



Venture Funding and the NIH SBIR Program

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VENTURE FUNDING AND THE NIH SBIR PROGRAM

Committee for
Capitalizing on Science, Technology, and Innovation:
An Assessment of the Small Business Innovation Research Program

Policy and Global Affairs

Charles W. Wessner, Editor

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Preface

Today's knowledge-based economy is driven in large part by the nation's capacity to innovate. One of the defining features of the U.S. economy is a high level of entrepreneurial activity. Entrepreneurs in the United States see opportunities and are willing and able to take on risk to bring new welfare enhancing, wealth generating technologies to the market. Yet, while innovation in areas such as genomics, bioinformatics, and nanotechnology presents new opportunities, converting these ideas into innovations for the market involves substantial challenges.¹ The American capacity for innovation can be strengthened by addressing the challenges faced by entrepreneurs. Public-private partnerships are one means to help entrepreneurs bring new ideas to market.²

The Small Business Innovation Research (SBIR) program is one of the largest examples of U.S. public-private partnerships. A premise of the SBIR program is that small businesses are an important font for new ideas, but that they likely will need some support in their early stages as they translate these ideas into innovative products and services for the market. Founded in 1982, SBIR is designed to encourage small business to develop new processes and products and to provide quality research in support of the many missions of the U.S. government. By including qualified small businesses in the nation's R&D effort, SBIR awards

¹See Lewis M. Branscomb, Kenneth P. Morse, Michael J. Roberts, and Darin Boville, *Managing Technical Risk: Understanding Private Sector Decision Making on Early Stage Technology Based Projects*, Washington, DC: Department of Commerce/National Institute of Standards and Technology, 2000.

²For a summary analysis of best practice among U.S. public-private partnerships, see National Research Council, *Government-Industry Partnerships for the Development of New Technologies: Summary Report*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2002.

are intended to stimulate innovative new technologies to help agencies meet their missions in many areas including health, the environment, and national defense.

Governments around the world are increasingly adopting SBIR type programs to encourage the creation and growth of innovative firms in their economies. Sweden and Russia have adopted SBIR-type programs. The United Kingdom's SIRI program is similar in concept. In the Netherlands, a successful pilot SBIR program has led the government to expand its scope across the government. In Asia, Japan, Korea, and Taiwan have adopted the SBIR concept as a part of their respective national innovation strategies. And India has adopted an SBIR type program to advance its biotechnology sector. Other countries are actively adopting SBIR type programs. This level of emulation across national innovation systems is striking and speaks to the common opportunities and challenges addressed by SBIR awards and contracts.

As a part of the 2000 reauthorization of the SBIR program, Congress called for a review of the SBIR programs at the Departments of Defense, the National Institutes of Health, the Department of Energy, the National Aeronautics and Space Administration, and the National Science Foundation.

HR 5667 directed the National Research Council (NRC) to evaluate the quality of research and value to the agency mission of the SBIR program. It called for an assessment of the extent to which SBIR projects achieve some measure of commercialization, as well as an evaluation of the program's overall economic and non-economic benefits. It also called for additional analysis as required to support specific recommendations in areas such as measuring outcomes for agency strategy and performance, increasing federal procurement of technologies produced by small business, and overall improvements to the SBIR program. These reports are being published by the National Academies Press.

While this study was still in progress, the Small Business Administration issued a policy directive in 2002 that to be eligible for SBIR the small business concern should be "at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States."³ The effect of this directive has been to exclude innovative small firms in which venture capital firms have a controlling interest from the SBIR program.

To better understand the impact of the SBA exclusion of firms receiving venture funding (resulting in majority ownership), the NRC proposed that the NIH study be extended to include this empirical analysis by the NRC. This report seeks to illuminate the consequences of the SBA ruling excluding majority-owned venture capital firms from participation in SBIR projects.

³Access the SBA's 2002 SBIR Policy Directive, Section 3(y) (3) at <<http://www.zyn.com/sbir/sbres/sba-pd/pd02-S3.htm>>.

STATEMENT OF TASK

This report presents the NRC analysis of the effect of the Small Business Administration's eligibility rules with regard to the majority-owned venture capital participation in the NIH SBIR program. Using data from SBIR awards made from fiscal years 1992 to 2002 and with specific attention to the challenges faced by firms in the biomedical field and employing a combination of surveys and case studies adapted from the Methodology developed as part of the current five-agency analysis,⁴ the NRC investigated the following questions:

- Which NIH SBIR participating companies have been or are likely to be excluded from the program as a result of the 2002 rule change on venture capital company ownership?
- What is the likely impact of the 2002 ruling had it been applied during the 1992-2002 timeframe and what is its probable current impact?

Key variables include the presence and amount of SBIR support, the receipt of venture capital funding or other outside funding, and output measures including those related to commercialization and knowledge generation.

This consensus report contains statistical analysis, case study findings, and also presents the NRC Committee's findings and recommendations.

ACKNOWLEDGMENTS

On behalf of the National Research Council, we express our appreciation and recognition for the insights, experiences, and perspectives made available by the participants of the overall study's conferences and meetings, as well as survey respondents and case study interviewees who contributed to elements of this study. We are also very much in debt to officials from the leading departments and agencies. Among the many who provided assistance to this complex study, we are especially in debt to Jo Anne Goodnight, the Program Coordinator for the National Institutes of Health SBIR program, who was instrumental in facilitating this review of the impact of policy directive on the NIH SBIR program.

As the lead member of the Committee's research staff, Dr. Robin Gaster deserves major recognition for his instrumental role in the research team's preparation of this report. Sujai Shivakumar also merits thanks for his careful review, edits, analysis, and written contributions which were essential for the preparation of this report. Without their sustained efforts, amidst many other competing priorities, it would not have been possible to prepare this report.

⁴National Research Council, *An Assessment of the Small Business Innovation Research Program—Project Methodology*, Washington, DC: The National Academies Press, 2004. Access at <http://www.nap.edu/catalog.php?record_id=11097>.

NATIONAL RESEARCH COUNCIL REVIEW

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Academies' Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process.

We wish to thank the following individuals for their review of this report: Richard Bendis, National Association of Seed and Venture Funds; Douglas Doerfler, Maxcyte Inc.; David Goldston, Harvard University; Heidi Jacobus, Cybernet Systems; Anu Mittal, United States Government Accountability Office; Carol Nacy, Sequella, Inc.; Michael Rodemeyer, University of Virginia; Donald Siegel, University of Albany; Michael Squillante, Radiation Monitoring Devices, Inc.; and Judith Tanur, Stony Brook University.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Robert White, Carnegie Mellon University. Appointed by the National Academies, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Jacques S. Gansler

Charles W. Wessner

Executive Summary

The Small Business Innovation Research (SBIR) program was created in 1982 through the Small Business Innovation Development Act. SBIR offers competition-based awards to stimulate technological innovation among small private-sector businesses while providing government agencies new, cost-effective, technical and scientific solutions to meet their diverse mission needs.”¹

During the first two decades of the program, some majority venture-funded companies participated in the program, receiving SBIR awards in conjunction with outside equity investments. During this lengthy period, the participation of majority venture-funded firms was not an issue. They participated in the SBIR program throughout this period without any apparent adverse consequence for the operation and achievements of the program.

THE 2002 SBA DIRECTIVE

In a 2002 directive, the Small Business Administration ruled that to be eligible for SBIR the small business concern should be “at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United

¹As stated in the Small Business Innovation Development Act (PL 97-219), the program’s goals are four-fold: “(1) to stimulate technological innovation; (2) to use small business to meet federal research and development needs; (3) to foster and encourage participation by minority and disadvantaged persons in technological innovation; and (4) to increase private sector commercialization derived from Federal research and development.”

States.”² This new interpretation of “individuals” resulted in the denial by the SBA Office of Hearings and Appeals of an SBIR grant in 2003 to Cognetix, a Utah biotech company, because the company’s equity was more than 50 percent owned by private investment firms. The ruling, issued by an Administrative Law Judge, stated that venture capital firms were not “individuals,” i.e., “natural persons,” and therefore SBIR agencies could not give SBIR grants to companies in which venture capital firms had a controlling interest. The effect of this directive has thus been to exclude companies in which venture capital firms have a controlling interest.³

DIVERGENT CLAIMS ABOUT THE IMPACT OF THE SBA DIRECTIVE

No empirical assessment of the likely impact of this new interpretation was made before the SBA ruling was implemented. Since then, claims about its impact have been made by both proponents and opponents, but both appear overstated. Those who support the SBA ruling predict that eliminating the new interpretation of the rule could lead to the participation of firms controlled by large venture capital firms, including venture capital arms of major industrial corporations such as General Electric or Intel, and argue that this outcome is contrary to the mission of the SBIR program. Arguing against this position, the National Institutes of Health, biotechnology companies, and the Biotechnology Industry Organization (BIO) have argued that the new eligibility requirements have a negative impact on the NIH mission and on the ability of high-technology firms to develop and commercialize promising new biomedical technologies.

CALL FOR AN EMPIRICAL ASSESSMENT BY THE NATIONAL RESEARCH COUNCIL

To better understand the impact of the SBA exclusion of firms receiving venture funding (resulting in majority ownership), the NRC proposed that the NIH study be extended to include this empirical analysis by the NRC.⁴ In particular,

²Access the SBA’s 2002 SBIR Policy Directive, Section 3(y)(3) at <http://www.zyn.com/sbir/sbres/sba-pd/pd02-S3.htm>.

³See Appendix F.

⁴As the SBIR program approached its twentieth year of operation, the U.S. Congress requested the National Research Council (NRC) of the National Academies to “conduct a comprehensive study of how the SBIR program has stimulated technological innovation and used small businesses to meet Federal research and development needs” and to make recommendations with respect to the SBIR program. Mandated as a part of the SBIR reauthorization in late 2000, the NRC study has assessed the SBIR program as administered at the five federal agencies that together make up some 96 percent of SBIR program expenditures. The agencies, in order of program size, are the Department of Defense (DoD), the National Institutes of Health (NIH), the National Aeronautics and Space Administration

this empirical analysis addresses two key questions that bear on the policy issue at hand. These are:

- How many firms have been or are likely to be excluded by the ruling from participation in the NIH SBIR program?
- What is the likely effect of this exclusion on these firms and on the NIH SBIR program?

MAIN CONCLUSIONS OF THE ACADEMIES' STUDY

The Academies' study finds that between 4.1 percent and 11.9 percent of firms that won SBIR Phase II awards from NIH between 1992 and 2002 have been excluded, or possibly excluded, from the program because of the SBA ruling. (See Table 3-4.) While the evidence is narrowly based and is by no means precise, it does also suggest that the impact of the ruling falls disproportionately on the most promising firms—i.e., those firms that have repeatedly been selected by both NIH for their promising technologies and by venture investors for their commercial potential. Firms that are venture-funded are somewhat less likely to commercialize but are much more likely to generate substantial sales from their SBIR-funded projects when they do commercialize than are firms that receive SBIR funds but are not venture-funded.

Restricting access to SBIR funding for firms that benefit from venture investments would thus appear to disproportionately affect some of the most commercially promising small innovative firms. To this extent, the SBA ruling has the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area.

It is important to note that the task of identifying firms that have received venture funding is a challenge. SBIR-funded firms, which are in most cases privately held, are not required to reveal whether they have received third-party investment. As a result, this information is not collected and stored by SBIR-funding agencies or SBA. Chapter 2 of this report explains the study methodology.

By selecting out some of the most commercially promising innovative small firms, the SBA directive appears to limit opportunities to exploit the nation's substantial investments in research at NIH. This is contrary to one of the four key goals of the SBIR program, which is the commercialization of federal research.⁵ Although the evidence is not definitive, the implementation of the SBA ruling

(NASA), the Department of Energy (DoE), and the National Science Foundation (NSF). For an overview report of this assessment, see National Research Council, *An Assessment of the SBIR Program*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2008.

⁵The goal of private-sector commercialization was moved in priority from being listed fourth when the program was initiated in 1982 to second in the 1992 reauthorization of the SBIR program.

appears to be negatively affecting current participation by firms and the long-term commercialization potential of the NIH SBIR program.⁶

Based on the Committee's analysis of the impact of restricting venture funding on the NIH SBIR program and its experience in the larger evaluation of SBIR programs at five agencies, the Committee recommends that consideration should be given either to restoring the *de facto status quo ante* eligibility requirements for participation in the SBIR program or to making some other adjustment that will permit the limited number of majority venture-funded firms with significant commercialization potential to compete for SBIR funding.⁷

⁶See the Committee's findings in Chapter 7 of this report. The Committee has not analyzed the impact on firms applying for SBIR grants from federal agencies other than NIH. It would be worth examining the impact of restricting venture funding on the SBIR program at other federal agencies.

⁷The Committee has published separate assessments of the SBIR programs at the Department of Defense, at the National Institutes of Health, the Department of Energy, the National Aeronautics and Space Administration and the National Science Foundation. In addition, the Committee has published a comprehensive overview report of the program's operations, achievements, and challenges. See National Research Council, *An Assessment of the SBIR Program*, op. cit.

1

Introduction

1.1 SBIR AND THE INNOVATION “VALLEY OF DEATH”

Created in 1982 through the Small Business Innovation Development Act, the Small Business Innovation Research (SBIR) is the nation’s largest innovation program. It provides competitively awarded grants to small high-technology firms with technically sound and commercially promising but unproven ideas.¹ In this way, SBIR helps small businesses bring pioneering technologies to market and advances the missions of federal agencies.²

Because new ideas are by definition unproven, the knowledge that an entrepreneur has about his or her innovation may not be fully appreciated by prospective investors.³ This means that new ideas with commercial potential often do not attract sufficient private investment. SBIR awards provide this seed capital and a positive signal to private venture markets, helping entrepreneurs to secure the funds needed to bring new ideas to market. The term “*Valley of Death*” has come to describe the period of transition when a developing technology is deemed

¹For a comprehensive review of the concept and performance of this 25-year-old program, see National Research Council, *An Assessment of the SBIR Program*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2008.

²For an extended discussion of the empirical evidence supporting the finding of high innovation performance of small firms, see Zoltan J. Acs and David B. Audretsch, “Innovation in Large and Small Firms: An Empirical Analysis,” *The American Economic Review*, 78(4):678-690, 1988.

³Joshua Lerner, “Public Venture Capital,” in National Research Council, *The Small Business Innovation Program: Challenges and Opportunities*, Charles W. Wessner, ed., Washington, DC: National Academy Press, 1999. For a seminal paper on information asymmetry, see Michael Spence, *Market Signaling: Informational Transfer in Hiring and Related Processes*, Cambridge, MA: Harvard University Press, 1974.

promising, but too new to validate its commercial potential and thereby attract the capital necessary for its continued development.⁴

SBIR is an important source of early-stage funding in the United States. Although business angels and venture capital firms, along with industry, state governments, and universities provide funding for early-stage technology development, the federal role is significant. Overall, SBIR awards provided over \$2.3 billion in research and seed funding in 2007 to the nation's innovative small businesses. In comparison, private venture markets provided \$1.2 billion in seed stage funding in 2007 in the course of only 414 deals.

There are often useful synergies between angel and venture capital investments and SBIR funding. In many cases, small business entrepreneurs use SBIR awards in close conjunction with funds from other sources, often at the most vulnerable stages of their firm's development. Reflecting this synergy, an initial NRC review showed about 25 percent of the top 200 NIH Phase II award winners (1992-2005) have acquired some venture funding in addition to the SBIR awards.⁵ In addition, angel investors often find SBIR awards to be an effective mechanism to bring a company forward in its development to the point where risk is sufficiently diminished to justify investment.⁶

Today, venture capital markets are retrenching as a result of the current financial crisis.⁷ Venture capital firms are undertaking fewer investments, especially at

⁴As the September 24, 1998, Report to Congress by the House Committee on Science notes, "At the same time, the limited resources of the federal government, and thus the need for the government to focus on its irreplaceable role in funding basic research, has led to a widening gap between federally-funded basic research and industry-funded applied research and development. This gap, which has always existed but is becoming wider and deeper, has been referred to as the 'Valley of Death.' A number of mechanisms are needed to help to span this Valley and should be considered." See U.S. Congress, House Committee on Science, *Unlocking Our Future: Toward a New National Science Policy: A Report to Congress by the House Committee on Science*, Washington, DC: U.S. Government Printing Office, 1998. Accessed at <<http://www.access.gpo.gov/congress/house/science/cp105-b/science105b.pdf>>. For an academic analysis of the Valley of Death phenomenon, see Lewis Branscomb and Philip Auerwald, "Valleys of Death and Darwinian Seas: Financing the Invention to Innovation Transition in the United States," *The Journal of Technology Transfer*, 28(3-4), August 2003.

⁵National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

⁶See the presentation "The Private Equity Continuum" by Steve Weiss, Executive Committee Chair of Coachella Valley Angel Network, at the Executive Seminar on Angel Funding, University of California at Riverside, December 8-9, 2006, Palm Springs, CA. In a personal communication, Weiss points out the critical contributions of SBIR to the development of companies such as Cardio-Pulmonics. The initial Phase I and II SBIR grants allowed the company to demonstrate the potential of their products in animal models of an intravascular oxygenator to treat acute lung infections and thus attract angel investment and subsequently venture funding. Weiss cites this case as an example of how the public and private sectors can collaborate in bringing new technology to markets. Steve Weiss, Personal Communication, December 12, 2006.

⁷See *The New York Times*, "In Silicon Valley, Venture Capitalists Turn Cautious," January 5, 2009.

BOX 1-1 How Small Biotechnology Firms Typically Use SBIR

Small biotechnology companies usually have three to five research projects ongoing at one time. The venture capital funding that they raise is usually tied to specific research milestones for a given project.^a

SBIR often plays a key role in providing small biotechnology firms funding for other research projects that are more early-stage and higher-risk and are, thus, not yet attractive to venture or even angel capital investors. Such research projects may include new alternate applications of a lead project or a completely new project. Given the extraordinary high risk of biomedical product development, SBIR provides an avenue for small companies to create a more diversified pipeline that can be essential for the success of small biotechnology businesses.

Most small biotechnology companies do not base their business plans on the SBIR program alone. Their goal is to raise capital in order to advance product development to the point of becoming a publicly traded, acquired, or stand-alone company with actual products in the market. The SBIR program is an important part of this process, but the focus of the business model is to commercialize a product—and to graduate out of the SBIR program.

^aFor a perspective of a small innovative business, see testimony by Douglas Doerfler of Maxcyte, Inc., before the House Committee on Small Business, January 29, 2008. For additional perspectives on the role of SBIR in the development of innovative products and businesses, see the case studies in National Research Council, *An Assessment of the SBIR Program*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2008. Appendix C.

the early stage, and conserving capital to preserve existing investment portfolios.⁸ In this environment, small innovative businesses find SBIR awards to be a stable and less cyclical source of early-stage innovation funding. Easing, rather than restricting access to capital is essential for economic recovery and would be consistent with other actions now being taken by the federal government to address the current economic crisis.

1.2 SBIR PROGRAM STRUCTURE

Eleven federal agencies are currently required to set aside 2.5 percent of their extramural research and development budget exclusively for SBIR awards. Each year these agencies identify various R&D topics, representing scientific

⁸See Rachel Metz, “Venture Capital Investments Fall 33 Percent in 4Q,” Associated Press, January 24, 2009.

BOX 1-2
Venture Capital Contraction and the
Financial Crisis of 2008-2009

“Venture investments dropped across almost all sectors in the [fourth] quarter [of 2008] compared with the prior year. For biotechnology and medical device industries, \$1.6 million was invested in 185 companies, which is a 31 percent decline in dollars and a 22 percent drop in deals.”

