

# FOSTERING DIVERSITY AND INCLUSION IN THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE'S SMALL BUSINESS PROGRAM

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The National Heart, Lung, and Blood Institute has developed a strategic approach to fostering diversity and inclusion within its community of small business innovators. The approach is focused on three central goals: 1) Increase awareness of NHLBI's support for small businesses among underrepresented groups through focused outreach; 2) Identify and eliminate barriers to entry into small business funding programs and entrepreneurial activities for minority and female applicants through specific, targeted training and support; and 3) Expand diversity and inclusivity within our networks by providing additional support for NHLBI-funded small businesses to hire members of underrepresented groups. Key partnerships with biomedical accelerators in underserved regions will be leveraged to maximize impact and achieve all three goals. This article describes the historical context and current state of policies in this arena; it also provides details about mechanisms and approaches used to achieve the goals. *Ethn Dis.* 2019;29(Suppl 1):71-76; doi:10.18865/ed.29.S1.71.

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## THE CASE FOR DIVERSITY IN TRANSLATIONAL RESEARCH AND MEDICINE

*"Give a man a fish and you feed him for a day. Teach him how to fish and you feed him for a lifetime"*  
*Lao Tzu, founder of Taoism*

As part of this special issue of *Ethnicity & Disease*, the National Heart, Lung, and Blood Institute (NHLBI) seeks to highlight our focus on the inclusion of disparity populations into the translational research enterprise. In the same way that noted Jewish physician Bernard Sachs led the way in understanding Tay-Sachs,<sup>1</sup> the disease that afflicted his community and now bears his name, we anticipate that groups traditionally underrepresented in biomedical research and development will bring forth innovative solutions to health problems that disproportionately affect them. In essence, what follows is a description of our efforts to "teach fishing" to those most in need of fish.

In accordance with the growing focus on the importance of diversity and inclusion as part of our national social contract, in 2015 the National Institutes of Health

(NIH) published a Notice of Interest in Diversity which reads in part:

"Every facet of the United States scientific research enterprise... (requires) superior intellect, creativity and a wide range of skill sets and viewpoints... There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the researchers, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust."<sup>2</sup>

This notice serves as a clarion call to cultivate a diversity of talent across the entire research enterprise in order to maintain America's position as the global leader in scientific discovery and innovation. In particular, the statement acknowledges that the benefits of health research related to populations experiencing health disparities is enhanced by their engagement as active contributors to the research enterprise.

The value of ethnic and gender diversity has similarly been recognized across all sectors of the American economy. In their landmark 2015 study, *Diversity Matters*, McKinsey and Company documented the connection between diversity and superior corporate performance in 366 companies.<sup>3</sup> In their latest update to that work, *Delivering Through Diversity*, McKinsey expanded their dataset to more than 1,000 companies in 12 countries.<sup>4</sup> The most gender diverse companies were 21% more

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likely to outperform their peers in terms of profitability, and were 27% more likely to have superior value creation. Further, culturally diverse executive teams were 33% more likely to have industry leading profitability, while companies in the bottom quartile for gender and ethnic diversity were 29% less likely to achieve superior results than their peers.

Other researchers, examining diversity specifically within research teams rather than business or industry leadership, found that gender diversity within R&D teams fosters novel solutions that lead to radical innovation.<sup>5</sup> These findings have significant implications in the context of the NIH Small Business Program, which supports the development of disruptive solutions to the age-old problems of human suffering, disease, and debilitation, by translating scientific innovations into medical tools, devices and therapeutics to improve public health. In order to advance the likelihood that populations experiencing health disparities benefit from health research, it is imperative that we expand their inclusion and participation in our small business innovation community.

## **HISTORY OF THE SMALL BUSINESS PROGRAM**

In July 1982, the 97<sup>th</sup> Congress of the United States enacted the Small Business Innovation Development Act (P.L. 97-219) with the stated purpose: “to strengthen the role of the small, innovative firms in federally funded research and development (and) to contribute to the growth and strength of the nation’s economy.”<sup>6</sup>

The initial authorization specifically identified the need to “foster and encourage participation by socially and economically disadvantaged small businesses in technological innovation”<sup>6</sup> as one of the four core purposes of the program. Later reauthorizations expanded the concept to include women-owned small businesses.

The Small Business Innovation Research (SBIR) program requires government agencies to support domestic small business research and development that has a strong potential for commercialization by funding competitive grants and research contracts. The Small Business Technology Transfer (STTR) program was added in 1992 to support small business research collaborations with nonprofit research institutions (such as universities). The laws have resulted in creating approximately 700 public companies, 70,000 patents, and an estimated \$41 billion in venture capital investment, profoundly impacting our economy.<sup>7</sup> In fiscal year 2017, the National Institutes of Health (NIH) provided \$23.8 billion in biomedical research funding, of which \$923 million were allocated to support the SBIR and STTR programs.<sup>8</sup> The National Heart, Lung, and Blood Institute (NHLBI) in turn provided \$73 million in SBIR and STTR funding as part of its FY2017 budget.<sup>9</sup>

We refer here to the SBIR and STTR programs collectively as the Small Business Program. Successful projects funded by NHLBI’s Small Business Program include: the production of clinical-grade human platelets from pluripotent stem cells, and a hyper-polarized gas MRI to quantify functional ventilatory changes of patients with COPD otherwise undetectable by CT scan. While these innovations have a broader public health impact, other funded projects (eg, a synthetic antibody that relieves sickle cell pain), specifically target conditions that disproportionately affect populations affected by health disparities.

