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Chair
Ranking Member
Committee on Small Business and Entrepreneurship
United States Senate
The Honorable Nydia Velázquez
Chairwoman
The Honorable Blaine Luetkemeyer
Ranking Member
Committee on Small Business
House of Representatives

Small Business Innovation Research: Three Agencies Made Awards to Businesses Majority-Owned by Investment Companies and Funds

As the United States competes in a global economy, the nation depends on innovation through research and development (R&D). The Small Business Innovation Research (SBIR) program was established to enable federal agencies to support R&D projects carried out by small businesses. Participating agencies are required to spend a certain percentage of their extramural R&D obligations on their SBIR program each year.¹ Eleven federal agencies participate in the SBIR program.²

To qualify for SBIR awards, a small business must meet certain ownership and other eligibility criteria. The Small Business Act, as amended, authorizes agencies to allow participation in their SBIR programs by small businesses that are more than 50 percent owned by multiple venture capital operating companies, hedge funds, or private equity firms, under 15 U.S.C. § 638(dd) (we refer to such small businesses eligible under this section as “qualified small businesses” in this report).³ According to the eligibility requirements in the Small Business Administration’s (SBA) policy directive for the SBIR program, a small business can be more than 50 percent

¹Agencies’ R&D efforts generally include funding for two types of R&D: intramural and extramural. Intramural R&D is conducted by employees of a federal agency in or through government-owned, government-operated facilities. Extramural R&D is generally conducted by nonfederal employees outside of federal facilities.

²These 11 agencies are: the Departments of Agriculture (USDA), Commerce, Defense (DOD), Education, Energy (DOE), Health and Human Services (HHS), Homeland Security (DHS), and Transportation; the Environmental Protection Agency (EPA); the National Aeronautics and Space Administration (NASA); and the National Science Foundation (NSF).

³SBIR/STTR Reauthorization Act of 2011 (Reauthorization Act), Pub. L. No. 112-81, div. E, § 5107(a), 125 Stat. 1822, 1827 (codified as amended at 15 U.S.C. § 638(dd)) (referred to in this report as Section 638(dd) authority). For the purposes of this report, a “qualified small business” refers to small business concerns, as that term is defined in 15 U.S.C. § 632(a), that are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms (consistent with the definition of those terms at 15 U.S.C. § 632(aa)-(cc)), that are eligible for SBIR awards under 15 U.S.C. § 638(dd). Venture capital companies often invest in businesses that are developing a new product or technology. Generally, hedge funds and private equity firms are entities that can invest in small businesses and are privately organized and available only to institutional investors or wealthy individuals. For

owned by multiple domestic investment companies and funds to be eligible as a qualified small business, but cannot be more than 50 percent owned by a single such entity. Upon providing a written determination to the Administrator of the SBA—the agency that oversees the SBIR program—and specified congressional committees, agencies may make SBIR awards to such qualified small businesses.⁴ A 2009 study by the National Academies of Sciences, Engineering, and Medicine (National Academies) found that such awards may open up the SBIR program to more commercially promising innovative small firms, which relates to one of the four key goals of SBIR—the commercialization of federal research.⁵

The Small Business Act, as amended, includes a provision for GAO to conduct a study of the impact of requirements relating to the involvement of investment companies and funds in the SBIR program and submit a report to Congress regarding the study every 3 years.⁶ Our first review covered fiscal years 2013 and 2014, and in December 2018, we issued our second report on this issue, for fiscal years 2015 through 2018.⁷ This third report addresses (1) SBIR participating agencies' awards to qualified small businesses in fiscal years 2019 and 2020 and (2) reasons participating agencies cited for allowing or not allowing the participation of qualified small businesses in the SBIR program.