SOURCE: Rachel Metz, “Venture Capital Investments Fall 33 Percent in 4Q,” Associated Press, January 24, 2009.

and technical problems requiring innovative solutions, for pursuit by small businesses under the SBIR program. These topics are bundled together into individual agency “solicitations”—publicly announced requests for SBIR proposals from interested small businesses. A small business can identify an appropriate topic it wants to pursue from these solicitations and, in response, propose a project for an SBIR award. At NIH, topics are treated as guidelines, and the agency does fund projects that do not address specific topics in the solicitation.

The Small Business Administration (SBA) coordinates the SBIR program across the federal government and is charged with directing its implementation at all 11 participating agencies. Recognizing the broad diversity of the program’s operations, SBA has traditionally administered the program with commendable flexibility, allowing the agencies to operate their SBIR programs in ways that best address their unique agency missions and cultures.

Reflecting this flexibility, the required format for submitting a proposal is different for each agency. Proposal selection also varies, though peer review of proposals on a competitive basis by experts in the field is typical. Each agency then selects the proposals that are found best to meet program selection criteria, and awards contracts or grants to the proposing small businesses.

Despite these differences, as conceived in the 1982 Act, the SBIR award-making process is structured in three phases at all agencies:

- Phase I awards essentially fund feasibility studies in which award winners undertake a limited amount of research aimed at establishing an idea’s scientific and commercial promise. Today, the legislation anticipates Phase I awards as high as \$100,000. Average award size at NIH is significantly higher (approximately \$150,000).⁹

⁹These higher average award sizes are possible under a blanket waiver provided to NIH by SBA.

- Phase II awards are larger—typically about \$750,000—and fund more extensive R&D to develop further the scientific and commercial promise of research ideas. Again, average award size at NIH is significantly higher (over \$1 million).
- Phase III. During this phase, companies do not receive additional funding from the SBIR program. Instead, award recipients should be obtaining additional funds from a procurement program at the agency that made the award, from private investors, or from the capital markets. The objective of this phase is to move the technology from the prototype stage to the marketplace.

1.3 THE NRC ASSESSMENT OF SBIR AT NIH

As the SBIR program approached the two decade mark in 2002, the U.S. Congress requested that the National Research Council (NRC) of the National Academies conduct a “comprehensive study of how the SBIR program has stimulated technological innovation and used small businesses to meet Federal research and development needs,” and make recommendations on improvements to the program at the National Institutes of Health and other major agencies of the federal government.¹⁰

Based on extensive research, a Committee of the NRC found that the NIH SBIR program is “making significant progress in achieving the congressional goals for the program.” It added that “the SBIR program is sound in concept and effective in practice at NIH.”

The NRC report on the SBIR program at NIH also noted that for firms seeking to capitalize on the progress made with SBIR awards, “venture funding may be the only plausible source of funding at the levels required to take a product into the commercial marketplace.”¹¹

The controversy over the issue of majority venture capital funding notwithstanding, SBIR has been a highly successful program.

1.4 THE SBA RULING ON VENTURE PARTICIPATION IN SBIR FIRMS

During the first two decades of the SBIR program, majority venture-funded companies participated in the program, receiving SBIR awards in conjunction with outside equity investments. During this lengthy period, the participation of majority venture-funded firms was not an issue.

In a 2002 directive, the Small Business Administration ruled that to be eligible for SBIR the small business concern should be “at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent

¹⁰National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, op. cit.

¹¹Ibid.

BOX 1-3
Chronology of the SBA Ruling

- 1982: The Small Business Innovation Development Act of 1982 creates the SBIR Program.
- 2002: SBA proposes a rule to modify the ownership requirement for SBIR awardees.
- 2003: (May 29) SBA Office of Hearings and Appeals denies an appeal by Cognetix.
- 2003: (June 4 to July 7) The proposed SBA rule is open for public comment.
- 2004: (December 3) SBA publishes a Final Rule in the *Federal Register*. (69FR 70180)
- 2005: (January 3) SBA Final Rule becomes effective.

resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.”¹²

During the period when SBA was developing the proposed rule, the SBA’s Office of Hearings and Appeals received an appeal from a Cognetix, a Utah biotechnology company that was majority venture-funded and, thus, ineligible for the SBIR program.¹³ In denying the appeal, an Administrative Judge of the SBA Office of Hearings and Appeals ruled that venture capital firms were not “individuals,” i.e., “natural persons,” and therefore SBIR agencies could not allocate SBIR awards to companies in which venture capital firms had a controlling interest.¹⁴ The ruling in the Cognetix case signified a change in practice, not in law.¹⁵ In effecting this change, the SBA did not attempt to analyze the impact of the exclusion of such firms on the operation of the SBIR program at NIH.

¹²SBA Policy Directive, published in the *Federal Register*, September 24, 2002. Access the SBA’s 2002 SBIR Policy Directive, Section 3(y) (3) at <<http://www.zyn.com/sbir/sbres/sba-pd/pd02-S3.htm>>.

¹³See *Federal Register*, Proposed Rules, 69(232), Friday, December 3, 2004.

¹⁴In his decision, Administrative Judge Blazsik stated that “The term ‘individuals’ in 13 C.F.R. Section 121.702(a) means only natural persons and does not include venture capital funds, pension funds, and corporate entities for purposes of an SBIR award. Thus, a firm that is otherwise eligible for an SBIR award is disqualified because it is less than 51 percent owned by natural persons.” Access this decision at <<http://www.sba.gov/aboutsba/sbaprograms/oha/allcases/sizcases/siz4560.txt>>.

¹⁵See statement by Administrator Steven C. Preston before the House Small Business Committee on the Reauthorization of the Small Business Innovation Research Program, March 13, 2008. See Appendix H of this report.

BOX 1-4
SBA Basis for Venture Disqualification in SBIR

Why does venture firm ownership or control disqualify a firm from SBIR funding? According to the SBA ruling, there are two issues here:

Breaching the size requirement. Venture capital firms own stakes in many companies. The 500 employee limit is measured by aggregating the size of the applying firm, the employees of venture capital firm(s), and all the other firms in which that limited partnership has a controlling interest.

Breaching the individual ownership requirement. SBIR firms must be owned by individual U.S. citizens, or by a firm that is itself owned by U.S. individuals. Venture capital firms are often more than half owned by the institutional investors who fund them, and hence in those cases these firms fail the individual ownership test.

SBA on a regular basis aggregates venture capital investors' other firms in which it has not only a controlling interest but a minority interest. The SBA uses tests such as affirmative control (majority ownership, control of board etc.) as well as negative control which is less clearly defined and can often lead to exclusion of small biotechnology companies, even if they are 51 percent owned by individuals.

1.5 OVERVIEW OF REACTIONS TO THE SBA RULING

The administrative ruling has since generated both considerable support and criticism.¹⁶ The claims made by advocates on both sides of this issue are summarized below. On closer examination, many of these claims appear to be overstated and lack compelling evidence. In reviewing these claims, it is worth noting that the SBIR program operated successfully for over twenty years without the benefit of this “clarification” by SBA.¹⁷ However, the impact of this ruling will very likely change the character of the SBIR program.

Those who support the SBA ruling predict that its elimination could lead to the participation of firms controlled by large venture capital firms, including venture capital arms of major industrial corporations such as General Electric

¹⁶The issue of whether small businesses can participate in the SBIR program if venture firms hold some ownership of the firm was addressed by both proponents and opponents in the congressional hearings to renew the SBIR program. See Small Business Innovation Research Reauthorization on the 25th Program Anniversary, Hearings before the Subcommittee on Technology and Innovation, 110th Congress, First Session, April 26, 2007, and June 25, 2007, Serial No. 110-23 and Serial 110-43, Washington, DC: U.S. Government Printing Office, 2008. Hearings were also held by the House Small Business Committee and the Senate Committee on Small Business and Entrepreneurship.

¹⁷The NRC Committee assessing the SBIR program found it overall to be “sound in concept and effective in practice.” See National Research Council, *An Assessment of the SBIR Program*, op. cit., Chapter 2.

or Intel, and argue that this outcome is contrary to the mission of the SBIR program.¹⁸ Arguing against this position, the National Institutes of Health and many biotechnology companies have argued that the new eligibility requirements have a negative impact on the NIH mission and on the ability of high technology firms to develop and commercialize promising new biomedical technologies.

Supporters of the Ruling Foresee a Negative Impact on the SBIR Program from Participation by Majority Venture-funded Small Businesses

Supporters of the SBA ruling argue that the SBA ruling is needed to prevent large venture capital firms and corporate venture firms from exploiting the SBIR program for their benefit to the detriment of the SBIR mission.¹⁹ They claim that the ruling is necessary on a variety of grounds. These include financial need, the risk of crowding out, and the attraction of firms backed by corporate venture capital to the program, especially as “super-sized” awards become more prevalent.²⁰ Key arguments made by supporters of the SBA ruling are listed below:

- **Firms that have venture funding do not need SBIR.**
 - Venture-funded firms have access to the capital and resources they need; so scarce SBIR resources should be focused on the firms that cannot or have not obtained venture funding and are therefore most in need these resources.²¹
- **Venture-funded firms “crowd out” deserving small firms.**
 - Venture-funded firms have more resources and are likely to be in a better position to apply for SBIR awards, so they could “crowd out” deserving firms that are not venture-funded.²²
- **Venture-funded firms have unfair advantages in the application process, so that these firms will be able to capture a disproportionate role in the program because of their superior resources.**
 - These resource rich firms will be able to submit better prepared applications to the SBIR agencies.
 - As a result, their applications will be seen to be superior and hence selected by the eleven different agencies that participate in SBIR.²³

¹⁸See, for example, testimony by Mr. Robert N. Schmidt at the April 26, 2007, hearing before the House Subcommittee on Technology and Innovation.

¹⁹See testimony of Jere Glover, Executive Director, SBTC, before the Subcommittee on Rural Enterprise, Agriculture and Technology Policy, House Small Business Committee, July 27, 2005.

²⁰Super-sized awards are actually on the decline.

²¹Ibid.

²²See testimony of Michael Squillante of RMD, Inc., before the Senate Committee on Small Business and Entrepreneurship, July 12, 2006.

²³See, for example, testimony by Robert N. Schmidt on April 26, 2007 before the Subcommittee on Technology and Innovation of the House Committee on Science and Technology. In his testimony, Mr. Schmidt noted that “Thanks to their deep-pocket backing, the companies that the VCs fund will

- **Corporate venture capital can capitalize on SBIR grants.**
 - Large corporations that have set up venture capital arms can use small firms they control to apply for SBIR. This would have the effect subsidizing large firms, which is not the objective of the legislation that established the SBIR program.²⁴
 - The large grants made on occasion by the NIH SBIR program are likely to motivate large venture capital firms to apply for SBIR awards.²⁵
- **Venture capital capture of the SBIR program will change the character of the SBIR program to its detriment by:**²⁶
 - Shifting the program toward lower-risk technologies that are closer to the market;
 - Increasing the geographic concentration of the program (in states like California and Massachusetts, where venture capitalists are most active);
 - Changing the profile of successful and unsuccessful SBIR companies; and
 - Leading to calls for a further change in the SBIR rules—for example, to allow large institutions such as universities to own SBIR companies.

Whatever the merit of these observations, and these impacts remain to be documented, it remains the case that the predicted capture of the program by venture capital did not take place over the twenty years that the restrictions on majority venture-funded firms were not in place (or were not enforced.)²⁷ It remains possible, however, that changing patterns of awards, especially significantly larger awards, could change the level of participation of venture-funded firms.

be able to submit multiple proposals per solicitation. They won't necessarily be more life-saving, but they will be more polished. They will also have features that do well under NIH's scoring system—like impressive looking 'teams' and extensive preliminary research. It costs money to submit multiple proposals, to make them polished, to keep impressive teams on hold until an award decision is reached, and to conduct preliminary research. That is exactly where large VC-backed companies will have the edge."

²⁴In 2000, at the peak of the Internet bubble, more than \$100 billion in venture capital was disbursed, of which about 20 percent was from corporations. See Joseph A. LiPuma, "Corporate Venture and the Intensity of Portfolio Companies," *Small Business Research Summary*, No. 306, June 2007. Access at <<http://www.sba.gov/advo/research/rs306tot.pdf>>. This participation ebbs and flows with the size of the venture capital market. See Hank Chesbrough and Christopher Tucci, "Corporate Venture Capital in the Context of Corporate Innovation," DRUID Summer Conference, 2004. More recently, Venture Capital funding has been level at about \$28 billion in 2007.

²⁵See testimony of Michael Squillante of RMD, Inc., before the Senate Committee on Small Business and Entrepreneurship, July 12, 2006.

²⁶See testimony of Jere Glover, Executive Director, SBTC, before the Subcommittee on Rural Enterprise, Agriculture and Technology Policy, House Small Business Committee, July 27, 2005.

²⁷See National Research Council, *An Assessment of SBIR at the National Institutes of Health*, op. cit., Chapter 2, Finding G on "Venture Funding and SBIR."

BOX 1-5
Characteristics of Majority-owned Venture-funded and Non-venture-funded SBIR Firms

Captured below are some expected general differences between SBIR firms that have secured venture funding and those that have not secured venture funding. Making such analytical distinctions sharpens the unique feature of each. In practice, however, these distinctions may not be as distinct.

Financial constraints. Businesses that receive venture capital support are often believed to face fewer financial constraints than non-venture-funded firms. This support is thought to give venture-funded firms greater resources in:

- Proposal preparation.
- Supporting complementary research and development.
- Filing patents and protecting their intellectual property.
- Identifying and assessing market opportunities.
- Gaining access to business strategy experts.
- Purchasing technical and marketing consulting and advisory board services.
- Affording larger scale commercialization activities and capabilities.

Focus on high returns. Venture-funded firms are expected to “swing for the fences” more of the time. In other words, we would expect venture capitalists to identify and fund firms that are working on technologies with large market potential. By comparison, non-venture-funded firms are more likely to work on technologies that, while important, are not seen to have market potentials that are as large. While some technologies may address specific and important mission needs of a sponsoring agency, they may have a smaller potential for widespread commercialization.

Possible selection effects. Given these advantages and focus, it is possible that venture-funded firms are more likely to identify and seek to win competitions for SBIR topics with high commercialization potential topics than non-venture-funded firms.

Critics of the SBA Ruling Predict That It Will Deter Small Business Innovation, Especially in Biomedicine

Critics of the SBA ruling believe that the ruling does not take proper account of the real world challenges of financing early-stage funding in innovation research, especially the high risk and long horizon needs of biomedical research.

Impact on the NIH Mission

Perhaps most telling is the criticism of this ruling by the leadership of the National Institutes of Health. In a letter to the Small Business Administration,

Dr. Elias A. Zerhouni, then the NIH director, noted the new eligibility rules “unduly restrict the ability of the National Institutes of Health (NIH) fund high quality, small companies that receive venture capital (VC) investment.”²⁸ This, he claimed, will have a negative impact on the mission of the National Institutes of Health and on the goals of the SBIR program.

Impact on Small Biotechnology Firms

Some high technology industries, notably the biotechnology industry, and representatives of the venture capital community have also expressed dismay at this ruling, calling it a new interpretation of the venture capital-small business relationship by SBA.²⁹ The Biotechnology Industry Organization (BIO) and the National Venture Capital Association (NVCA), as well as some individual biotech firms, have testified before congressional committees against the new interpretation.³⁰ Criticisms of the SBA ruling center on the following arguments:

- **The ruling does not take into account the realities of biotechnology research.**
 - The scale of biotechnology research calls for multiple sources of funding. For firms seeking to capitalize on the progress made with SBIR awards, venture funding may be the only plausible source of funding at the levels required to take some products into the commercial marketplace. It can take several hundred million dollars and an average of eight years to develop a drug from concept through to

²⁸See Dr. Zerhouni’s letter to H. Barreto, Small Business Administration, June 28, 2005. See Appendix G.

²⁹See National Venture Capital Association, “NVCA Supports Clarifications to SBIR Eligibility Requirements,” November 9, 2005. Access at <http://www.nvca.org/policy.html>. Mark Heesen, president of the National Venture has noted that “by eliminating venture-backed companies from the pool of SBIR applicants, the SBA is effectively dismissing the most promising organizations—ones that have been vetted by professionals and have the most chance of succeeding as viable, ongoing businesses. The current dynamic is now hobbling young companies across the country, particularly in the life sciences sector, where the cost and time associated with bringing a discovery to market is colossal.”

³⁰See, for example, testimony by Thomas Bigger of Paratek Pharmaceuticals before the U.S. Senate Small Business Committee, July 12, 2006. See the statements by Ron Cohen, CEO of Acorda Technologies, and Carol Nancy, CEO of Sequella, Inc., at the House Science Committee Hearing on “Small Business Innovation Research: What is the Optimal Role of Venture Capital,” July 28, 2005. Dr. Nancy’s testimony captures the multiple sources of finance for the 17-person company (June 2005). They included—founder equity investments; angel investments; and multiple, competitive scientific research grants, including SBIR funding for diagnostics devices, vaccines, and drugs. SBIR funding was some \$6.5 million out of a total of \$18 million in company funding. Dr. Nancy argues that SBIR funding focuses on research to identify new products while venture funding is employed for product development.

the market.³¹ In the absence of product revenue, biotechnology firms are almost entirely reliant on capital markets and other sources of financing during this period. As a result, biotechnology companies often seek venture investment to push products towards the market while relying on grants, e.g., SBIR as funding sources, to fund their early-stage, high-risk research and development.³²

- Small biotechnology companies must often develop multiple lines of research. Representatives of small biotechnology companies point out that sustaining multiple lines of research is necessary for an innovative small business to diversify its risks. The venture capital funding raised by a small business to support its lead product is often tied closely to milestones in that product's development.³³ In order to develop secondary or tertiary candidates or therapies, a company has to find secondary sources of capital. SBIR grants can and do play an instrumental role in supporting projects at the very earliest stages of development.³⁴

- **The SBA ruling is based on a misunderstanding of the roles and objectives of venture funding.**

- Venture capital does not focus on very early-stage funding. It is this type of activity that the SBIR program has historically supported in the past. Venture capital dollars are normally applied later in the life cycle, and are used to bring promising discoveries to market.³⁵
- SBIR and venture funding address the needs of small businesses at different stages of the innovation process. And as noted, small innovative businesses often have multiple projects in their development

³¹See, for example, testimony by Gary McGarrity, a member of BIO, on April 26, 2007, before the Subcommittee on Technology and Innovation of the House Committee on Science and Technology. Dr. McGarrity noted in his testimony that "Promising biotechnology research has a long, arduous road from preclinical research, through Phase I, safety, Phase II, efficacy, and Phase III broader population clinical trials, and ultimately to FDA approval of a therapy. It is estimated that it takes 97.7 months, or 8 years to bring a biotechnology therapy to market and costs between \$800 million and \$1.2 billion. For the majority of biotechnology companies that are without any product revenue, the significant capital requirements necessitate fundraising through a combination of angel investors and venture capital firms. The role and importance of private equity fundraising in the biotechnology industry cannot be understated."

³²See testimony by Douglas Doerfler of Maxcyte, Inc., before the House Committee on Small Business, January 29, 2008.

³³See testimony by Mark G. Heeson of the National Venture Capital Association before the House Committee on Small Business, March 13, 2008.

³⁴See testimony by James C. Greenwood, President of BIO, before the House Committee on Small Business, March 13, 2008.

