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Agency-Related Nonprofit Research Foundations and Corporations

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SUMMARY

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Agency-Related Nonprofit Research Foundations and Corporations

Federal research and development (R&D) has played a significant role in strengthening the innovative capacity of the United States to achieve goals such as economic competitiveness, national security, improved healthcare, and protection of the environment. The results of federal R&D have led to scientific breakthroughs and new technologies with broad social and economic impacts, including artificial intelligence, the internet, and magnetic resonance imaging. The global landscape for innovation is rapidly evolving—the pace of innovation has increased and the composition of R&D funding has changed (e.g., public versus private funding and the U.S. share of global R&D has declined). These changes have led some to call for new approaches and the expansion of existing federal authorities to help the United States maintain its leadership in innovation, research, and technology.

Over the years, Congress has created several agency-related nonprofit research foundations and corporations to advance the R&D needs of the federal government. The stated goals and potential benefits of these quasi-governmental entities include: (1) providing a flexible and efficient mechanism for establishing public-private R&D partnerships; (2) enabling the solicitation, acceptance, and use of private donations to supplement the work performed with federal R&D funds; (3) increasing technology transfer and the commercialization of federally funded R&D; (4) improving the ability of federal agencies to attract and retain scientific talent; and (5) enhancing public education and awareness regarding the role and value of federal R&D.

This report provides an overview of the purpose and intent, governance structure, and federal funding associated with selected congressionally mandated, agency-related nonprofit research foundations and corporations: the Foundation for the National Institutes of Health, the National Foundation for the Centers for Disease Control and Prevention, the Reagan-Udall Foundation for the Food and Drug Administration, the Foundation for Food and Agriculture Research, the Henry M. Jackson Foundation for the Advancement of Military Medicine and the nonprofit research and education corporations associated with the Department of Veterans Affairs.

The report also identifies potential issues for consideration related to oversight of existing agency-related nonprofit research foundations and corporations as well as potential issues for consideration should Congress elect to establish additional ones. Specifically, while government agencies are, with certain exceptions, subject to management laws and regulations designed to ensure accountability, transparency, and fairness, agency-related research foundations and corporations are generally exempt from them. This situation may raise questions about how Congress and federal agencies can protect the public interest and ensure confidence in the decisionmaking of such entities. Additionally, recent concerns that some have raised related to conflict of interest, the potential for industry influence, and questions about effectiveness may prompt further examination of these entities.

Among the options that Congress might consider are:

- crafting a broad, general nonprofit research foundation authority that federal science agencies could draw on to create an entity that meets their specific needs;
- examining the existing authorities of individual federal science agencies and, as appropriate, supplementing those authorities to increase the flexibility of an agency to enter into public-private partnerships;
- creating additional agency-related nonprofit research foundations on a case-by-case basis, tailored to the specific needs of particular federal science agencies; and
- maintaining the status quo, i.e., allowing agency-related nonprofit research foundations and corporations that currently exist to continue, and requiring other federal agencies to use their existing authorities to enter into public-private R&D partnerships and transfer federal technologies to the marketplace.

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Introduction

Congress maintains an ongoing interest in the pace of U.S. innovation and technological advancement due to its influence on the economy, national security, public health, and other national goals. Historically, the federal government has played a significant role in supporting research and development (R&D)—especially basic research—that has led to scientific breakthroughs and new technologies. The global landscape for innovation is rapidly evolving—the pace of innovation has increased and the composition of R&D funding has changed (i.e., private R&D investments are larger than public R&D investments and the U.S. share of global R&D has declined). These changes have led some to call for new approaches and the expansion of existing mechanisms to help the United States maintain its leadership role in innovation and technology. One mechanism that has received some attention is the possibility of establishing additional agency-related entities that would facilitate the use of private donations in federally generated research projects.[1] In addition, such entities might play a role in the commercialization of new technologies. The potential establishment of such entities in statute raises several questions: What kinds of organizations has Congress established in the past to address similar needs in the federal government? What are the strengths and weaknesses of these potential models? What are the opportunities and risks of developing a new entity for federal R&D using one of these models?

The varied organizational arrangements of the executive branch have resulted from more than two centuries of legislative and administrative actions. These arrangements reflect a diversity of viewpoints, policy preferences, and political goals among the thousands of elected and appointed officials who have played a role in creating and shaping them. During the middle of the 20th century, hybrid organizational forms—incorporating both public and private characteristics—began to grow in number. These organizational forms, sometimes collectively referred to as "quasi-governmental entities," differ from one another in their specific features, relationship to the federal government, funding mechanisms, purposes, levels of accountability to elected officials, and use of private sector incentives and efficiencies, among other characteristics.[2] Agency-related nonprofit research foundations and corporations fall into this category of organizations.

Background on Quasi-Governmental Entities

Working with successive administrations, Congress has established, or provided for the establishment of, many quasi-governmental entities.[3] Some of the considerations that contributed to their creation and development were linked to political and policymaking dynamics that were idiosyncratic to the specific time and issue at hand. Nonetheless, observers have identified some common purposes for, and expected benefits of, establishing such entities:

- providing for stable funding during federal budget tightening and uncertainty;

[1] See, for example, National Institute of Standards and Technology, U.S. Department of Commerce, *Return on Investment Initiative: Draft Green Paper to Advance the President's Management Agenda*, NIST Special Publication 1234, Washington, DC, December 2018, pp. 58-64, https://doi.org/10.6028/NIST.SP.1234.

[2] Ronald C. Moe, "The Emerging Federal Quasi Government: Issues of Management and Accountability," *Public Administration Review*, vol. 61, no. 3 (May/June 2001). Hereinafter cited as Moe.

[3] For a partial inventory of such entities, see "Other Federally Established Organizations" in U.S. Government Accountability Office, *Federally Created Entities: An Overview of Key Attributes*, GAO-10-97, October 2009, p. 23, https://www.gao.gov/products/GAO-10-97.

- freeing a program from general government management laws, particularly those pertaining to caps on personnel and compensation;
- harnessing business principles and mechanisms with the aim of providing government-driven solutions without the "red tape" associated with the federal bureaucracy; and
- providing authorities tailored to the desired mission and functions that allow flexible approaches not typically allowed under statutes or regulations, such as those in the area of financial management.[4]

In comparison to traditional government agencies, quasi-governmental entities of various kinds have been touted for their potential to harness business-like entrepreneurial incentives and drive, greater managerial flexibility, and increased employee input in decisionmaking to better carry out the entity's responsibilities.[5]

As quasi-governmental organizations have grown in number and variety, some observers have criticized the exemption from government management laws of many such entities. A complex legal framework has been established over time to guide government agencies so that their actions adhere to the values of democratic governance, such as accountability, transparency, and fairness.[6] It might be difficult for stakeholders to verify on an ongoing basis that the activities of a quasi-governmental entity, established by statute and vested with the power to carry out some public purpose, are directed to the public good rather than private gain without the routine accountability and transparency provided by this legal framework. Many of these laws and regulations specify the processes by which action must be taken. Some have criticized such governmental processes as "red tape," particularly in cases where they appear to have been applied overzealously, slowly, or seemingly without regard for an individual's or business's need for a service or flexibility. Arguably, quasi-governmental entities involve a tradeoff: What appears to some to be red tape during an administrative encounter may appear to others to be an essential accountability or transparency mechanism.

Most federal agencies are funded through the annual appropriations process, and Congress has sometimes used the "power of the purse" to influence agency priorities and activities. Most federal agencies are headed by appointees of the President subject to Senate advice and consent, and the confirmation process provides Senators with an opportunity to discuss agency issues and concerns with these leaders. Congress establishes, or provides for the establishment of, quasi-governmental entities, but it might not have the same level of influence over them as it does over conventional federal agencies. Congressional committees have reviewed the actions and structure of some of these entities during oversight hearings,[7] and Congress has sometimes enacted

[4] See Moe, pp. 290-291.

[5] Elaine Ciulla Kamarck, "The End of Government as We Know It," in *Market-Based Governance: Supply Side, Demand Side, Upside, and Downside*, ed. John D. Donahue and Joseph S. Nye Jr. (Washington, DC: Brookings Institution Press, 2002), pp. 227-263; National Performance Review, *Reinvention's Next Steps: Governing in a Balanced Budget World: A Speech by Vice President Al Gore and Supporting Background Papers* (Washington, NPR: 1996), pp. 6-8, 17-20. The Vice President's remarks were delivered at the National Press Club on March 4, 1996.

[6] Among the general management laws that most government agencies must adhere to are those pertaining to internal auditing by inspectors general, control of improper payments, internal control and accounting systems, access to public records, access to public meetings, and availability of federal contract and grant information. U.S. Government Accountability Office, *Federally Created Entities: An Overview of Key Attributes*, GAO-10-97, October 2009, pp. 24-34, https://www.gao.gov/products/GAO-10-97.

[7] See, for example, U.S. Congress, House Committee on Financial Services, Subcommittee on Capital Markets and Government Sponsored Enterprises, *Examining the Agenda of Regulators, SROs, and Standards-Setters for Accounting, Auditing, and Municipal Securities*, 114th Cong., 2nd sess., September 22, 2016 (Washington: GPO, 2018),

changes to their enabling statutes.[8] At the same time, many quasi-governmental entities do not receive appropriated funds and are not led by advice and consent appointees, shielding them from two potential avenues of congressional influence.

In addition to criticisms related to oversight, accountability, and transparency, some have questioned whether private sector management techniques are always appropriate for managing government functions. Most public administration scholars have agreed that public enterprises can benefit from some general management mechanisms developed in the private sector. Some scholars have argued, however, that the blanket application of private sector management assumptions to the public sector might miss important differences between the two.[9]

These differences include, for example, the role of constitutional law. As one public administration scholar stated, "although politicians, reformers, and media pundits often call for running government like a business, constitutional law makes the public's business very different from others."[10] Some observers also have noted differences in the "bottom line" of the two sectors, and the consequent complexity associated with measuring performance in accomplishing a public purpose.[11]

This report discusses a specific category of quasi-governmental entities: agency-related nonprofit organizations that have been established in statute for the express purpose of advancing or facilitating the R&D mission of a federal agency.[12] It describes the characteristics of several illustrative organizations of this type. It examines the available record of these entities' performances and discusses related praise and criticism of these organizational arrangements. Finally, the report identifies potential issues for consideration related to oversight of existing quasi-governmental R&D support organizations as well as potential issues for consideration should Congress elect to establish similar organizations.

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which includes a discussion of the activities of the Public Company Accounting Oversight Board; and U.S. Congress, House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations, *Lack of Oversight of Interagency Agreements-VA Procurement Failures Continued*, 114th Cong., 1st sess., July 21, 2015 (Washington: GPO, 2016), which includes a discussion of the relationship between the Department of Veterans Affairs and federally funded research and development centers.

