10 USC 2373 Agreement Between Ology Bioservices, Inc. (Awardee or Contractor) and Natick Contracting Division (Government), Agreement No. W911QY-20-9-0003 (Feb. 21, 2020)(on file with author)(hereinafter, "Ology OTA")(collectively, "the COVID-19 OTAs"). The Ology Bioservices OTA is not identified as an OTA in its title, but is identified as an OTA at beta.SAM.gov and FPDS.gov, which are databases maintained by the government. *See* W911QY2090003, https://beta.sam.gov/awards/89036033%2BAWARD?keywords=W911QY2090003&sort=-relevance&index=&is_active=true&page=1 and https://www.fpds.gov/common/jsp/LaunchWebPage.jsp?command=execute&requestid=108474544&version=1.5.

[10] The FAR is codified at title 48 of the Code of Federal Regulations.

[11] 48 C.F.R. pt. 201.

[12] *See* the COVID-19 OTAs, *supra* note 9.

[13] *See id.*

In addition to the four complete OTAs that KEI obtained and reviewed under the FOIA, KEI obtained

- amendments to a BARDA OTA with Johnson & Johnson for a COVID-19 vaccine,[14]
- what appears to be a traditional procurement contract for a COVID-19 vaccine between BARDA and Moderna Therapeutics,[15] which has funded preclinical and clinical research on Moderna's investigational mRNA-1273 vaccine, and
- amendments to a contract between BARDA and Protein Sciences Corporation, which is part of Sanofi.[16]

The Moderna contract, unlike the other COVID-19 OTAs, incorporates full Bayh-Dole Act legal safeguards.

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.

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[14] Amendment of Other Transaction Agreement (OTA) Other Transaction Agreement for Advanced Research (OTAR) between Janssen Research & Development LLC and the United States of America Department of Health and Human Services Biomedical Advanced Research and Development Authority Concerning Influenza Portfolio and Other Emerging Pathogens Development Candidates, Agreement No. HHSO100201700018C Amendment No. 0006 (Feb. 11, 2020); Amendment of Other Transaction Agreement (OTA) Other Transaction Agreement for Advanced Research (OTAR) between Janssen Research & Development LLC and the United States of America Department of Health and Human Services Biomedical Advanced Research and Development Authority Concerning Influenza Portfolio and Other Emerging Pathogens Development Candidates, Agreement No. HHSO100201700018C Amendment No. 0007 (March 20, 2020); and Amendment of Other Transaction Agreement (OTA) Other Transaction Agreement for Advanced Research (OTAR) between Janssen Research & Development LLC and the United States of America Department of Health and Human Services Biomedical Advanced Research and Development Authority Concerning Influenza Portfolio and Other Emerging Pathogens Development Candidates, Agreement No. HHSO100201700018C Amendment No. 0008 (March 27, 2020)(all on file with author)(collectively, the "Johnson & Johnson Vaccine OTA Amendments").

[15] Award/Contract No. 75A50120C00034, ASPR-BARDA and Modernatx, Inc. (Feb. 14, 2020)(on file with author)(hereinafter, the "Moderna Contract").

[16] Order for Supplies or Services, Contract No. HHSO100201600005I, ASPR-BARDA and Protein Services Corporation (Feb. 14, 2020); Order for Supplies or Services, Contract No. HHSO100201600005I, ASPR-BARDA and Protein Services Corporation (Feb. 7, 2020)(both on file with author)(collectively, the "Protein Sciences Amendments").Protein Sciences Corporation was acquired by Sanofi on August 28, 2017. Sanofi, *Sanofi completes the acquisition of Protein Sciences* (Aug. 28, 2017), http://www.news.sanofi.us/press-releases?item=137157.

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),[17] 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[.]"[18]

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.[19] 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.[20] 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.[21] Unlike grants, however, cooperative agreements are used when "substantial involvement" of the federal government is anticipated.[22]

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."[23] The government may contribute personnel, services, facilities, equipment, and other resources to a CRADA but it may not contribute funds.[24]

While OTAs are legally binding contracts, they are referred to as transactions to distinguish them from procurement contracts.[25] When OTAs are defined as being other than contracts, grants, and cooperative agreements, "contracts" is synonymous with "procurement contracts."[26]

Most procurement contracts are governed by the Federal Acquisition Regulation (FAR),[27] a set of regulations that "establishes the framework that controls the solicitation, award, and

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[17] 31 U.S.C. §§ 6301-6308.
[18] 31 U.S.C. § 6301.
[19] 31 U.S.C. § 6303.
[20] 31 U.S.C. § 6304.
[21] GAO-16-209, *supra* note 1, at 3-4.
[22] 31 U.S.C. § 6304.
[23] GAO-16-209, *supra* note 1, at 4.
[24] Nancy O. Dix, Fernand A. Lavallee, 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).
[25] Castellano, *supra* note 4, 494–95 (2019).
[26] *Id.*
[27] Kate M. Manuel et al., Cong. Research Serv., R42826, *The Federal Acquisition Regulation (FAR): Answers to Frequently Asked Questions* 3 (2015).

administration of government contracts."[28] 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."[29] 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).[30]

In addition to the FAR, DFARS, and other agencies' procurement regulations, several statutes address procurement contracts.[31] Because they are not procurement contracts, OTAs are widely believed to be exempt from the FAR, DFARS, and statutes that govern traditional procurements.[32]

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'."[33] Among the statutes on that list are the Competition in Contracting Act,[34] the Contracts Dispute Act,[35] the Anti-Kickback Act,[36] and the Buy American Act.[37][38]

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."[39] The report, which was specific to the Department of Defense (DOD), concluded that the majority of 30 statutes reviewed, including the Procurement Integrity Act,[40] the Truth in Negotiations Act,[41] and the Cost Accounting Standards Act,[42] do not apply to OTAs.[43] 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."[44]

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[28] 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).
[29] Manuel et al., *supra* note 27, at 10.
[30] Armani Vadiee and Todd M. Garland, *The Federal Government's 'Other Transaction' Authority,* 18-5 Briefing Papers 1 (2018).
[31] *Id.*
[32] Peters, *supra* note 2, at 4.
[33] Dix et al., *supra* note 24, at 26.
[34] 41 U.S.C. §§ 253a-b, 416, 418 and 31 U.S.C. §§ 3551-3556.
[35] 41 U.S.C. §§ 601-613.
[36] 41 U.S.C. §§ 51-58.
[37] 41 U.S.C. §§ 10a-10d.
[38] Dix et al., *supra* note 24, at 3.
[39] Halchin, *supra* note 3, at 17.
[40] 41 U.S.C. § 423.
[41] 10 U.S.C. § 2306a.
[42] 41 U.S.C. § 1502.
[43] Halchin, *supra* note 3, at 19-21.
[44] *Id.* at 22.