³⁵See testimony by Mark G. Heeson of the National Venture Capital Association before the House Committee on Small Business, March 13, 2008. For a comparison of the trajectories of venture-funded firms with those without venture funding, see Manju Puri and Rebecca Zarutskie, "On the Lifecycle Dynamics of Venture-Capital- and Non-Venture-Capital-Financed Firms," EFA 2007 Ljubljana Meetings Paper, June 2007, available at SSRN: <<http://ssrn.com/abstract=967841>>.

portfolio at different stages of maturity. They may need to draw on a variety of different types of funding to succeed.³⁶

- Venture capital firms are most often small businesses themselves. Contrary to some popular characterizations, venture capital firms are almost entirely private partnerships that are typically comprised of less than a dozen professionals.³⁷
- Venture-funded companies are normally not controlled by venture capitalists, even where they own 51 percent or more of the company. Most small biotechnology companies have multiple venture capital investors with minority ownership status. The entrepreneur often selects the investors. These investors normally they do not exert day-to-day control over the firm. In fact, partners at venture funds typically work with a portfolio of several companies at once, making it impractical (if not impossible) to exert effective control of day-to-day management. They do work with the management team to make the strategic level decisions needed for the firms to grow.³⁸

- **The ruling results in a set of confusing SBA eligibility rules that deter small business innovation.**

- Counting venture capital firm employees: If SBA determines that a venture capital company has a controlling interest in a small business, not only are the employees of the venture capital company included in the size determination but so are the employees of all other businesses in which the venture firm has a controlling interest.³⁹
- The rules do not reflect the reality that micro small businesses often rely on a syndicate of investors: According to the current SBA interpretation “a private company with 400 employees, \$200 million in venture capital from multiple venture capital firms that equal 49 percent of equity with additional angel investment dollars” is eligible, whereas “a private company with 20 employees, \$50,000 in annual revenue and \$8 million in venture capital by multiple venture capital funds equaling 56 percent of equity—even though no one venture capital firm has more than 35 percent of total equity—is ineligible.”⁴⁰

³⁶See testimony by Mark G. Heeson of the National Venture Capital Association before the House Committee on Small Business, March 13, 2008. SBIR more actively supplements angel round funding where the funding levels are comparable (in the order of \$100,000). By the time a company is looking for venture funding, it typically seeks larger amounts (in the order of \$1,000,000). SBIR is at this stage in a firm’s evolution a relatively smaller component of funding.

³⁷*Ibid.*

³⁸*Ibid.*

³⁹See testimony by James C. Greenwood, President of BIO, before the House Committee on Small Business, March 13, 2008.

⁴⁰See testimony by Douglas Doerfler of Maxcyte, Inc., before the House Committee on Small Business, January 29, 2008.

- **The ruling may be reducing the pool of applicants to the NIH SBIR program.**
 - Excluding potential applicants: It may be that an unintended consequence of the ruling is to exclude a portion of applicants who might otherwise be able to participate in the SBIR program. Following the SBA ruling, some biotech companies have been denied grant money. Others have opted to delay SBIR submission in the hope that the issue will be resolved. Representatives of the Biotechnology Industry Organization (BIO) argue that by reducing the applicant pool, the ruling reduces the program's ability to award projects with high scientific merit and commercialization potential.⁴¹
 - Decline in NIH SBIR applications: BIO cites the decline in SBIR applications at NIH, which declined by 11.9 percent in 2005, 14.6 in 2006, and by 21 percent in 2007, as evidence of the negative impact of this ruling.⁴² (See Figure 1-1.) Such a correlation, of course, does not necessarily imply a causal link and there may be other factors at play for this decrease in applications. BIO also notes that the NIH Program Coordinator has testified that the number of new small businesses participating in the program has decreased to the lowest proportion in a decade.⁴³

1.6 THE NATIONAL RESEARCH COUNCIL'S STUDY OF THE VENTURE CAPITAL ELIGIBILITY RULING

While the SBA ruling concerning eligibility alters the way the program operated, at least on a *de facto* basis, from the program's origin until 2002, no empirical assessment of its potential impact was made before the ruling was implemented.

The GAO did conduct a study of venture capital activity within the NIH and DoD SBIR programs, and while this study broke some important new ground and

⁴¹See testimony by James C. Greenwood, president of BIO, before the House Committee on Small Business, March 13, 2008. According to the organization's Web site, "BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. Our mission is to be the champion of biotechnology and the advocate for our member organizations—both large and small." Access Web site at <<http://bio.org/>>. According to an Ernst & Young report, "Beyond Borders: Global Biotechnology Report 2008," there are approximately 1,500 public and private U.S. biotechnology companies. Therefore, BIO represents over half of the biotechnology companies in the United States. See Ernst & Young, "Beyond Borders: Global Biotechnology Report 2008," New York: Ernst & Young, 2008.

⁴²Ibid.

⁴³See testimony of Jo Anne Goodnight to the House Subcommittee on Technology and Innovation, Committee on Science and Technology, June 26, 2007.

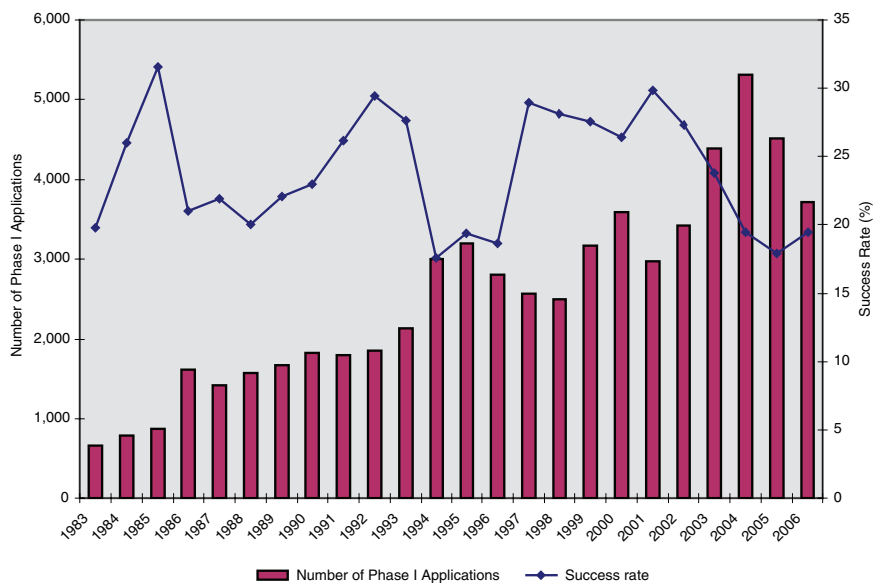


FIGURE 1-1 NIH SBIR application and success rates.

SOURCE: NIH SBIR Program.

provided the first estimate of the number of firms affected by the ruling, it did not address two key questions that bear on the policy issue at hand.⁴⁴ These are:

- How many firms would appear to be excluded by the ruling from participation in the NIH SBIR program?
- What is the likely effect of this exclusion on these firms and on the NIH SBIR program?

These questions may be of particular importance in the biotechnology sector, where there is a substantial concentration of venture capital funding. (See Box 1-6.) However, these are not easy questions to answer. Data on venture fund-

⁴⁴U.S. Government Accountability Office, *Small Business Innovation Research: Information on Awards Made by NIH and DoD in Fiscal Years 2002 through 2004*, GAO-06-565, Washington, DC: U.S. Government Accountability Office, April 2006. The GAO report provides the number and characteristics of all awards, the number and characteristics of awards above the size guidelines, changes in award characteristics after 2002, the factors agencies consider in deciding awards, and the data they collect on SBIR awards. The GAO report, however, does not provide grounds to determine whether firms identified as venture-funded are in fact excluded from the SBIR program based on majority ownership grounds.

BOX 1-6 Venture Capital Investments in Biotechnology

The MoneyTree Survey indicates that venture capital deals in biotechnology are larger than average. The biotechnology sector accounts for 18 percent of all venture capital deals in 2007 and the average size of a deal for the year was \$10.9 million. By comparison, the software sector accounted for 17.9 percent of venture capital funding for 2007, with average deal size of \$5.8 million. If we combine venture investments in medical devices with biotechnology into a category called “life sciences,” they would together account for over 30 percent of all venture funding in 2007. Given NIH’s focus on life sciences, this data indicates that the SBA ruling on venture capital participation has a major impact on its capacity to use SBIR to advance its mission to develop knowledge about living systems, extend healthy life, and reduce the burdens of illness and disability.

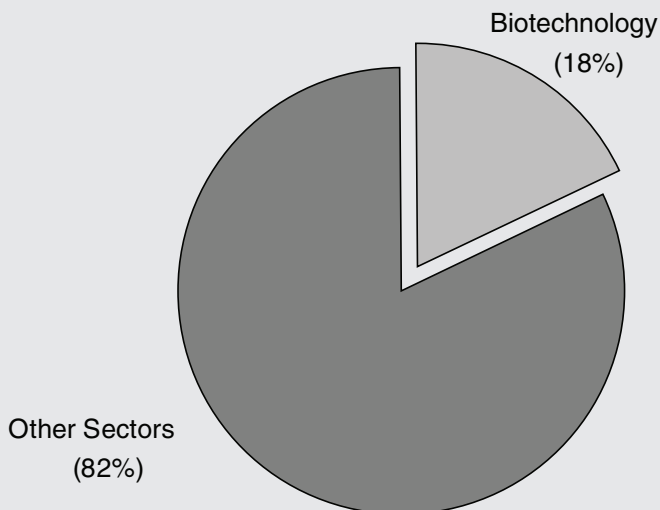


FIGURE B-1-5 2007 Venture capital dollars invested.

SOURCE: Based on data from PriceWaterhouse MoneyTree Survey 2007.

ing for individual firms can be hard to find in a systematic fashion—and data on the impact of this funding is even harder to establish.

To better understand the impact of the SBA exclusion of firms receiving majority venture funding (resulting in majority ownership), the NIH commissioned this empirical analysis by the National Research Council. In this report,

we seek to illuminate the ramifications of the SBA ruling on the participation of majority-owned venture capital based firms in the SBIR program.

The analysis in this report complements the Academies' recent assessment of the SBIR program at NIH, the Department of Defense, the Department of Energy, NASA and the National Science Foundation.⁴⁵ Covering the approximately twenty years of the program's existence (over which period, the restrictions of the SBA ruling were not in place) this comprehensive study found that the program is meeting its congressional objectives and is effective in practice. Moreover, the Academies' study did not detect any effect (positive or negative) from the participation of a limited but significant number of small innovative firms that were majority owned by venture capital firms in the SBIR program.⁴⁶

⁴⁵For a summary report of this first comprehensive assessment of the SBIR program, see National Research Council, *An Assessment of the SBIR Program*, op. cit.

⁴⁶See National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, op. cit., Chapter 2, Finding G on "Venture Funding and SBIR."

2

Study Methodology

Reflecting the two core questions (How many firms have actually been excluded by the ruling from participation in the NIH SBIR program? And what is the likely effect of this exclusion on these firms and on the NIH SBIR program) the methodology for this study is divided into two areas.

2.1 IDENTIFYING VENTURE-FUNDED FIRMS AND ESTIMATING THE “EXCLUSION EFFECT”

Identifying Venture-funded Firms

Identifying firms that have received venture funding is a challenge. SBIR-funded firms, which are in most cases privately held, are not required to reveal whether they have received third-party investment. As a result this information is not collected and stored by SBIR-funding agencies or SBA.

In order to establish the distribution of venture funding *prior* to the SBA ruling,¹ this research initially focused on firms winning Phase II awards from 1992-2002 inclusive.

Phase II awards were selected for study because they account for the largest amount of NIH SBIR funding. As Phase II awards continue to grow in size, and are extended in length, the proportion of funding allocated for post-Phase I continues to grow. What is more, commercial success almost always comes after

¹The years prior to the ruling are years when a “natural” level of participation for venture-funded companies might be established.

Phase II rather than just Phase I—so a focus on the latter includes almost all commercial successes.

The focus on 1992-2002 coincides with the rapid development and maturation of the biotechnology industry. It also reflects the reauthorization of the program in 1992, which led to prioritization of the legislative goals of SBIR with an emphasis on commercialization. Finally, and not least, the focus on data from 1992 to 2002 is driven by the availability of data.

The firms winning Phase II awards also constitute the universe of firms addressed by the NRC's Phase II Survey,² and the NIH Phase II Survey,³ which provide the best available data on outcomes from the SBIR program. These data will be critical to the second phase of the analysis, identifying impacts.

The standard database on venture funding—also used by GAO in its 2006 study⁴—is the Thomson VentureSource database, and this is the primary source of venture funding data utilized in this National Research Council study.⁵ The NRC compiled a list of firms that received at least one Phase II award at NIH between 1992 and 2002 inclusive and Thomson VentureSource ran that list against its own database of firms that had received venture funding as of the end of 2006.

Because VentureSource requires that firms be identified based on company name, a process was developed to broaden the net, identifying all firms that could conceivably be matched to firms in the NIH awards database (using wildcards in the database search⁶). These possible matches were then tested manually against known company addresses to eliminate false positives from the results dataset.⁷

The final list from VentureSource provides considerable detail on venture capital investments: It indicates the name of the company, the date of the round of funding, the type of funding, and the amount.⁸ This appears to be the most

²For details on the NRC Phase II Survey, which included at least one questionnaire to every Phase II winner 1992-2002 inclusive, see National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

³For details on the methodology and scope of the NIH Phase II Survey, see National Institutes of Health, *National Survey to Evaluate the NIH SBIR Program: Final Report, July 2003*, available at <<http://grants.nih.gov/grants/funding/sbir.htm>>.

⁴U.S. Government Accountability Office, *Small Business Innovation Research: Information on Awards Made by NIH and DoD in Fiscal Years 2002 through 2004*, GAO-06-565, Washington, DC: U.S. Government Accountability Office, April 2006.

⁵A secondary database owned by <*Inknowvation.com*> was also used by GAO but was not made available to the NRC.

⁶We supplied a list of firm names; VentureSource replaced part of the name with wildcards and then searched the database.

⁷The VentureSource search results included information on the city and state of the firm, and these data were cross-checked against city and state data from the SBIR awards database.

⁸"Type of funding" refers to terminology within the venture capital community. Thomson and others distinguish between seed funding, A round funding, B round funding and C round funding.

definitive list of venture-funded firms available and it is used in the first phase of this study.⁹

Estimating the “Exclusion Effect”

It is important to keep in mind that simply receiving some venture funding is in itself not disqualifying. To be disqualified from participating in the SBIR program, firms must be owned or controlled by firms that themselves fail one of the two tests—breaching the size requirement and/or the individual ownership requirement—outlined above in Box 1-1.¹⁰ Thus, the list of venture-funded firms was then analyzed to determine whether it was likely that these firms would in fact be excluded by the SBA ruling.

Unfortunately, privately owned firms are often very reluctant to provide information about their ownership structure. It is therefore not possible to determine directly which venture-funded firms are owned or controlled by their venture investors (and hence excluded) and which are not. Nor it is practical to examine the ownership structure of every venture capital firm that provides funding in order to determine whether their ownership structure or the collective character of their other investments breach the eligibility requirements.

It is also worth noting that firm ownership and control are by no means synonymous.¹¹ Ownership of a majority of outstanding voting shares is sufficient to provide formal control. However, key personnel may still exert significant—sometimes predominant—control over key decisions. Conversely, 51 percent ownership is not necessarily required in order to exert effective control. However, both because the SBA ruling focuses on 51 percent ownership and because any statistical analysis must find ways to draw bright lines through murky questions, this study assumes that the critical delineator for the purpose of access to SBIR is 51 percent ownership.

After considerable discussion, and drawing on their extensive experiences, the Committee agreed on two proxies for venture control of a firm¹²:

⁹It is important to note that there is considerable heterogeneity among venture capital firms themselves. For a review of some of the differences, see William A. Sahlman, “The Structure and Governance of Venture-capital Organizations,” *Journal of Financial Economics*, 27(2):473-521, October 1990.

¹⁰There are also small biotechnology companies that are 51 percent owned by individuals but are excluded based on affiliation of a venture capital company’s other portfolio companies.

¹¹Eugene Fama and Michael Jensen distinguished between ownership and control in their classic 1983 paper. See Eugene Fama and Michael Jensen, “Separation of Ownership and Control,” *Journal of Law and Economics*, XXVI, 1983. The role of venture capital control of small innovative businesses is discussed in Paul Gompers and Josh Lerner, “The Venture Capital Revolution,” *The Journal of Economic Perspectives*, 15(2):145-168, Spring 2001.

¹²Committee members with extensive knowledge of venture capital include Linda Powers (Toucan Capital Corporation), Michael Borrus (X/Seed Capital), Clark McFadden (Dewey & LeBoeuf, LLP), and Pete Linsert (Columbia Biosciences Corporation).

- Venture capital investments of \$5 million or more; *or*
- At least two separate rounds of venture funding.

In both cases, it is reasonable to assume that 51 percent of company shares will have passed into the hands of the new investors.¹³

Using these proxies, the Committee screened the original list of venture-funded firms to develop a list of firms that it identified as having been excluded from the SBIR program on the basis of the SBA ruling. This screened list is referred to as “venture-funded firms” throughout this report.¹⁴

Next, this list was adjusted to take into account other grounds for exclusion. Most notably, this list includes firms that would be subject to exclusion from the SBIR program on other grounds, regardless of their venture capital ownership structure. This includes circumstances where the firm—

1. Had more than 500 employees.
2. Was purchased by a foreign firm, or by a U.S. firm not 51 percent individual-owned.

After eliminating firms that were venture-funded and met criteria 1 or 2 above for venture control, but also met one or more of the criteria above, we were left with a final list of venture-funded companies that were likely to be excluded based on the SBA ruling.

Grouping the Firms

In order to provide the most relevant analysis, the Committee focused on two sets of variables:

- Whether a firm was or was not venture-funded, as defined above.
- Whether a firm was among the top 200 most prolific winners of NIH Phase II funding during the 1992-2002 period.¹⁵

This approach generated the matrix in Table 2-1.

¹³This assumption was later tested against companies *known* to be excluded on venture capital grounds. We found that our criteria in these cases matched known outcomes with a high degree of accuracy.

¹⁴It is important to note that these categories of majority venture funded firms as opposed to venture-funded firms are frequently not static. As often happens in the biotechnology industry, a company may have some venture funding and be eligible for SBIR Phase I and Phase II awards, but then receive venture capital additional funding and become ineligible for further SBIR funding.

¹⁵The numerical basis for whether a firm was among the top 200 most prolific winners was driven by the need for more detailed data and the constraints imposed by limited study resources. “Prolific” is defined as being among the winners of the most NIH Phase II SBIR awards in 1992-2002.

TABLE 2-1 Firms Funded by the NIH SBIR Program (1992-2002)

	Top 200 Winners	Other Winners	Totals	Percent
VC-Funded	35	150	185	12
Not VC-Funded	165	1,186	1,351	88
Total	200	1,336	1,536	100

SOURCE: U.S. Small Business Administration Tech-Net Database, VentureSource.

NOTE: Table 2-1 refers only to majority venture-funded firms that meet the two core venture capital investment criteria for control—namely more than \$5 million in investment or more than one round of venture control funding. The Top 200 winners accounted for 42.3 percent of Phase II awards during 1992-2002.

Majority venture-funded firms were clustered among the top 200 winners. They accounted for a higher percentage of the top 200 winners (17.5 percent) than they did of all NIH winners. Table 2-1 shows that overall, about 12 percent of firms that won SBIR Phase II awards from 1992-2002 inclusive were also venture capital-funded.

In addition, firms that were more prolific in winning SBIR awards were also more successful in attracting significant venture capital funding: 35 (17.5 percent) of the top 200 award winners were majority venture-funded, as against 11.2 percent of the remaining 1,336 SBIR award winners.¹⁶

2.2 METHODOLOGY FOR MEASURING THE IMPACT OF THE SBA RULING

The primary objective of this part of the assessment is to compare outcomes for SBIR projects implemented by venture-funded and non-venture-funded firms respectively.

Two kinds of outcomes are utilized:

- *Project-level outcomes* identified by the NRC and NIH surveys. These include sales and the attraction of additional funding as the two key metrics.¹⁷
- *Firm-level outcomes*, generated by cross-referencing firms with Phase II awards against revenue and employment data extracted from the Hoover's database of small firms.