[8] For example, Congress first chartered the American National Red Cross in 1900, then repealed this charter and enacted a new one in 1905. The 1905 charter has been amended at least nine times, twice making substantive changes to the organization's governance structure. For more, see https://www.redcross.org/about-us/who-we-are/history/federal-charter.html.

[9] For a discussion of the distinctions and similarities between public and private management, see Hal G. Rainey, Robert W. Backoff, and Charles H. Levine, "Comparing Public and Private Organizations," *Public Administration Review*, vol. 36, no. 2 (March/April 1976), pp. 233-244; and Graham T. Allison, "Public and Private Management: Are They Fundamentally Alike in All Unimportant Respects?" Remarks presented at the Public Management Research Conference, Washington, DC, November 19-20, 1979.

[10] David H. Rosenbloom, "The Constitutional Context of U.S. Public Administration," in *Administrative Law for Public Managers* (Boulder: Westview Press, 2003), p. 19. Among other aspects of this dynamic, administrators in the federal government are under the authority of Congress, the President, and the federal courts in a way that private sector entities are not. In addition, federal agencies must take into account individuals' constitutional rights during an administrative encounter.

[11] In most cases, the bottom line in the private sector is profitability, and measures of this are well established. In contrast, the bottom line in the public sector is the achievement of one or more public purposes that have been set out in a statute, regulation, or presidential directive. The ability to measure success in achieving such purposes might be more challenging than measuring profitability, particularly where the articulated purposes are vague or conflicting. Mark H. Moore, "Privatizing Public Management," in *Market-Based Governance: Supply Side, Demand Side, Upside, and Downside*, ed. John D. Donahue and Joseph S. Nye Jr. (Washington: Brookings Institution Press, 2002), pp. 305-313.

[12] Other agency-related nonprofit organizations have been created by Congress to support the mission of federal agencies (i.e., National Fish and Wildlife Foundation, the National Park Foundation, the National Forest Foundation), however, such entities are not included in this report as R&D is not their primary focus.

Existing Agency-Related Nonprofit R&D Organizations

Congress has created a number of agency-related nonprofit research foundations and corporations to advance the R&D needs of the federal government and to overcome perceived barriers associated with federal agencies' ability to partner or otherwise engage with industry, academia, and other entities. The stated goals and potential benefits of these quasi-governmental R&D support organizations are that they may:

- provide a flexible and efficient mechanism for establishing public-private R&D partnerships (see the box, "What Are Public-Private Partnerships?" for more information);
- enable the solicitation, acceptance, and use of private donations to supplement the work performed with federal R&D funds;
- increase technology transfer and the commercialization of federally funded R&D;
- improve the ability of federal agencies to attract and retain scientific talent, including through the use of fellowships, personnel exchanges, and endowed positions; and
- enhance public education and awareness regarding the role and value of federal R&D.

What Are Public-Private Partnerships?

Public-private partnerships come in many forms and are used for many purposes, from advancing R&D to constructing and maintaining transportation infrastructure. According to the 2012 *Global Innovation Index*, a public-private partnership (PPP) is "a relationship in which public and private resources are blended to achieve a goal or set of goals judged to be mutually beneficial to both the private entity and to the public." The United Nations describes PPPs as "collaborative relationships between various parties, both public and non-public, in which all participants agree to work together to achieve a common purpose or undertake a specific task and, as mutually agreed, to share risks and responsibilities, resources and benefits."

Sources: Louis Witters, Revital Marom, and Kurt Steinert, "The Role of Public-Private Partnerships in Driving Innovation," in *The Global Innovation Index 2012*, ed. Soumitra Dutta (INSEAD and the World Property Organization, 2012), p. 8;1 and General Assembly resolution 60/215, *Towards Global Partnerships*, A/RES/60/215 (December 22, 2005), https://digitallibrary.un.org/record/563759?ln=en.

The following sections provide a brief overview of the purpose and intent, governance structure, and federal funding of selected congressionally mandated, federal agency-related nonprofit research foundations and corporations. The foundations discussed include those connected with the work of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Uniformed Services University of the Health Sciences (USU). Nonprofit research and education corporations associated with the work of the Department of Veterans Affairs (VA) are also discussed.

All the foundations discussed have been funded through a combination of public and private monies and foster public-private R&D partnerships. However, the level of public support received by the foundations differs, as do the composition and appointment of their governing boards.

Federal agencies and Congress have also initiated the creation of other organizations and entities to advance the R&D needs of federal agencies. Federally initiated venture capital firms and strategic investment initiatives, including In-Q-Tel, are often mentioned as an effective model.

See the **Appendix**, "Federally Initiated and Funded Venture Capital Firms," for more information and illustrative examples of such organizations.

Foundation for the National Institutes of Health (FNIH)

In 1990, Congress directed the Secretary of Health and Human Services (HHS) to establish a nonprofit corporation—the National Foundation for Biomedical Research, which is now known as the Foundation for the National Institutes of Health (FNIH).[13] Initially, the foundation was tasked with attracting and retaining internationally known scientists to NIH "by offering competitive support for salaries, equipment, and space" through privately funded endowed positions.[14] In 1993, Congress broadened the purpose of the foundation to include "support [for] the National Institutes of Health in its mission, and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations."[15]

According to FNIH, the foundation creates public-private partnerships and alliances to advance breakthrough biomedical discoveries that can change and improve the quality of people's lives. FNIH raises funds, provides scientific expertise, and administers research programs to address a wide range of health challenges in support of NIH's mission. FNIH also supports the training of new researchers, supports patient programs, and organizes health-related educational events and symposia.[16]

One example of an FNIH-initiated project is the Biomarkers Consortium. FNIH manages the consortium—consisting of 32 companies, 15 nonprofit organizations, NIH, and FDA—with the goal of increasing the identification, development, and regulatory approval of biomarkers to support and improve drug development, preventative medicine, and medical diagnostics.[17] In 2018, FDA approved the use of a new biomarker—supported by the consortium—that is expected to improve the detection of kidney injury in healthy volunteers participating in clinical drug trials.[18]

FNIH's governance structure and powers are specified in its organic act and bylaws.[19] FNIH is governed by a board of directors composed of non-voting, ex officio members and voting, appointed members with day-to-day operations overseen by an executive director. Congress designated certain Members of Congress and federal officials as ex officio board members and tasked them with appointing the initial members of the board from a list of candidates provided

[13] The foundation was established by P.L. 101-613, 42 U.S.C. §290b. In 1998, P.L. 105-392, §418(2)(A) changed the foundation's name.

[14] U.S. Congress, Senate Committee on Labor and Human Resources, *National Institutes of Health Reauthorization Act of 1990*, report to accompany S. 2857, 101st Cong., 2nd sess., September 12, 1990, S. Rept. 101-459, p. 15.

[15] P.L. 103-43, §1701.

[16] Foundation for the National Institutes of Health, "Frequently Asked Questions," https://fnih.org/about/faq.

[17] Biomarkers are defined characteristics of the body that can be measured and used to indicate normal or abnormal biological processes or responses to an exposure or intervention. Blood pressure and body temperature are two examples of common biomarkers; other, more specialized biomarkers are less well known. Many experts consider the development of new disease-specific biomarkers an important component for the advancement of precision medicine. Foundation for the National Institutes of Health, "Biomarkers Consortium," https://fnih.org/what-we-do/biomarkers-consortium.

[18] Foundation for the National Institutes of Health, "FNIH Biomarkers Consortium and Critical Path Institute Achieve the First Ever Qualification of a Clinical Safety Biomarker by the U.S. Food and Drug Administration," press release, October 24, 2018, https://fnih.org/news/press-releases/fnih-biomarkers-consortium-critical-path-institute-PSTC.

[19] P.L. 101-613, 42 U.S.C. §290b and FNIH bylaws available at https://fnih.org/sites/default/files/final/pdf/FNIH%20By-Laws%20as%20of%20May%2023%2C%202019.pdf.

by the National Academy of Sciences.[20] According to FNIH's bylaws, the number of appointed board members must be at least 6 and no more than 32; the term of an appointed member is 3 to 5 years; there is no limit on the number of terms an appointed member may serve; and any vacancies in the membership of the board shall be filled through election by the board.[21] Congress empowered the board to establish bylaws to govern the general operations of the foundation, including policies for the acceptance, solicitation, and disposition of donations and grants. It also required the board to ensure that the bylaws do not compromise, appear to compromise, or reflect unfavorably on NIH and the ability of NIH to fulfill its responsibilities to the public. Furthermore, Congress made the board of directors accountable for "the integrity of the operations of the Foundation" through the development and enforcement of standards of conduct, financial disclosure statements, and conflict of interest policies and procedures.[22]

FNIH operations and activities have been funded through a combination of private donations and a share of NIH appropriations. According to FNIH, since its initial incorporation in 1996, the foundation has raised more than $1 billion in support of NIH's mission.[23] According to tax filings, FNIH provided NIH with $22.6 million in assistance in 2017 and $16.9 million in 2016.[24] Congress authorized the Director of NIH to "provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health" and to transfer no less than $500,000 and no more than $1.25 million of the agency's annual appropriations to FNIH.[25] Between FY2015 and FY2019, NIH transferred between $1 million and $1.25 million annually to FNIH for administrative and operational expenses (less than 0.01% of NIH's annual budget).[26] In the President's FY2020 budget, NIH requested $1.1 million for this purpose. Additionally, since FY2008, FNIH has received $602,803 in federal grants, contracts, and other financial assistance.[27]

National Foundation for the Centers for Disease Control and Prevention

In 1992, Congress authorized the establishment of the National Foundation for the Centers for Disease Control and Prevention (CDC Foundation) to "support and carry out activities for the

[20] 42 U.S.C. §290b(d)(1); The Chair and Ranking Member of the Subcommittee on Health and Environment in the House, the Chair and Ranking Member of the Committee on Labor and Human Resources in the Senate, and the Director of NIH and the Commissioner of FDA were designated as ex officio members of the board. Congress ended the terms of service of the Members of Congress after the selection of the initial board members.

[21] FNIH bylaws available at https://fnih.org/sites/default/files/final/pdf/FNIH%20By-Laws%20as%20of%20May%2023%2C%202019.pdf.

[22] 42 U.S.C. §290b(d)(6) and 42 U.S.C. §290b(j).

[23] Foundation for the National Institutes of Health, "Frequently Asked Questions," https://fnih.org/about/faq.

[24] CRS analysis of FNIH IRS 990 forms for 2017 and 2016, available at https://fnih.org/sites/default/files/final/pdf/FNIH%202017%20Form%20990.pdf and https://fnih.org/sites/default/files/final/pdf/FNIH_2016_990_for_public_inspection.pdf.

[25] 42 U.S.C. §290b(k)(2) and 42 U.S.C. §290b(l).

[26] CRS analysis of congressional budget justifications for FY2016-FY2020 for NIH's Office of the Director available at https://officeofbudget.od.nih.gov/history.html.