To examine SBIR participating agencies' awards to qualified small businesses in fiscal years 2019 and 2020, we obtained data on the number and dollar amount of awards to qualified small businesses from SBIR participating agencies that had submitted a written determination to the SBA and congressional committees on their use of Section 638(dd) authority. We assessed the reliability of the data by examining a sample of source documents, interviewing officials knowledgeable about the data, reviewing prior assessments of the reliability of SBIR data, and clarifying any discrepancies with agency officials. We found the data to be sufficiently reliable for the purpose of providing information on the number and dollar amount of SBIR awards to qualified small businesses. We also reviewed guidance for using the program included in the SBA policy directive for the SBIR program.⁸

To examine the reasons cited by all participating agencies for allowing or not allowing the participation of qualified small businesses in the SBIR program, we used a standardized set of questions to interview or obtain written answers from program managers from the 11 agencies that participate in the SBIR program to obtain their perspectives on their use of Section 638(dd) authority. Specifically, we obtained information on whether agencies allowed the participation of qualified small businesses in the SBIR program and the reasons agencies had for their decision.

purposes of this report, we refer to venture capital operating companies, hedge funds, and private equity firms that invest in small businesses as "investment companies and funds."

⁴15 U.S.C. § 638(dd)(1). The written determination is to be provided not later than 30 days before the date on which such an award is made.

⁵National Research Council of the National Academies, *Venture Funding and the NIH SBIR Program*, (Washington, D.C.; National Academies Press, 2009).

⁶15 U.S.C. § 638a. In accordance with the statute, we submitted a draft report containing the results of our study to Congress on December 18, 2020.

⁷GAO, *Small Business Innovation Research: Change in Program Eligibility Has Had Little Impact*, [GAO-15-68](#) (Washington, D.C.: Nov. 20, 2014) and *Small Business Innovation Research: Few Agencies Made Awards to Small Businesses Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Funds, or Private Equity Firms*, [GAO-19-205R](#) (Washington, D.C.: Dec. 21, 2018).

⁸Small Business Administration, *SBIR/STTR Policy Directive*, (May 2, 2019). The SBA issued an updated policy directive that went into effect on October 1, 2020, for fiscal year 2021 and does not pertain to the fiscal years covered by our report.

We conducted this performance audit from May 2020 to January 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

To qualify for SBIR awards, a small business must meet certain SBIR ownership and other eligibility criteria, such as having, together with its affiliates, not more than 500 employees. Over the SBIR program's first two decades, some businesses that were owned by investment companies and funds participated in the SBIR program without any apparent adverse consequence for the program's operation and achievements, according to a study by the National Academies.⁹ However, in 2003, an SBA administrative law judge held that venture capital operating companies could not be considered "individuals" for the purpose of satisfying the ownership criteria for the SBIR program, so businesses that were majority-owned by such companies were therefore ineligible to receive SBIR awards.¹⁰ Under current regulations, small businesses are required to be more than 50 percent directly owned and controlled by one or more individuals who are U.S. citizens or permanent resident aliens.¹¹

Later, Congress considered whether to revise these ownership requirements and, in 2011, the Reauthorization Act authorized agencies to make SBIR awards to businesses with majority ownership by multiple investment companies and funds.¹² Awards to such small businesses cannot exceed 25 percent of the funds allocated for the SBIR programs of the Department of Energy (DOE), National Science Foundation (NSF), or the National Institutes of Health (NIH) within the Department of Health and Human Services (HHS).¹³ All other agencies participating in the SBIR program may not award more than 15 percent of the funds allocated for their SBIR programs to such small businesses.¹⁴

Agencies that choose to open up their SBIR program under this provision must submit a written determination to the SBA and Congress. The written determination is to explain how using the authority to allow participation by qualified small businesses in the SBIR program will, among other things, induce additional venture capital, hedge fund, or private equity firm funding of small business innovations; substantially contribute to the mission of the federal agency; and otherwise fulfill the capital needs of small businesses for additional financing for SBIR projects.¹⁵

⁹National Research Council of the National Academies, *Venture Funding and the NIH SBIR Program*.

¹⁰Size Appeal of Cognetix, Inc., SBA No. SIZ-4560 (2003).