¹⁶It is important to note, as well, that while SBIR enhances the success of venture-backed firms, the obverse is also true. It is also possible that the top 200 SBIR award winners had topics that were more advanced in their development.

¹⁷Additional funding as used in the NRC and NIH surveys means funding from all sources, including VCs, angel funding, and additional non-SBIR federal funding (a major component).

Project-level Outcomes

Until recently, there were no available data on outcomes from SBIR programs through which to compare the performances of venture-funded and non-venture-funded firms. Recent surveys by the NRC and the NIH, however, provide at least initial indications of relative outcomes.¹⁸

The NIH survey generated 768 responses (1 per firm) and the NRC 496 responses from 368 firms.¹⁹ Together, the surveys generated responses covering at least one project from 861 firms that received Phase II awards during this period.²⁰

Firm-level Outcomes

While the NRC/NIH data provide important insights into outcomes from specific surveyed projects, it is also useful to generate a different perspective based on the development of the firm, rather than an individual project.

Utilizing the Hoover's database of small firms, we developed a dataset of current revenue and employee data, which provides a useful proxy for the overall commercial success of the firm.²¹ Unfortunately, Hoover's does not maintain time-series data on individual firms, so our metrics were based on the size of firm revenues and number of employees as of the most recent data available from Hoover's (in most cases, for 2006).

As each data point in this dataset had to be collected manually, it was not cost effective to collect individual data on more than 1,200 firms. Accordingly, while we collected data for all 183 venture-funded firms,²² we limited data collection for non-venture-funded firms to an equivalent random sample: 35 firms among the top 200 most prolific Phase II winners, and 148 firms from among the pool of firms that were not among the most prolific winners and were not venture-funded.

¹⁸See National Institutes of Health, *National Survey to Evaluate the NIH SBIR Program: Final Report*, op. cit. The NRC survey results for NIH are presented in National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, C. Wessner, op. cit.

¹⁹There is some overlap between the projects surveyed by the NIH and NRC. However, as project ID data is not directly comparable, it is not possible to determine exactly the dimensions of that overlap.

²⁰Not every firm responded to the survey questionnaires. The 861 firms are a subset of the 1,536 firms that won Phase II awards 1992-2002.

²¹The Hoover's database of small firms is an extension of the well-known Dunn and Bradstreet database. It is the most comprehensive source of information on small businesses in the United States. Even so, it offers only a current snapshot (no historical data), and is not entirely comprehensive as it, in turn, is based in part on survey data. Hoover's Small Business Database can be accessed on line at <http://www.hoovers.com>.

²²Table 3-4 derives the total number of firms that were excluded or possibly excluded as a direct impact of the SBA directive.

BOX 2-1 Downward Bias in the Estimation of the Impact of the SBA Directive

Assessing the impact of the SBA exclusion of majority venture-funded firms is difficult because obtaining data on the ownership structure of companies, especially private-held small firms, is hard to do. This assessment therefore relies on a sample of firms that received Phase II SBIR awards during the period 1992-2002 (before the directive was issued). The use of such data is likely to yield a downward bias in the estimate of the effects of the SBA exclusion for two reasons:

- **Recent shift of venture capital to the biotechnology sector.** The life sciences and biotechnology were relatively embryonic industries during the sample period (before 2002). More importantly, venture capital started shifting towards biotechnology and life sciences after the Internet bubble burst in 2001.^a Thus, the number and proportion of small life science-based firms receiving venture funding may be much higher than can be captured from data focused on the 1992-2002 period.
- **Venture funding barred as biotechnology firms matured.** Leading papers in the economics of innovation literature point out that technological and product development opportunities (and thus, commercialization of research) become more prevalent as an industry matures.^b Venture funding is focused mainly on product development. This implies that it is likely that the SBA ruling may be excluding a higher percentage of firms in this sector as the industry matures.

^aDouglas P. Lee and Mark D. Dibner, "The Rise of Venture Capital and Biotechnology in the US and Europe," *Nature Biotechnology*, 23:672-676, 2005.

^bOn product innovation and commercialization in a wide variety of industries, see Edwin Mansfield, "Academic Research and Industrial Innovation: An Update of Empirical Findings," *Research Policy*, 26(7-8):773-776, April 1998.

2.3 CASE STUDY AND OTHER DATA

One final area of analysis concerns the impact of the ruling on the biotech industry itself. As noted earlier, BIO and other groups have claimed that the exclusion of venture funded companies from SBIR will result in a critical "gap" in the funding flow, one that may prevent important discoveries from being commercialized.

To substantiate these claims, BIO conducted telephone and Internet surveys of its "emerging company" membership—defined as firms with fewer than 350 employees and no marketable products.²³ The surveys suggest that a large

²³BIO appears to have contacted all 650 firms that make up its emerging company membership, with a response rate of about 41 percent. BIO provided no additional background information about the surveys. For a description of the surveys, see Appendix E of this report.

majority of responding biotech companies would apply for NIH funding absent the ruling, and that most would *not* use the funds for their lead product. Two thirds of the proposed research was reported to be focused on preclinical or discovery stages.

BIO also conducted six case studies designed to show that promising lines of early-stage research have been abandoned or delayed as a result of the ruling. These cases, however, do not provide counterfactual evidence based on products that *were* funded prior to the SBA ruling, which would have been excluded by the ruling.

These cases will be discussed in the context of the NRC's own cases, which included some venture-funded firms. An analysis of the evidence submitted by BIO is included in Appendix E of this report.

3

Venture Funding for NIH Phase II Winners, 1992-2002

Using the methodology and approach outlined above, we provided VentureSource with a list of the 1,536 firms that had won Phase II awards at NIH, 1992-2002 inclusive.¹ VentureSource compared these company names with those in its database, using wildcards to ensure that the widest possible net of possible matches was identified.²

The resulting VentureSource list of 296 firms with identified venture capital funding was cross-checked against address data of the firms and other sources to ensure that the firms that VentureSource identified as venture-funded were in fact the same firms as those identified as receiving NIH Phase II funding. As a result of this review, 62 VentureSource names were eliminated, leaving a final list of 234 firms with both Venture funding and NIH Phase II funding.

The 234 firms identified here include all firms identified as receiving any venture capital funding. These 234 firms constitute the possible pool for firms that *might* be excluded from future NIH awards by the SBA ruling. However, not all of these firms are excluded by the implementation of the SBA ruling.

¹U.S. Small Business Administration Tech-Net Database.

²In other words, we supplied a list of firm names; VentureSource replaced part of the name with wildcards and then searched the database. For example, we provided the name Illumina Inc. VentureSource deleted the “inc.” because this can be spelled with different punctuations, which could break a match, and replaced these letters with a wildcard character (“*”). The search then identified Illumina as venture-funded.

TABLE 3-1 Phase II Awards and Venture Funding

	Number
Total Firms Winning NIH Phase II Awards 1992-2002	1,536
Firms Identified as a Match by VentureSource	296
Firms Excluded from Match after Further Review	62
Revised List of Venture-funded Firms Winning NIH Phase II Awards	234

SOURCE: U.S. Small Business Administration Tech-Net Database; VentureSource.

NOTE: Table 3-1 shows all firms receiving NIH SBIR Phase II funding, and firms receiving venture capital funding as identified by VentureSource.

3.1 CONTROL AND INDIVIDUAL OWNERSHIP³

Venture funding is not in and of itself disqualifying for firms seeking SBIR funding. In order for a firm to be eligible for SBIR funding under the SBA's revised eligibility tests, a firm must be effectively controlled by U.S. individuals, or be controlled by another firm or firms that are themselves majority-owned by U.S. individuals. It has been argued—by venture capitalists and other experts—that most firms receiving venture funding cannot meet these criteria.⁴

A first issue concerns control of the SBIR firm. Given the high risks involved in funding early-stage companies, and the low existing capitalization relative to the investment being made in the firm, venture capitalists often make substantial investments in a firm, but do not always acquire control of the firm at an early stage. It is often the case that there are multiple venture capital investors who invest in a single small biotechnology firm that in combination make up a

³Is majority ownership of a firm synonymous with control of a firm? Some economics theorists, including Oliver Williamson and William Baumol have argued that differences in motivation are likely to arise between owner and management groups and that management insulated from effective owner control may pursue policies at variance with the owner's interests. However, Public Choice scholars, including Henry Manne and Gordon Tullock, point out that a variety of incentive mechanisms in the real world, including for example the threat of takeover, help to align the motivations of managers and owners. Some economists have also questioned whether the commonly used standard of 50 percent plus ownership benchmark actually provides an effective indicator of control of a corporation. Adolph Berle and Gardiner Means, in an early empirical study, demonstrated that effective control can be exercised with as little as 20 or even 10 percent ownership. Conversely, nominal ownership of greater than 50 percent of a firm need not necessarily imply effective control of firm. For small biotechnology companies, this case occurs when "majority ownership" is in fact divided among a syndicate of investors who each hold a small ownership share. For a review of the classic economics literature concerning the tension between ownership and control, see Robert Sorensen, "The Separation of Ownership and Control and Firm Performance: An Empirical Analysis," *Southern Economic Journal*, 41(1):145-148, July 1974.

⁴See Thomas Hellman and Manju Puri, "Venture Capital and the Professionalization of Start-Up Firms: Empirical Evidence," in *The Journal of Finance*, 57(1):169-197, February 2002; See also Steven N. Kaplan and Per Strömberg, "Financial Contracting Theory Meets the Real World: An Empirical Analysis of Venture Capital Contracts," *Review of Economic Studies*, 70(2):281-315, April 2003.

majority stake, though each individual venture capital investor almost always has a minority share. Control may shift in the course of the very first investment in the firm, or it may come later. In some cases, individual owners retain their control until an IPO or even in some exceptional cases afterwards. This question is addressed in the next section.

A second issue concerns the firms that are still owned by 51 percent individuals but would be deemed ineligible under the 500 employee limit as interpreted by the SBA, whereby an investor's portfolio companies can be included under the 'informal' aspects of control used by SBA to determine affiliation. There appears to be no useful way to develop a proxy that could differentiate between VC funds that breach this component of the SBA interpretation and those that do not.⁵

3.2 ELIMINATION I: EFFECTIVE CONTROL

The issue of control in majority venture-funded firms is exceptionally complex. There are both formal and informal aspects to control, and the question of control is often the subject of very carefully defined and tightly worded legal contracts.⁶ The difficulties in identifying controlling interests are of course compounded because privately-held companies in many cases do not publicly reveal their share owning structure. As a result, it is not possible to determine directly which firms are now ineligible under the 51 percent rule. Yet at the same time, any analysis of the impact of the SBA ruling must develop a good estimate for that number.

If direct access to relevant information is not available, it becomes necessary to turn to the identification of proxy indicators that we have determined to be closely associated with "control." Upon deliberation, the Committee determined that it was reasonable to assume that firms that meet *either* of the following criteria are in fact venture-controlled for purposes of analyzing the impact of the SBA ruling⁷:

- a) They received more than one round of venture funding; *or*
- b) They received at least \$5 million in venture funding.

This approach is captured in the Venn Diagram shown in Figure 3-1.

⁵Discussions with venture firms indicate that most successful VC firms believe that they would be in breach of this requirement.

⁶See Gordon Smith, "Control and Exit in Venture Capital Relationships," University of California, Berkeley, Law and Economics Workshop 2005, Paper 9, pp. 18-21.

⁷Committee members with extensive knowledge and experience of venture capital investment include Pete Linsert (Columbia Biosciences Corporation), Michael Borrus (X/Seed Capital), Linda Powers (Toucan Capital Corporation), and Clark McFadden (Dewey & LeBoeuf, LLP).

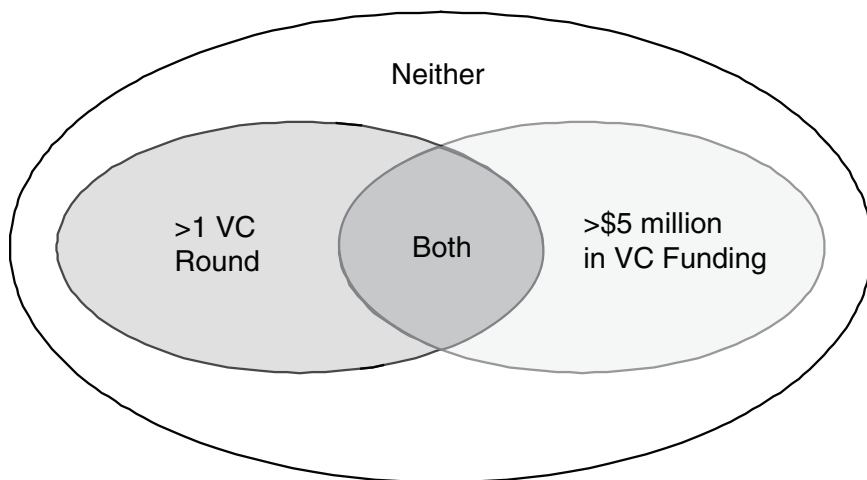


FIGURE 3-1 Venn Diagram of Criteria for Elimination.

Firms that have less than two rounds of venture capital funding *and* less than \$5 million in venture capital investments are excluded from the list of venture capital-funded companies because this evidence is insufficient to support the claim that on balance of probability they are venture capital-controlled.

While some firms with less than \$5 million in venture funding may have exceeded 51 percent or more of share ownership to venture investors, it is also possible that founders or other individuals still retain ownership of more than 50 percent at some firms which received more than \$5 million in investment from venture funders. Similarly, in some cases, venture investors making a single major investment may acquire more than 50 percent of firm ownership; in other cases, firms that have received several small rounds of venture investment may remain predominantly in private hands. Thus while these criteria are not accurate in all cases, they represent the best available proxies for institutional ownership.

The Committee further assumed that all venture capital firms fail to meet the individual ownership criterion themselves. This assumption is used in this study to meet the possible objection that a venture capital firm that raised more than half of its funding from U.S. individuals would find that even firms in which it owned 51 percent would remain eligible. As venture funds typically do not reveal their sources of funding, it is not practical to differentiate between venture capital firms in terms of their ability to meet the eligibility criteria. Thus, we assume that all firms meeting either a) or b) criteria above are excluded from the NIH SBIR program.

Using these assumptions, we generate the following results from further analysis of the VentureSource data.

TABLE 3-2 Exclusion of Venture-funded Firms

	Number
SBIR Phase II Winners Receiving VC Funding	234
>\$5 Million	154
>1 Round	166
>\$5 Million or >1 Round	183

SOURCE: Thomson VentureSource.

The 183 firms meeting one or both of the criteria constitute our pool of potentially excluded companies. They constitute 11.9 percent of all the 1,536 NIH Phase II winners 1992-2002 reported by SBA.

For the remainder of this report, we define “Venture-funded firms” as those 183 firms that would, based on the criteria above, have been excluded from the SBIR program.

3.3 ELIMINATION II: FIRM SIZE AND OWNERSHIP

However, these firms have not all in practice been excluded from eligibility by the SBA ruling. Some have gone out of business. Others have been acquired, still others have gone public (see below for a more detailed discussion of the last).

We performed an individual review of each of the 183 firms identified above, using the individual company pages of the Hoover’s database of small firms, data from the SEC, and web searches for firms that appear to be out of business or otherwise no longer operating. The results of this analysis are shown in Table 3-3.

As a result of this analysis, we can identify three groups of firms:

- Those that are definitely excluded from the program *on grounds other than venture ownership* (out of business, acquired, or foreign-owned).⁸
- Those apparently still eligible aside from venture ownership (privately held).
- Those possibly excluded on other grounds (publicly traded companies).

⁸The four foreign owned firms were not affected because they were always ineligible. Including the 21 firms that went out of business is preferable to excluding them. They were, after all, affected even if the net result was close to zero given that they went out of business.

TABLE 3-3 Status of Venture-funded Firms

Status	Number of Firms	Percentage of Firms
Likely Excluded by SBA Ruling		
Still privately held	63	34.4
Excluded Also by Other Factors		
Out of business	19	
Now foreign owned	4	
Acquired	46	
Total	69	37.7
Possibly Excluded		
NASDAQ	45	
AMEX	3	
NYSE	1	
OTC	1	
IPO	1	
Total	51	27.9
Total Venture-funded Firms	183	

SOURCE: VentureSource, Hoover's Small Business Database.

TABLE 3-4 Exclusion Status of Venture-funded Firms

Status	Number of Firms	Percent of Excludable VC-funded Firms	Percent of All Phase II Winners
Excluded (privately held, still otherwise eligible)	63	34.4	4.1
Excluded (other grounds)	69	37.7	4.5
Possibly Excluded (publicly traded)	51	27.9	3.3
Total	183	100.0	11.9

SOURCE: U.S. Small Business Administration; VentureSource. **NRC calculations.**

NOTE: Notes on total sample: Estimating the total number of NIH award winners is not an exact science. Data are maintained by firm names, which not only change, but are often recorded in non-standard ways—a firm can be recorded separately as “Inc” “Inc,” Inc.” “Incorporated” or the “Inc” excluded altogether. Typos are frequently found in addition. The method used here for addressing this problem is to take the raw data from SBA, eliminate all suffixes, commas, and periods, and then review each individual record by hand. This was a three-step process. Initial review eliminated most of the duplicate entries. A second review generated a list of 1,567 firms. Final review, which took a more aggressive approach by eliminating duplicate names for firms in the same state and region, generated a final list of 1,536 firms.

Privately held excluded firms. The privately held firms meet our criteria for being excluded and hence their exclusion is regarded as a direct impact of the SBA ruling. These firms account for about one-third of all the VC-funded firms, or 4.1 percent of all firms receiving NIH Phase II awards 1992-2002.

Otherwise excluded firms. Firms that meet our criteria, but which are also excluded on other grounds, constitute the second group of firms. This group presents a conceptual challenge: These firms would be excluded from the program based on the SBA ruling, although they are, in any event, no longer eligible for the program. However, in seeking to determine the impact of the SBA ruling, we assume that the ruling would at a minimum have had some short term impact on these firms, because it would have excluded them between the time of the ruling and the time at which they became ineligible for other reasons.⁹

Publicly traded companies—possibly excluded. The third group is made up of publicly traded companies. These firms seem likely to fail the individual ownership criterion, because the preponderance of stock ownership in U.S. capital markets is through institutional owners, pension funds, investment entities of various kinds, and other companies.¹⁰ However, there are also cases where publicly traded firms are still owned and controlled by a group of U.S.-based individuals. In addition, some publicly owned firms have continued to apply for and receive Phase II funding at NIH, although it is also worth noting that these numbers have declined substantially in recent years, a trend that may indicate that the impact of the ruling is only now becoming apparent. This point is discussed further in Section 3.4 below.

These publicly owned firms also pose conceptual challenges for the analysis. One question concerns the extent to which their exclusion is in fact based on the ruling. Some firms self-excluded on the grounds that they were not individually owned long before the SBA ruling. Others however may have responded directly to the ruling itself. This distinction is pursued below, in Section 5.1.

Overall, publicly traded firms cannot be assumed as a group to be either included or excluded from the program based on these ownership criteria. To identify firms definitively that specifically breach the individual ownership criteria, it would be necessary to undertake an extensive analysis of each firm's share ownership structure, including an analysis of the ownership structure of each significant shareholder. This however is beyond the scope of this study.

Conclusions—Excluded firms. Altogether then, we conclude that using our criteria, a minimum of 4.1 percent (63 firms) of firms that received Phase II awards 1992-2002 have been excluded because of the SBA ruling; a further 4.5 percent (69 firms) would have been excluded by the ruling, but were also

⁹Data from Hoover's covers only 2006—so we know that they were ineligible on other grounds as of 2006. We do not know when they became ineligible.

¹⁰Carolyn Kay Brancato and Stephan Rabimov, *Institutional Investment Report*, Washington, DC: Conference Board, 2007, R-1400-07-RR, reports that approximately 64 percent of U.S.-listed stocks were held by institutional investors.