[27] CRS analysis of USAspending.gov (accessed on October 30, 2019) which contains information on entities that have received federal awards in the form of contracts, grants, loans, or other financial assistance back to FY2008.

prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health."[28] A House committee report stated:

> In the midst of budget restraint and personnel limitations, CDC itself is often strained to meet the basic demands of its mission. Efforts to experiment (some of which will necessarily fail), to do long-term planning, and to recruit and retain temporary staff are usually luxuries that the agency cannot afford, however productive they may ultimately be.
>
> The Committee has, therefore, undertaken to create a mechanism for the establishment of a private non-profit foundation to provide these innovative and supplementary activities in public health in association with the CDC. Once established, such a foundation could seek private support for these efforts from both individuals and organizations, and could bring charitable funds and flexibility to these goals.[29]

The CDC Foundation is authorized to support a number of activities, including using private funds to establish endowed positions at CDC; creating programs for state, local, and international public health officials to work and study at CDC; conducting forums for the exchange of public health information; and funding research and other public health studies.[30] The foundation guidelines state that it:

> helps CDC pursue innovative ideas that might not be possible without the support of external partners.... CDC Foundation partnerships help CDC launch new programs, expand existing programs that show promise, or establish a proof of concept through a pilot project before scaling it up. In each partnership, external support gives CDC the flexibility to quickly and effectively connect with other experts, information and technology needed to address a public health challenge.[31]

For example, in 2018, the CDC Foundation used funding from the United Nation Children's Fund (UNICEF) to create a partnership between researchers from CDC, the Georgia Institute of Technology, and Micron Biomedical to develop a dissolving measles and rubella microneedle vaccination patch. While the current measles and rubella vaccination is effective, challenges associated with delivery of the vaccine that have impeded eradication efforts. For example, the vaccine must be refrigerated until it is injected, and it must be administered by a trained medical professional. The dissolving microneedle patch has the potential to overcome such challenges and improve vaccination coverage.[32]

The CDC Foundation's governance structure and powers are specified in statute and through the foundation's bylaws. The CDC Foundation is governed by a board of directors composed of appointed members and overseen by an executive director. Congress created a committee composed of representatives from the public health and nonprofit sectors to incorporate the foundation, to establish its general policies and initial bylaws, and to appoint the initial members of the board of directors.[33] The term of service of a board member is five years, and any vacancies

[28] Title II of P.L. 102-531.

[29] U.S. Congress, House Committee on Energy and Commerce, *Preventative Health Amendments of 1991*, report to accompany H.R. 3635, 102nd Cong., 1st sess., November 15, 1991, H. Rept. 102-318 (Washington: GPO, 1991), p. 10.

[30] 42 U.S.C. §280e-11(c) and 42 U.S.C. §280e-11(d).

[31] CDC Foundation, "Public-Private Partnerships and Conflict of Interest Guidelines," https://www.cdcfoundation.org/public-private-partnership-guidelines.

[32] CDC Foundation, "Game-Changing Vaccine Delivery: Tiny Patch Makes a Huge Impact in the Fight Against Measles and Rubella," https://www.cdcfoundation.org/stories/tiny-patch-makes-huge-impact-changing-game-vaccination.

[33] 42 U.S.C. §280e-11(j).

in the membership of the board are filled through appointment by the board.[34] Congress tasked the CDC Director with serving as a liaison between the agency and the CDC Foundation, but did not designate the CDC Director as an ex officio member of the board.[35] According to the CDC Foundation, such an arrangement guarantees that the foundation remains independent from CDC, while ensuring that the CDC Foundation's "programs and activities have the greatest possible impact for CDC and public health."[36] Additionally, Congress required the board of directors to establish bylaws and general policies for the foundation, including policies for ethical standards, the acceptance and disposition of donations, and the general operation of the foundation. Congress required that the bylaws not reflect unfavorably upon the ability of the foundation or CDC to carry out its responsibilities or official duties in a fair and objective manner; or compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.[37]

CDC Foundation operations and activities have been funded through a combination of private donations and a share of CDC appropriations. Since 1995, the CDC Foundation has raised more than $800 million in support of CDC and its mission. In both 2015 and 2016, the CDC Foundation transferred $5.6 million to CDC. Additionally, the CDC Foundation provided the agency with $38.5 million in noncash donations (e.g., insecticides and contraceptives in response to the Zika virus) over that same period.[38] Congress authorized the CDC to provide the CDC Foundation with $1.25 million annually (roughly 0.02% of CDC's annual budget). According to the CDC Foundation's audited financial statements, CDC has provided the foundation with a $1.25 million for operating expenses each year since 2012.[39] Additionally, since FY2008, the CDC Foundation has received $55.4 million in federal grants, contracts, and other financial assistance.[40]

Reagan-Udall Foundation for the Food and Drug Administration

In 2007, Congress established the Reagan-Udall Foundation for the Food and Drug Administration (Reagan-Udall Foundation) with the purpose of advancing FDA's mission "to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety."[41] The duties of the Reagan-Udall Foundation include identifying unmet needs and supporting regulatory science research and other programs to improve the development, manufacture, and evaluation (including post-market evaluation) of FDA-regulated products. According to the Reagan-Udall Foundation, it accomplishes its tasks by establishing public-private research collaborations, ensuring new knowledge is in the public

[34] 42 U.S.C. §280e-11(f)(4).

[35] 42 U.S.C. §280e-11(h)(8).

[36] CDC Foundation, "Public-Private Partnerships and Conflict of Interest Guidelines," https://www.cdcfoundation.org/public-private-partnership-guidelines.

[37] 42 U.S.C. §280e-11(f).

[38] CRS analysis of CDC Foundation IRS 990 forms for 2015 and 2016 available at https://www.cdcfoundation.org/sites/default/files/files/CDCF-Form990-2017.pdf and https://www.cdcfoundation.org/sites/default/files/files/CDCF-Form990-2016.pdf. The CDC Foundation's tax year for 2016 was from July 1, 2016 to June 30, 2017 and the foundation's tax year for 2015 was from July 1, 2015 to June 30, 2016.

[39] For more information, see https://www.cdcfoundation.org/financials.

[40] CRS analysis of USAspending.gov (accessed on October 30, 2019) which contains information on entities that have received federal awards in the form of contracts, grants, loans, or other financial assistance since FY2008.

[41] P.L. 110-85, Title VI, §601(a).

domain, allowing broad-based participation, training the next generation of regulatory scientists, and leveraging outside resources for its activities.[42]

In 2017, the Reagan-Udall Foundation launched the Innovation in Medical Evidence Development and Surveillance (IMEDS) program which provides FDA regulated industries, universities, and nonprofits with access to distributed electronic healthcare data that can be used to evaluate medical product safety and assess drug effectiveness.[43] Thus far, IMEDS is the largest program supported and managed by the foundation.

The governing structure, purposes, and powers of the Reagan-Udall Foundation are specified in the statute establishing the foundation and further defined by the foundation's bylaws. The Reagan-Udall Foundation is governed by a board of directors composed of appointed and ex officio members, including the FDA Commissioner and the Director of NIH. A board-appointed executive director oversees the day-to-day operations of the foundation.

Congress directed federal officials—FDA Commissioner, NIH Director, CDC Director, and the Director of the Agency for Healthcare Research and Quality—to appoint the initial board members from candidates provided by the National Academy of Sciences, patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations.[44] Subsequent to these initial appointments, board vacancies are to be filled through appointment by the board.[45] According to the foundation's bylaws, the board of directors shall be composed of no more than 17 appointed members, including no more than 5 members from the general pharmaceutical, device, food, cosmetic and biotechnology industries and at least 3 members from academic research organizations, 2 members representing patient or consumer advocacy organizations, and 1 member representing health care providers.[46]

Furthermore, Congress directed the board of directors to craft bylaws for the foundation, including establishing policies for ethical standards, conflicts of interest, the acceptance, solicitation, and disposition of donations and grants, carrying out memoranda of understanding and cooperative agreements, and for review and awarding of grants and contracts.[47]

As detailed in financial reports, the Reagan-Udall Foundation has raised or received nearly $21 million in support of the foundation since 2009, including grants, contributions, and funds transferred from FDA.[48] Congress authorized FDA to provide the Reagan-Udall Foundation with between $500,000 and $1.25 million annually. FDA transferred $1.25 million to the Reagan-Udall Foundation in 2017 and $1 million in 2016 (less than 0.03% of FDA's annual budget).[49]

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[42] Reagan-Udall Foundation, "Advancing Public-Private Partnerships," https://reaganudall.org/advancing-public-private-partnerships.

[43] June S. Wasser, "Innovation in Medical Evidence Development and Surveillance (IMEDS) and the Evolution of Postmarket Safety Studies," *DIA Global Forum*, July 2017, https://reaganudall.org/sites/default/files/sites/default/files/IMEDS%20DIAglobal%20Article%208-2017.pdf.

[44] 21 U.S.C. §379dd(d)(1)(C)(i).

[45] 21 U.S.C. §379dd(d)(3)(B)(ii).

[46] By-Laws of Reagan-Udall Foundation, Inc., for the Food and Drug Administration available at https://reaganudall.org/sites/default/files/sites/default/files/RUF-Bylaws%20Approved%20Sept%2028%202017.pdf.

[47] 21 U.S.C. §379dd(d)(2).

[48] CRS analysis of Reagan-Udall financial reports available at https://reaganudall.org/financial-reports.

[49] Reagan-Udall Foundation, "Financial Statements and Independent Auditor's Report December 31, 2017 and 2016," pp. 4-5, https://reaganudall.org/sites/default/files/RUF-17-FS-Final.pdf.

Additionally, since FY2008, the Reagan-Udall Foundation has received $1 million in federal grants, contracts, and other financial assistance.[50]

Foundation for Food and Agriculture Research (FFAR)

In 2014, Congress created the Foundation for Food and Agriculture Research (FFAR) to advance the research mission of the U.S. Department of Agriculture (USDA) by focusing on agricultural issues of national and international significance, including food security and safety.[51] In establishing FFAR, Congress expressed the importance of American leadership in meeting the needs of a growing population, cited the difficulty associated with overcoming declining federal investments in agriculture research, and highlighted the potential role of the foundation in "supplementing USDA's basic and applied research activities."[52] According to the conference report:

> The Managers do not intend for the Foundation to be duplicative of current funding or research efforts, but rather to foster public-private partnerships among the agricultural research community, including federal agencies, academia, non-profit organizations, corporations and individual donors to identify and prioritize the most pressing needs facing agriculture. It is the Managers view that the Foundation will complement the work of USDA basic and applied research activities and further advance USDA's research mission. Furthermore, the Managers do not intend in any way for the Foundation's funding to offset or allow for a reduction in the appropriated dollars that go to agricultural research.[53]

FFAR is authorized to award grants, or enter into contracts, memoranda of understanding, or cooperative agreements with universities, industry, non-profits, USDA, or consortia, to "efficiently and effectively advance the goals and priorities of the Foundation."[54] It is required to identify unmet and emerging needs, facilitate technology transfer, and to coordinate its activities with those of USDA to minimize duplication and avoid potential conflicts with the department.[55]

The foundation currently supports research in six challenge areas—soil health, sustainable water management, next generation crops, advanced animal systems, urban food systems, and the health-agriculture nexus—in addition to supporting graduate fellowships and early and mid-career awards for agricultural researchers.[56] FFAR also supports strategic initiatives with the potential to further the foundation's mission. For example, in 2017, FFAR awarded researchers at the University of Illinois $15 million to expand their work in improving photosynthesis efficiency and crop yields to soybeans and other crops critical to food security in developing countries. FFAR's investment was matched by $30 million from the Bill and Melinda Gates Foundation and the United Kingdom Department for International Development.[57] According to FFAR, public-private partnerships are generally funded through a competitive grants process or through direct

[50] CRS analysis of USAspending.gov (accessed on October 30, 2019) which contains information on entities that have received federal awards in the form of contracts, grants, loans, or other financial assistance back to FY2008.