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,[45] 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[.]"[46]

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.[47] 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[.][48]

The Strategic Institute, which was founded by Other Transactions Authority proponent Richard Dunn,[49] 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."[50]

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.[51]

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

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[45] 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)).
[46] U.S. Gov't Accountability Office, GAO-05-136, *Further Action Needed to Promote Successful Use of Special DHS Acquisition Authority* 6 (2004).
[47] Dix et al., *supra* note 24, at 26.
[48] Halchin, *supra* note 3, at 1-2.
[49] 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.
[50] Strategic Institute, *Other Transactions & Intellectual Property — an open field* (June 4, 2019), https://www.strategicinstitute.org/other-transactions/ots-ip/.
[51] GAO-16-209, *supra* note 1, at 12.

the government alike don't really like the [FAR]. It costs money to comply with all of it."[52] Likewise, the CRS has reported that "complying with government statutes and regulations constitutes, for some companies, an unacceptable administrative burden."[53]

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).[54] When the Soviet Union launched the *Sputnik* satellite into orbit, Congress became concerned that the United States was falling behind in the Space Race,[55] and it became "clear that 'business as usual' [was] not going to close the gap between United States and Soviet Capabilities."[56] 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[.]"[57]

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."[58] 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.[59] 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."[60]

Since the passage of the Space Act, Congress extended Other Transactions Authority to 10 other federal agencies or departments within agencies.[61]

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."[62] Also, "DOD has had [Other

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[52] 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/.
[53] Halchin, *supra* note 3, at 4.
[54] *See MD Helicopters Inc. v. United States*, No. CV-19-02236-PHX-JAT, 2020 WL 516469, at *1 (D. Ariz. Jan. 24, 2020).
[55] Peters, *supra* note 2, at 1.
[56] H.R. Rep. No. 85-1770, at 3163 (May 24, 1958).
[57] National Aeronautics and Space Act of 1958, Pub. L. No. 85-568, § 203(5), 72 Stat. 426, 430 (1958) (emphasis added).
[58] Halchin, *supra* note 3, at 6.
[59] Castellano, *supra* note 4, at 487.
[60] *Id.*
[61] GAO-16-209, *supra* note 1, at 35.
[62] Halchin, *supra* note 3, at 6.

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.'"[63]

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 DARPA[64] 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."[65] 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.[66] The authority was set to terminate on September 30, 1991.[67]

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.
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> 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 and Capitol Hill, who convinced Congress to add appropriate language to the Defense Authorization Bill for FY 1990.[68]

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]

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[63] *Id.* (quoting Dix et al., *supra* note 24, at 9).
[64] 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").
[65] National Defense Authorization Act for Fiscal Years 1990 and 1991, Pub. L. No. 101-189, § 251, 103 Stat. 1352, 1403-04 (1989).
[66] *Id.*
[67] *Id.*
[68] Richard N. Kuyath, *The Untapped Potential of the Department of Defense's "Other Transaction" Authority,* 24 Pub. Cont. L.J. 521, 527–28 (1995).

procurement regulations."[69] 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."[70]

DOD's Other Transactions Authority was initially narrow and has expanded incrementally over time, through NDAAs.[71] 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.[72] The NDAA for FY 1994 gave DOD a new type of Other Transactions Authority, for prototype projects.[73] Congress extended this authority to all military departments in 1996.[74] In 2001, DOD was granted Other Transactions Authority for follow-on production.[75] 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.[76]

Congressional directives to DOD for how to implement OTA have similarly evolved over time. The Senate Report for the NDAA for FY1990 & FY1991, for example, "enjoin[ed] [DOD] to utilize [Other Transactions Authority] only in instances in which traditional authorities are *clearly not appropriate*."[77] Similarly, the Conference Report for 1999 NDAA directed DOD to use OTA 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."[78] 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[.]"[79] In contrast, the FY 2018 NDAA states that "the Secretary of Defense *shall*

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[69] 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).
[70] 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.
[71] Angle, *supra* note 5, at 97.
[72] National Defense Authorization Act for Fiscal Years 1992 and 1993, Pub. L. No. 102-190, § 826, 105 Stat. 1290, 1442 (1991).
[73] National Defense Authorization Act for Fiscal Year 1994, Pub. L. No. 103-160, § 845, 107 Stat. 1547, 1721, 1722 (Nov. 30, 1993).
[74] National Defense Authorization Act for Fiscal Year 1997, Pub. L. No. 104-201, § 804, 110 Stat. 2422, 2605 (1996).
[75] National Defense Authorization Act for Fiscal Year 2002, Pub. L. No. 107-107, § 822, 115 Stat. 1019, 1182 (2001).
[76] 10 U.S.C. § 2371b(a)(2)(A).
[77] S. Rep. No. 101 - 81 at 126-127 (1989)(emphasis added).
[78] H.Rept. 105-736 at 590 (1998).
[79] McCain, *supra* note 70.

establish a preference, to be applied in circumstances determined appropriate by the Secretary, for using transactions other than contracts, cooperative agreements, and grants."[80]

Perhaps due to Congress's encouragement, the use of OTAs has exploded in recent years.[81] In 2018, Bloomberg Government reported that spending on OTAs doubled from 2012 to 2017.[82] 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.[83] 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."[84] 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.[85]

The expansion resumed with respect to COVID-19, with the enactment of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[86] 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 executed in connection with COVID-19.[87] 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."[88]

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

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[80] National Defense Authorization Act for Fiscal Year 2018, Pub. L. No. 115-91, § 867, 131 Stat. 1283, 1495 (2017)(emphasis added).
[81] 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.").
[82] Bloomberg Government Announcement, *OTA Spending on the Rise* (June 19, 2018), https://platform.cinchcast.com/ses/eXdvbvAoZOMD6XFNens-BQ~~.
[83] U.S. Gov't Accountability Office, GAO-20-84, DOD's Use of Other Transactions for Prototype Projects Has Increased 8 (2019).
[84] H. Rep. No. 115-676, at 75-76 (2018).
[85] John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, § 873, 132 Stat. 1636, 1905 (2018).
[86]Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 13006, 134 Stat. 281, 552 (2020).
[87] *Id.*
[88] *Id.*

Agencies/Field Activities with contracting authority, Commanding Officers of Combatant Commands with contracting authority, and the Director of the Defense Innovation Unit."[89] 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 []."[90]

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[.]"[91] Second, the government must share costs equally with the contractor.[92] Third, OTAs for research projects are only an option when traditional procurement mechanisms are "not feasible or appropriate."[93]

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
4. "The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of [an OTA]."[94]

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.[95]

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[89] Memorandum of Ellen M. Lord, Under Sec'y of Def. for Acquisition and Sustainment, to Sec'ys of the Military Dep'ts (April 5, 2020), https://www.acq.osd.mil/dpap/policy/policyvault/USA000752-20-DPC.pdf
[90] *Id.*
[91] 10 U.S.C. § 2371(e)(1)(A).
[92] 10 U.S.C. § 2371(e)(1)(B).
[93] 10 U.S.C. § 2371(e)(2).
[94] 10 U.S.C. § 2371b(d)(1).
[95] *See* 10 U.S.C. § 2302(9).