¹¹See 13 C.F.R. § 121.702(a)(1). A small business could also be eligible if it was more than 50 percent owned and controlled by another business that was itself more than 50 percent owned and controlled by individuals who are U.S. citizens or permanent resident aliens, among limited others, or it was a joint venture in which each entity in the venture met either of the percentage requirements.

¹²Pub. L. No. 112-81, § 5107, 125 Stat. 1822, 1827 (2011). Five of the SBIR agencies—DOD, DOE, HHS, NASA, and NSF—also participate in the Small Business Technology Transfer (STTR) program, but the investment companies and funds provision does not apply to the STTR program.

¹³15 U.S.C. § 638(dd)(1)(A).

¹⁴15 U.S.C. § 638(dd)(1)(B).

¹⁵15 U.S.C. § 638(dd)(2).

Each year, small businesses may apply for SBIR awards from a participating agency to develop and commercialize innovative technologies. Each agency that participates in the SBIR program administers its program consistent with requirements established in law, solicits proposals for projects in topic areas determined by the agency (and subject to change over time), and reviews proposals to determine which ones should receive awards from its SBIR program. Agencies issue phase I awards to determine the scientific and technical merit and feasibility of ideas that appear to have commercial potential and phase II awards to allow small businesses with phase I projects that demonstrate scientific and technical merit and feasibility, in addition to commercial potential, to continue the R&D project for an additional period.¹⁶ As of November 2019, agencies may issue a phase I award (including modifications) up to \$256,580 and a phase II award (including modifications) up to \$1,710,531 without seeking approval from the SBA.

The SBA is responsible for surveying and monitoring the operation of participating agencies' SBIR programs, issuing policy directives, establishing and maintaining electronic databases of program data, and reporting to Congress, among other things. According to the SBIR program policy directive, the SBA maintains a system that records SBIR award information using data submitted by the agencies and small business applicants. For example, a small business that is qualified to participate in SBIR under Section 638(dd) authority is to register with the SBA on the date that the small business submits an application for a SBIR award and indicate in any SBIR proposal that the small business is registered as majority-owned by investment companies and funds.¹⁷ Additionally, all small businesses must submit a certification at the time of the SBIR award and at any other time set forth in the funding agreement, in which the applicant states that it meets size, ownership, and other requirements.¹⁸

In November 2014, we found that the change to allow agencies to make awards to qualified small businesses under Section 638(dd) authority had little impact on the program in fiscal years 2013 and 2014, with three agencies—DOE, NIH, and the Centers for Disease Control and Prevention (CDC)—opening up their SBIR programs to qualified small businesses.¹⁹

Furthermore, we found that the SBA could have been missing an opportunity to help agencies better understand the evidence required for the written determination to use the new authority. We recommended that the SBA discuss the evidence required for the written determination with participating agencies and, if needed, amend the SBIR policy directive to provide additional guidance. The SBA addressed our recommendation in January 2015 by discussing our findings and the written determination requirement with SBIR program managers, which provided an opportunity for the program managers to clarify the evidence required for the written determination. In December 2018, we found that three agencies—DOE's Advanced Research Projects Agency-Energy (ARPA-E), NIH, and the Department of Education—had made awards to qualified small businesses during the period of our review; the other eight agencies in the SBIR program chose not to make awards to qualified small businesses.²⁰

¹⁶The SBA SBIR policy directive also outlines the ability for agencies to supplement or extend phase II awards. Each such supplemental award must be linked to a base phase II award.

¹⁷15 U.S.C. § 638(dd)(3).

¹⁸Small Business Administration, *SBIR/STTR Policy Directive*, (May 2, 2019).

¹⁹[GAO-15-68](#).

²⁰[GAO-19-205R](#).