## THE LEGISLATIVE AND POLICY MANDATE

The Small Business Administration (SBA), within the Department of Commerce, is the federal agency charged with policy implementation and oversight of the Small Business Program across the government. Through annual reports to Congress, the SBA is required to provide information on efforts to increase outreach to small businesses owned or controlled by women and socially or economically disadvantaged individuals. Thus, all participating agencies are required to conduct outreach efforts to increase diversity within the Small Business Program.

Historically, the NIH has attempted to tackle the thorny issues surrounding women and minority participation with marginal success. Assessments of the NIH Small Business Program conducted by the National Research Council (NRC) in 2009 and in 2015 came to similar conclusions: “Current outcomes data show that the objective of fostering the participation of women and underserved minorities has not been met by the NIH SBIR/STTR programs and efforts to foster their participation are inadequate.”<sup>10</sup>

The National Defense Act of 2011 reauthorized the Small Business Program and perpetuated its core goals, but with some key changes based on the recommendations of the NRC reports. One of these changes allowed federal agencies to use a small percentage of the Small Business Program funding to support administrative activities to improve the program, such as the

implementation of the Small Business Program diversity and inclusion strategic framework described below.

## WOMEN AND MINORITY PARTICIPATION

The effort to increase the number of applications and awards from/to small businesses owned by women and other socially and economically disadvantaged groups to the Small Business Program is challenged by the need for applicants to self-identify as a member of these groups on their application form. An internal analysis of applications received between 2007 and 2013 was conducted to better understand the problems of underreporting and inconsistent self-identification by companies. The study found that 11.5% of applications came from companies that did not consistently self-identify in one or more categories when applying across multiple receipt dates, or within the same receipt dates when applying to different institutes.<sup>11</sup> It is also possible that a significant number of applications come from women-owned and socially and economically disadvantaged small businesses that never self-identify as such, and would therefore be invisible to such analysis. Consequently, the number of applications from women-owned and socially and economically disadvantaged small businesses appears to be underestimated, which complicates our ability to accurately quantify the participation of these groups in the program. The NIH is investigating ways to improve and encourage self-reporting in collaboration with other

federal agencies and interest groups.

The percentage of funded awards for women and socially and economically disadvantaged applicants (ie, the percentage of awards/applications) ranges between 9%-14% for both groups over the four-year period from 2014 to 2017. As a percentage of overall awards, women-owned businesses hold between 8%-10% of the awards while socially and economically disadvantaged businesses hold between 2%-3% of the awards.<sup>12</sup> The small number of applications and awards for these groups results in significant year-to-year variability, but there is a recognition that each group requires strategies and interventions that are separate and distinct, and that they cannot simply be lumped together under the rubric of “women and minorities.”

## THE DIVERSITY AND INCLUSION STRATEGIC FRAMEWORK

In response to the congressional mandate and social imperative to increase the numbers of underrepresented populations participating in the Small Business Program, NHLBI has developed a strategic approach to fostering diversity and inclusion focused on three key objectives: 1) Increase awareness of the benefits and opportunities of the Small Business Program within communities of minority and women scientists and entrepreneurs. 2) Identify the barriers to entry, real or perceived, for minority and women applicants and eliminate those barriers by providing guided instruction and mentor-

ing to encourage more applications and increase their chances of receiving funding. 3) Expand diversity and inclusion within our existing portfolio of funded companies by providing additional support for the hiring of under-represented persons.

We leverage partnerships with life science incubators and accelerators in underserved regions to maximize the impact of all initiatives related to the following objectives.

### **Objective 1: Increase Awareness of NHLBI's Small Business Program among Underrepresented Groups**

The goal to encourage participation by women and people from socially and economically disadvantaged groups in innovation and entrepreneurship is part of the broader NHLBI Enduring Principle to train and nurture a diverse new generation of leaders for the biomedical workforce.<sup>13</sup> Two initiatives are noteworthy in this respect: Concept to Clinic and Innovation Corps. The Concept to Clinic: Commercializing Innovation Program (C3i) is a 24-week entrepreneurial training course based on an approach developed by the Wallace H. Coulter Foundation, which is designed to provide researchers with the specialized business tools to successfully translate biomedical device technologies from the lab to the clinical marketplace.<sup>14</sup> The Innovation Corps (I-Corps™) program at NIH provides project teams with access to instruction and mentoring to refine and modify their commercialization plans to address customer and marketplace needs. NIH partnered with CDC and committed \$1.2 million

to support this program in FY2018.<sup>15</sup>

To enhance awareness of these activities in targeted communities, NHLBI entrepreneurs-in-residence and subject matter experts in business development, regulatory affairs, and investor relations collaborate with the NIH Office of Scientific Workforce Diversity to leverage the nationwide programs and partnerships established through that office. Data and findings to be obtained from a nationwide assessment (described below) will also inform our strategy for customizing and expanding our engagement with gender or ethnic diversity focused stakeholders.