[51] P.L. 113-79, Title VII, §7601.

[52] U.S. Congress, House Committee on Agriculture, *Agricultural Act of 2014*, conference report to accompany H.R. 2642, 113th Cong., 2nd sess., January 27, 2014, H.Rept. 113-333 (Washington: GPO, 2014), p. 508.

[53] Ibid.

[54] 7 U.S.C. §5939(d).

[55] Ibid.

[56] Foundation for Food and Agriculture Research, "What We Do," https://foundationfar.org/what-we-do/.

[57] Foundation for Food and Agriculture Research, "RIPE Reinvestment," https://foundationfar.org/ripe/.

contract; however, the foundation also uses prize competitions to encourage the development of new technologies.[58]

The governance structure of FFAR is specified in the statute establishing the foundation and further defined by the foundation's bylaws. FFAR is governed by a board of directors composed of appointed and ex officio members. The day-to-day operations of FFAR are overseen by an executive director, who is appointed by the board. Congress required the ex officio members of the board—the Secretary of Agriculture, the Under Secretary of Agriculture for Research, Education and Economics, the Administrator of the Agriculture Research Service, the Director of the National Institute of Food and Agriculture, and the Director of the National Science Foundation—to select the initial appointed board members from lists of candidates provided by the National Academy of Sciences and by industry.[59] According to FFAR's bylaws, the board must consist of no less than 15 and no more than 21 appointed members; any vacancies in the membership of the board shall be filled through appointment by the board; a board member's term of service is 5 years; and a board member may be reappointed, but may not serve for more than 10 years.[60] Additionally, Congress tasked the board of directors with crafting bylaws for the general operation of the foundation and with establishing ethical standards for the acceptance, solicitation, and disposition of donations and grants. Congress also required that the bylaws and policies of FFAR preserve the integrity of the foundation and USDA, including the development and enforcement of a conflict of interest policy.[61]

In addition to the board of directors, FFAR has established advisory councils for each of the foundation's challenge areas. According to FFAR, advisory council members provide board members and foundation staff with advice and recommendations on "program development and implementation, potential partnerships and other matters of significance" and represent a diverse set of industries, professional backgrounds, and geographic areas.[62]

FFAR activities and operations have been funded through a combination of public and private funds. Through the Agricultural Act of 2014 (), Congress provided FFAR with $200 million to enter into public-private partnerships and advanced agricultural research. However, federal funds can only be expended if the foundation secures matching funds from a non-federal source.[63] In testimony before the Senate, the executive director of FFAR, Dr. Sally Rockey, stated:

> What we have discovered over the past two years is that we have two distinct advantages over other government-established research foundations. First is our public funding, which gives FFAR the flexibility to seek out diverse partnerships, especially with the private sector. Rather than raising money for a government agency, which is the model for most government established research foundations, FFAR leverages public funding—more than doubling that funding—for the public good and, in the process, develops a new community of partners. Second is our independence, which allows us to focus almost exclusively on results. When partners are focused just on the science and equally invested in seeing measurable outcomes as soon as possible, new partnerships may develop.[64]

[58] Foundation for Food and Agriculture Research, "How We Work," https://foundationfar.org/about-us/how-we-work/.

[59] 7 U.S.C. §5939(e).

[60] Foundation for Food and Agriculture Research, *By-Laws of Foundation for Food and Agriculture Research*, https://foundationfar.org/wp-content/uploads/2019/08/FFAR-Bylaws-July-2019-Final.pdf.

[61] 7 U.S.C. §5939(e)(4) and 7 U.S.C. §5939(f)(4).

[62] Foundation for Food and Agriculture Research, "Advisory Councils," https://foundationfar.org/advisory-councils/.

[63] 7 U.S.C. §5939(g).

[64] Testimony of Dr. Sally Rockey, Executive Director of the Foundation for Food and Agriculture Research, in U.S. Congress, Senate Committee on Agriculture, Nutrition, and Forestry, *Agricultural Research: Perspectives on Past and*

In 2017, FFAR awarded 39 grants and $45.8 million in funding ($110.6 million when matching funds are included).[65] In 2018, FFAR awarded 55 grants and $32.2 million in funding (more than $60 million when matching funds are included). USDA's Agricultural Research Service (ARS) was the recipient of three grants and $1.7 million in funding from FFAR ($3.6 million when matching funds are included) in 2018.[66]

In the Agriculture Improvement Act of 2018 (P.L. 115-334), Congress directed the Secretary of Agriculture to transfer an additional $185 million to FFAR "to leverage private funding, matched with federal dollars to support public agricultural research"; however, these federal funds were not to be transferred until FFAR provided Congress with a strategic plan detailing how the foundation will become self-sustaining.[67] Congress required the strategic plan to describe agricultural research opportunities and objectives identified by FFAR's advisory councils and approved by the board, and to provide transparency into the foundation's grant review and awards process.[68] FFAR released the required strategic plan in 2019; the plan outlines several actions that the foundation will pursue to diversify its funding base, but also indicates that federal funds are a "critical component of FFAR's model."[69]

Henry M. Jackson Foundation for the Advancement of Military Medicine

In 1983, Congress created the Foundation for the Advancement of Military Medicine—now known as the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF)—to carry out and participate in cooperative medical research and education projects with the Uniformed Services University of the Health Sciences (USU).[70] In describing the purpose and role of HJF, Congress stated:

> The Foundation will be a nonprofit, charitable corporation which will receive gifts, grants and legacies on behalf of both itself and the Uniformed Services University…. [By] channeling private resources to the Uniformed Services University, the Foundation will help the University and military medicine maintain advanced scientific teaching and research. In addition, the Foundation will support the growing international role of the University in its cooperative research in other countries and in its programs with medical schools training military officers both here and abroad.[71]

Future Successes for the 2018 Farm Bill, 115th Cong., 1st sess., June 15, 2017, S. Hrg. 115-172 (Washington, DC: GPO, 2017).

[65] Foundation for Food and Agriculture Research, *2017 Annual Report: Cultivating Innovation*, Washington, DC, 2018, p. 12, https://foundationfar.org/wp-content/uploads/2018/06/2017-Annual-Report-6.6.pdf.

[66] CRS analysis of Foundation for Food and Agriculture Research, *2018 Annual Report: Transforming Agriculture's Future*, Washington, DC, 2019, https://foundationfar.org/wp-content/uploads/2019/07/FFAR2018AnnualReportFinal-web7-15-FINAL.pdf.

[67] U.S. Congress, House Committee on Agriculture, *Agriculture Improvement Act of 2018*, conference report to accompany H.R. 2, 115th Cong., 2nd sess., December 10, 2018, H.Rept. 115-1072 (Washington: GPO, 2018), pp. 698-699.

[68] 7 U.S.C. §5939(f)(3)(B).

[69] Foundation for Food and Agriculture Research, Strategic and Sustainability Plan, Washington, DC, 2019, https://foundationfar.org/about-us/governance/strategic-plan/.

[70] P.L. 98-132. The mission of the Uniformed Services University of Health Sciences—charted by Congress in 1972 (P.L. 92-426)—is to educate, train, and prepare uniformed services health professionals and scientists in support of the U.S. military and public health systems.

[71] U.S. Congress, Senate Committee on Armed Services, *Foundation for the Advancement of Military Medicine*, report

In general, HJF implements its mandate by offering research support and services to USU and other military research centers and facilities, including proposal development, research program administration and management, regulatory compliance, technical staffing, and technology transfer assistance.[72] P.L. 98-132 authorized HJF to enter into contracts with USU "for the purposes of carrying out cooperative enterprises in medical research, medical consultation, and medical education, including contracts for the provision of such personnel and services as may be necessary to carry out such cooperative enterprises."[73]

According to HJF, more than 1,100 of HJF's employees participated in or supported collaborative research and education projects at USU in FY2018.[74] For example, HJF entered into a license agreement from the USU-HJF Joint Office of Technology Transfer with Profectus BioSciences to develop a human vaccine for the Nipah virus—an infection that can lead to inflammation of the brain and respiratory illness—based on a technology created more than 15 years ago by a USU scientist. Specifically, HJF, USU, and Profectus are collaborating on the development of a clinical assay to evaluate the Nipah virus vaccine response. The collaborative research is supported, in part, by NIH.[75]

HJF is governed by a council of directors composed of appointed and ex officio members, including the chair and ranking members of the Senate and House Committees on Armed Services and the Dean of USU. The ex officio members are responsible for appointing the other members of the council of directors.[76] In 2018, Congress increased the number of appointed members from four to six.[77] A council-appointed executive director oversees the day-to-day operations of HJF.

In 1986, Congress appropriated $10 million to HJF "to support the purposes of the Foundation, its on-going educational and public services programs and to serve as a memorial to the late Senator Henry M. Jackson."[78] However, HJF's revenue is generally derived from the administration of grants and contracts—HJF manages or administers grants and contracts on behalf of USU or other military research centers and collects indirect costs or overhead associated with the provided services. According to HJF, in FY2018, the foundation received $483.9 million in grants and contracts and expended $468.7 million on program services associated with research grants and contracts.[79] According to USAspending.gov, since FY2008, HJF has received $6.1 billion in federal grants, contracts, and other financial assistance, primarily from the Department of Defense.[80]

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to accompany S. 653, 98th Cong., 1st sess., March 31, 1983, S. Rept. 98-39 (Washington: GPO, 1983), p. 2.

[72] Henry M. Jackson Foundation for the Advancement of Military Medicine, "Services," https://www.hjf.org/services.

[73] 10 U.S.C. §178(g)(1).

[74] Henry M. Jackson Foundation for the Advancement of Military Medicine, *HJF Annual Report 2018*, Bethesda, MD, 2019, p. 5, https://annualreports.hjf.org/download-pdf/.

[75] Ibid., p. 8 and Henry M. Jackson Foundation for the Advancement of Military Medicine, "Developing Vaccines and Therapies for the Highly Pathogenic Nipah and Hendra Viruses," press release, April 18, 2019, https://www.hjf.org/news/developing-vaccines-and-therapies-highly-pathogenic-nipah-and-hendra-viruses.