Four Agencies Received Proposals from Qualified Small Businesses and Three Made Awards

Four agencies participating in the SBIR program received proposals from qualified small businesses in response to solicitations for such proposals, and three of the four made awards to such small businesses in either fiscal year 2019, 2020, or both.²¹ Specifically, NIH, the Navy, and the Department of Education made a combined 45 awards worth \$31.6 million to qualified small businesses during this period. DOE’s ARPA-E received one proposal but made no awards. Table 1 shows the number of such awards made by each agency from fiscal years 2015 through 2020.²²

Table 1: SBIR Awards and Total Dollar Amounts to Qualified Small Businesses, Fiscal Years (FY) 2015 through 2020
Amounts in dollars

Agency	Award Phase	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Department of Energy, Advanced Research Projects Agency-Energy	Supplemental phase II ^a	1 award, 250,000	—	—	—	—	—
	I ^b	—	—	—	1 award, 200,000	—	—
Department of Education	II ^c	—	—	—	—	1 award, 899,072	—
	I ^b	7 awards, 1,760,000	8 awards, 1,916,805	14 awards, 2,995,049	8 awards, 1,640,000	9 awards, 2,280,340	11 awards, 8,090,876
Department of Health and Human Services, National Institutes of Health	II ^c	1 award, 698,000	5 awards, 4,207,924	13 awards, 10,698,865	4 awards, 3,410,000	6 awards, 6,845,780	5 awards, 4,390,401
	Supplemental phase II ^a	—	3 awards, 2,964,821	5 awards, 3,090,561	16 awards, 9,790,000	6 awards, 3,353,104	6 awards, 5,625,635
	I ^b	—	—	—	—	—	1 award, 149,900

Legend: — = no awards made

Source: GAO analysis of agency data. | GAO-21-223R

Note: “Qualified small businesses” are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms that are eligible for Small Business Innovation Research (SBIR) awards under 15 U.S.C. § 638(dd).

^aThe Small Business Administration (SBA) SBIR policy directive permits agencies to offer special SBIR awards that supplement or extend phase II awards. Each such supplemental award must be linked to a base phase II award.

^bAgencies issue phase I awards to determine the scientific and technical merit and feasibility of ideas that appear to have commercial potential.

^cAgencies issue phase II awards to allow small businesses with phase I projects that demonstrate scientific and technical merit and feasibility, in addition to commercial potential, to continue the research and development project for an additional period.

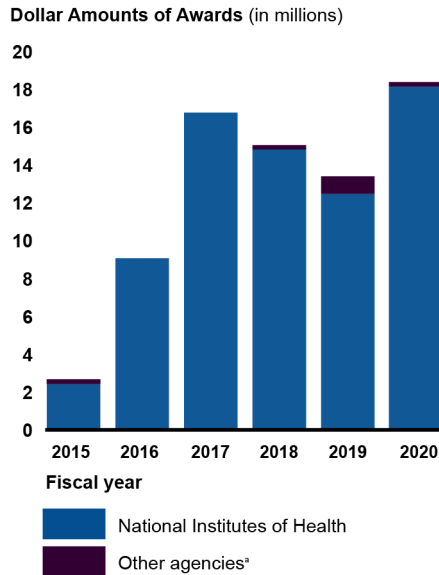
Agencies’ use of Section 638(dd) authority is varied and only NIH uses it with regularity. NIH made the most awards and awarded the most funds to qualified small businesses in every year from fiscal year 2015 through fiscal year 2020. NIH made 20 phase I awards and 11 phase II awards in fiscal years 2019 and 2020 (the 2 fiscal years we focused on in this review), as well as 12 supplemental phase II awards. In fiscal year 2019, it awarded over \$12 million (or just over 1 percent of NIH’s \$988 million in fiscal year 2019 SBIR awards), and in fiscal year 2020, it

²¹According to HHS, the CDC submitted a written determination to the SBA in 2014. In fiscal years 2019 and 2020, the agency did not receive SBIR proposals from, and therefore did not make awards to, qualified small businesses.

²²As we reported in [GAO-19-205R](#), the Defense Advanced Research Projects Agency submitted a written determination to allow awards to qualified small businesses for a single solicitation in fiscal year 2016, but the agency did not make any awards using Section 638(dd) authority.

awarded over \$18 million. Figure 1 shows the trend in NIH awards to qualified small businesses over the past five fiscal years compared to other participating agencies.