TABLE 3-5 Awards to Venture-funded firms 2003-2006

Status	Number of Firms	Percent of Category
Foreign	1	25.0
Private	15	23.8
Acquired	2	4.3
Publicly Traded	11	21.6
Out of Business	0	0.0

SOURCE: VentureSource; Hoover's Small Business Database; U.S. Small Business Administration Tech-Net Database.

excluded on other grounds. Finally, 3.3 percent (51 firms) became publicly traded, which may have required that they cease applying for SBIR funding as they would no longer meet the 51 percent individual ownership requirement. *In short, between 4.1 percent and 11.9 percent of firms that won SBIR Phase II awards between 1992 and 2002 are excluded from the program as a result of the SBA ruling.*

It should be noted that 11.9 percent reflects the upper bound of firms from this period that were potentially excluded. It includes firms that were acquired, and that became ineligible for other reasons. The 4.1 percent reflects the lower bound—the percentage of NIH SBIR Phase II winners 1992-2002 firms that appear to have been excluded by the ruling, and are not potentially excluded by other factors.

3.4 FURTHER AWARDS TO POSSIBLY EXCLUDED FIRMS

One way to test the effectiveness of our exclusion criteria is to examine whether potentially excluded firms have continued to operate within the NIH Phase II SBIR program.

We found that 29 of the 183 venture-funded firms had in fact received an award during 2003-2006.

It is possible that we are simply seeing lags here: There appears to be a substantial drop-off in awards in the most recent year for which data are available: In 2006, only six of the 183 potentially excluded firms received awards; five of these were privately held, one was publicly traded. This may indicate that the status of the firms changed over time or that firms now have a better understanding of the eligibility requirements and are no longer applying to the program.¹¹

This last point is significant. It suggests that the excludability criteria we have used are broadly effective, in that by 2006, only six of the 183 firms that we iden-

¹¹However, there has also been a substantial decline in overall applications for NIH SBIR funding, which may not be related to the venture capital issue (see Section 5.1).

tified as potentially excluded were still receiving funding. The five still in private hands can be regarded as examples of the imprecision of our assumptions—they may, as discussed in Section 3.2, be firms that received more than \$5 million or more than one round of venture funding, but did not for various reasons cede a controlling interest. The fact that only one of the 51 firms identified as publicly traded was still applying suggests even more strongly that these firms have been largely excluded.

4

Focus on the Top 200 Award Winners

In an effort to ensure that the most prolific award winners at NIH were fully analyzed, the Committee focused additional attention on the 200 firms that won the most Phase II awards in 1992-2002.

4.1 METHODOLOGY

Data from the Thomson VentureSource database was supplemented by a manual cross-check using data from the RDNA database, for the top 200 NIH recipients of Phase II funding 1992-2002.¹ This manual cross-check resulted in identification of 13 firms not identified by the VentureSource database alone, for a total of 51 firms with some venture investment.

The 51 firms among the top 200 NIH Phase II award winners identified as venture-funded are listed in Appendix A. In aggregate, these 51 firms received a total of \$272 million in NIH funding (Phase I and Phase II awards), largely through 285 Phase II awards. They also received a total of \$1.59 billion in venture funding, spread over a total of 224 rounds. These data support the hypothesis that venture funding—when it comes—is considerably larger than Phase II funding (an average of \$31.2 million per firm for venture investment, as against an average of \$5.3 million in SBIR funding per firm).

¹RDNA is a trademarked term for a commercial database of venture funding, now owned by Deloitte.

4.2 ADDITIONAL RESEARCH

In order to ensure that venture-funded firms among firms winning the most NIH awards are not missed as a result of incomplete data, we conducted telephone interviews with the top 25 recipients of Phase II awards from NIH identified as *not* having received venture funding. These companies do not appear in the three databases used in the initial assessment of the top 200 Phase II award winners.

The analysis did identify additional firms with some links to venture funding that were not previously identified as such:

- Two companies were identified as having received venture funding in the past—in one case more than ten years ago, the other at some indeterminate point before going public. Both are now publicly traded.
- Two companies were in some indirect way connected to venture capital (respondents did not wish to be clear on this point).
- Four companies would not respond.

This suggests that of the top 200 recipients of Phase II funding at NIH, 53 can now be identified as receiving venture capital. It does not seem likely that this analysis missed a significant number of venture-funded firms. And the two additional firms identified as receiving funding cannot be determined to breach the *de minimis* conditions used for identifying venture-funded companies in this report.

4.3 SEQUENCING

Analysis of the top 200 winners can also help to answer another question about the role of venture funding is its relationship to SBIR funding. One conceptualization of this relationship suggests that SBIR awards can often serve as a bridge toward venture funding. On this view, SBIR awards not only fund the very-early-stage funding needed to get to proof of technical concept, they may also provide a “halo effect”: Funding by the NIH SBIR program, with its attendant well-respected peer review program, provides additional support for the proposed investment and in particular validation of the technical approach.

An alternative view is that resources available to venture-funded firms are likely to result in greater success in garnering SBIR awards—a point argued by some supporters of the SBA ruling. This view would seem to be *prima facie* supported by the data in Table 4-1, which shows that two-thirds of SBIR award recipients received their first Phase II funding *after* their first venture round.

This linear conceptualization of innovation—distinguishing a sequence of successive stages from very-early-stage to proof-of-concept to commercialization—has its merits. However, our analysis of top 200 firms at NIH indicates

TABLE 4-1 Sequencing of SBIR Awards and Venture Funding

No.	Sequence	Number of Firms
1	First venture funding before first SBIR Phase II	34
2	Last venture funding after start of latest SBIR Phase II	17
3	First venture funding after last start date for SBIR Phase II	6
4	Total venture capital-funded companies identified as NIH SBIR Top 200	51

SOURCE: VentureSource; other VC databases; NIH.

NOTE: Categories 1-3 are not necessarily exclusive and hence do not total to 51.

that the story is more complex.² The presence of SBIR funding may enhance the likelihood of venture funding, but the obverse may also be true. With regard to the firms identified here, the actual sequencing of awards and venture funding does not support a simple linear hypothesis, as illustrated in Table 4-1.

Looking closely at the 51 venture-funded firms for which we have detailed data on individual venture investments, we find that:

- Thirty-four of the firms (67 percent) received their first Phase II funding *after* their first venture round. For these firms, it appears that SBIR funding is typically auxiliary or complementary to the venture funding they have already received.³ This view is supported by case studies completed for the NRC report on the NIH SBIR program. Representatives of Illumina, Neurocrine, and Martek among other firms indicated that once funded by venture partners, it was not necessary to rely on highly uncertain funding like SBIR to develop the company's primary commercial product or service, but that such funding could be critical to the development of additional products.

- Seventeen firms (33 percent) received their most recent venture funding after the start of their most recent Phase II award. This suggests the existence of a "halo effect" where the SBIR award provides a signal of quality to investors. It also suggests that SBIR and venture funding are used in a complementary, parallel fashion by these recipients.

- Six firms (12 percent) received their first venture funding after the start of their most recent NIH Phase II award. For these firms too, it is possible that

²Interviews and surveys in the course of the NRC SBIR analysis identified firms where founders and other interviewees believed that the halo effect had made a difference.

³Case study interviews for the NRC's NIH SBIR Assessment indicated that venture-funded firms may find important uses for SBIR funding (for example, exploring avenues of research) that they could not otherwise accomplish. It is also true that where alternative sources of funding are available, SBIR is not typically used to fund the firm's primary efforts toward commercialization, given the constraints of timing and award size in the SBIR program. SBIR can be a crucial funding source when there are no other alternatives available. See the case studies of Neurocrine and Illumina in National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

the SBIR award had a “halo effect,” helping venture capital firms to identify especially promising firms and technologies for investment.

This sequencing analysis does not support a simple view of SBIR and venture funding—that SBIR is seed funding and is subsequently replaced by venture funding later in the development cycle. Only six of the 51 firms exhibit sequencing that matches the seed-development distinction.

A different, more nuanced analysis of the SBIR-venture funding relationship is therefore necessary. This analysis must include the important distinction between *firms* and *projects*. A firm may have multiple projects in its portfolio with multiple sources of financing and may grow and develop in a non-linear fashion. By contrast, individual projects may indeed develop in a somewhat linear direction from idea to prototype, testing, and eventually development. However, there is now growing evidence—including from recent NRC research—to indicate that even for individual projects the road to the market is far more winding and circuitous than suggested by simple linear models.⁴ Simple linear models do not tell the full story.⁵

These complexities at the project level are multiplied many times at the firm level, where different projects at different stages of development compete for scarce resources. Several interviewees indicated that funding from venture partners was in many cases tied very tightly to the costs of development for a particular lead product; more speculative or alternative research projects were often excluded from venture funding, and had therefore to turn to SBIR and other resources.⁶ In some cases, such as Illumina, these alternative paths became over time highly successful.

Thus it is simplistic to conclude that the receipt of venture funding is itself sufficient to insulate firms from the need to find more resources for other projects outside the critical path being funded by the venture capital investment. This is an important conclusion.

⁴This evidence comes from case studies of firms that have won SBIR awards conducted as a part of the National Research Council’s comprehensive assessment of the SBIR program. See, for example, National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, op. cit.

⁵For a discussion of the limitations of the linear model of innovation, see the Introduction chapter of National Research Council, *An Assessment of the SBIR Program*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2008.

⁶See, for example, the case studies of Illumina and Neurocrine in National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, op. cit.

5

Other Sources of Data on the Participation of Venture-owned Firms

5.1 NON-PARTICIPANT SURVEY

In conducting its assessments of the SBIR program, members of the Committee have drawn on multiple perspectives.¹ For this study on venture capital and SBIR, in addition to the data discussed above, and NIH and NRC surveys discussed below, the Committee sought to develop data relating to the firms and principal investigators who applied for NIH funding during the period leading up to the 2002 SBA ruling, but who have not since applied for funding. This dataset may provide direct evidence about the impact of the SBA ruling.

Accordingly, in cooperation with NIH, the Committee developed a survey of these non-participants that focused on the question of why these firms were no longer applying for NIH SBIR funding. The survey questionnaire is found in Appendix B.

NIH identified a total of 3,913 firms that applied for NIH funding during 1992-2002 inclusive, but did not do so during 2003-2006. Of these, 3,382 had email addresses, and these formed the initial target of our survey.²

Of the 3,382 potential targets, 1,331 did not have a current valid email (i.e. at least two emails to those addresses were returned to sender). This is in line with the NRC's experience with other email-based SBIR surveys. The final baseline for the survey is therefore the 2,051 respondents with valid email addresses.

¹National Research Council, *An Assessment of the Small Business Innovation Research Program—Project Methodology*, Washington, DC: The National Academies Press, 2004. Access at <http://www.nap.edu/catalog.php?record_id=11097>.

²The survey questionnaire is included as Appendix B.

From this base, we received a total of 386 responses, an 18.8 percent response rate.³ These results provide an additional basis for assessing relative importance of the venture capital exclusion among those not applying for further SBIR funding from NIH.

Of the 386 responses, 49 identified their firms as having received, in fact, further SBIR funding. This may be because the names of firm can change, or because of inaccuracies in the tracking databases. These responses were eliminated from our analysis. Also eliminated were 87 respondents who indicated that they had not applied during the 2003-2006 timeframe but that they still expected to apply again in the future. These firms were therefore not “excluded” for the program by rule. The remaining 269 responses—13.1 percent of the target population—provided valuable data.

These respondents were asked two key questions. First, they were asked to provide multiple-choice answers as to why their firms were no longer applying.

The survey data summarized in Table 5-1 indicate that the three most frequent reasons for not applying were drawn from the operation of the program itself. These are: the level of competition (which at one level is a very positive statement about the quality of the program⁴); concerns about selection mechanisms; and funding delays.⁵

Conversely, venture ownership was one of the three lowest-scoring options, along with foreign ownership, and the shift to public ownership of the company. Only 12 responses (1.8 percent of the total) indicated that the venture funding exclusion was one of their reasons for leaving the program.

This suggests that at least for the firms that responded to the survey, the impact of the ruling on non-participation has been very modest. The survey data generate a result that identifies excluded firms at a considerably lower rate than our direct analysis of eligibility in Chapter 3.

Because being excluded is itself a sufficient condition for non-participation, it also seemed possible that venture ownership would be an especially powerful reason for non-application among those who mentioned it at all, so we also asked

³The response rates for the SBIR survey are high for a technology survey, especially given that this survey is targeted to small firms. Fledgling companies tend to have a very high attrition rate. See Vangelis Souitaris, “Technological Trajectories As Moderators of Firm-Level Determinants of Innovation,” *Research Policy*, 31:877-898, 2002. Also see Vangelis Souitaris, “Firm-Specific Competencies Determining Technological Innovation. A Survey in Greece,” *R&D Management*, 32(1):61-77, 2002. Finally, see Pilar Rodolfo Vargas, Zárata Salinas, and Luis Ángel Guerras, “Does the Technological Sourcing Decision Matter? Evidence From Spanish Panel Data,” *R&D Management*, 37(2):161-172, 2007.

⁴It is also true that if success rates fall below a certain level, the incentive for firms to apply diminishes as well.

⁵These concerns are discussed in National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

TABLE 5-1 Survey Question: Why Is Your Firm No Longer Applying to the NIH SBIR Program? (Multiple answers permitted.)

	Response	Number of Responses	Percent of Responses
1	Company is out of business	81	12.2
2	No longer a research oriented company	24	3.6
3	No longer working in technical areas that are likely to be funded by NIH	31	4.7
4	The competition for awards is such that the likelihood of winning an award is too small to justify the effort to apply	102	15.3
5	The selection mechanism is not one that we believe will allow us to make winning proposals	96	14.4
6	Risk to our IP or business secrets during the selection procedure is too high	25	3.8
7	The delays in funding are too long to make the effort worthwhile	89	13.4
8	No longer eligible for the program because we have more than 500 employees	12	1.8
9	No longer eligible for the program because we are now a publicly owned company with more than 50 percent institutional ownership	10	1.5
10	No longer eligible for the program because we are majority foreign-owned	7	1.1
11	No longer eligible for the program because we are majority institution-owned (e.g., by venture capital companies)	12	1.8
12	The size of awards is insufficient to justify the effort involved in applying	69	10.4
13	Other	108	16.2
	(Denominator)	666	100.0

SOURCE: NRC Non-participant Survey.

respondents to identify the single primary reason for not applying to the program. The results are summarized in Table 5-2.

Firms that indicate ownership-related concerns in Table 5-2 also indicate that these issues tend to dominate their application decisions. Of the 12 respondents that mentioned venture ownership as a reason for not applying, eight (or two-thirds) identified this as the primary reason. However, we should also note that this still only accounts for 2.5 percent of all responses.

In contrast, the company going out of business was the most important single reason—although this merely reflects the normal, but high, levels of churn among small, early-stage companies. More than one-third of all respondents indicated that some characteristic of the program—notably the degree of competition for awards and concerns about the selection mechanism—were their primary reasons for non-application. Conversely, 6 percent indicated that ownership considerations prevented further applications for funding.

TABLE 5-2 Survey Question: Why Is Your Firm No Longer Applying to the NIH SBIR Program? (Primary reason only.)

	Response	Number of Responses	Percent of Responses
1	Company is out of business	74	22.8
2	No longer a research oriented company	11	3.4
3	No longer working in technical areas that are likely to be funded by NIH	14	4.3
4	The competition for awards is such that the likelihood of winning an award is too small to justify the effort to apply	44	13.6
5	The selection mechanism is not one that we believe will allow us to make winning proposals	49	15.1
6	Risk to our IP or business secrets during the selection procedure is too high	2	0.6
7	The delays in funding are too long to make the effort worthwhile	26	8.0
8	No longer eligible for the program because we have more than 500 employees	7	2.2
9	No longer eligible for the program because we are now a publicly owned company with more than 50 percent institutional ownership	5	1.5
10	No longer eligible for the program because we are majority foreign-owned	6	1.9
11	No longer eligible for the program because we are majority institution-owned (e.g., by venture capital companies)	8	2.5
12	The size of awards is insufficient to justify the effort involved in applying	27	8.3
13	Other	51	15.7
	(Denominator)	324	100.0

SOURCE: NRC Non-participant Survey.

NOTE: There may be more than one response for some firms because more than one project was surveyed in firms with multiple projects. Hence the 321 denominator reflects responses, not firms.

Though interesting, these results must be treated with some caution given relatively low response rate. However, they do provide a useful cross-check on our other estimates for excludability, and they indicate that this survey at least provided no evidence that our estimates of the percentage of firms negatively affected by the ruling are too low.

5.2 NIH-IDENTIFIED EXCLUDED FIRMS

Much of the analysis in this report is focused on the years 1992-2002, because these are years for which the most data are available, in particular outcomes data to which we will turn in the next section. These are also the years

immediately before the SBA ruling, when firms applied at a rate not affected by the ruling.

However, there are other more recent indications that firms are being excluded based on venture ownership. The most important source is NIH itself, which has provided a list of firms it believes have been excluded.⁶

NIH lists a total of 55 firms, (provided in Appendix C). Approximately half of the firms were self-certified as ineligible, and half were so certified by SBA. Of these firms, 11 had won NIH Phase II awards during the study period 1992-2002. Of these 11, five were identified within the VentureSource database. All of these five firms were also marked as being excluded under the criteria for exclusion developed above (either at least two rounds of funding or at least \$5 million in venture funding). This suggests both that the VentureSource database is not a complete record of venture funding activity in the sector, and that the excludability assumptions developed in Section 3.2 are again validated.

While the list (which is not definitive) contains a considerable number of firms, this should be put into perspective. During 2003-2006, NIH made 1,442 Phase II awards to 942 different firms.⁷ The firms on the NIH list of firms excluded on venture ownership grounds amounts therefore to 5.8 percent of all firms winning Phase II awards 2003-2006.

This is not an insignificant number, and it is likely the NIH list is incomplete.⁸ It is also a figure approximately in line with the data from the non-participant survey, and with the analysis of awards undertaken in Chapters 3 and 4.

5.3 BALANCING OBJECTIVES: A VIEW FROM MARTEK'S EXPERIENCE⁹

Martek—a commercially successful company, with a market capitalization of over \$665 million in 2007—provides the perspective of a successful firm that has benefited from complementarities between SBIR awards and venture funding.¹⁰

Martek has licensed its nutritional oils to 28 infant formula manufacturers, who collectively represent approximately 70 percent of the estimated \$8.5 to \$9.5 billion worldwide wholesale market for infant formula and nearly 100 percent of the estimated \$3.0 to \$3.5 billion U.S. wholesale market for infant formula, including the wholesale value of Women, Infant & Children program (“WIC”)

⁶The list, which is not dated, was received in 2007 and covers firms believed to be excluded in the period after the ruling.

⁷National Institutes of Health, Private communication, October 2007.

⁸There is no central registry of eligible and ineligible firms.

⁹Based on an interview with Pete Linsert. Mr. Linsert serves on the NRC Committee evaluating the SBIR program. He stepped down as CEO of Martek Biosciences in June 2006.

¹⁰Data in this section is provided from Martek's annual statement of accounts, for the year ending October 31, 2008, accessed at <<http://investors.martek.com/phoenix.html?c=116214&p=irof-fundhighlightsa>>, and from Martek's 2007 Annual Report, <http://library.corporate-ir.net/library/11/116/116214/items/281192/MATK_2007_Annual.pdf>.

BOX 5-1
Martek's Path to Success^a

- University of MD—Incubator—Taps—1985.
- Venture Capital—1986.
- SBIRs: NIH, NSF, DoE—1980s & 1990s.
- More Venture Capital—1989 & 1990s.
- Maryland Industrial Partnerships—MIPS—1980s & 1990s.
- Infant Formula Licensees—1990s.
- Public Market Finance—1993 IPO.
- Limited Sales—1990s.
- Secondary Public Offerings—1990s.
- Sales Sky Rocket—2000s.
- Profitable in Q4 2003.
- Major Expansion of Plants.