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."[96] 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.[97]

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."[98] 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."[99] The authority to approve such OTAs may not be delegated (except as provided under the CARES Act).[100]

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 Advanced Research and Development Authority (BARDA).[101] 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.[102] HHS exercises its Other Transactions Authority under the PAHPA through ASPR/BARDA.

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[96] 10 U.S.C. § 2371b(f)(1).
[97] 10 U.S.C. § 2371b(f)(2).
[98] 10 U.S.C. § 2371b(a)(2)(A).
[99] 10 U.S.C. § 2371b(a)(2)(B).
[100] 10 U.S.C. § 2371b(a)(3).
[101] Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109-417 § 401, 120 Stat. 2831, 2865-72 (2006).
[102] U.S. Dep't of Health and Human Servs., *Biomedical Advanced Research and Development Authority*, https://www.phe.gov/about/barda/Pages/default.aspx.

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."[103] The CARES Act eliminated the special approval requirement for OTAs in excess of $100 million in public health emergencies.[104] 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)[105] 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.

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.[106] Specifically, agencies told the GAO that OTAs allow them to attract companies that "wished to secure greater protection of intellectual

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[103] 42 U.S.C. § 247d-7e(c)(5)(A)(ii).
[104] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 3301, 134 Stat. 281, 383-84 (2020).
[105] 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).
[106] GAO-16-209, *supra* note 1, at 12.

property rights than would be possible under traditional contracting mechanisms."[107] 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."[108]

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.[109] It allows contractors to elect to retain title to subject inventions,[110] i.e., "one[s] conceived or first actually reduced to practice in the performance of work under a funding agreement",[111] and authorizes federal agencies to license the rights to inventions developed by federal employees in federal laboratories on an exclusive basis.[112]

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.[113] In both cases, there are a number of safeguards to protect the public interest in federally-funded inventions.[114] 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."[115] In addition, the Bayh-Dole Act 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.[116] 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."[117] Achieving "practical application of the subject invention" requires "establish[ing]

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[107] *Id.*
[108] Strategic Institute, *supra* note 50.
[109] 35 U.S.C. § 200.
[110] 35 U.S.C. § 202(a)
[111] 35 U.S.C. § 201(e).
[112] 35 U.S.C. § 207.
[113] 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.
[114] U.S. Gov't Accountability Office, GAO-09-742, Information on the Government's Right to Assert Ownership of Federally Funded Inventions 9 (2009).
[115] 35 U.S.C. §§ 202(c)(4), 209(d)(1).
[116] 35 U.S.C. § 203(a).
[117] 35 U.S.C. § 203(a)(1)-(2).

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*."[118]

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,[119] although there is a vocal contingent of opponents of any restraints on pricing who have argued otherwise.[120] 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",[121] 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 government[122] and the requirement to "manufacture[] substantially" products derived from federally-funded inventions in the United States.[123]

Procurement contracts subject to the Bayh-Dole Act must incorporate "Standard Patent Rights" clauses[124] which memorialize these public-interest safeguards.[125] 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.[126] For DOD procurement contracts with small businesses and nonprofits, FAR 52.227-11 applies.[127] DOD procurement contracts with large businesses must use the clauses at DFARS 252.227–7038 Patent Rights—Ownership by the Contractor (Large Business).[128]

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.

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[118] 35 U.S.C. § 201(f).
[119] *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).
[120] *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/.
[121] 35 U.S.C. § 200 (emphasis added).
[122] 35 U.S.C. § 202(c)(1).
[123] 35 U.S.C. § 204.
[124] 37 C.F.R. § 401.3.
[125] 37 C.F.R. § 401.14.
[126] FAR § 52.227–11.
[127] FAR § 227.303(1).
[128] FAR § 252.227–7038.

The government generally has unlimited rights in data delivered or produced under a civilian procurement contract.[129] 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."[130] 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*."[131]
[132]

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."[133] 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[.]"[134]

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."[135]

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."[136] "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."[137]"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 the United States Government to foreign governments or international organizations."[138] 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."[139] Use of limited rights data outside the government is restricted.[140]

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[129] FAR § 52.227-14(b)(1).
[130] FAR § 52.227-14(a)(2)(emphasis added).
[131] 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).
[132] *Id.*
[133] FAR § 52.227-14(a).
[134] FAR § 52.227-14 alt II.
[135] DFARS § 252.227-7013(b).
[136] DFARS § 252.227-7013(a)(15).
[137] DFARS § 252.227-7013(a)(13).
[138] DFARS § 252.227-7013(a)(12).
[139] DFARS § 252.227-7013(a)(14).
[140] *Id.*

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[.]"[141] 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."[142]

Similarly, the NIH asserts, in its OTA Participant Guide, that OTAs enable "[f]lexibility in [the] allocation of [IP] rights"[143] and that "[c]ost savings are possible by limiting the government's need for data license rights in OTs."[144] 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[.]"[145]

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.***[146]

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

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[141] 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).
[142] 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").
[143] 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"].
[144] *Id*.
[145] *Id*.
[146] 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 [hereinafter, "DOD OTA Guide"](emphasis in original).

- "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.[147]

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,[148] 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.

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."[149] The GSK OTA had a term of up to five years and a ceiling of $200 million.[150] 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,[151] 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."[152]

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.

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[147] U.S. Gov't Accountability Office, GAO-01-980T, *Information on the Federal Framework and DOD's Other Transaction Authority* 6-8 (2001).
[148] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, tit. VIII, 134 Stat. 281, 561 (2020).
[149] 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.
[150] *Id.*
[151] 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.
[152] 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."[153] 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."[154] The Regeneron OTA has a term of 10 years, and BARDA is obligated to cover 80 percent of the costs.[155]

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.[156] That OTA was HHSO100201700018C, which was first announced by BARDA on September 15, 2017.[157] It originally had a $43 million contribution from BARDA and a ceiling of $237 million.[158] 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."[159]

On February 11, 2020, the 2017 J&J OTA was amended to reflect an "[a]ddition of new asset for 2019 Novel Corona Virus[.]"[160] 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.[161]

On February 18, 2020, Johnson & Johnson announced that it had expanded a different OTA with BARDA, HHSO100201800012C.[162] The goal of this expanded OTA is to identify a

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[153] 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.
[154]Regeneron Pharmaceuticals, Inc., Quarterly Report (Form 10-Q)(Nov. 8, 2017).
[155]*Id.*
[156] 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.
[157] 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.
[158] *Id.*
[159] *Id.*
[160] HHSO100201700018C (P00006), https://beta.sam.gov/awards/88171845%2BIDV?keywords=HHSO100201700018C&sort=-relevance&index=&is_active=true&page=1.
[161] HHSO100201700018C (P00008), https://beta.sam.gov/awards/89139853%2BIDV.
[162] 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), 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.

compound from a library of existing antiviral molecules that is effective against SARS-CoV-2."[163] 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."[164] Records reflect that 75A50118C00012 was first executed on September 21, 2018, and amended several times since the outset of COVID-19.[165] The description for a February 14, 2020 amendment is as follows: "In response to the current novel coronavirus (?COVID-19?) outbreak, a."[166]