Figure 1: Value of SBIR Awards to Qualified Small Businesses, Fiscal Years 2015 through 2020



Source: GAO analysis of agency data. | GAO-21-223R

Data table for Figure 1: Value of SBIR Awards to Qualified Small Businesses, Fiscal Years 2015 through 2020

Year	Agency	HHS NIH*
FY 2015	244,200	250,000
FY 2016	909,000	0
FY 2017	1,678,400	0
FY 2018	1,484,000	200,000
FY 2019	1,247,900	899,000
FY 2020	1,810,700	15,000

* "Qualified small businesses" are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms that are eligible for the Small Business Innovation Research (SBIR) program under 15 U.S.C. § 638(dd).

† Other agencies include the Department of the Navy, the Department of Education, and the Advanced Research Projects Agency – Energy.

According to its written determination in March 2013, one reason that NIH decided to allow qualified small businesses to participate in its program is that it would increase the chances of promising technologies reaching the marketplace. The determination states that very few small businesses are capable of commercializing their technologies without private investment funding because of the significant cost needed to take a biomedical product from idea to market. It further states that small businesses that have been able to attract early funding from investment companies and funds are more likely to succeed in bringing breakthrough public

health discoveries to the public. In fiscal years 2019 and 2020, NIH made SBIR awards to qualified small businesses for projects that included a therapy to cure insulin-dependent diabetes, an anti-malarial drug project, an endometriosis diagnostic tool, and message-based psychotherapy and digital treatment sequences for depression. Additionally, in fiscal year 2020, NIH provided supplemental funds under an existing award for emergency response to the Coronavirus Disease 2019 (COVID-19) pandemic. The original award was for a vaccine development platform for other viruses, such as influenza and respiratory syncytial virus, and the awardee believes it can apply the same platform towards vaccine development for SARS-CoV-2, the virus that causes COVID-19.

Within DOD, the Department of the Navy used Section 638(dd) authority for the first time in fiscal year 2020. In May 2020, the Navy submitted a written determination to the SBA and Navy officials said it was also sent to the required congressional committees. The determination stated that the Navy wanted to better leverage private sector resources in technology sectors important to the National Defense Strategy. Navy officials further told us that broadening participation in the SBIR program to a wider universe of small businesses would help the Navy to develop and deploy the strongest innovations in support of its mission. The Navy opened up its fiscal year 2020 SBIR solicitations to qualified small businesses and received four proposals from such companies. The Navy made one award under this provision – a phase I award for \$149,900 for a project to allow the Navy to combine and make better use of medical supply chain and patient care data.

In fiscal year 2019, the Department of Education's Institute of Education Sciences issued one phase II award under Section 638(dd) authority; the recipient company received a phase I award for this project in fiscal year 2018. This SBIR project involves a mobile game app for grade school students to learn foundational coding skills through creative expression. During phase I testing, the prototype functioned as planned, so the awardee intended to expand the app in phase II, according to agency documentation. The Department of Education's August 2018 written determination for using Section 638(dd) authority states that the department decided to allow qualified small businesses to participate in the Institute for Education Sciences' SBIR program after receiving inquiries from such small businesses in 2017. According to the written determination, the department found that products by qualified small businesses appear to be used in schools frequently and that access to more venture capital allows the businesses to develop scalable technologies and market them effectively. Further, according to the department's written determination, allowing SBIR awards to qualified small businesses would fill a potential gap in private sector investment in the development of new products and in research, development, and evaluation.

ARPA-E had a SBIR solicitation open to qualified small businesses, as well as other small businesses, under Section 638(dd) authority and received one proposal from a qualified small business; however, it did not issue any awards using this authority during fiscal year 2019 or 2020. Officials from ARPA-E stated that in the agency's merit review process, the proposal from the qualified small business for this solicitation did not rank high enough among the SBIR applications to receive an award recommendation. ARPA-E officials told us that their solicitations are open to qualified small businesses because they are interested in ideas and technology regardless of the source. In its written determination, ARPA-E stated that its rationale for using Section 638(dd) authority is that as overall venture capital investment in the energy sector has declined, small businesses have had to seek funding from multiple sources. ARPA-E officials stated that, as a result, it is likely that an increasing number of potential ARPA-E SBIR applicants will be majority-owned by multiple investment companies and funds.