^aSlide presentation by Pete Linsert, "The Martek Experience," at National Research Council, Accelerating Innovation 2005 Conference, Washington, DC, October 19, 2005.

rebates. Licensees include Mead Johnson Nutritionals, Nestle, Abbott Laboratories, Wyeth and Royal Numico. Licensees now sell infant formula products containing Martek ingredients in over 70 countries. In 2006 and 2007, Martek signed multiyear sole source agreements with Abbott Laboratories and Mead Johnson to provide proprietary ingredients for infant formula, a core business of Martek.

6

Comparing Project Outcomes

Up to this point, the focus of this report has been on identifying the firms affected by the SBA ruling, and assigning their share of the NIH SBIR program.

The next step is to compare outcomes of SBIR awards to firms that are venture-funded and those that are not venture-funded. While the limitations of data, outlined below, preclude a precise impact assessment, a reasonable estimate of the impact of the SBA ruling on the program can be made. Nonetheless, the limitations of this impact analysis need to be kept in mind.

6.1 CAVEATS

For the following reasons, a precise analysis of outcomes from SBIR awards is not feasible.¹

- **Skew in the distribution of outcomes.** SBIR awards result in sales numbers that are highly skewed, with a small number of awards accounting for a very large share of the overall sales generated by the program. This is to be expected in funding early-stage technological innovation. It is also broadly consistent with the general experience of other sources of financing for early technology, (for example, by angel investors.) To avoid survey fatigue, both the NRC and NIH surveys limited the number of responses from larger firms with multiple awards. This approach, however, risks not capturing the major successes.

¹An extended discussion of many of these factors can be found in the Committee's SBIR Methodology Report. See National Research Council, *An Assessment of the Small Business Innovation Research Program—Project Methodology*, Washington, DC: The National Academies Press, 2004. Access at <http://www.nap.edu/catalog.php?record_id=11097>.

- **Selection effects.** It is likely that venture-funded firms will concentrate their efforts on projects that have a high potential for commercialization rather than projects with limited markets.

- **Multiple program objectives.** This statistical analysis is primarily focused on commercialization, with a strong focus on sales. However, commercialization is only one of four primary objectives for the program. Other core objectives—including the dissemination of new knowledge, support for the NIH mission, and support in particular for women and minorities, are not easily amenable to this kind of statistical analysis. NIH chooses to support projects that vary widely in terms of their commercial potential, depending on weight placed on one or another of these objectives.²

- **Limited data.** Our observations and conclusions are based on limited data. For instance, we have a relatively small sample of VC-funded SBIR firms. It is also difficult for us to determine whether we have random samples of VC-funded and non-VC-funded SBIR firms. While accurate and, the Committee believes, sufficient to justify the conclusions reached, they cannot provide definitive conclusions. By definition, these data limitations also limit the reach of our conclusions.

- **Varied time lags.** The limited number of data points available do not make it possible to correct for different lags in the receipt of funding and of SBIR awards, though both undoubtedly affect the commercial outcomes that result. We have made one major adjustment, limiting the study period to 1992-2002, in part specifically in order to ensure that outcomes for more recent projects surveyed closely approximate those for older ones. However, differential lag effects still exist and necessarily bias commercialization outcomes against firms with a preponderance of more recent awards.

Bearing the limitations imposed by the points reviewed above in mind, we have accumulated data primarily from the 2002 NIH Phase II Recipient Survey (and updates through 2007) and the 2005 NRC Phase II Survey.³ Together, these generated 1,105 responses from 861 firms, allowing us to draw initial conclusions from an assessment of the different outcomes from projects implemented by venture-funded and non-venture-funded firms.

6.2 RESPONDENT POOLS AND RESPONSE RATES

For assessment purposes, we divided the survey respondents into four pools:

²Commercialization patterns of SBIR projects supported by venture-funded firms, compared to non-VC firms, may be affected by the possible propensity of venture capital firms to focus their efforts more strongly on areas where they identify substantial commercial returns.

³These two sets of companies are not directly differentiated in the case of the NIH survey. In addition, only a relatively small number of responses come from ineligible companies.

TABLE 6-1 Responses to NIH and NRC Surveys (combined), by Venture Capital and Multiple-award Status

		Top 200 Phase II Winners	Others	Total
VC-funded	Number of awards	171	182	353
	Number of responses	42	73	115
Not VC-funded	Number of awards	980	1,575	2,555
	Number of responses	234	756	990
Total	Number of awards	1,151	1,757	2,908
	Number of responses	276	829	1,105

SOURCE: Awards—U.S. Small Business Administration Tech-Net Database; Responses—NRC Phase II Survey and NIH Phase II Survey and updates.

- Firms among the top 200 NIH Phase II award winners 1992-2002, who also received sufficient venture funding to meet the *de minimis* conditions. (42 responses.)
- Firms among the top 200 NIH Phase II award winners that did not receive sufficient venture funding to meet the *de minimis* conditions. (234 responses.)
- Firms not among the top 200 NIH Phase II award winners 1992-2002, who also received sufficient venture funding to meet the *de minimis* conditions. (73 responses.)
- Firms not among the top 200 NIH Phase II award winners that did not receive sufficient venture funding to the *de minimis* conditions. (756 responses.)

Recall that the *de minimis* conditions refer to more than one round of venture funding OR more than \$5 million in venture funding. These conditions, and the number of relevant responses, are captured in Table 6-1.

Just under 10 percent of responses overall came from firms which were venture-funded. The chart summarizes the combined responses to questions about sales from SBIR-funded projects,⁴ from the NRC and NIH Phase II surveys.⁵ The data indicate that venture-funded firms responded slightly less frequently to these surveys, generating a combined response rate of 32.6 percent, as against a rate of 38.7 percent for firms without venture funding. Overall, 23 percent of responses came from firms in the top 200 award winners.

⁴Response rates to both surveys vary by question.

⁵While there is likely to be some overlap in responses, this is less likely for firms which won more than one award, and unlikely for firms with several awards. Thus, the data for the top 200 firms is likely to contain fewer duplicate entries. However, there is no way to exclude these duplicate entries, and it appears that these do not substantially affect outcomes.

6.3 OUTCOMES FROM SURVEYS

In this section, we review outcomes in terms of two key variables—sales and additional investments—associated with projects funded by SBIR. These are metrics established in the course of the NRC SBIR assessment of NIH and other SBIR programs.⁶ While SBIR projects do generate other kinds of commercial return—for example licensing revenues and the ability to partner with other companies—these are not easily aggregated for statistical analysis. It is also important to recall the earlier observation that the SBIR program has other congressionally mandated objectives, which are not part of this analysis but nonetheless are important when assessing program outcomes.⁷

Sales

Figure 6-1 provides the most basic of all SBIR metrics: What percentage of projects has reached the market—that is, generated at least some sales. This is, as we shall see below, by no means the only metric, but it is the first clear point of differentiation so far as commercial outcomes are concerned.

Figure 6-1 shows that projects that did not receive venture funding were considerably more likely to reach the market.⁸ And the difference is not trivial: 38 percent of venture-funded projects reached the market, compared with 55 percent of projects at firms that were not venture-funded.

Overall, this is positive news, suggesting robust commercialization rates for both venture and non-venture-funded SBIR awardees. However, it also poses a question that should be addressed: Why do venture-funded firms commercialize at a lower rate?

Two preliminary hypotheses can be advanced to explain this outcome. First, the high level of initial commercialization for non-venture capital backed firms does not take into account the nature of the technology. Some types of research and development (for example, drug development) that offer the prospect of significant gains require large amounts of capital (often drawn from venture funding), and may also take much longer to reach the market. This would be reflected in lower commercialization rates at any given point in time (e.g., when a survey was answered).

Second, firms with venture funding may utilize SBIR for research not focused on immediate commercialization. Several executives at venture-funded firms interviewed for the NRC study of the SBIR program at NIH pointed out that the role of SBIR changed with the addition of investment funding from venture

⁶See, for example, National Research Council, *An Assessment of the SBIR Program at the Institutes of Health*, Charles W. Wessner, ed., The National Academies Press, 2009.

⁷See National Research Council, *An Assessment of the SBIR Program at the Institutes of Health*, op. cit., for extensive discussion and analysis of other outcomes.

⁸However, it does not compare the extent of this success of firms with and without venture funding.

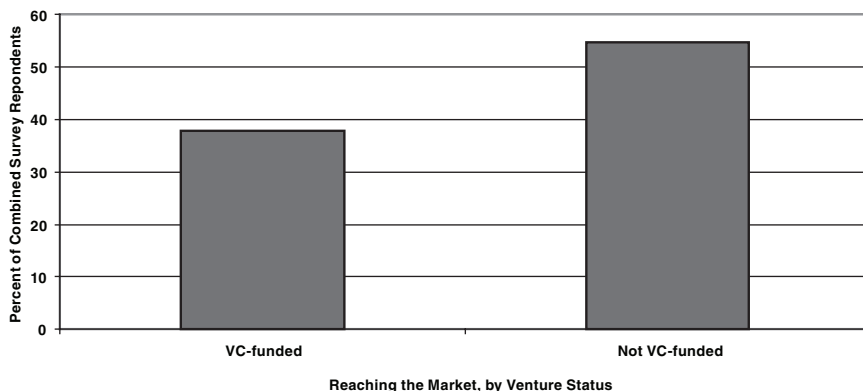


FIGURE 6-1 SBIR projects generating some sales revenue by VC investment status: VC-funded: 38 percent; Not VC-funded: 55 percent.

NOTE: N = 115 (venture-funded) and 990 (not venture-funded).

SOURCE: NRC Phase II Survey, NIH PODS database.

capitalists.⁹ These firms now used SBIR to fund alternative or supplementary research, or longer term and more basic research that might not otherwise be funded with the company's core venture capital backed budget. Such projects are naturally much less likely to reach the marketplace immediately but can result in promising research that does provide alternative paths for the firm. They can also represent a leveraging of venture-funded facilities to carry out SBIR-funded research that may not have been possible in the absence of the venture funding.¹⁰

Larger Returns

The NRC's methodology in this area goes beyond identifying projects that just reach the market: The scale of market success is also important. By including an assessment of product returns once sales have been achieved and ignoring projects that did not generate sales greater than zero, the data show that venture-funded firms tended to return larger sales than firms not funded by venture capitalists, once they reach the market.

The overall distribution is quite similar for projects from both venture-funded and not venture-funded firms, where the particular characteristics of each were

⁹See the case studies of Illumina and Neurocrine Biosciences in National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, op. cit.

¹⁰Source of complexity include the type of product, the lead times and capital requirements involved, the level of risk (e.g., with drug development) and regulatory hurdles to reach the market (e.g., medical devices versus software), and market size. As noted earlier, sales are also subject to significant skews.

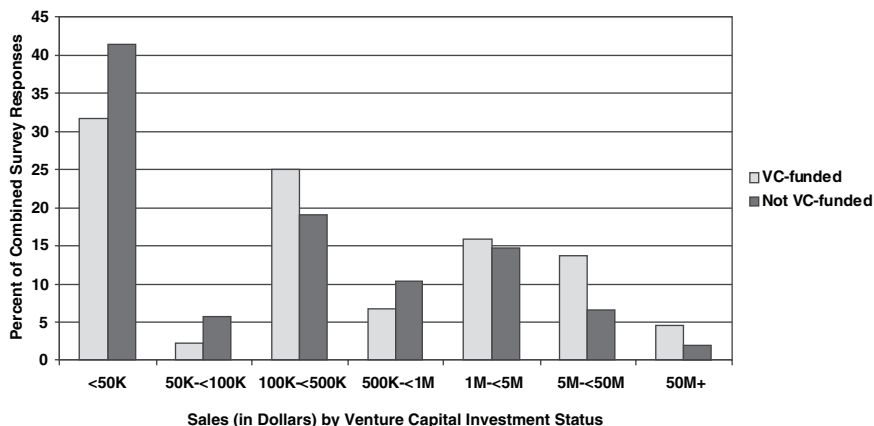


FIGURE 6-2 Distribution of sales, by venture funding.

SOURCE: NRC Phase II Survey, NIH PODS database.

NOTE: N=115 (venture-funded) and 990 (not venture-funded). This figure shows cumulative revenue for the referenced SBIR award only. It is important to bear in mind that firms usually also have other projects and other sources of revenue. For a summary of the differences between venture-funded firms and those without venture funding, see Box 1-5.

highlighted in Chapter 1. Figure 6-2 shows that few projects generate very substantial successes; most barely reach the market.

However, there is a significant difference at the upper end of the distribution. Projects from venture-funded firms are more likely to generate high returns—above \$5 million in sales—while more projects from firms not funded by venture capitalists are clustered below \$50,000 in total sales. More than 17 percent of projects that reported any sales at venture-funded firms generated at least \$5 million in overall sales, compared with less than 10 percent at firms without venture backing. However, though interesting, the numbers are in both cases based on a sample that is too small to be used as the basis for firm conclusions. At this point, we can simply state that venture-funded firms appear to generate large winners at a higher rate.

Additional Investment

Aside from sales, a second commercialization metric used by the NRC assessment is the extent to which SBIR-funded projects have been able to leverage additional investment. Survey data on additional investment is summarized in the Table 6-2.

TABLE 6-2 Additional Investment Related to Surveyed SBIR Project

	Number of Responses		Percentages	
	Venture-funded	Not Venture-funded	Venture-funded	Not Venture-funded
No	48	560	42.9	49.2
Yes	64	578	57.1	50.8
Total	112	1,138		

SOURCE: NIH PODS database, NRC Phase II Survey.

TABLE 6-3 Size of Additional Investment

	Number of Responses	Average Additional Funding (\$)
Venture-funded	43	3,538,984
Not Venture-funded	415	852,251

SOURCE: NRC Phase II Survey.

It would be very surprising if venture-funded firms—which have by definition received some third-party funding—did not report more instances of such funding than firms that had not received venture funding.

The data, however, show that non-venture-funded firms were also quite successful in securing further investment for their projects, possibly through self funding, leveraging supplier contracts, and/or angel investors. Overall, just over 50 percent of non-venture-funded firms reported additional funding for the SBIR projects, compared with 57 percent of venture-funded firms reported.

Unfortunately, the NIH survey did not ask respondents to estimate *the amount* of additional investment generated. Results from the NRC survey only are summarized in Table 6-3.

The data show that venture-funded firms have benefited from much larger additional investments than have non-venture-funded firms. The former generated \$3.55 million in additional funding per responding project reporting more than zero additional funding; the latter \$0.85 million.

Other data support the view that the amounts of additional investment made by venture capital investors can be considerable. VentureSource data indicate that venture investments in firms that were also funded through the NIH SBIR program during 1992-2002 totaled more than \$5.9 billion. The median total investment in each firm was approximately \$25 million.¹¹

¹¹Note that the survey data provides a per project response; the VentureSource data is per firm.

TABLE 6-4 Amount of Venture Funding Investment in Firms Receiving Phase II SBIR Awards from NIH 1992-2002

	Total	Total Dollars	Average Dollars (Thousands)
Venture Financing Rounds	946	5,937,651	6,277
Companies Participating in One or More Venture Rounds	234	5,937,651	25,375

SOURCE: Thomson VentureSource.

Given the “due diligence” and strong internal reviews of venture investors, this suggests a strong outside validation of the perceived market potential of these companies, and the technologies and products they have developed.¹²

Knowledge Effects

While commercial results have been at the core of the argument about access to SBIR for venture funded companies, it is important to underscore that this is only one of four congressional objectives for the SBIR program. A second such objective is support for the nation’s knowledge base, and one way to measure an impact in this area is the receipt of patents. Respondents to both the NRC and NIH surveys were asked about whether they had received patents related to their work funded by SBIR.

For both surveys, responses indicate that venture-funded firms received more patents per project than did the non-venture-funded companies.¹³ Of course, in most cases, venture-funded firms have more resources and can, hence, afford to file more patents.

Table 6-5 presents data indicating that 45 percent of VC-funded SBIR firms generated at least one patent related to the surveyed SBIR award; the corresponding figure for non-VC-funded SBIR firms is 36.4 percent. This difference in the

¹²The external assessment of venture funders, while normally rigorous, does not assure success. In fact, the success rates for many venture firms are quite limited. Drawing on a VentureOne database, Cochrane plots a histogram of net venture capital returns on investments that “shows an extraordinary skewness of returns. Most returns are modest, but there is a long right tail of extraordinary good returns. 15 percent of the firms that go public or are acquired give a return greater than 1,000 percent! It is also interesting how many modest returns there are. About 15 percent of returns are less than 0, and 35 percent are less than 100 percent. An IPO or acquisition is not a guarantee of a huge return. In fact, the modal or ‘most probable’ outcome is about a 25 percent return.” See John Cochrane, “The Risk and Return of Venture Capital,” *Journal of Financial Economics*, 75(1):3-52, 2005.

¹³Here, “patent” means one successful patent filing related to the surveyed project. Patents per project is an average of the numerical responses received to the question: How many patents have your company received in relation to the funded project?

TABLE 6-5 Respondents Reporting Receipt of Patents Related to SBIR-funded Projects

Venture Capital-funded			Not Venture Capital-funded		
Response	Number	Percent	Response	Number	Percent
No	60	55.0	No	675	63.6
Yes	49	45.0	Yes	386	36.4
Total	109		Total	1,061	

propensity to patent between VC-funded and non-VC-funded firms is statistically significant at the 10 percent level (although not at the 5 percent level).¹⁴

The result that between 35 and 45 percent of all companies with SBIR awards (whether venture-funded or not) developed sufficient technical knowledge to be worth the time and expense of a patent application (and award) is impressive. The relative advantage of venture-funded firms is, however, not surprising. Venture-funded firms often have additional resources to expend on protecting their intellectual property through patenting. In some cases, venture capital companies can also provide enhanced access to important sources of expertise in patenting.

At the same time, SBIR firms that are less focused on commercial outcomes are also less likely to patent their inventions. These firms are also less likely to be supported by venture capital. Such firms tend to pull down the overall average amount of patenting by firms that are not venture-funded.

However, the overall message from the surveys is a positive one: Firms patent results from SBIR projects at a substantial rate.

6.4 FIRM-LEVEL OUTCOMES FROM HOOVER'S SMALL BUSINESS DATABASE

Partly as a cross-check on the conclusions drawn from the NRC and NIH surveys, we sought to develop an entirely different data set, based on the Hoover's Small Business Database. Hoover's maintains current revenue and employment data on more than 2 million U.S. firms, and has historical data on many firms that have gone out of business in recent years.

¹⁴There is considerable debate in the economics profession regarding the relative importance of statistical and economic significance (usually in the context of an econometric analysis). That is, whereas the statistical significance of an estimated coefficient is used for establishing the existence of a relationship between two variables, the real-world relevance of a relationship depends on the size or magnitude of the estimate. See Deirdre McCloskey and Stephen Ziliak, "The Standard Error of Regressions," *Journal of Economic Literature*, 34(1):97-114, 1996. See also Stephen Ziliak and Deirdre McCloskey, "Size Matters: The Standard Error of Regressions in the American Economic Review," *Journal of Socio-Economics*, 33:527-549, 2004.