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."[167] 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.[168] 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."[169] It thus appears that this agreement contemplates the future issuance of a related OTA. The agreement obligates $413,200,000.[170]

On April 9, 2020, KEI submitted a FOIA request to HHS for all contracts listed in BARDA's COVID-19 Medical Countermeasure Portfolio, which lists the public-private partnerships in which BARDA has engaged in order to fund the development of COVID-19 diagnostics, therapeutics, and vaccines.[171] After HHS's FOIA office stated that the request would take a long time to fulfill, KEI agreed to narrow the initial scope of the request to six partnerships in the

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[163] *Id.*
[164] 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.
[165] The author searched "75A50118C00012" at beta.SAM.gov.
[166] 75A50118C00012 (P00004), https://beta.sam.gov/awards/88796845%2BAWARD?keywords=75A50118C00012%20&sort=-relevance&index=&is_active=true&page=1.
[167] 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.
[168] The author searched "Astrazeneca" in the search engine at fpds.gov and sorted the results by "Date Signed."
[169] 75A50120C00114 (0), https://beta.sam.gov/awards/90205157%2BAWARD?keywords=75A50120C00114&sort=-relevance&index=&is_active=true&page=1.
[170] *Id.*
[171] U.S. Dep't of Health and Human Servs., *BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio*, https://www.medicalcountermeasures.gov/App/barda/coronavirus/COVID19.aspx.

BARDA COVID-19 portfolio. We specifically referenced the following language from the BARDA website at the time:

> Sanofi Pasteur is developing a novel coronavirus vaccine candidate using its recombinant DNA platform technology that BARDA has previously supported for production of influenza vaccines. This technology produces an exact genetic match to proteins of the coronavirus and is designed for more rapid production than traditional manufacturing methods.
> **Janssen Research & Development**, part of Johnson & Johnson, is partnering with BARDA to help accelerate an investigational COVID-19 vaccine into clinical evaluation. Janssen will use the same approach used to develop and manufacture its investigational Ebola vaccine, which was supported by BARDA and is being used in the Democratic Republic of the Congo as part of the response to the current Ebola outbreak and to prevent spread of the disease to Rwanda.
> **Moderna** is partnering with BARDA to speed the development and manufacturing of SARS-CoV-2 mRNA-1273, a vaccine to prevent COVID-19. BARDA will support Phase 2 and 3 clinical trials of the vaccine.
> **Regeneron Pharmaceuticals** is developing multiple monoclonal antibodies that, individually or in combination, could be used to treat COVID-19. Under its expanded agreement with BARDA, Regeneron is leveraging its existing monoclonal antibody discovery platform called VelocImmune, part of the company's VelociSuite technology, to develop therapeutic products to treat COVID-19 infections. VelociSuite was used to develop a promising investigational three-antibody therapeutic, which was deployed to treat Ebola in the most recent outbreak in the Democratic Republic of the Congo, as well as an investigational therapeutic to treat Middle East Respiratory Syndrome coronavirus (MERS-CoV).
> **Janssen Research & Development** is developing treatments for COVID-19 infections. BARDA will collaborate with Janssen to screen library of approved therapeutics as well as investigational therapeutics that have completed some clinical trials where basic safety and pharmacology data are available for these compounds. If screening is promising, candidates then could be considered for further, accelerated development, including assessment in additional clinical studies.
> **Genentech** is accelerating a phase 3 clinical trial of a novel COVID-19 therapeutic treatment potential treatment of patients with severe cases of COVID-19. BARDA expanded an existing partnership with Genentech to accelerate a Phase 3 clinical trial of Actemra® (tocilizumab) as a potential treatment of patients with severe cases of COVID-19. Currently, Actemra® is approved by the U.S. Food and Drug Administration and in more than 100 countries to treat rheumatoid arthritis or other inflammatory conditions.

On June 25 and June 26, 2020, KEI received the following documents from HHS in response to the FOIA request:

- **HHSO100201700020C, the OTA between BARDA and Regeneron Pharmaceutical described above, which was expanded to cover a COVID-19 therapeutic[172] and has an upper limit of $305,797,957.60[173];**

[172] Although HHS has inexplicably chosen to redact the statement of work in the Regeneron OTA, we know that HHSO100201700020C is the OTA that BARDA and Regeneron expanded in February 2020 to cover the development of a COVID-19 therapeutic because KEI asked for the contract embodying that partnership in the FOIA request, and the document HHS produced is HHSO100201700020C and amendments thereto.
[173] HHSO100201700020C (P00008), https://beta.sam.gov/awards/90777063%2BAWARD?keywords=HHSO100201700020C&sort=-modifiedDate&index=&is_active=true&page=1.

- **HHSO100201800012C, an OTA between BARDA and Johnson & Johnson described above, which was expanded to cover a COVID-19 therapeutic and has an upper limit of $211,693,687[174];**
- **Amendments to HHSO100201700018C, another OTA between BARDA and Johnson & Johnson described above, which was expanded to develop a COVID-19 vaccine, and has an upper limit of $689,525,867[175];**
- **HHSO100201800012C, an OTA between BARDA and Genentech (owned by Roche), which was expanded to develop tocilizumab (marketed as Actemra) as a treatment for COVID-19 and has an upper limit of $598,490,994[176];**
- **75A50120C00034, a $430,298,520 contract between BARDA and Moderna Therapeutics to develop a vaccine for COVID-19[177];**
- **Amendments to HHSO100201600005I, a contract between BARDA and Protein Sciences Corporation, a subsidiary of Sanofi, to develop and manufacture a COVID-19 vaccine.[178]**

KEI also received an OTA between DOD and Ology Bioservices, from a separate FOIA request, which this Note addresses in Part 7, ***infra***.

The Moderna Contract has funded a study that demonstrated Moderna's investigational COVID-19 vaccine, mRNA-1273, to be effective against COVID-19 in mice, with no negative immune response.[179] The article reporting the findings of the study cites International Patent Application Number WO/2018/081318 titled "Prefusion Coronavirus Spike Proteins and Their Use."[180] The Moderna Contract is also listed as funding Clinical Trial No. NCT04405076, titled, "Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults Aged 18 Years and Older".[181] The Moderna Contract does not appear to be an OTA, as it incorporates various FAR clauses, including FAR.227-11, "Patent Rights-Ownership by the Contractor". As noted above, FAR.227-11 requires that civilian

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[174] 75A50118C00012 (P00006), https://beta.sam.gov/awards/90574274%2BAWARD?keywords=75A50118C00012&sort=-relevance&index=&is_active=true&page=1.
[175] HHSO100201700018C (P00009), https://beta.sam.gov/awards/89202026%2BIDV?keywords=HHSO100201700018C&sort=-modifiedDate&index=&is_active=true&page=1.
[176] 75A50118D00036 (P00006), https://beta.sam.gov/awards/90460005%2BIDV?keywords=75A50118D00036&sort=-modifiedDate&index=&is_active=true&page=1.
[177] 75A50120C00034 (0), https://beta.sam.gov/awards/89559161%2BAWARD?keywords=75A50120C00034&sort=-modifiedDate&index=&is_active=true&page=1.
[178] Protein Sciences Amendments, *supra* note 15.
[179] Corbett, Kizzmekia S et al. "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness." *bioRxiv : the preprint server for biology* 2020.06.11.145920. 11 Jun. 2020, doi:10.1101/2020.06.11.145920. Preprint.
[180] *Id.*
[181] https://clinicaltrials.gov/ct2/show/NCT04405076?term=75A50120C00034&draw=2&rank=1.

agency procurement contracts incorporate the government's rights to federally-funded IP under the Bayh-Dole Act. Thus, if any intellectual property rights are developed under the Moderna Contract, the federal government will have the authority to ensure the mRNA-1273 vaccine is reasonably priced.