[76] 10 U.S.C. §178(c).

[77] Section 739 of P.L. 115-232, the John S. McCain National Defense Authorization Act for Fiscal Year 2019.

[78] P.L. 99-591.

[79] Henry M. Jackson Foundation for the Advancement of Military Medicine, *HJF Annual Report 2018*, Bethesda, MD, 2019, p. 26, https://annualreports.hjf.org/download-pdf/.

[80] CRS analysis of USAspending.gov (accessed on October 30, 2019) which contains information on entities that have received federal awards in the form of contracts, grants, loans, or other financial assistance back to FY2008.

Department of Veterans Affairs Nonprofit Research and Education Corporations

In 1988, Congress authorized the Secretary of Veterans Affairs (VA) to establish a nonprofit corporation (NPC) at any of the VA medical centers "to provide a flexible funding mechanism" and facilitate the conduct of approved research.[81] Congress extended the authority of NPCs in 1999 to include approved education and training activities (e.g., educational courses for patients and families and training for VA employees associated with new technologies or specialties).[82] Congress also authorized any NPC to facilitate the conduct of approved research and education activities at more than one VA medical center (such NPCs are known as multi-medical center research corporations). In general, NPCs implement their mandate by providing research and management services to VA medical researchers conducting projects using non-VA funds.

In describing the need for NPCs, Congress indicated that support for research from non-VA funding sources, including NIH, DOD, private foundations, and companies, benefited veteran patients, where existing mechanisms for administering non-VA funds had disadvantages.[83] A committee report on the authorizing legislation stated:

> Funds that are channeled through affiliated medical schools [to VA medical centers] are subject to the terms and conditions which the school applies to funds obtained by researchers employed by the school. In many cases, this means that a percentage, which varies from 15 to 40 percent or more, of the funds obtained is retained by the medical school for "overhead" and related expenses of the school.[84]

In contrast, by authorizing NPCs to accept, administer, retain, and spend non-VA research funding on behalf of VA investigators, indirect costs or overhead derived from such funds could be applied to the VA medical center.[85] According to the U.S. Government Accountability Office (GAO):

> Nonprofit corporations support VA's research environment by funding a portion of the department's research needs, such as laboratory equipment and improvements to infrastructure, and by providing flexible personnel and contracting arrangements to respond to investigators' needs.[86]

The governance structure of NPCs is specified in the statute providing the authority for their establishment and further defined by VA procedures and instructions.[87] Each NPC is governed by a board of directors with its day-to-day operations overseen by an executive director. The VA Secretary is responsible for appointing all members of an NPC's board of directors. Each board of directors must include the director of the VA medical center, the chief of staff, and associate

[81] P.L. 100-322.

[82] P.L. 106-117.

[83] U.S. Congress, House Committee on Veterans' Affairs, *Veterans' Omnibus Health Care Amendments of 1987*, report to accompany H.R. 3449, 100th Cong., 1st sess., October 15, 1987, H. Rept. 100-373 (Washington: GPO, 1987), p. 4.

[84] Ibid.

[85] VA investigators often have dual appointments at both a VA medical center and its affiliated medical school, meaning that either institution can serve as the prime contractor or awardee on behalf of the VA researcher.

[86] U.S. Government Accountability Office, *VA Health Care: Nonprofit Corporations Enhance VA Research, but Would Benefit from Increased Oversight*, GAO-02-1103T, September 19, 2002, p. 2, https://www.gao.gov/assets/110/109582.pdf.

[87] 38 U.S.C. §7363 and Veterans Health Administration, *VA Nonprofit Research and Education Corporations*, Department of Veterans Affairs, VHA Handbook 1200.17, Washington, DC, May 9, 2017, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3194.

chief(s) of staff of the medical center—all acting within their official capacities—and two non-federal members. Additionally, the board of directors of a multi-medical research corporation must include the director of each of the VA medical centers served by the NPC. The executive director of an NPC is appointed by its board of directors with the concurrence of the VA Under Secretary of Health.[88]

Congress placed NPCs under the jurisdiction of VA's Inspector General; required each NPC to conduct regular audits and provide an annual statement of operations, activities, and accomplishments to VA; and made all NPC employees, including members of the board of directors, subject to conflict of interest policies adopted by the NPC.[89] Additionally, VA conducts oversight of NPCs through the agency's Nonprofit Program Oversight Board (NPOB), the Nonprofit Program Office (NPPO), and the Veteran Health Administration's Chief Financial Officer (VHA CFO).[90] Specifically:

- The NPOB is VA's senior management oversight body for NPCs. It reviews the activities of NPCs to ensure they are consistent with VA policies and makes recommendations to the VA Secretary (through the Under Secretary of Health) regarding any changes in NPC policy.
- The NPPO serves as a liaison between VHA and the NPCs. It provides oversight, guidance, and education to the NPCs to ensure compliance with VA policies and regulations, conducts triennial reviews of NPCs, compiles NPC data for an annual report to Congress, and ensures any corrective measures are implemented.
- The VHA CFO provides financial oversight of NPCs.[91]

There are currently 83 NPCs located in 42 states, Puerto Rico, and the District of Columbia.[92] According to VA, in 2017, NPCs generated $261 million in revenue—spending 84% on research, 15% on administrative overhead, and 1% on education related activities.[93] VA describes NPCs as "self-sustaining…. [F]unds are not received into a government account. No appropriation is required to support these activities."[94] However, approximately 70% of the revenue generated by NPCs in 2017 ($183 million) was from federal sources—primarily NIH and DOD grants and

[88] 38 U.S.C. §7363.

[89] 38 U.S.C. §7366.

[90] Veterans Health Administration, *VA Nonprofit Research and Education Corporations*, Department of Veterans Affairs, VHA Handbook 1200.17, Washington, DC, May 9, 2017, pp. 2-3, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3194.

[91] Ibid.

[92] U.S. Department of Veterans Affairs, *Volume II: Medical Programs and Information Technology Programs, Congressional Submission, FY2020 Funding and FY2021 Advance Appropriations*, pp. VHA-389-391, https://www.va.gov/budget/docs/summary/fy2020VAbudgetVolumeIImedicalProgramsAndInformationTechnology.pdf.

[93] U.S. Department of Veterans Affairs, *2017 NPC Annual Report to Congress Summary*, July 12, 2018, https://www.research.va.gov/programs/nppo/docs/2017-ARC-NarrativeSummary.docx. Revenue can include grants, gifts, fees, contracts, investment income, and royalties, among other sources.

[94] U.S. Department of Veterans Affairs, *Volume II: Medical Programs and Information Technology Programs, Congressional Submission, FY2020 Funding and FY2021 Advance Appropriations*, p. VHA-389, https://www.va.gov/budget/docs/summary/fy2020VAbudgetVolumeIImedicalProgramsAndInformationTechnology.pdf.

contracts. VA states that from 2008 to 2017 NPCs contributed $2.2 billion to VA research.[95] In 2018, NPCs generated $236 million in revenues.[96]

Issues for Congress

In an April 2019 report, the National Institute of Standards and Technology described benefits that might be realized if Congress provided all federal R&D agencies with the authority to establish agency-related nonprofit research foundations.[97] For example, they can actively seek "gifts and other monetary donations from private donors and organizations," and they "have facilitated technology commercialization and generated revenue to reinvest in R&D."[98]

In addition, while government agencies are, with certain exceptions, subject to management laws designed to ensure accountability, transparency, and fairness, agency-related foundations may be exempt from them. Such exemptions may facilitate flexibility, but they may also make it difficult for stakeholders to verify on an ongoing basis that the foundation's activities are directed to the public good rather than private gain.

Prior to extending the authority to establish agency-related nonprofit research foundations and corporations to additional federal agencies and laboratories there are a number of issues that Congress might consider. The following sections examine some of these issues, including transparency, independence, and effectiveness.

Conflict of Interest and Industry Influence

To date, most federal agencies with affiliated nonprofit research foundations or corporations work in the area of medicine and public health—an area where public trust is considered essential. The conflict of interest policies of affiliated nonprofit research foundations and corporations vary. For example, all HJF employees are required to submit annual conflict disclosure and certification forms; under its cooperative agreement with the CDC, the CDC Foundation is required to conduct a conflict of interest review prior to accepting a gift for the CDC from a potential donor; and VA employees serving as NPC directors are subject to federal conflict of interest laws and regulations.[99]

Recent media reports and investigations have nevertheless raised concerns about conflicts of interest and the potential for undue industry influence in public-private R&D partnerships formed and managed by agency-related nonprofit foundations.[100] According to some, industry

[95] U.S. Department of Veterans Affairs, *2017 NPC Annual Report to Congress Summary*, July 12, 2018, https://www.research.va.gov/programs/nppo/docs/2017-ARC-NarrativeSummary.docx.

[96] U.S. Department of Veterans Affairs, *Volume II: Medical Programs and Information Technology Programs, Congressional Submission, FY2020 Funding and FY2021 Advance Appropriations*, p. VHA-389, https://www.va.gov/budget/docs/summary/fy2020VAbudgetVolumeIImedicalProgramsAndInformationTechnology.pdf.

[97] National Institute of Standards and Technology, *Return on Investment Initiative for Unleashing American Innovation*, NIST Special Publication 1234, Gaithersburg, MD, April 2019, pp. 2 , 64-65, https://doi.org/10.6028/NIST.SP.1234.

[98] Ibid., pp. 59-60.

[99] Henry M. Jackson Foundation for the Advancement of Military Medicine, *Code of Ethics*, January 2018, p. 15, https://www.hjf.org/ethics#tab-1; CDC, Administration of Gifts to CDC, 2016, p. 4, https://www.cdc.gov/maso/Policy/ADMINISTRATION-OF-GIFTS_Policy_20170329_Version-for-CDC-gov_508.pdf; and Veterans Health Administration, *VA Nonprofit Research and Education Corporations*, Department of Veterans Affairs, VHA Handbook 1200.17, Washington, DC, May 9, 2017, p. 9, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3194.

[100] For example, Lev Facher, "Signaling Concern over Industry Funding, Congress Presses for Transparency at Groups

involvement in R&D partnerships has the potential to erode public trust and confidence in federal agency decisionmaking, which may be based, in part, on the results of R&D supported by the public-private partnership.[101] Others assert that issues associated with conflict of interest are overstated and rare, that other biases—beyond financial ties—also influence research, and that policy responses to such concerns have been overly burdensome and are impeding the translation of R&D into new products and technologies.[102] Three recent examples illustrate these conflict of interest and undue influence concerns.