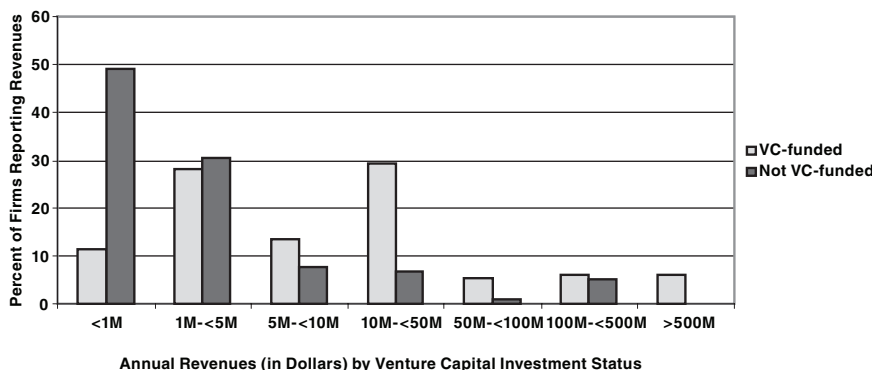


FIGURE 6-3 Distribution of annual revenues among firms, by venture status.
SOURCE: Hoover's Small Business Database.

Given that Hoover's database must be queried manually for each firm, we determined that this additional data set could best be constructed by examining all records for firms with venture funding, and for an equivalent sample of firms that did not received funding.

Of the 183 venture-funded firms, Hoover's had recent revenue data on 95. We selected an additional pool of 183 firms not venture-funded as a comparison. The distribution of revenue data is captured in Figure 6-3.

Of the 183 venture-funded firms, 95 (52 percent) reported revenues through the Hoover's database, in comparison to 118 firms (64 percent of the sample) that were not venture-funded. Given the high cost and long timeframes of research and development in biotechnology, reaching the market, at whatever scale, reflects very positively on the SBIR program and on the NIH selection process.

Revenues are a key indicator, indeed the major indicator of commercial success, and the distribution of revenues reported by Hoover's is quite different for the two groups of firms. We can see from Figure 6-3 that firms that have not received venture investment are clustered at the lower end of the revenue distribution. Eighty percent of these firms generated less than \$5 million in annual revenues, with almost 50 percent reporting less than \$1 million in revenues. Although their sales still count as commercialization, firms with less than one million dollars in revenue cannot be viewed as achieving significant commercial success.

In contrast, venture-funded firms whose revenues were reported were distributed far more evenly, with a concentration among firms with \$10 million to \$50 million in annual revenues. Only 40 percent of firms reported less than \$5 million, and 18 percent reported revenues of at least \$50 million.

These data are significant. They suggest that successful venture funding is associated with considerably larger annual revenues among the firms that survive.¹⁵ SBIR firms that are venture-funded are somewhat less likely to commercialize but are much more likely to generate substantial revenues when they do commercialize than are firms that receive SBIR funds but are not venture-funded.¹⁶ This sharply different performance between venture-funded firms and those that are not venture-funded is reflected in the median revenues generated by these two groups: \$9.3 million for venture-funded firms, \$1.0 million for those not venture-funded—a ratio of nine to one. This strongly suggests that firms selected by venture capitalists and benefiting from those investments are substantially more successful commercially when they are successful.

6.5 CONCLUSIONS: OUTCOMES FROM SBIR FUNDING

This analysis allows us to draw a number of important conclusions.

First, venture and non-venture-funded SBIR projects both reach the market in significant proportions, but the latter reach the market in considerably greater numbers. It seems reasonable to hypothesize that venture-funded firms typically follow riskier research and thus fail more often.

Second, venture-funded firms tended to generate larger revenues when their projects did reach the market, and recorded a substantially larger percentage of “big winner” projects among those surveyed by NIH and the NRC.

Third, venture-funded firms were somewhat more likely to receive additional third-party funding related to their SBIR award. More significantly, this funding was in itself likely to be much greater than for non-venture-funded firms—almost four times as much per project.¹⁷

¹⁵The revenues reflect current performance while the awards are from 1992-2002.

¹⁶The high-risk nature of investing in early-stage technology means that the SBIR program must be held to an appropriate standard when it is evaluated. While venture capitalists are a referent group, they are not directly comparable insofar as the bulk of venture capital investments occur in the later stages of firm development. SBIR awards often occur earlier in the technology development cycle than where venture funds normally invest. Nonetheless, returns on venture funding tend to show the same high skew that characterizes commercial returns on the SBIR awards. See John H. Cochrane, “The Risk and Return of Venture Capital,” *op. cit.* Drawing on the VentureOne database, Cochrane plots a histogram of net venture capital returns on investments that “shows an extraordinary skewness of returns. Most returns are modest, but there is a long right tail of extraordinary good returns. 15 percent of the firms that go public or are acquired give a return greater than 1,000 percent! It is also interesting how many modest returns there are. About 15 percent of returns are less than 0, and 35 percent are less than 100 percent. An IPO or acquisition is not a guarantee of a huge return. In fact, the modal or ‘most probable’ outcome is about a 25 percent return.” See also Paul A. Gompers and Josh Lerner, “Risk and Reward in Private Equity Investments: The Challenge of Performance Assessment,” *Journal of Private Equity*, 1(Winter):5-12, 1977. Steven D. Carden and Olive Darragh, “A Halo for Angel Investors,” *The McKinsey Quarterly*, 1, 2004, also show a similar skew in the distribution of returns for venture capital portfolios.

¹⁷See Table 6-3.

Fourth, venture-funded firms were somewhat more likely to file for patent protection for the intellectual property developed with support from the NIH SBIR program.

Fifth, a comparison of firm-level outcomes using Hoover's Small Business Database indicated that firm revenues for venture-funded firms were considerably higher—an average of \$9.3 million annually as against \$1 million for non-venture-funded firms. Venture-funded firms had a much higher concentration of firms generating at least \$10 million in annual revenues.

In short, while SBIR projects at venture-funded firms do not reach the market as often as those without venture investment, other indicators suggest that, over time, venture-funded firms do commercialize more effectively than non-venture-funded firms. It appears likely that firms with SBIR projects that receive venture funding typically pursue riskier technologies and therefore these projects fail more often. When they do reach the market, they tend to generate higher value.

7

Impact of the SBA Ruling on the NIH SBIR Program

FINDINGS AND RECOMMENDATIONS

This report develops a picture of the NIH SBIR program and the role of venture-funded firms within it and sheds light on the impact of the SBA ruling. This chapter outlines the Committee's findings and, based on this and previous analysis, sets out its recommendations.

7.1 MAIN FINDINGS

A. A limited number of venture-funded firms appear to have been excluded as a direct result of the SBA ruling.¹

- Firms that *either* received more than one round of venture funding, *or* received at least \$5 million in venture funding are considered “venture-controlled” for purposes of analyzing the impact of the SBA ruling.² The 183 firms identified as meeting one or both of the criteria constitute our pool of potentially excluded companies. They constitute 11.9 percent of all the 1,536 NIH Phase II winners 1992-2002 reported by SBA.³

- Altogether, using our criteria, a minimum of 4.1 percent (63 firms) of participating firms have been excluded because of the SBA ruling; a further 4.5 percent (69 firms) would have been excluded by the ruling, but were also excluded on other grounds. A further 3.3 percent had become publicly traded companies, which are also likely to be excluded.

¹The estimates below are based on information from the VentureSource database, the NRC Non-participant Survey, and NIH data.

²See Figure 3-1.

³See Table 3-4.

BOX 7-1 Caveat on Data

Our analysis of the effect of the SBA's venture ruling on the participation of firms in the NIH program, and on the program itself naturally reflects the limitations in the data that are available.

Biases in the data may well cause an underestimate of the impact of the ruling. While we have developed good estimates for the impact of the ruling on firms within the program as of 2002, it is not possible to know how many firms have since been discouraged from applying to the program as a result of the SBA ruling. Anecdotal evidence submitted by BIO and associated surveys suggest that this impact may be considerable, but the NRC survey we present in this report indicates that the impact of the SBA ruling has been limited in the absolute number of affected firms, but significant in terms of its impact on program commercialization.^a (See the findings.) Applications for SBIR grants at NIH have declined substantially in recent years, falling by 14.6 percent in 2006 (see Figure 1-1), but previous NRC analysis indicates that this decline may be related to issues of increased competition, concern about selection procedures, and funding delays. Moreover, the number of new businesses participating in the program has also decreased to its lowest proportion in a decade, although this may reflect a growth over time in the pool of previous SBIR awardees.^b

It is also important to remember that the analysis in this report relies on proxy indicators for important variables. Data on firms, information on their ownership structures, and the impact of the SBA ruling on their eligibility to participate in SBIR is difficult to obtain directly. Firms are often reluctant to share the proprietary data that is involved.

These caveats notwithstanding, the data assembled by the Committee are revealing, and they allow us to draw some initial yet significant conclusions.

^aThe BIO survey may support the view that some firms have stopped promising work as a source because of the ruling. See Appendix E, which presents an analysis of the BIO report.

^bSee National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009, Chapter 3.

- Not all firms receiving venture funding are excluded as a result of the ruling: Current levels of venture funding for 3.2 percent of all Phase II recipients were insufficient meet the proxy indicators developed for this study that reflected breach of the SBA eligibility rules.
- In short, between 4.1 percent and 11.9 percent of firms that won SBIR Phase II awards from NIH between 1992 and 2002 are excluded from the program as a result of the SBA ruling.⁴

⁴See Table 3-4

B. The ruling seems to disproportionately affect firms with demonstrated potential for significant commercialization.

- Of the top 200 Phase II winners at NIH, 43 (21.5 percent) received sufficient VC funding or VC rounds of funding to meet the criteria for VC control and are therefore excludable from the NIH SBIR program under the SBA ruling. This compares with 148 out of 1,336 (11.1 percent) for the remaining firms outside the top 200 Phase II award winners.⁵

- The evidence suggests that the impact of the ruling falls most heavily on the limited number of firms that have been selected both by NIH for their promising technologies and by venture investors for their commercial potential.

C. SBIR firms—with or without venture funding—commercialize in significant numbers.⁶ Firms that are venture-funded are somewhat less likely to commercialize but are much more likely to generate substantial sales from their SBIR-funded projects when they do commercialize than are firms that receive SBIR funds but are not venture-funded.

- Non-venture-backed firms actually reach the market more frequently. Specifically, SBIR projects at venture-funded firms are somewhat less likely to reach the market than non-venture-funded firms—38 percent do so, compared with 55 percent for other SBIR firms.⁷

- It is important to note that in both cases, this is positive news for the NIH SBIR program; non-venture-funded and venture-funded firms both reach the market in significant proportions.

- Among the firms that reach the market, projects at firms that are venture-funded are much more likely to generate significant sales from their SBIR-funded projects than are firms that are not venture-funded. Evidence from Hoover's data-

⁵See Table 2-1.

⁶The high-risk nature of investing in early-stage technology means that the SBIR program must be held to an appropriate standard when it is evaluated. While venture capitalists are a referent group, they are not directly comparable insofar as the bulk of venture capital investments occur in the later stages of firm development. SBIR awards often occur earlier in the technology development cycle than where venture funds normally invest. Nonetheless, returns on venture funding tend to show the same high skew that characterizes commercial returns on the SBIR awards. See John H. Cochrane, "The Risk and Return of Venture Capital," *Journal of Financial Economics*, 75(1):3-52, 2005. Drawing on the VentureOne database, Cochrane plots a histogram of net venture capital returns on investments that "shows an extraordinary skewness of returns. Most returns are modest, but there is a long right tail of extraordinary good returns. 15 percent of the firms that go public or are acquired give a return greater than 1,000 percent! It is also interesting how many modest returns there are. About 15 percent of returns are less than 0, and 35 percent are less than 100 percent. An IPO or acquisition is not a guarantee of a huge return. In fact, the modal or 'most probable' outcome is about a 25 percent return." See also Paul A. Gompers and Josh Lerner, "Risk and Reward in Private Equity Investments: The Challenge of Performance Assessment," *Journal of Private Equity*, 1(Winter):5-12, 1977. Steven D. Carden and Olive Darragh, "A Halo for Angel Investors," *The McKinsey Quarterly*, 1, 2004, also show a similar skew in the distribution of returns for venture capital portfolios.

⁷See Figure 6-1.

base indicates that about 80 percent of non-venture-funded firms in existence as of 2006 (that received SBIR Phase II funds from NIH) had less than \$5 million in annual revenues, with 6 percent having annual revenues of \$50 million or more. By contrast, only 40 percent of venture-funded firms have less than \$5 million in annual revenues, and 18 percent generated at least \$50 million.⁸

- Venture-funded firms generated considerably more annual revenues than non-venture-funded firms. According to Hoover's database, median revenues for reporting venture-funded firms were \$9.3 million, and for non-venture-funded firms were \$1.0 million. It is also true that a smaller percentage of venture-funded firms were currently reporting revenue data.⁹

D. At NIH, SBIR awards with venture-funding received marginally more patents per project than did the non-venture-funded firms.¹⁰

- It is noteworthy that between 35 and 45 percent of all companies with SBIR grants—whether venture-funded or not—contribute to the creation of patentable knowledge.

- With regards to the relative difference, in some cases, this may be because venture-funded firms have additional resources to expend on protecting their intellectual property through patenting. In addition, some venture capital firms may provide sources of expertise on patenting.

E. A survey of non-participants indicates that the SBA ruling has played a limited role in the decisions of small firms not to participate in the NIH SBIR program.

- NRC surveyed firms and principal investigators who applied for NIH funding during the period leading up to the 2002 SBA ruling, but who have not since applied for NIH SBIR funding.¹¹

- NIH identified 3,913 such non-participant firms, of which 2,051 had valid email addresses. The NRC survey sent to these addresses yielded 386 responses, or an 18.5 percent response rate. Of these 386, some 49 firms were found to have in fact received further funding. A further 87 indicated that they expect to apply for SBIR awards in the future.

- The remaining 269 respondents were asked why their firms were no longer applying for SBIR awards. The three most frequent reasons for not applying were the level of competition, concerns about the selection mechanism, and funding delays. Venture ownership (along with foreign ownership and shifts to foreign ownership) was one of the three lowest scoring reasons for leaving the program.

⁸See Figure 6-3.

⁹In some cases, this may be because venture-funded firms had been acquired and hence were no longer independent reporting entities, but this is not certain.

¹⁰See Table 6-5.

¹¹See Table 5-1.

- Because being excluded is itself a sufficient condition for non-participation, we also asked respondents to identify a reason for not applying to the program.¹² 3.7 percent of respondents indicated that ownership exclusions arising from the 2002 SBA ruling was a reason for not applying; 2.5 percent reported that it was the single primary reason for not applying—a figure somewhat lower than the NRC’s estimate for affected companies overall.

F. Recognizing that the number of affected firms is small, it is the judgment of the Committee that restricting access to SBIR funding to firms that benefit from venture investments would risk disproportionately affecting some of the most promising small innovative firms. To this extent, the SBA ruling has the potential to diminish the positive impact of the nation’s investments in research and development, especially in the biomedical area.

- Small businesses use SBIR awards and venture funding in complementary ways to help them bring new ideas to the market. Small business entrepreneurs note that innovative small businesses often support their primary line of research and development with non-SBIR sources, while SBIR helps to advance additional lines of research.¹³ Firms interviewed for the NRC SBIR study also indicate that the kind of research funded by SBIR has sometimes been closely combined with venture funding to support the research on which to build, over time, a highly successful company.¹⁴

- Data gathered for this study indicate that the number of major SBIR successes would be reduced under the 2002 eligibility requirements, and that the average amount of commercialization per project would decrease.

7.2 RECOMMENDATIONS

A. Based on the Committee’s analysis of the impact of restricting venture funding on the NIH SBIR program, and its experience in the larger evaluation of the SBIR program at five agencies, the Committee recommends that consideration should be given either to restoring the de facto status quo ante eligibility requirements for participation in the SBIR program or to making some other adjustment that will permit the limited number of majority venture-funded firms with significant commercial potential to compete for SBIR funding.¹⁵

¹²See Table 5-2.

¹³See, for example, testimony by Douglas Doerfler of Maxcyte, Inc., before the House Committee on Small Business, January 29, 2008.

¹⁴See, for example, case studies of Illumina and Neurocrine in Appendix D of National Research Council, *An Assessment of the SBIR Program at the National Institutes of Health*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

¹⁵The advantages of an SBIR award include not only the undiluted equity that the grant represents but also the fact that awardees retain intellectual property rights to their product. Perhaps most important, the rigorous reviews of technological and commercial potential that are a part of the award

- In its comprehensive assessment of SBIR in the period prior to the 2002 SBA directive, the Committee found the program to be “sound in concept and effective in practice.”¹⁶
- Although the evidence is not definitive, the implementation of the SBA ruling appears to be negatively affecting current participation by firms and the long term commercialization potential of the NIH SBIR program.¹⁷
- There is no evidence that non-venture-funded firms have been crowded out by venture-funded firms. Should this occur, SBIR managers can and should address it, as appropriate.

B. In its recent assessment of SBIR, the Committee found that the concept of the program is sound and recommended that the basic program structure of SBIR be preserved. Accordingly, the Committee recommends that SBA and the agencies should maintain an open competition that is based on scientific quality and commercial potential.¹⁸

- Scientific quality and responsiveness to agency topic solicitations are the primary criteria for selecting SBIR funding. SBA and the participating departments and agencies should maintain an open, science-based competition for the program’s resources and rely on the judgment of the agency program managers and the established selection procedures of the SBIR program.
- Given the small number involved, allowing a percentage of majority-owned applicants to participate might be an effective solution. At the same time, the use of this type of solution should be sharply limited, insofar as dividing the program up with quotas runs the risk of initiating a Balkanization of the pro-

process confer a certification or “halo effect” on the company that in turn is a positive signal to the private capital markets. For an analytical discussion of the halo effect, see Maryann Feldman and Maryellen Kelley, “Leveraging Research and Development: The Impact of the Advanced Technology Program,” in National Research Council, *The Advanced Technology Program: Assessing Outcomes*, Charles W. Wessner, ed., Washington, DC: National Academy Press, 2001. For a discussion of the certification effect, see Josh Lerner, “Public Venture Capital,” in National Research Council, *The Small Business Innovation Research Program: Challenges and Opportunities*, Charles W. Wessner, ed., Washington, DC: National Academy Press, 1999.

¹⁶National Research Council, *An Assessment of the SBIR Program*, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2008.

¹⁷The Committee has not analyzed the impact on firms applying for SBIR grants from federal agencies other than NIH. It would be worth examining the impact of restricting venture funding on the SBIR program at other federal agencies.

¹⁸In its cross-agency assessment of SBIR, an NRC Committee recommended that the basic program structure of SBIR be preserved, even as it called for more program experimentation and evaluation to help the program adapt to changing mission needs and technological opportunities. See, in particular recommendations G and H in Chapter 2 of National Research Council, *An Assessment of the SBIR Program*, op. cit. In particular, Recommendation G rejects the idea of bypassing Phase I for firms that are ready to apply for a Phase II award. Such a bypass would differentially advantage firms that have other sources of early-stage funding.

gram that would undermine the open competition that underpins the program's effectiveness.¹⁹

- By making some innovative small businesses ineligible for SBIR, the ability of the program to address the program's legislative goals would appear to be reduced, although it should again be noted that the absolute number of firms with venture funding does not appear to be large.

C. The Committee reaffirms the recommendation made in its overall assessment of SBIR that SBA should maintain the commendable program flexibility it has exercised in the past.²⁰

- Continue to rely on agency managers' judgment, experience, and understanding of mission needs to effectively administer the SBIR program.
- Ongoing assessment of this and other issues would be beneficial to program management. The National Research Council's recent assessment of the operation of SBIR at the five agencies accounting for most of the program calls for regular internal and external evaluation of SBIR to assess and reinforce or change, as necessary, agency practices and experimentation.²¹

D. NIH should conduct follow up assessments of its SBIR program, including the impact of venture capital participation and eligibility requirements on program involvement and outcomes.

- The rapid growth of the NIH SBIR program, and the subsequent sharp decline in applications call for follow-up analysis to this report. NIH should use the data for 1992-2002, used in this study as a baseline for subsequent analysis.
- A second snapshot: It would be especially useful to assess the subsequent behavior of the largest winners at NIH as their departure from the SBIR program would signal a significant and potentially important shift in the program's effectiveness.

