

November 11, 2019

**Congressman Jason Crow
U.S. House of Representatives
1229 Longworth House Office Building
Washington, DC 20515**

Dear Congressman Crow,

Thank you for taking the time during the August work period to meet with the Colorado BioScience Association (CBSA) and several of our members located in your district. We appreciated the opportunity to discuss the continued growth of Colorado's life sciences ecosystem as well as some of the challenges our member companies encounter as they work to develop new treatments and technologies.

CBSA represents over 720 life sciences organizations across Colorado that drive innovations, products, and services to improve and save lives. Our state is the center of bioscience for the Rocky Mountain Region, directly employing 30,000 people and spinning out an average of 20 new bioscience companies each year. The industry is largely comprised of small, early-stage companies that play a crucial role in the development of breakthrough technologies and therapies that are leading to improved patient outcomes and reduced health care costs.

A major priority for CBSA is supporting our ecosystem's need for increased access to capital. The association works closely with public and private partners to accelerate investment in life sciences companies. Public sources like the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are critically important, as they provide early non-dilutive funding to help advance high-risk, early stage innovative research. As the high cost of conducting biomedical research continues to grow, this "first money" becomes increasingly important for attracting additional capital and private investors.

While our members appreciate the important role these programs play in stimulating innovation and increasing private-sector commercialization, we believe there are significant opportunities to improve effectiveness and efficiency. As an outcome of our August discussion, CBSA convened a small group of member companies with extensive experience with the SBIR and STTR programs to discuss and identify potential opportunities for improvement. This letter outlines our comments and recommendations.

1. Increased Funding

The SBIR and STTR programs are critically important in the development of new treatments and technologies, often providing the earliest funding to further biomedical research and spur technological innovation. One of the initial goals of the programs was to harness the innovation of small businesses to help meet the needs of the federal government and benefit the national economy. Almost 40 years later, the programs have clearly demonstrated a high return on investment. A 2018 report on the economic impact of the National Cancer Institute's SBIR program revealed that the \$787 million invested in NCI's SBIR Phase II awards from 1998 to 2010 generated \$2.9 billion in tax revenue, \$9.1 billion in sales, and \$8.1 billion in labor income. During that time, NCI funded 690 separate projects, resulting in \$26.1 billion in total economic output nationwide.¹ Given this high return on investment, we recommend increasing agency budget

¹ National Cancer Institute. (2018). *2018 NCI Overview, Economic Impact Analysis of the NCI SBIR Program*. Retrieved from https://sbir.cancer.gov/sites/default/files/documents/NCI_SBIR_ImpactStudy_2pager.pdf?cid=eb_eb_sbir_ig

allocations over time to allow for greater flexibility in award size and more generous paylines. We encourage Congress to work with the Small Business Administration (SBA) and the White House Office of Science and Technology Policy (OSTP) to grow the budget until the amount invested better reflects the tax revenue generated and the economic impact nationwide.

Additionally, one of the challenges for bioscience companies applying for SBIR or STTR funding is that the cost of conducting biomedical research is high and continues to grow, but the budget caps for program awards have not increased at rates that completely reflect the high cost of research. As a result, applicants are not able to submit proposals that will meet the Phase I and Phase II program goals (proof of concept and receipt of commercialization data). We encourage Congress to consider raising the funding limits for Phase I and Phase II awards so applicants can request the budget they need to achieve grant objectives that will satisfy program goals. We also think it would be valuable to explore a new, more competitive financing mechanism that could fund a project through commercialization if the company meets approved milestones. By dedicating additional funding to a more competitive grant mechanism for those projects with the best chance of reaching commercialization, we have an opportunity to significantly improve program efficiency.

If budget growth is achieved over time, CBSA also proposes adjusting paylines to ensure a greater number of strong applications are funded. Recent reports show that on average participating agencies are funding close to 20 percent of the applications they receive through the SBIR program. We have heard anecdotally that the next 10 percent of applications are equally promising, but the funding is not there. Setting paylines that will fund a higher number of promising applications will improve the already high return on investment.

Lastly, the SBIR program currently offers very limited financial support to awardees for commercialization activities. We support amending the program to ease restrictions on how funds are used – particularly increasing the percentage of funding that can be used for commercialization activities like market validation, intellectual property protection, market research, and business model development.

2. Timeliness

CBSA appreciates changes that were made in the SBIR/STTR Reauthorization Act to reduce review deadlines for the program, however, for some participating agencies, the timeline from application submission to award is still too long. We have heard repeatedly about companies that have had to wait six, eight, or more than 10 months before they found out whether they received an award. At that point, it's not uncommon that the company has moved on from the original project or is no longer in operation.

We recommend implementing new requirements for agencies to meet shorter review deadlines. Currently, the NIH and NSF must make final decisions on SBIR and STTR awards within one year after close of solicitation and other participating agencies must do so within 90 days. While we recognize that not every agency will be able to reduce their review times quickly, there are some agencies that have demonstrated notable success in speeding up timelines and showing innovation in how they administer program awards. Earlier this year, the United States Air Force held its inaugural SBIR Pitch Day in New York City. After an application and selection process, 59 companies were invited to pitch solutions and by the end of the day, 51 contracts were awarded to companies on the spot. The success of the first Pitch Day event led to 12 additional SBIR Pitch Days in 2019 and serves as an example of how the Air Force is evolving in how they work with small innovative startups and companies.

It's important for Congress to work with the SBA and participating agencies to set realistic goals for shortening the review timeframe and look to agencies that have had success in streamlining the process to share best practices.

3. Collaboration

CBSA commends the SBA and participating federal agencies for the steps taken in recent years to create new partnerships with state and local organizations and foster collaboration among participating agencies.

Since the SBIR/STTR Reauthorization Act was signed into law in 2011, interagency working groups have been working to identify and implement new methods of communication and outreach to attract qualified small businesses to the program. We applaud the creation of the interagency outreach plan, which was formed to assess current outreach structures, identify gaps, and create tactics that address any shortcomings. This type of coordination and collaboration is vital to improving outreach strategies and educating new participants about the program opportunities.

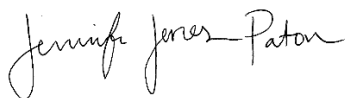
We also appreciate ongoing efforts by the SBA and participating agencies to connect and partner with state and local organizations. In fact, we would encourage greater investment in partnering with state and local education and support services. There is a real opportunity to foster the development of local educational workshops, grant writing services, or mentorship programs pairing successful awardees with new applicants. Partnering with the right local organizations and agencies will enable participating federal agencies to tap into the right innovation pipelines and market the opportunity to the next generation of innovators and entrepreneurs.

Additionally, we know that the effectiveness and efficiency of the SBIR/STTR programs vary by agency. As mentioned, some agencies have been more innovative in how they administer the program and have succeeded in speeding up timelines and providing valuable support to their awardees. We support existing efforts for interagency dialogue and would recommend regular interagency meetings that allow program managers to share ideas and exchange best practices. This would create opportunities for agencies to learn from each other and see how others have created successful program models.

As a state that has received one of the highest total award dollars, we know the SBIR and STTR programs are critically important to our life sciences ecosystem, but we also appreciate that there are meaningful opportunities to make improvements. We look forward to working with you on how we can increase funding over time to improve commercialization, reduce process timelines, and continue to foster collaboration among agencies and state and local partners.

Thank you for your consideration. If you have any questions, please contact Emily Roberts, Vice President of the Colorado BioScience Association at eroberts@cobioscience.com or (303) 592-4071.

Sincerely,



Jennifer Jones Paton
President & CEO
Colorado BioScience Association