R&D Partnership Between the National Football League and NIH

In 2015 and 2016, reporting by ESPN and others alleged that the National Football League (NFL) attempted to influence the selection of a grant recipient by NIH for a study on a degenerative brain disease known as CTE, or chronic traumatic encephalopathy.[103] NIH had planned to fund the CTE study from a $30 million NFL donation to NIH through FNIH. Democratic committee staff of the House Committee on Energy and Commerce launched an investigation of the allegations and issued a report in May 2016. The report stated:

> Democratic Committee staff received evidence to support the allegations that the NFL inappropriately attempted to influence the selection of NIH research applicants funded by the NFL's $30 million donation to NIH…. Despite the NFL's attempts to influence the selection of research applicants, the integrity of the peer review process was preserved and funding decisions were made solely based on the merit of the research applications.[104]

The report included findings and recommendations directed at FNIH and its role in the creation and management of R&D partnerships between NIH and the private sector. Specifically, the investigation found that "FNIH did not adequately fulfill its role of serving as an intermediary between NIH and the NFL" and recommended the following actions:

- FNIH must establish clearer guidelines regarding donor communications with NIH.
- FNIH must come to a mutual understanding with donors at the beginning of the process regarding their degree of influence over the research they are funding and remind donors that NIH policy prohibits them from exerting influence at any point in the grant decision-making process.

Supporting NIH, CDC," *Stat News*, July 2, 2018, https://www.statnews.com/2018/07/02/congress-transparency-funding-nih-cdc/.

[101] Nell Greenfieldboyce, "FDA to Fund Controversial Research Foundation," NPR, April 3, 2012, https://www.npr.org/sections/health-shots/2012/04/03/149931282/fda-to-fund-controversial-research-foundation.

[102] Ronald Bailey, *Scrutinizing Industry-Funded Science: The Crusade Against Conflicts of Interest*, American Council on Science and Health, New York, NY, March 2008, p. 4, https://www.acsh.org/sites/default/files/111408281-Scrutinizing-Industry-Funded-Science-The-Crusade-Against-Conflicts-of-Interest.pdf; and Aaron E. Carroll, "Congratulations on the Promotion. But Did Science Get a Demotion?," *New York Times*, December 31, 2018, https://www.nytimes.com/2018/12/31/upshot/congratulations-on-the-promotion-but-did-science-get-a-demotion.html.

[103] Steve Fainaru and Mark Fainaru-Wada, "NFL Backs Away from Funding BU Brain Study; NIH to Fund It Instead," *ESPN*, December 22, 2015, https://www.espn.com/espn/otl/story/_/id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher; and Ike Swetlitz, "NFL's 'Unrestricted' Grant to Fund Brain Research Has Strings Attached," *STAT News*, January 8, 2016, https://www.statnews.com/2016/01/08/nfl-concussion-research-grant/.

[104] Democratic Staff, *The National Football League's Attempt to Influence Funding Decisions at the National Institutes of Health*, U.S. House of Representatives, Committee on Energy and Commerce, Washington, DC, May 2016, p. 3, https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/Democratic%20Staff%20Report%20on%20NFL%20NIH%20Investigation%205.23.2016.pdf.

- FNIH should provide donors with the clear, unambiguous language from the NIH Policy Manual, which states that a donor may not dictate terms that include "any delegation of NIH's inherently governmental responsibilities or decision-making," or "participation in peer review or otherwise exert real or potential influence in grant or contract decision-making."
- NIH and FNIH should jointly develop a process to address concerns about donors acting improperly.[105]

FNIH issued the following statement in response to the report:

> The FNIH acted appropriately, with integrity and transparency, in fulfilling its mandate under SHRP [Sports and Health Research Program]. As acknowledged by the Democratic Staff report, the governing documents among the FNIH, NIH and NFL made clear that the NIH had exclusive control over the scientific and administrative aspects of the program.
>
> The report makes recommendations regarding communication issues that the FNIH has already identified and taken steps to address. The FNIH has strengthened protocols around communications among NIH, NIH researchers and FNIH donors that will prevent unauthorized contact among parties.
>
> The FNIH has had a long history of successful and productive public-private partnerships in support of the NIH mission. These adjustments to governing agreements will help ensure the success of future scientific partnerships in support of human health.[106]

On September 15, 2016, four Republican members of the House Committee on Energy and Commerce sent a letter to the Inspector General of the Department of Health and Human Services related to the allegations of undue influence by the NFL. The letter stated:

> There appear to be important questions and concerns related to these events that have not been adequately vetted or addressed…. This grant award has become the source of tremendous public debate and, therefore, clear answers and lessons are necessary. For these the reasons, the Committee refers this matter to your attention and requests a thorough and objective review by the Office of the Inspector General to assess whether the policies and procedures concerning public-private partnerships under the authority of FNIH were followed, and if not, what revisions or reforms should be considered. This will help SHRP, and other public-private partnerships, avoid similar distractions in the future so all parties can focus on what matters most—the science.[107]

Opioid Epidemic Public-Private Partnership

In 2018, NIH was engaged with FNIH and potential donors, including pharmaceutical companies, regarding the development of a public-private partnership that would seek to address the opioid crisis. Potential conflicts of interest and ethical concerns were raised by both NIH and FNIH. The Director of NIH asked a working group of the Advisory Committee to the NIH Director (ACD) and the FNIH Board to examine the appropriateness of establishing a partnership between NIH,

[105] Ibid., pp. 3-4.

[106] Foundation for the National Institutes of Health, "The FNIH's Statement on the Democratic Staff Report of the Committee on Energy and Commerce," press release, May 23, 2016, https://fnih.org/news/announcements/the-fnihs-statement-on-the-democratic-staff-report-of-the-committee-on-energy-and-commerce.

[107] Letter from Chairman Fred Upton et al. to the Honorable Daniel Levinson, Inspector General, U.S. Department of Health and Human Services, September 15, 2016, https://web.archive.org/web/20180926092407if_/https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/letters/20160915HHS_OIG.pdf.

FNIH, and various pharmaceutical companies.[108] On March 16, 2018, the FNIH Board held a meeting to discuss the possibility of forming such a partnership. The FNIH Board decided

> that an approach that relies disproportionately on input and financing from pharmaceutical companies is not appropriate in this circumstance. The FNIH is uncomfortable seeking or receiving monetary donations from any pharmaceutical company or industry representative at this time to support implementation of the research plan as presented. Doing so poses unacceptably high risk of public skepticism concerning the eventual scientific outcomes given the responsibility some companies may bear in having created the crisis. Also, it would likely undermine public confidence in the many other valuable public-private partnerships that the NIH and FNIH have created and will create to improve human health.[109]

The principal recommendation of the ACD working group was that "to mitigate the risk of real or perceived conflict of interest, it would be preferable if only Federal funds were used to support the research efforts included in this public-private partnership."[110] The working group also offered a number of recommendations if a public-private partnership were to be established, including that any industry funding should be provided without preconditions and in full, that NIH should publicly disclose its research plan for the partnership, and that the agency should clarify and define the governance structure associated with the collaboration.[111]

In April 2018, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative—an agency-wide "effort to speed scientific solutions to stem the national opioid public health crisis."[112] In a press release on the use of public-private partnerships as part of HEAL, the Director of NIH stated:

> I fully embrace [the ACD Working Group's] recommendation that NIH should vigorously address the national opioid crisis with government funds and decline cash contributions through partnerships from the private sector.
>
> It is clear, however, that the opioid crisis is beyond the scope of any one organization or sector. NIH and biopharmaceutical companies bring unique skills and assets to bear on this crisis. NIH will use the ACD guidance as we continue our discussions with biopharmaceutical organizations to advance focused medication development for addiction and pain…We agree with and appreciate the ACD's guidance to verify donated assets and tailor the governance structures for each initiative that may be pursued through public-private partnerships to ensure appropriate oversight and guidance. Any partnerships that

[108] Letter from Lawrence A. Tabak, Principal Deputy Director, National Institutes of Health, to Maria C. Freire, President and Executive Director, Foundation for the National Institutes of Health, February 23, 2018, https://fnih.org/sites/default/files/final/nih-letter%20to-fnih-2-23-2018.pdf.

[109] Letter from Maria C. Freire, President and Executive Director, Foundation for the National Institutes of Health, to Lawrence A. Tabak, Principal Deputy Director, National Institutes of Health, March 20, 2018, https://fnih.org/sites/default/files/final/finih-response-to%20nih-3-20-2018.pdf.

[110] Advisory Committee to the Director, Working Group on Ethical Considerations for Industry Partnerships on Research to Help End the Opioid Crisis, *Ethical Considerations for Industry Partnerships on Research to Help End the Opioid Crisis*, National Institutes of Health, Bethesda, MD, March 2018, https://acd.od.nih.gov/documents/presentations/032018_opioids-report.pdf.

[111] Ibid.

[112] National Institutes of Health, "NIH Launches HEAL Initiative, Doubles Funding to Accelerate Scientific Solutions to Stem National Opioid Epidemic," press release, April 4, 2018, https://www.nih.gov/news-events/news-releases/nih-launches-heal-initiative-doubles-funding-accelerate-scientific-solutions-stem-national-opioid-epidemic.

> NIH does establish with biopharmaceutical organizations as part of the HEAL Initiative will be done with the utmost transparency.[113]

Coca-Cola Funding for Obesity Research

Some have raised concerns regarding the ability of industry to influence CDC and FDA decisionmaking by way of donations to the CDC Foundation and Reagan-Udall Foundation. For example, some have questioned donations made by the Coca-Cola Company to the CDC Foundation for research and other activities associated with obesity and diet issues.[114] In February, two members of Congress sent a letter asking the Department of Health and Human Services' Inspector General to "investigate the relationship between the CDC and Coca-Cola outlined in this report [a 2019 paper by Hessari et al.], determine whether there is a broader pattern of inappropriate industry influence at the agency, and make recommendations to address this issue."[115]

In addition to managing conflicts of interest that may result from public-private partnerships facilitated by an agency-related nonprofit foundation, a 2016 report by a working group of the Advisory Committee to the CDC Director noted the need for clarity in managing conflict of interest between the nonprofit foundation and the federal agency itself. The working group pointed out that the CDC Foundation "benefits financially from the grants it accepts and manages on the CDC's behalf," and noted that "ongoing oversight and management transparency are essential components of a conflict-of-interest policy, particularly where, as here, one of the partners is an agency whose greatest asset is the confidence of the public in its impartiality and integrity."[116]

Transparency and Accountability

In response to concerns regarding conflict of interest and the potential for industry influence, in addition to the need to maintain public confidence in related decisionmaking, some have called for additional transparency in the development and management of public-private partnerships.[117] These calls extend to agency-related nonprofit research foundations.

For example, the Advisory Committee to the Director of the CDC recommended that the CDC should expect the CDC Foundation to provide the agency with a "complete record of evidence" and a "fully reasoned analysis" as to why a proposed public-private partnership would meet the agency's standards for entering into a private financial relationship. The advisory committee recommended that CDC only enter into a private financial relationship if the proposed project

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[113] National Institutes of Health, "Statement on Public-Private Partnerships as Part of the NIH HEAL Initiative," press release, April 13, 2018, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-public-private-partnerships-part-nih-heal-initiative.