The Genentech OTA is numbered HHSO100201800012C in the document we obtained from HHS, but it appears to be identified as 75A50118D00036 at FPDS.gov and beta.SAM.gov (where a search for HHSO100201800012C returned no results). According to those databases, 75A50118D00036 was first executed on September 27, 2018,[182] the same day that HHSO100201800012C was signed.[183] 75A50118D00036 was amended on March 26, 2020, with the following description: "Genentech OTA - activation of CLIN 0008 for Actemra Phase 3 RCT for COVID-19 and extension of CLIN 0005 (LepB) period of performance to December 31, 2021".[184] Actemra is the brand name for tocilizumab.[185] It thus appears that 75A50118D00036 is an alternative identifier for HHSO100201800012C.

The Protein Sciences/Sanofi Contract, HHSO100201600005I, was first executed on August 16, 2016,[186] and amended in February 2020 for research and manufacture of a COVID-19 vaccine.[187]

The benefits of using Other Transactions Authority, according to the ASPR/BARDA, 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 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."[188]

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[182] 75A50118D00036 (0), https://beta.sam.gov/awards/78883485%2BIDV?keywords=75A50118D00036&sort=-modifiedDate&index=&is_active=true&page=1.
[183] Genentech OTA, *supra* note 9, at 2.
[184] 75A50118D00036 (P00005), https://docs.google.com/document/d/1c_V-t_pBQfZ_uV58IIDrBK-DI0BHDrQP2HWlCHAy3sQ/edit#.
[185] https://www.actemra.com/?c=act-170f429dc8b&gclid=CjwKCAjwxev3BRBBEiwAiB_PWMH9hS_Jb_-i8OGTXGG4Pj0MXJIQ0O1AwHKq_iZaixL6klxG8buQ6xoCrx4QAvD_BwE&gclsrc=aw.ds.
[186] HHSO100201600005I (0), https://beta.sam.gov/awards/67475771%2BIDV?keywords=HHSO100201600005I&sort=-relevance&index=&is_active=true&page=2.
[187] Protein Sciences Amendments, *supra* note 15.
[188] Elizabeth Jarrett, *Innovative partnerships support antibiotic development,* ASPR Blog (Sept. 23, 2015), https://www.phe.gov/ASPRBlog/Lists/Posts/Post.aspx?ID=157.

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.[189] The OTA, W911QY1690001, was executed on August 17, 2016 by Gilead and the Army.[190] The description of the OTA is "OTA for prototype, Ebola virus."[191] The Army collaborated with Gilead around this same time period to test Remdesivir against the Ebola virus.[192] When tested against Ebola and other coronaviruses, Remdesivir was shown to be effective against coronaviruses.[193] The Gilead OTA had an upper limit of nearly $50 million.[194]

Another example of a COVID-related DOD OTA is the Medical Technology Enterprise Consortium (MTEC). MTEC is a "biomedical technology consortium."[195] It was established by an OTA with U.S. Army Medical Research and Development Command.[196] MTEC's members include large and small companies and universities.[197] The purpose of MTEC is to support "the health and performance of U.S. military personnel."[198] MTEC publishes a list of active and closed solicitations on its websites. On the list of closed solicitations are 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."[199]

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

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[189] 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.

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

[191] *Id.*

[192] 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.

[193] 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.

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

[195] *About MTEC*, MTEC, https://www.mtec-sc.org/about-us/.

[196] *Id.*

[197] *Current Members,* MTEC, https://www.mtec-sc.org/current-members/.

[198] *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.

[199] *Solicitations*, https://www.mtec-sc.org/solicitations/.

managed by Advanced Technology International, a "Collaboration Management Firm."[200] 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.[201] Notably, Ology Bioservices, Inc. ("Ology") and Inovio Pharmaceuticals ("Inovio") are members of the MCDC.[202]

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."[203] On March 25, 2020, KEI submitted a FOIA request to DOD for this agreement. In late June 2020, KEI received a redacted copy of the Ology-DOD contract, Agreement No. W911QY-20-9-0003.

The title of the DOD-Ology agreement, "10 U.S.C. 2373 Agreement between Ology Bioservices, Inc. (Awardee or Contractor) and Natick Contracting Division (Government)",[204] references a different section of the U.S. Code than the sections that codify DOD's Other Transactions Authority. However, the agreement is identified as an OTA at beta.SAM.gov and FPDS.gov.[205] It obligates up to $148,009,976.25.[206]

The Ology OTA does not incorporate any legal safeguards under the Bayh-Dole Act. Rather, it specifically states that the Bayh-Dole Act does not apply to the agreement.[207] As such, if Ology employees conceive any patents related to a COVID-19 vaccine under the agreement, the government will not have access to the remedies provided under the Bayh-Dole Act to ensure that the vaccine is reasonably priced or to enhance competition and expand supply.

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.

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[200] *Accelerating DoD's Fielding of Prototypes for Medical Countermeasures*, https://www.medcbrn.org/.
[201] *Solicitations*, https://www.medcbrn.org/solicitations/#1547817555427-f9628bb4-f0b9.
[202] *Current Members,* https://www.medcbrn.org/current-members/.
[203] 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.
[204] Ology OTA, *supra* note 9, at 1.
[205] W911QY2090003 (0), https://beta.sam.gov/awards/89036033%2BAWARD?keywords=W911QY2090003&sort=-relevance&index=&is_active=true&page=1; https://www.fpds.gov/common/jsp/LaunchWebPage.jsp?command=execute&requestid=108528862&version=1.5.
[206] W911QY2090003 (P00005), https://beta.sam.gov/awards/89052534%2BAWARD?keywords=W911QY2090003&sort=-modifiedDate&index=&is_active=true&page=1.
[207] Ology OTA, *supra* note 9, at 2.

Both BARDA and the NIH are using OTAs to eliminate or limit certain government's rights in patents and data developed with taxpayers' dollars.