### **Objective 2: Identify and Eliminate Barriers to Entry**

In 2018, the NIH partnered with the CDC to conduct a nationwide assessment addressing three key diversity and inclusion questions: 1) What are the social or market factors that enable an innovator from an underrepresented population to create a successful life science small business? 2) Are there unique strengths and addressable weaknesses of Small Business Program applications from underrepresented groups that may be leveraged or remediated through tailored outreach programs? 3) What best practices exist at other federal agencies or in the private sector that may be readily adapted to improve success?

The nationwide assessment will also deliver a database of women-owned and/or socially and economically disadvantaged businesses that meet the requirements for submitting applications to the NIH or CDC Small Business Programs. Those companies will be surveyed to illu-

minate issues contributing to their success or failure in competing for Small Business Program awards, in concert with a systematic literature review to advance understanding of any unique barriers faced by women and minority biomedical innovators and entrepreneurs. We anticipate that these findings will allow us to develop short- and long-term improvements to diversity and inclusion in the Small Business Program.

In addition to the activities outlined above, the NHLBI, the National Cancer Institute, and the National Institute of Neurological Disorders and Stroke joined the Small Business Administration's Application Assistance Program in 2017 to support individuals from underrepresented groups who have never received a Small Business Program award from NIH. The pilot program provides potential applicants with access to a needs assessment, small business mentoring, application preparation support, team/facilities development, market research, and intellectual property consultation.<sup>16</sup> NHLBI provided assistance to four small businesses in the first cohort of the program, one of which has already received an SBIR Phase I grant.

### **Objective 3: Expand Diversity and Inclusion within our Existing Portfolio of Funded Companies**

In May 2016, the NIH made supplemental funds available to the holders of all grants to recruit and support students, post doctorates, and eligible investigators from groups that have been shown to be underrepresented in health-related research.<sup>17</sup> Ultimate-

ly only one small business applied for the diversity supplement in 2016.

In October 2016, NIH sought public input to understand why Small Business Program awardees were not applying for diversity supplements, and to inform the consideration of a new supplement specifically tailored to small businesses.<sup>18</sup> The re-

not work well for the shorter duration Small Business Program awards.

To address these shortcomings, NIH released a new diversity supplement program in June 2018 modified to address the unique needs of small businesses and shorter time frame of Small Business Program awards.<sup>19</sup> Some of the key provisions incorporated into the new funding program were to allow supplements to grants with less than a year remaining, as well as permitting supplement applications prior to the award of the parent grant.

In tandem with the program's development, NHLBI implemented a focused communication plan to proactively encourage businesses within its portfolio to find and request funding for diversity candidates using this mechanism, which generated significant interest within the first 30 days of the program announcement.

## CONCLUSION

The NHLBI has implemented a strategic combination of programs and policies designed to increase awareness of NHLBI's Small Business Program among underrepresented groups, identify and eliminate barriers to entry, and expand diversity and inclusion within our existing portfolio of funded companies. These activities will ensure that we fulfil the Small Business Program's congressional mandate to foster and encourage participation in innovation and entrepreneurship by businesses owned by women and socially and economically disadvantaged persons, while stimulating technological innovation, meeting federal research and develop-

ment needs, and increasing the private sector commercialization of federally funded research and development. Ultimately, by expanding the engagement of researchers and entrepreneurs from disadvantaged populations in the small business program, NHLBI believes that new and innovative solutions to improve health equity and reduce health disparities can and will emerge from those communities.

## CONFLICT OF INTEREST

No conflicts of interest to report.

## AUTHOR CONTRIBUTIONS

Data analysis and interpretation: Padmore, McMahon; Manuscript draft: Padmore, McMahon; Administrative: Padmore; Supervision: McMahon

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*Additional information about the NIH Small Business Program, including funding opportunities, eligibility criteria, application instructions, and program contacts for the NHLBI and other NIH institutes may be found at [www.sbir.nih.gov](http://www.sbir.nih.gov). Questions about any NHLBI small business program or initiative may be submitted to [nhlbi-smallbiz-inquiry.force.com](mailto:nhlbi-smallbiz-inquiry.force.com).*

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sponses to the Request for Information revealed that the administrative requirements and review processes of the supplement program, designed for 5 to 7 year grant awards, did

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