[114] Sheila Kaplan, "New C.D.C. Chief Saw Coca-Cola as Ally in Obesity Fight," *The New York Times*, July 22, 2017, https://www.nytimes.com/2017/07/22/health/brenda-fitzgerald-cdc-coke.html and Nason Maani Hessari, Gary Ruskin, and Martin McKee, et al., "Public Meets Private: Conversations Between Coca-Cola and the CDC," *The Milbank Quarterly*, vol. 97, no. 1 (2019), pp. 74-90.

[115] Congresswoman Chellie Pingree, "Pingree, DeLauro to HHS Inspector General: Investigate Coca-Cola's Lobbying of CDC," press release, February 4, 2019, https://pingree.house.gov/news/documentsingle.aspx?DocumentID=291.

[116] Ethical Considerations for Public Private Partnerships Workgroup, *Summary Report Submitted to the Advisory Committee to the Director*, 2016, pp. 2-3, https://www.cdc.gov/about/pdf/advisory/EthicalConsiderationsPPPRecommendationsACD.pdf.

[117] Bernard Lo and Deborah Grady, "Protecting NIH's Integrity and Trustworthiness in Public-Private Partnerships," *JAMA*, vol. 320, no. 5 (2018), pp. 439-440.

aligns with a stated CDC priority, the projected benefits to public health outweigh any potential risks to public trust in CDC, and the proposed project does not primarily benefit the private funder or position the private funder to exercise undue influence over CDC.[118]

Some have also called for the harmonization of policies, procedures, and standards used by federal agencies and agency-related nonprofit research foundations in the evaluation of proposed public-private partnerships and in addressing conflict of interest and undue influence concerns associated with such partnerships.[119]

In 2018, House appropriations report language directed both the CDC Foundation and FNIH to abide by existing reporting requirements and include in their respective annual reports

> the source and amount of all monetary gifts to the Foundation, as well as the source and description of all gifts of real or personal property. Each annual report shall disclose a specification of any restrictions on the purposes for which gifts to the Foundation may be used. The annual report shall not list "anonymous" as a source for any gift that includes a specification of any restrictions on the purpose for which the gift may be used.[120]

According to media reports, officials from FNIH and the CDC Foundation assert they are in compliance with existing disclosure requirements as outlined in their governing statutes and their annual reporting is similar to other nonprofit organizations.[121]

Independence and Oversight

By design, quasi-governmental entities, including agency-related nonprofit research foundations and corporations, are independent from the federal government. Congress explicitly states in the statutes creating each of the organizations described above that the entity is "not an agency or instrumentality of the United States." In addition, these entities generally are not controlled by federal officials. However, Congress also structured these organizations so they would be associated with and in some instances largely reliant on the federal agencies they were created to support. The degree of independence an agency-related nonprofit research foundation or corporation has—and by extension the degree of congressional oversight and influence—varies (i.e., the more independent, the less opportunity for oversight and vice versa). This variability can be ascribed, in large part, to the primary function of the organization and the governance structure established by Congress.

For example, the primary function of HJF and the VA NPCs is to provide research and grant management services to USU and VA medical researchers, respectively. These researchers are full- or part-time federal employees who are, in general, conducting approved research using federal funds from other agencies (NIH and DOD). The financial strength of these entities is thus closely tied to the ability of USU and VA researchers to compete successfully for NIH, DOD, and other research grants. Additionally, the boards governing HJF and VA NPCs include Members of

[118] Ethical Considerations for Public Private Partnerships Workgroup, *Summary Report Submitted to the Advisory Committee to the Director*, 2016, p. 6, https://www.cdc.gov/about/pdf/advisory/EthicalConsiderationsPPPRecommendationsACD.pdf.

[119] Bernard Lo and Deborah Grady, "Protecting NIH's Integrity and Trustworthiness in Public-Private Partnerships," *JAMA*, vol. 320, no. 5 (2018), pp. 439-440.

[120] U.S. Congress, House Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2019*, report to accompany H.R. 6470, 115th Cong., 2nd sess., July 23, 2018, H.Rept. 115-862 (Washington: GPO, 2018), pp. 52, 73-74.

[121] Jeffrey Mervis, "U.S. Lawmakers Want NIH and CDC Foundations to Say More About Donors," *Science*, June 29, 2018, https://www.sciencemag.org/news/2018/06/us-lawmakers-want-nih-and-cdc-foundations-say-more-about-donors.

Congress and federal officials. Specifically, the board of a VA NPC must include the director, chief of staff, and associate chief(s) of staff of the VA medical center—all acting in their official capacities—and the board of HJF includes the chair and ranking members of the Senate and House Committees on Armed Services. These factors likely make HJF and VA NPCs less independent than some of the other agency-related nonprofit foundations described in this report. However, given their dependency—in particular on other federal funds—several questions arise: Why are these entities needed? Are there alternative mechanisms for administering research funds from other federal agencies? Should these entities be soliciting more private funds?

Comparatively, FNIH, the CDC Foundation, and the Reagan-Udall Foundation likely have more autonomy given their primary function of raising funds from the private sector to benefit and advance the mission of their affiliated federal agencies. Nonetheless, the success of these entities requires some level of interconnectedness to ensure their efforts are closely aligned with the priorities and needs of the federal agencies they support. Additionally, FNIH, the CDC Foundation, and the Reagan-Udall Foundation all receive administrative and operating costs from their affiliated federal agencies, in addition to having federal officials as ex officio members of their boards. These factors likely provide the federal agencies with the ability to influence and shape the relationship. The use of federal funds in supporting the operating expenses of these entities also provides a mechanism for congressional oversight.

FFAR's purpose to advance the research mission of USDA is similar to that of FNIH, the CDC Foundation, and the Reagan-Udall Foundation. However, the way in which FFAR executes its mission—primarily as a grant-making organization—may offer more independence. Congress tasked FFAR with developing and pursuing an agricultural R&D agenda that minimizes the duplication of existing USDA efforts and is focused on unmet needs and emerging areas of national and international significance. Currently, FFAR executes its R&D agenda by leveraging federal funds with non-federal sources. The use of federal funds provides Congress with an effective oversight mechanism. Congressional intent, however, is for FFAR to become self-sufficient. In the Agriculture Improvement Act of 2018 (P.L. 115-334), Congress made the transfer of federal funds contingent upon the development of a strategic plan detailing how FFAR will become self-sustaining.[122] Opportunities for congressional oversight or influence may diminish as FFAR becomes self-sustaining. That being said, FFAR's strategic plan states:

> This strategic planning and sustainability exploration demonstrates that FFAR requires Congressional funding to remain relevant, viable, to maintain velocity, and increase impact toward conquering the food and agriculture challenges of this time…. In the event that public funding for FFAR diminishes, the Foundation would be severely limited in its ability to deliver on the ambition and scale of impact that Congress originally envisioned. In this scenario, FFAR's capacity to fund ambitious, potentially transformative research projects would be restricted. Indeed, stakeholders indicate that FFAR will find it much more challenging to bring partners to the table and mobilize private funding as its credibility and matching power will be weakened without the "halo effect" of its Congressional funding and mandate.[123]

FFAR's strategic plan also indicates that the foundation will increase the non-federal matching requirement for some projects, diversify its co-funders, develop an annual fundraising program,

[122] U.S. Congress, House Committee on Agriculture, *Agriculture Improvement Act of 2018*, conference report to accompany H.R. 2, 115th Cong., 2nd sess., December 10, 2018, H.Rept. 115-1072 (Washington: GPO, 2018), pp. 698-699.

[123] Foundation for Food and Agriculture Research, *Strategic and Sustainability Plan*, Washington, DC, 2019, pp. 8, 34, https://foundationfar.org/about-us/governance/strategic-plan/.

pursue fees for services, and expand the size and number of consortia as part of its sustainability plan.[124]

Effectiveness and Need

To date, the effectiveness of agency-affiliated nonprofit research foundations or corporations has not been formally assessed. In a 2002 report on the VA NPCs, GAO noted, "VA headquarters has not evaluated nonprofit corporations to measure their effectiveness or compare their operations. This type of high-level oversight and evaluation is a critical element of success." It is also unclear what might constitute an appropriate measure of success: number of partnerships formed? amount of private funds raised? number of technologies commercialized?

Some have argued—based on the amount of private funds raised—that the Reagan-Udall Foundation is not meeting expectations and is less successful than the CDC Foundation and FNIH.[125] The Reagan-Udall Foundation has raised approximately $21 million over the last decade for FDA. In comparison, FNIH provided NIH with that amount in a single year ($22 million in 2017). Lower than expected fundraising efforts have led some to question the purpose and need for the Reagan-Udall Foundation.[126]

It is difficult to determine the degree to which the partnerships developed and managed by some of the agency-affiliated nonprofit research foundations would have occurred in the absence of such foundations. Federal agencies engage in public-private partnerships through other mechanisms, including cooperative research and development agreements, and while federal agencies are not permitted to solicit gifts from the private sector, many are authorized to accept donations.

Report language in the Senate energy and water appropriations bill for FY2020 directs the Department of Energy (DOE) to contract with the National Academy of Public Administration for a study that would assess existing agency-affiliated nonprofit research foundations to assist Congress in evaluating the merits of creating a DOE-related nonprofit research foundation.[127] House appropriators included similar language in their version of the energy and water appropriations bill, but directed DOE to undertake the review on its own.[128]

Concluding Observations

Congress established each of the agency-related nonprofit research foundations and corporations described in this report with the aim of advancing the R&D mission of the associated federal agency. While the way each organization pursues its mandate varies, three broad categories of activity emerge: (1) soliciting private funds to support R&D performed by federal scientists; (2) soliciting private funds (leveraged against federal funds in the case of FFAR) to support R&D performed by non-federal researchers; and (3) administering and managing research funds from

[124] Ibid., p. 8.

[125] Ike Swetlitz, "Questions About Funding and Purpose Loom over a Foundation Congress Created to Help the FDA," STAT News, October 9, 2018, https://www.statnews.com/2018/10/09/reagan-udall-foundation-struggles/

[126] Ibid.

[127] U.S. Congress, Senate Committee on Appropriations, *Energy and Water Development Appropriations Bill, 2020*, report to accompany S. 2470, 116th Cong., 1st sess., September 12, 2019, S.Rept. 116-102 (Washington: GPO, 2019), pp. 71-72.

[128] U.S. Congress, Senate Committee on Appropriations, *Energy and Water Development and Related Agencies Appropriations Bill, 2020*, report to accompany H.R. 2960, 116th Cong., 1st sess., May 23, 2019, H.Rept. 116-83 (Washington: GPO, 2019), p. 117.

federal and non-federal sources. These activities are often carried out as part of public-private R&D partnerships formed and managed by an agency-related nonprofit research foundation or corporation. While public-private partnerships are generally viewed as an effective mechanism for advancing the state of science and facilitating the transfer and commercialization of technologies to the marketplace, some say it is less clear whether agency-related nonprofit research foundations and corporations represent an effective model for the formation and management of such partnerships. Federal science agencies already have the authority to create partnerships, and many have the authority to accept gifts from individuals, nonprofits, and private sector firms in support of federal R&D and other agency activities. Federal agencies, however, are not permitted to solicit private funds, and many argue that the "red tape" associated with the establishment of public-private partnerships by federal agencies is a deterrent.