KEI has reviewed three complete BARDA OTAs related to COVID-19 that KEI obtained under the FOIA and two that are available online. The three BARDA OTAs that KEI obtained under the FOIA (with Regeneron, Genentech, and Johnson & Johnson) have been previously identified in part 6, ***infra***. The OTAs obtained online are HHSO100201500029C, the 2015 AstraZeneca OTA identified in part 6, ***infra***, included as a "BARDA OT[A] Sample" in an NIH OTA training document,[208] and HHSO100201600026C, the Medicines Company OTA, also identified in part 6, ***infra***.[209]

The BARDA OTAs reviewed by KEI eliminate or dilute government rights to IP and data developed through federally-funded research under the Bayh-Dole Act, FAR, and DFARS. 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.

Practical application has been redefined to eliminate "on reasonable terms".

As demonstrated by Table 1, all of the BARDA OTAs that KEI reviewed redefine the term "practical application" under the Bayh-Dole Act to eliminate the requirement that the fruits of federally-funded R&D are made available to the public "on reasonable terms".

Table 1: Definitions of "practical application" in BARDA OTAs eliminate the requirement of the availability of subject inventions to the public "on reasonable terms".

Source	Definition of Practical Application
Bayh-Dole Act "funding agreements" [210]	"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.**"[211]

[208] NIH OTA Participant Guide, *supra* note 143, at 405 - 461.
[209] 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, "Medicines Company OTA").
[210] The term "funding agreement" is defined as "any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government." 35 U.S.C. § 201(b).
[211] 35 U.S.C. § 201(f)(emphasis added).

BARDA/Regeneron OTA Agreement No.: HHSO100201700020C (COVID-19 therapeutic)	"Practical Application: With respect to a Subject Invention, 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 Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, **available to the public for a regulatory approved product."**[212]
BARDA/Johnson & Johnson OTA Agreement No.: HSO100201800012C (COVID-19 therapeutic)	"Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product or a medical device; to use in manufacturing, in the case of an invention useful in manufacturing; 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 so as to establish that the Subject Invention **is capable of being utilized."**[213]
BARDA/Genentech OTA Agreement No.: HHSO100201800036C (COVID-19 therapeutic)	"Practical Application: With respect to a Subject Invention, 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 Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, **available to the public for a regulatory approved product."**[214]
BARDA/AstraZeneca OTA Agreement No.: HHSO100201500029C	"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."**[215]

[212] Regeneron OTA, *supra* note 9, at 7 (emphasis added).
[213] Johnson & Johnson OTA, *supra* note 9, at 6 (emphasis added).
[214] Genentech OTA, *supra* note 9, at 7 (emphasis added).
[215] NIH OTA Participant Guide, *supra* note 143, at 413 (emphasis added).

BARDA/Medicines Company OTA, Agreement No.: HHSO100201600026C	"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**."[216]

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,"[217] 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.[218]

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, although this is the first time that an organization has reported about attempts by HHS to use Other Transactions Authority to circumvent the Bayh-Dole Act, particularly with respect to COVID-19.

The NIH has applied the OTA definition of practical application (removing the words "on reasonable terms") when deciding march-in petitions, where the petitioners argued that the NIH should use its march-in authority to address unreasonable prices charged for products embodying federally-funded inventions.

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.[219] In the 2016 Xtandi case, Astellas Pharmaceutical charged $129 thousand per

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[216] Medicines Company OTA, *supra* note 209 (emphasis added).
[217] *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").
[218] 35 U.S.C. § 200.
[219] *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.pd. 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*

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.[220] 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 charging unreasonable prices for them,[221] 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.[222]

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.

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 is inconsistent with 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 in the NIH OTA Participant Guide.

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

Examples	NIH efforts to redefine practical application
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,	"[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."

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_Ritionavir_march_in_complaint.pdf

[220] *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

[221] *See* Essential Inventions*, supra* note 219, and Knowledge Ecology International and the Union for Affordable Cancer Treatment, *id*.

[222] 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 .

2004. http://ott.od.nih.gov/Reports/March-In-Norvir.pdf	
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	"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."
Other Transaction Authority Training, Participant Guide. 2018. Sample OTA, page 228. https://oamp.od.nih.gov/sites/default/files/DSAPS/NPI-3000%20NIH%20NOTAB%20Participant%20Guide%2001-18v2.pdf	**"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."

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,"[223] in the *Tulane Law Review.*[224] 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*.[225] 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."[226]

[223] *See* Arno and Davis, *supra* note 119.
[224] *See id.*
[225] 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/
[226] 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/.

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,[227] 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,[228] a firm with clients such as Eli Lilly and the Intellectual Property Owners Association,[229] and he created the lobbying firm Bob Dole Enterprises, to sign up clients such as Johnson and Johnson.[230] He also worked for Alston & Bird, another firm with a powerful lobbying practice, where Dole represented companies such as Celgene.[231]

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.[232]

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).[233] JHU had licensed its patent to a company called Becton Dickinson, which relicensed them to the medical device maker Baxter.[234]

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.[235]

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:

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[227] 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.
[228] 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").
[229] 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.
[230] 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.
[231] Bob Dole Employment Timeline, *supra* note 228.
[232] https://www.venable.com/about/news/2001/06/former-us-senator-birch-bayh-joins-venable.
[233] 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.
[234] *Id.* at 6-7.
[235] *Id.* at 15-16.

> 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.[236]

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 stated that "I should emphasize that I am not being compensated to appear here today."[237] What Bayh did not mention was that Abbott (the subject of the march-in request) was a client of Venable,[238] his employer, or that his work at Venable, advocating for technology transfer, was listed as part of Venable's pharmaceutical practice.[239]

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.[240] 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 opinion in *Stanford v Roche*.[241] Bayh filed an amicus brief with the Court, regarding the intent of the provision of the Bayh-Dole Act addressing contractors' right to retain

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[236] https://web.archive.org/web/20040323092744/http://www.venable.com/pharm_licensing.cfm.
[237] 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.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf.
[238] *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 include Abbott Laboratories).
[239] https://web.archive.org/web/20040323092744/http://www.venable.com/pharm_licensing.cfm.
[240] *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280 (2010).
[241] *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776 (2011).

title to subject inventions.[242] The Court not only ruled contrary to Bayh's position, but it did not even bother to cite his brief.[243]
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."[244] It is also contrary to the "rule against surplusage"—that "words cannot be meaningless, else they would not have been used."[245] 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,[246] but this effort was blocked by opposition from members of Congress and patient advocacy groups.[247] A 2019 report in the *Washington Pos*t 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.[248]

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[242] 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").
[243] *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.").
[244] *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)).
[245] *See United States v. Butler*, 297 U.S. 1, 65 (1936).
[246] 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.
[247] 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.
[248] Chistopher Rowland, *supra* note 120.

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.[249]

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

March-in rights are narrowed.

The BARDA OTA contracts reviewed by KEI provide weakened march-in rights for the government.

For example, the Genentech, Johnson & Johnson, AstraZeneca, and Medicines Company OTAs eliminate two of the four circumstances in which the federal government may march in, as illustrated in Table 3.