Agencies' Decisions on Allowing Qualified Small Businesses Depended on Various Reasons

Since the enactment of Section 638(dd) authority in 2011, participating SBIR agencies have considered whether to use the authority to allow qualified small businesses to participate in the SBIR program. In our December 2018 report, we described several reasons that participating agencies did not use the authority. For example, agencies did not know the level of interest from such businesses or believed the level was low, agencies believed that such companies did not need SBIR funds, the SBIR program focuses on early-stage research, and there was limited funding available for SBIR awards in general.²³ In our current review, we found that each of these reasons still holds true for at least one, if not multiple, SBIR participating agencies. For example, officials at NASA and DHS said that qualified small businesses have not expressed much interest in their SBIR programs. Additionally, the Department of Transportation noted that it has limited funds available for SBIR awards overall and is concerned about an increase in proposals with its limited resources for the program.

In contrast, in 2020, the Air Force considered whether to include qualified small businesses in its SBIR program and decided it will open up its SBIR solicitations to qualified small businesses within the next year, once the Air Force submits its written determination. Air Force program officials said they found that providing SBIR funding to such qualified small businesses would expand the Air Force's investment in cutting-edge technologies with both commercial and military uses. They further noted a cultural change in the military departments geared toward increased funding for private-sector technology development. Finally, Air Force officials cited the Navy's successful use of the provision, with its first SBIR award to a qualified small business in fiscal year 2020, as a driver in the Air Force's plan to use Section 638(dd) authority. In addition to the Navy and the Air Force, Army SBIR officials stated that they are interested in using Section 638(dd) authority and will be exploring their options toward this end in the near future.

As discussed above, the agencies that have decided to allow qualified small businesses to participate in their SBIR program—NIH, ARPA-E, the Navy, and the Department of Education—do so for a variety of reasons: they believe that it helps deploy the strongest innovations, fills potential gaps in private sector investment, or are interested in ideas regardless of the source. According to NIH—the agency that has made the majority of awards to qualified small businesses—the agency has continued to use Section 638(dd) authority in its SBIR program since submitting a determination to the SBA and the requisite congressional committees in March 2013. NIH officials stated that for all NIH awards with multiple budget periods, including awards to qualified small businesses, the agency continues funding for subsequent years only if the recipient shows satisfactory progress towards the stated aims of the award. They also noted that, in addition to being subject to standard NIH progress reporting requirements, SBIR recipients provide information on specific project impacts, such as technology transfer and commercialization activities. NIH provided us with examples of several successful projects using Section 638(dd) authority. For example, a pharmaceutical company is developing a long-release capsule for medication. According to a NIH press release, the company is using SBIR awards to apply the technology to medications for HIV, organ transplants, and malaria.

Agency Comments

We provided a draft of this report for review and comment to the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, and Transportation; the Small Business Administration; the Environmental Protection Agency; the

²³[GAO-19-205R](#).

National Aeronautics and Space Administration; and the National Science Foundation. The Department of Health and Human Services provided technical comments, which we incorporated as appropriate.

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We are sending copies of this report to the appropriate congressional committees; the Secretaries of Defense and Homeland Security; the Acting Secretaries of Agriculture, Commerce, Education, Energy, Health and Human Services, and Transportation; the Acting Administrators of the Small Business Administration, Environmental Protection Agency, and National Aeronautics and Space Administration; the Director of the National Science Foundation; and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-6888 or WrightC@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report include Joseph Cook (Assistant Director), Bethann E. Ritter Snyder (Analyst in Charge), Rodney Bacigalupo, Jenny Chanley, Jehan Chase, Ben Shouse, Nathan Steele, and Edith Yuh.



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