This situation may cause some observers to raise the question—would a federal agency have achieved similar results in the absence of its agency-related nonprofit research foundation or corporation? While this question cannot be answered with any certainty, it does offer an opportunity for consideration of potential policy options. Among the options that Congress might consider are:

- crafting a broad, general nonprofit research foundation authority that federal science agencies could draw on to create an entity that meets their specific needs;
- examining the existing authorities of individual federal science agencies and, as appropriate, supplementing those authorities to increase the flexibility of an agency to enter into public-private partnerships;
- creating additional agency-related nonprofit research foundations on a case-by-case basis, tailored to the specific needs of particular federal science agencies; and
- maintaining the status quo, i.e., allowing agency-related nonprofit research foundations and corporations that currently exist to continue, and requiring other federal agencies to use their existing authorities to enter into public-private R&D partnerships and transfer federal technologies to the marketplace.

If Congress decides to create additional agency-related nonprofit research foundations, clear articulation of purpose, role, and governance structure may be needed to maintain an appropriate balance between the flexibility associated with being a nongovernmental entity and the need for accountability, transparency, and public confidence in the results of R&D partnerships and other supported activities.

Appendix. Federally Initiated and Funded Venture Capital Firms

Over the last two decades, federal agencies and Congress have established several venture capital (VC) firms. The intent of these firms, including In-Q-Tel (IQT), the Army Venture Capital Initiative (AVCI), and Red Planet Capital (RPC), has been to help ensure agency access to leading-edge technologies and input into technology development to address mission needs. Several factors have contributed to the initiation of these organizations: a long-term shift in the composition of U.S. research and development funding from the federal government to the private sector; the substantial role of small start-ups in driving innovation, especially in information technology; and expanded U.S. and global commercial market opportunities that have diminished the relative attractiveness of serving the federal government market.

In-Q-Tel. The Central Intelligence Agency (CIA), with congressional approval, established the first federal government-sponsored VC firm, In-Q-Tel, in 1999.[129] IQT is an independent, not-for-profit, non-stock company. It is a strategic investor that works closely with intelligence community (IC) entities and the Department of Defense (DOD). IQT's portfolio includes data analytics, cybersecurity, artificial intelligence, machine learning, ubiquitous computing, information technology solutions, communications, novel materials, electronics, commercial space, remote sensing, power and energy, and biotechnology.[130] While the CIA has broad statutory authority in how it may expend its funds,[131] according to a RAND Corporation report, the agency reportedly used an approach based on DOD's "other transaction" authority (10 U.S.C. 2371) for developing its contract with IQT.[132]

IQT has a management team and a board of trustees. The CIA is the executive agent for IQT.[133] Federal agencies, primarily the CIA, provide funding to IQT, which in turn provides investments to selected firms based on needs articulated by the CIA. The In-Q-Tel Interface Center (QIC), a small group of CIA employees, serves as a liaison between the CIA and IQT.

IQT investments generally range from $500,000 to $3 million. IQT asserts that for each dollar it has invested, private investors have provided $16. IQT pairs its investment with a development

[129] For additional information, see Business Executives for National Security, *The Report of the Independent Panel on the Central Intelligence Agency In-Q-Tel Venture*, June 2001.

[130] In-Q-Tel, "Insights and Access," https://www.iqt.org/insights-access/.

[131] Under 50 U.S.C. §3510, the CIA has the authority to expend appropriated funds for purposes necessary to carry out its functions, "notwithstanding any other provisions of law."

[132] Tim Webb, Christopher Guo, and Jennifer Lamping Lewis, et al., RAND Corporation, *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, prepared for the Office of the Secretary of Defense, 2014, p. 27. Under certain circumstances, DOD can enter into an other transaction (OT) agreement instead of a traditional contract. OT agreements are generally exempt from federal procurement laws and regulations. These exemptions grant government officials the flexibility to include, amend, or exclude contract clauses and requirements that are mandatory in traditional procurements (e.g., termination clauses, cost accounting standards, payments, audit requirements, intellectual property, and contract disputes). OT authorities also grant more flexibility to structure agreements in numerous ways, including joint ventures; partnerships; consortia; or multiple agencies joining together to fund an agreement encompassing multiple providers. For more information see, CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters.

[133] The White House, Office of the Director of National Intelligence, *U.S. National Intelligence: An Overview, 2013*, April 9, 2013, https://www.dni.gov/files/documents/USNI%202013%20Overview_web.pdf. According to the Government Accountability Office, an executive agent is a management arrangement where the head of a component is designated specific roles and responsibilities to accomplish objectives when more than one component is involved.

agreement in which IQT and the company work together to adapt the technology to meet IC needs. If successful, IC customers can buy the product directly from the company.[134] IQT asserts that its model delivers rapid, cost-effective solutions:

> IQT identifies and adapts "ready-soon" technologies—off-the-shelf products that can be modified, tested, and delivered for use within 6 to 36 months depending on the difficulty of the problem. Approximately 75% of our deals involve multiple agencies from the [IC] and defense communities, which means a more cost efficient use of taxpayers' dollars.[135]

Profits from the liquidation of an IQT investment are allocated between additional IQT investing activity and other strategic information technology initiatives defined by the CIA, in accordance with a memorandum of understanding between the CIA and IQT.[136]

Army Venture Capital Initiative. In January 2002, Congress directed the Secretary of the Army to establish a venture capital investment corporation using $25 million previously appropriated to the Army for basic and applied research.[137] The Army and Arsenal Venture Capital (formerly Military Commercial Technologies, Inc. (MILCOM)) jointly manage the AVCI through OnPoint Technologies, LLC (OPT), a not-for-profit corporation.[138] In this relationship, the Army serves as strategic investor; provides guidance on technology priorities to OPT through its Communications Electronics Command (CECOM); and, through CECOM, provides administrative and contractual support to OPT. Army funds provided to OPT support investments and OPT expenses. Proceeds from the liquidation of investments are used in part to pay compensation to Arsenal Venture Capital with the balance used for new investments.[139] In addition to providing $25 million in FY2002, Congress appropriated $12.6 million in FY2003 and $14.3 million in FY2005 for the AVCI. In addition, in FY2004, the Army reprogrammed $10 million for the AVCI.[140] Since FY2005, Congress has not appropriated funds to the AVCI.

AVCI invests alongside other VC firms at all stages of development, making investments of $500,000 to $2 million. AVCI asserts that for each dollar it has invested, private investors have provided $22.[141] Focused initially on innovative power and energy technologies, AVCI's technology focus areas have expanded to include emerging technologies such as autonomy, cyber,

[134] In-Q-Tel, "How We Work—Startups," https://www.iqt.org/how-we-work/startups/.

[135] In-Q-Tel, "How We Work—National Security," https://www.iqt.org/how-we-work/national-security/.

[136] Tim Webb, Christopher Guo, and Jennifer Lamping Lewis, et al., RAND Corporation, *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, prepared for the Office of the Secretary of Defense, 2014, p.28.

[137] Section 8150 of the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act, 2002 (P.L. 107-117). Funding was to be derived by making pro rata reductions from FY2002 Army RDT&E funds for basic and applied research, except for amounts for research projects designated as congressional special interest items and Army RDT&E related to the Future Combat System.

[138] Dr. John A. Parmentola and Dr. Robert S. Rohde, "Army Venture Capital Initiative," *Army AL&T Magazine*, November-December 2003, pp. 28-29, 43, https://asc.army.mil/docs/pubs/alt/2003/6_NovDec/articles/28_Army_Venture_Capital_Initiative_200306.pdf; and Tim Webb, Christopher Guo, and Jennifer Lamping Lewis, et al., RAND Corporation, *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, prepared for the Office of the Secretary of Defense, 2014, p. 17.

[139] Tim Webb, Christopher Guo, and Jennifer Lamping Lewis, et al., RAND Corporation, *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, prepared for the Office of the Secretary of Defense, 2014, p. 24.

[140] Army, DOD Investment Budget Search, "End Item Industrial Preparedness Activities," PE 0708045A, FY2004, FY2005, FY2006, FY2007.

[141] Army Venture Capital Corporation, "Army Venture Capital Corporation," https://armyvci.org/.

health information systems, and advanced materials.[142] AVCI seeks to foster the development of these technologies and their transfer to the soldier while attaining net returns for the investing organizations from commercial and defense markets.[143] AVCI asserts that it is able to engage technology firms outside the traditional reach of DOD.

Red Planet Capital. In September 2006, the National Aeronautics and Space Administration (NASA) announced a partnership with Red Planet Capital, Inc., a non-profit organization, to establish a venture capital fund, Red Planet Capital (RPC). The fund was "to support innovative, dual-use technologies [to] help NASA achieve its mission, [and] better position these technologies for future commercial use."[144]

NASA was to provide strategic direction and technical input to RPC, while the organization's principals were to identify investment opportunities, perform due diligence, and manage its equity investments. NASA intended to invest approximately $75 million over five years. Congress provided $6 million for RPC in FY2007. In FY2008, President George W. Bush proposed termination of the program:

> Government-sponsored venture capital funds provide a mechanism for Government agencies to indirectly take equity stakes in private firms, which potentially creates significant conflicts of interest and market distortions. The Administration believes that this mechanism poses difficult challenges to Government oversight and should only be used in exceptional situations…. The Administration further evaluated the fund and determined that, for NASA, these funds are better directed towards current priorities that will produce cost-effective, ascertainable outcomes.[145]

Congress provided no further appropriations for RPC. According to NASA, the fund was eliminated before it took an equity stake in any company.[146] A RAND Corporation study states that RPC made a single investment prior to its termination, though it did not specify the amount.[147]

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[142] Army Venture Capital Corporation, "Investment Focus," https://armyvci.org/.

[143] John A. Parmentola and Robert S. Rohde, "Army Venture Capital Initiative," *Army AL&T* (a publication of the Assistant Secretary of the Army for Acquisition, Logistics and Technology), November-December 2003, pp. 28-29, 43.

[144] NASA, *Request for Information – Venture Capital Project*, Solicitation Number: NNH0622806L, February 6, 2006, http://www.spaceref.com/news/viewsr.html?pid=19532.

[145] Office of Management and Budget, *Major Savings and Reforms in the President's 2008 Budget, Budget of the United States Government, Fiscal Year 2008*, p. 73, February 2007.

[146] Email correspondence between NASA and CRS, October 21, 2016.

[147] Tim Webb, Christopher Guo, and Jennifer Lamping Lewis, et al., RAND Corporation, *Venture Capital and Strategic Investment for Developing Government Mission Capabilities*, prepared for the Office of the Secretary of Defense, 2014, p. 18.