One of the two grounds that has been eliminated in the march-in provision concerns the obligation in the Bayh-Dole Act that, unless obtaining a waiver, a "subject invention will be manufactured substantially in the United States."[250] Genetech is owned by Roche, a Swiss firm, AstraZeneca is a British-Swedish firm, and the Medicines company has been acquired by Novartis, a Swiss firm.

The Johnson & Johnson OTA further restricts march-in authority under the Bayh-Dole Act by narrowing the second grounds for march-in, "to alleviate health or safety needs which are not reasonably satisfied by the contractor"[251] to declarations of public health or national security threats by HHS or the WHO.

The Genentech, Johnson & Johnson, AstraZeneca, and Medicines Company OTAs all narrow march-in rights by forfeiting the government's authority to intervene if contractors charge unreasonable prices for products embodying inventions arising from the funded research. The first basis for march-in rights, failure to achieve practical application of the subject invention,[252] is significantly weakened by the definition of practical application in the OTAs, which only requires that the pharmaceutical companies ensure that subjection inventions achieve regulatory approval or are capable of being utilized.

March-in rights under the Regeneron OTA are redacted completely, preventing the public from even being aware of the grounds on which it may petition the federal government to march-in on any patents related to a COVID-19 therapeutic which arise from the funded research.

Table 3 provides a comparison of the grounds for march-in rights under Bayh-Dole Act "funding agreements" versus the BARDA OTAs we reviewed.

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[249] *See, e.g.*, https://bayhdole40.org/category/news/march-in-rights/.
[250] 35 U.S.C. § 204..
[251] 35 U.S.C. § 203(a)(2).
[252] 35 U.S.C. § 203(a)(1).

Table 3: BARDA OTAs narrow the government's march-in rights.

Source	Grounds for March-in Rights
Bayh-Dole Act "funding agreements"	"[I]f the Federal agency determines that such— (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; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (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 (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."[253]
BARDA/Regeneron OTA Agreement No.: HHSO100201700020C (COVID-19 therapeutic)	Redacted completely.[254]
BARDA/Johnson & Johnson OTA Agreement No.: HHSO100201800012C (COVID-19 therapeutic)	"[I]f HHS determines that: 1. Such action is necessary because Recipient, assignee their licensees or Affiliates have not taken steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or 2. Such action is necessary to alleviate the following urgent health or safety needs that effect the United States and that are not reasonably satisfied by Recipient, assignee, or their licensees or their Affiliates: a. declaration for Public Health Emergency by the Secretary of HHS; b. determination that there is a significant potential for public Health emergency that has a significant potential to effect a national or health security of U.S. citizens as determined by the Secretary of HHS; or c. declaration by WHO Director General of a public health emergency of international concern. 3. Where the circumstances described in subsection H.2 are met, Recipient will act promptly to negotiate in good faith with responsible third party a non-exclusive license on terms that are reasonable under the circumstances under the SI

[253] 35 U.S.C. § 203(a).
[254] Regeneron OTA, *supra* note 9, at 27.

	Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States."[255]
BARDA/Genentech OTA Agreement No.: HHSO100201800036C (COVID-19 therapeutic)	"[I]f the Government determines that: 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 2. Such action is necessary to alleviate health or safety needs, which are not reasonably satisfied by Recipient, assignee, or their licensees."[256]
BARDA/AstraZeneca OTA Agreement No.: HHSO100201500029C	"[I]f HHS determines that: 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 2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by Subcontractor, assignee, or their licensees."[257]
BARDA/Medicines Company OTA Agreement No.: HHSO100201600026C	"[I]f HHS determines that: 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 2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by Recipient, assignee, or their licensees."[258]

The Government's royalty-free license to subject inventions is limited or eliminated.

With respect to subject inventions under the Bayh-Dole Act, the government has "a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world[.]"[259] This right is narrowed or eliminated in the COVID-19 BARDA OTAs that KEI reviewed. For example, the Regeneron and Genentech OTAs both specify that the "license does not include the right to use or allow others to use the Subject Invention for commercial purposes."[260] No such limitation appears in the Bayh-Dole Act.

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[255] Johnson & Johnson OTA, *supra* note 9, at 26-27.
[256] Genentech OTA, *supra* note 9, at 27.
[257] NIH OTA Participant Guide, *supra* note 143, at 429.
[258] Medicines Company OTA, *supra* note 209.
[259] 35 U.S.C. § 202(c)(4).
[260] Regeneron OTA, *supra* note 9, at 24, and Genentech OTA, *supra* note 9, at 23.

The Regeneron and Genentech limitations on the government's royalty-free license are reminiscent of an effort by NIST, in 2018, to develop regulations narrowing the license. The 2018 draft NIST Green Paper titled, "Return on Investment Initiative to Advance the President's Management Agenda", proposed, in pertinent part:

> Defin[ing] the scope of the "government use license" for use directly by the government—or a government contractor in the performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services.[261]

The effort to formally enact regulations narrowing the government license to subject inventions disappeared after it faced opposition from the public and members of Congress but apparently found an outlet in BARDA OTAs.

Notably, the Johnson and Johnson OTA to develop a COVID-19 therapeutic eliminates the government's royalty-free license altogether.

Table 4 provides a comparison between the government license to subject inventions under the Bayh-Dole Act and BARDA OTAs.

Table 4: BARDA OTAs narrow or eliminate the government's license to use federally-funded inventions.

Source	Government's License to Federally-Funded Inventions
Bayh-Dole Act 35 U.S.C. § 202(c)(4) (Licenses for inventions developed outside the government, with federal funding)	"With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production."[262]
Bayh-Dole Act 35 U.S.C. § 209(d)(1) (Licenses for inventions developed by government	"Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions— (1) retaining a nontransferrable, irrevocable, paid-up license for any Federal

[261] NIST, supra note 246, at 28.
[262] 35 U.S.C. § 202(c)(4).

employees but licensed outside the government)	agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;"[263]
BARDA/Genentech OTA Agreement No.: HHSO100201800036C (COVID-19 therapeutic)	"License to Government For Subject Inventions To Which Recipient Retains Ownership. With respect to any Subject Invention Made Under This Agreement in which Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. **For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.**[264]
BARDA/Johnson & Johnson OTA Agreement No.: HHSO100201800012C (COVID-19 therapeutic)	No government royalty-free license was included in the OTA.[265]
BARDA/Regeneron OTA Agreement No.: HHSO100201700020C (COVID-19 therapeutic)	With respect to any Subject Invention developed under this Agreement in which Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. **For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes**.[266]

Government rights in data are limited.

The government's unlimited rights in data developed through government contracts are either eliminated or narrowed in the OTAs that KEI has reviewed. Because HHS is a civilian agency, if the OTAs were FAR-based contracts, the government would have unlimited rights in any data developed under the agreement. This means that regardless of how the data was funded, the government could use the data in any manner that it desires, including allowing a competitor to use the data for commercial purposes.

Table 5 provides examples of BARDA OTA provisions which eliminate or narrow government rights in technical data.

Table 5: BARDA OTAs eliminate or narrow unlimited government rights in technical data delivered under the contract.

Procurement contracts under the FAR	The government has **unlimited rights** in data delivered under the contract, regardless of how it was funded, 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***."[267]

[263] 35 U.S.C. § 209.
[264] Genentech OTA, *supra* note 9, at 23 (emphasis added).
[265] Johnson & Johnson OTA, *supra* note 9.
[266] Regeneron OTA, *supra* note 9, at 24 (emphasis added).
[267] FAR 52.227-14(a)(emphasis added).

	This includes the right to allow competitors to use data delivered under the contract, for any reason, including commercial purposes.[268] Unlimited rights apply to all data delivered under the contract regardless of how they were funded.[269]
Regeneron OTA HHSO100201700020C (COVID-19 therapeutic)	"i. For Data produced under this Agreement including Computer Software, to the extent developed with Government funds, the Recipient grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise **Government Purpose Rights** except as expressly provided elsewhere in this Agreement. For Data produced under this Agreement, excluding Computer Software, to the extent developed with private funds, the Recipient grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Agreement to the extent developed with private funds."[270]
BARDA/Johnson & Johnson OTA Agreement No.: HHSO100201800012C (COVID-19 therapeutic)	"1. The Government will receive **Limited Rights** in Data delivered in the performance of the SOW that is marked with the "Limited Rights" legend required by Article X, Section C below. Any Data which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article IX, Section B of this Agreement. 2. The Government **may not,** without the prior written permission of Recipient, release or disclose Data outside the Government, use Data for competitive procurement or manufacture, release or disclose Data for any purpose, or authorize Data to be used by another party. The Government will be able to share Data within the Government provided that the Government recipient is obligated to keep the information confidential. The Government shall inform all Government recipients of Data of the relevant restrictions of this Agreement. Data in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article IX of this Agreement . . . ."[271]
Genentech OTA HHSO100201800036C (COVID-19 therapeutic)	"The Government shall have unlimited rights for use in the Field in-- (i). Preexisting data funded by the Government. For clarity, Government rights in any preexisting data produced by Recipient and funded by the Government under a separate agreement shall be governed by such separate agreement, and this Agreement shall not alter any Government rights in such data produced outside of this Agreement. (ii). Data first produced in the performance of this Agreement

[268] Cassidy et al., *supra* note 131.
[269] *Id.*
[270] Regeneron OTA, *supra* note 9, at 21 (emphasis added).
[271] Johnson & Johnson OTA, *supra* note 9, at 27 (emphasis added).

	exclusively with government funds (iii). Form, fit, and function data delivered under this Agreement; (iv). Data delivered under this Agreement (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this Agreement; and 2. The Government shall have **Government purpose rights to all data produced in performance of this contract that was funded jointly by both parties** under the cost sharing arrangement contained in this Agreement. 3. The Government shall have Limited Rights to (a) all data, other than restricted computer software, that embody trade secrets or are commercial or financial and confidential or privileged, that pertains to items, components, or processed developed at private expense in the performance of this Agreement, and (b) data contained in a disclosure of a Subject Invention provided to the agency prior to the filing of a patent application."[272]
AstraZeneca OTA Agreement No.: HHS0100201500029C	"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."[273]
Medicines Company OTA Agreement No.: HHSO100201600026C	"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."[274]

10. 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."[275]

[272] Genentech OTA, *supra* note 9, at 20 (emphasis added).
[273] NIH OTA Participant Guide, *supra* note 143, at 424-425 (emphasis added).
[274] The Medicines Company OTA, *supra* note 209 (emphasis added).
[275] 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."[276] 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."[277]

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."[278] In April of 2004, the GAO reported that FCS was "at significant risk for not delivering required capability within budgeted resources[.]"[279] 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.[280] 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.[281]

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.[282] 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.[283] 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.[284] He called upon the Army to "provide an estimate as to what additional costs the

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[276] GAO-16-209, *supra* note 1, at 1.
[277] Peters, *supra* note 2.
[278] 47 No. 12 Gov't Contractor ¶ 134.
[279] 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).
[280] *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).
[281] *Id.* at 414-15.
[282] McCain, *supra* note 70.
[283] *Id.*
[284] *Id.*

program would incur if the current OTA were converted to [a FAR-based contract]."[285] The 2006 NDAA ordered the Army to convert the FCS OTA to a FAR-based contract.[286]

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."[287] 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.[288] 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."[289]

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."[290] 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.[291]

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[285] *Id.*
[286] National Defense Authorization Act for Fiscal Year 2006, Pub. L. No. 109-163, § 212, 199 Stat. 3136, 3167 (2006).
[287] 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/.
[288] *Id.*
[289] 0001 (2), https://beta.sam.gov/awards/81393114%2BAWARD?keywords=W15QKN189P001&sort=-relevance&index=&is_active=true&page=1.
[290] 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.
[291] *Id.* at 11-12.

According to CRS, "DOD documents" demonstrate that traditional contractors participate more than nontraditional contractors in OTAs.[292] Federal News Network recently reported that only $7.4 billion of the nearly $21 billion spent by DOD on OTAs from 2015 to 2017 went to traditional contractors.[293] Lockheed Martin, Northrop Grumman, and Boeing, were among the top five recipients of DOD OTA funds as of August 7, 2018.[294]

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.[295] DOD does not maintain a record of the "time it takes to execute [OTAs] vs. traditional contracts."[296]

Regarding the possible benefits of a consortium, CRS notes that "[s]ome analysts . . . have argued that many of today's consortia do not operative as collaborative organizations, but function more like managed multiple award task order contracts."[297] CRS also reports that "[s]ome analysts have argued that consortia reduce competition", because only consortium members can apply for a bid.[298]

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."[299] According to the CRS, the main source of information about OTAs is the FPDS-NG, but that data is not "fully reliable."[300] 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."[301]

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[292] Peters, *supra* note 2, at 24.
[293] 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/.
[294] 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/.
[295] Peters, *supra* note 2, at 16.
[296] *Id.*
[297] *Id.* at 4.
[298] *Id.*
[299] Halchin, *supra* note 3, at 10.
[300] *Id.* at 10-11.
[301] 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).

11. 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 titled, "Since 2017, Dr. Bright Has Objected to HHS Leadership's Cronyism and Award of Contracts to Companies with Political Connections to the Administration,"[302] 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

[302] Dr. Rick Bright, *Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and Human Services*, pgs. 6-7, https://assets.documentcloud.org/documents/6882560/Rick-Bright-Whistleblower-Complaint.pdf.

> 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.
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> 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 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.[303]

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.

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[303] *Id.*

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.

12. 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 existence of an agreement with a foreign government or other party to be in existence prior to the signing of a funding agreement.[304] 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.[305]

13. OTAs should 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."[306] 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.

14. 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.

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[304] 35 U.S.C. § 202(c)(4).
[305] 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 for use of patents, data or know-how.
[306] 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.

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.

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.