¹⁹One version of the pending legislation in Congress would allow the National Institutes of Health to award up to 18 percent of its SBIR dollars to venture capital-funded firms. The other ten agencies that participate in the SBIR program could award up to 8 percent of their SBIR dollars to these types of companies.

²⁰The first recommendation of the NRC assessment of the SBIR emphasizes the need to preserve program flexibility. It states that "Agencies, SBA, and the Congress should seek to ensure that any program adjustments made should not reduce the program's flexibility." See National Research Council, *An Assessment of the SBIR Program*, op. cit., p. 73. This flexibility is an important element in the success of the SBIR program. Although each agency's SBIR program shares a common three-phase structure, the SBIR concept is interpreted uniquely at each agency. This flexibility is a positive attribute in that it permits each agency to adapt its SBIR program to the agency's particular mission, scale, and working culture.

²¹The second recommendation of the NRC assessment of SBIR states that "Regular evaluations are needed." See National Research Council, *An Assessment of the SBIR Program*, op. cit.

Appendixes

Appendix A

Venture-funded Firms Among the 200 Most Prolific Winners of NIH Phase II Awards 1992-2002

Company Name	Phase II Awards		
	First Phase II Funded	Start of Latest Phase II	Number of NIH Phase II Awards
Aastrom Biosciences, Inc.	2/1/1993	3/1/1999	5
Abiomed, Inc.	3/1/1990	9/30/2000	13
Ambion, Inc.	1/1/1993	9/1/2001	8
Biomedical Development Corporation	5/1/1992	9/1/2000	9
Cambridge Neuroscience, Inc.	9/27/1989	9/30/1997	3
Cengent Therapeutics, Inc.	4/1/1999	9/1/1999	3
Centaur Pharmaceuticals, Inc.	2/1/1994	9/30/1996	4
Conductus, Inc.	4/15/1994	6/15/1994	3
Corixa Corporation	9/15/1994	9/1/2000	8
Cortechs Labs, Inc.	5/1/1998	6/15/2002	5
Cubist Pharmaceuticals, Inc.	4/1/1995	4/1/1999	4
Cytel	4/15/1994	7/20/2001	5
Diversa	9/30/1996	11/1/1997	4
EKOS Corporation	6/1/1998	12/1/2000	4
Electro-Optical Sciences, Inc.	6/23/1993	4/19/2001	4
Epoch Biosciences	9/1/1990	1/1/1999	4
Exocell, Inc.	7/1/1992	7/1/2003	6
Foster Miller	5/1/1990	4/15/2001	10
Genaissance Pharmaceuticals, Inc.	9/1/1993	8/29/1997	4
GenPharm International, Inc.	4/1/1991	5/1/1992	4
Gliatech, Inc.	2/24/1995	9/15/1998	3
Hawaii Biotech, Inc.	7/1/1991	2/15/1999	7
IDEC Pharmaceuticals Corporation	8/15/1991	9/30/1997	3
Illumina, Inc.	2/1/1999	7/1/2000	5
Immusol, Inc.	9/30/1996	9/1/1999	4
Inotek Pharmaceuticals Corporation	3/1/1998	8/1/2001	14
Invitrogen Corporation	9/1/1995	9/30/1998	4
Isis Pharmaceuticals	9/1/1991	3/1/1999	4
Martek Biosciences Corporation	9/30/1991	9/30/1995	3
Medical Physics Colorado	5/1/1990	2/15/1992	4
Medimmune, Inc.	3/1/1992	5/1/1996	3
Meridian Instruments, Inc.	2/1/1991	5/1/1993	3
Micronix Corporation	8/1/1992	3/1/2001	6
Neurocrine Biosciences, Inc.	9/30/1994	1/1/2001	8
Nimbus Medical, Inc.	9/1/1990	2/1/1995	4
OSI Pharmaceuticals, Inc.	5/1/1990	2/1/1997	10
Photon Imaging Corporation	4/1/1995	7/1/2001	7
Physical Optics Corporation	2/15/1993	9/30/2001	10
Physical Sciences, Inc.	3/1/1990	3/15/2003	11
Progenics Pharmaceuticals, Inc.	9/1/1991	9/30/1996	5
RiboGene, Inc.	8/1/1994	9/30/1996	4
Scios Nova, Inc.	1/5/1992	11/1/1997	4
Spencer Technologies	9/1/1992	8/1/2000	4
Spire Corporation	9/25/1989	2/15/2002	8
State of The Art, Inc.	8/23/1993	9/14/2000	8

All Awards	VC Funding			
	Total SBIR Funding	1st Round	Most Recent Round	Number of Rounds
4,905,444	8/18/1989	10/30/2002	8	36,385,000
8,924,132	12/1/1984	12/1/1984	1	3,000,000
8,566,387	5/1/2003	5/1/2003	1	10,500,000
6,967,861	10/1/1987	10/1/1987	1	150,000
2,267,025	1/1/1986	6/21/1997	9	35,879,000
2,647,188	1/11/1996	11/30/2000	5	47,350,000
3,989,316	12/1/1992	11/2/2001	7	26,561,000
2,904,807	9/1/1987	3/27/2002	6	45,700,000
7,971,063	12/2/1994	10/2/1997	3	59,330,000
3,793,553	1/9/1987	11/23/1992	4	51,000,000
4,758,137	9/1/1992	9/23/1998	5	36,283,000
4,026,867	8/1/1987	11/22/1991	4	68,000,000
4,228,546	12/1/1994	2/14/2000	5	210,200,000
3,350,438	10/1/1996	8/30/2001	5	42,900,000
3,262,764	1/15/1986	6/20/2003	8	32,440,000
3,238,220	3/1/1986	7/1/1993	13	29,980,000
4,352,150	3/1/1988	3/1/1988	1	900,000
11,827,620	1/1/1980	1/1/1980	1	750,000
3,581,611	4/1/1998	5/22/2000	7	73,522,000
1,748,679	12/3/1988	4/1/1995	9	40,100,000
3,342,616	7/1/1988	6/1/1995	7	32,596,000
9,643,061	6/7/2002	6/6/2003	2	7,300,000
2,441,576	5/1/1986	2/1/1990	4	43,870,000
5,715,123	11/30/1998	11/1/1999	2	36,567,000
3,347,984	6/1/2001	9/24/2003	2	23,500,000
29,421,600	3/31/2004	3/31/2004	1	20,000,000
4,254,170	6/20/1997	6/20/1997	1	15,000,000
3,210,263	2/1/1989	8/11/1994	6	17,490,000
3,220,694	1/15/1986	11/23/1993	5	22,750,000
2,698,149	12/30/1991	12/30/1991	1	20,000
2,912,945	5/1/1988	12/9/1991	5	143,850,000
1,746,413	5/1/1983	10/1/1993	4	3,557,000
4,264,334	5/1/1981	7/1/1987	15	76,598,000
10,349,174	9/25/1992	5/23/1996	12	43,000,000
3,147,990	7/1/1986	3/1/1987	2	5,598,000
8,563,722	3/1/1988	3/1/1988	1	4,000,000
7,889,307	9/1/1983	9/1/1983	1	750,000
9,782,753	8/1/1987	8/1/1990	4	3,337,000
8,175,374	5/9/1995	7/1/1995	2	492,000
14,190,507	1/1/1995	12/1/1995	1	5,670,000
3,727,127	1/1/1990	2/1/1997	14	43,577,000
2,704,476	6/1/1982	6/1/1982	1	5,425,000
3,334,165	7/1/1997	7/1/1997	1	435,000
7,514,150	11/1/1979	1/1/1987	3	3,750,000
8,231,063	9/1/1983	1/1/1986	2	3,400,000

continued

Company Name	Phase II Awards		
	First Phase II Funded	Start of Latest Phase II	Number of NIH Phase II Awards
Stratagene Cloning Systems	7/1/1991	4/7/1997	6
Talaria Holdings, LLC	7/12/1996	7/1/2001	8
Third Wave Technologies, Inc.	4/1/1993	9/25/2001	5
Transoma Medical, Inc.	4/1/1996	8/1/1999	3
Valentis	3/26/1993	3/1/1997	4
Volumetrics Medical Imaging	8/1/1993	6/1/2000	3
Total			285

Legend

34		First VC funding before first SBIR Phase II
17		Last VC funding after start of latest SBIR Phase II
6		First VC funding after last start date for SBIR Phase II
51		Total VC-funded companies identified as NIH SBIR Top 200

SOURCE: Award data: National Institutes of Health data delivered to the National Research Council; VC data: Thomson Financial, VentureSource, and RDNA databases.

All Awards	VC Funding			
Total SBIR Funding	1st Round	Most Recent Round	Number of Rounds	Total VC Funding
4,754,214	4/1/1987	12/31/1992	2	1,873,000
7,068,657	1/1/2001	4/1/2001	2	28,673,000
3,778,257	6/30/1995	7/26/2000	5	78,064,000
3,384,761	2/5/2002	2/5/2002	1	12,075,000
3,350,068	8/12/1993	10/1/2002	6	47,405,000
2,432,255	1/1/1995	6/27/2003	6	10,706,000
272,332,457			224	1,592,258,000

Appendix B

NRC Non-participant Survey

1. As no database is 100 percent accurate, please confirm whether your firm is still participating in the NIH SBIR program. Has your firm applied for an NIH SBIR award at any time in the years 2003-2006 inclusive?

- Yes.
- No.

2. Are you still employed with the firm mentioned in the email that invited you to participate in this survey?

- Yes.
- No.

3. Does your firm plan to submit SBIR applications to NIH in the future?

- Yes.
- No.

4. Your company has not applied for a new NIH SBIR award since the end of 2002. Your answers to the questions below will help us to understand why you have decided not to apply. Please select as many responses as required.

- Company is out of business.
- We are no longer a research oriented company.
- We are no longer working in technical areas that are likely to be funded by NIH.
- The competition for awards is such that the likelihood of winning an award is too small to justify the effort to apply.

- The selection mechanism is not one that we believe will allow us to make winning proposals.
- The risk to our IP or business secrets during the selection procedure is too high.
- The delays in funding are too long to make the effort worthwhile.
- We are no longer eligible for the program because we have more than 500 employees.
- We are no longer eligible for the program because we are now a publicly owned company with more than 50 percent institutional ownership.
- We are no longer eligible for the program because we are majority foreign-owned.
- We are no longer eligible for the program because we are majority institution-owned (e.g., by venture capital companies).
- The size of awards is insufficient to justify the effort involved in applying.
- Other (please specify).

5. If you had to pick just one factor as the primary reason for non-participation in the program, what would it be? Please select one answer only:

- Company is out of business.
- We are no longer a research oriented company.
- We are no longer working in technical areas that are likely to be funded by NIH.
- The competition for awards is such that the likelihood of winning an award is too small to justify the effort.
- The selection mechanism is not one that we believe will allow us to make winning proposals.
- The risk to our IP or business secrets during the selection procedure is too high.
- The delays in funding are too long to make the effort worthwhile.
- We are no longer eligible for the program because we have more than 500 employees.
- We are no longer eligible for the program because we are now a publicly owned company with more than 50 percent institutional ownership.
- We are no longer eligible for the program because we are majority foreign-owned.
- We are no longer eligible for the program because we are majority institution-owned (e.g., by venture capital companies).
- The size of awards is insufficient to justify the effort involved in applying.
- Other (please specify).

6. You indicated above that the primary reason why your company is ineligible is because of ownership rules. Would a change in the rules to make firms with 51 percent or more institutional ownership eligible lead you to start applying to the program again?

- Yes.
- No.
- Not applicable.

7. You indicated above that the small size of awards was your primary reason for non-participation. If Phase I and Phase II awards were increased in size by 50 percent, would you start to apply again?

- Yes.
- No.
- Not applicable.

8. You indicated that funding delays were the primary reason for non-participation. If there were a reduction of 50 percent in delays between Phase I application and funding, and between Phase I and II funding, would you start to apply again for the program?

- Yes.
- No.
- Not applicable.

9. Has your firm received investment funding from institutions such as venture capital firms or other corporations (not U.S. individuals)?

- Yes.
- No.

10. Do these institutions own more than 50 percent of your company?

- Yes.
- No.

11. When did your firm become 51 percent institution-owned (mm/yy)? (Please estimate if necessary.)

12. What other sources of funding have you found for your projects since you last applied for SBIR funding at NIH?

- Other federal agency funding.
- SBIR funding from other agencies.
- U.S. venture capital.
- Funding from other companies.
- Contract research funding.
- Angel investors.

- Capital from your personal resources.
- Investment by your company.
- University funding.
- Investment from state sources.

Appendix C

NIH List of Firms Excluded on the Grounds of Venture Capital Ownership*

FIRM NAME

Altus Biologics, Inc.
Applied Genetic Technologies Corp.
Arginox Pharmaceuticals
Argolyn Bioscience, Inc.
Arizeke Pharmaceuticals
Ascenta Therapeutics, Inc.
Aspect Medical Systems, Inc.
Biospect Inc./Predicant Biosciences
BrainCells, Inc.
Calypso Medical Technologies, Inc.
Cell Biosciences
Cengent Therapeutics, Inc.
CEPTYR, Inc.
Cerus Corporation
Chlorogen
CUMBRE, Inc.
Diversa Corp.
Encysive Pharmaceuticals
FivePrime Therapeutics
GlycoFi, Inc.
Gryphon Therapeutics, Inc.

*These firms were submitted by NIH as an illustrative list of firms they believe were excluded.

Handylab Inc.
IDM Pharma, Inc.
Infigen, Inc.
Inotek Pharmaceuticals
Lincoln Technologies
Macrogenics, Inc.
MEMX
Metabolon, Inc.
MicroOptical Corporation
MicroOptical Engineering Corporation
Myomatrix Therapeutics
NanoMix, Inc.
NanoString Technologies, Inc.
Natus Medical (BioLogics)
Nephros Therapeutics, Inc.
Neurogenetics, Inc.
Norak Biosciences, Inc.
Northwest Medical Physics Equipment
Paratek Pharmaceuticals
Peptx, Inc.
Phenomix Corp.
PTC Therapeutics, Inc.
Saegis Pharmaceuticals Inc.
Sentrx Surgical/Carbylan Biosurgery
Sirtris Pharmaceuticals
Threshold Pharmaceuticals, Inc.
Transave, Inc.
Traxtal, Inc.
Trellis Bioscience
Tularik, Inc.
Vion Pharmaceuticals, Inc.
Virxsys Corp.
VisEn Medical, Inc.
Yasoo Health, Inc.

Appendix D

Venture-funded Firms: Data from Hoover's Small Business Database and VentureSource

Company	Venture Capital (Thousands of Dollars)	Rounds	Last Round Date
Advanced Tissue Sciences, Inc.	90,578.0	3	11/2/2001
Albion Instruments	8,968.0	7	1/1/1990
Ambion, Inc.	10,500.0	1	5/1/2003
Applied Immune Sciences, Inc.	44,060.1	11	1/1/1991
Applied Molecular Evolution, Inc.	32,350.0	6	6/1/2000
Aronex Pharmaceuticals, Inc.	9,496.0	3	3/2/1999
Aviron (FKA: Vector Pharmaceuticals, Inc.)	87,340.1	4	11/1/2000
Argus Software, Inc.	3,815.9	4	7/30/1999
Aurora Biosciences Corporation	18,720.0	3	12/15/1996
AcryMed, Inc.	3,500.0	4	3/1/2003
Alexion Pharmaceuticals, Inc.	5,800.0	2	12/23/1994
Automatix, Inc.	21,850.0	7	12/1/1987
Aastrom Biosciences, Inc.	36,384.9	8	10/30/2002
ABIOMED, Inc.	35,800.0	1	3/27/2007
Adolor Corporation	137,483.0	7	5/31/2001
Alkermes, Inc.	12,384.3	5	10/1/1992
Amylin Pharmaceuticals, Inc.	84,200.0	9	9/20/2002
ARIAD Pharmaceuticals, Inc.	56,075.0	3	5/20/2003
Aradigm Corporation	139,454.0	9	3/7/2003
Altea Therapeutics	54,546.9	4	6/15/2007
Amedica Corporation	44,569.0	4	4/27/2007
Amnis Corporation	18,750.0	3	3/27/2006
Ancile Pharmaceuticals, Inc.	30,365.0	6	10/27/2002

First Round Date	Status	Ticker Symbol	Last Known Date	Annual Revenue (Millions of Dollars)	Number of Employees	Profit/Loss
4/1/1996	Out of business		2003			
6/1/1986	Sold		2000			
5/1/2003	Sold		2006	13.6		
11/1/1984	Sold		1995			
3/1/1990	Sold			10.2		
7/1/1991	Sold		2001			
6/1/1992	Sold					
1/1/1995	Foreign					
3/7/1996	Foreign					
4/1/1994	n/a					
11/12/1993	NASDAQ	ALXN		1.6	241	(131.5)
1/1/1980	n/a					
8/18/1989	NASDAQ	ASTM		0.7		(17.6)
3/27/2007	NASDAQ	AMMD		50.7	324	
11/1/1994	NASDAQ	ADLR		15.9	179	(69.7)
10/1/1987	NASDAQ	alks		240.0	830	9.9
11/1/1987	NASDAQ	AMLN		510.9	1,550	(218.9)
2/1/1991	NASDAQ	ARIA		0.9	108	(61.9)
10/16/1992	OTC	ARDM		4.8	103	(13.0)
11/21/2002	private					
1/28/2004	private	failed IPO	2007	0.1	33	(6.3)
2/28/2000	private			3.5	37	
11/4/1998	private			3.2	30	

continued

Company	Venture Capital (Thousands of Dollars)	Rounds	Last Round Date
Artecel Sciences, Inc.	4,135.2	2	5/29/2002
Atherotech, Inc.	21,399.9	4	1/31/2005
Avocet Medical, Inc.	36,801.0	3	7/1/2001
BioCryst Pharmaceuticals, Inc.	39,964.9	3	9/30/2007
BioMarin Pharmaceutical, Inc.	53,000.0	2	5/16/2001
BIOQUAL, Inc. (FKA: Diagon Corporation)	1,351.0	2	5/1/1983
Biosearch, Inc.	1,800.0	2	12/1/1983
Biosym Technologies, Inc.	5,168.0	3	4/1/1992
BioTransplant, Inc.	9,561.0	3	6/30/2001
Cambridge Neuroscience, Inc. (FKA: Synax, Inc.)	35,879.0	9	6/21/1997
Cell Based Delivery, Inc.	11,175.0	2	5/7/2002
Centaur Pharmaceuticals, Inc.	63,451.0	7	11/2/2001
Cephalon, Inc.	40,037.8	8	2/25/1999
Chektec Corporation	846.0	3	4/1/1993
Clarus Medical LLC (Medilase, Inc.)	27,548.9	12	5/1/1997
Clontech Laboratories, Inc.	28,836.0	2	7/1/1998
CoCensys, Inc.	24,071.0	9	1/7/1997
Cognetix, Inc.	19,010.0	2	6/1/2006
CompuCyte Corporation	18,700.0	3	8/1/1999
Conductus, Inc.	45,699.9	6	3/27/2002
Control Delivery Systems, Inc. (AKA: CDS, Inc.)	34,500.0	1	8/22/2000
COR Therapeutics, Inc.	20,652.0	6	1/1/1998
Corixa Corporation	157,581.1	6	6/10/2003
Cortex Pharmaceuticals, Inc.	9,100.0	2	7/1/1989
Creative BioMolecules, Inc.	23,284.0	18	7/1/1995
Cryolife, Inc.	3,057.0	3	6/1/1988
Cryopharm Corporation	30,346.0	10	1/1/1994
Cubist Pharmaceuticals, Inc.	36,283.0	5	9/23/1998
CuraGen Corporation	26,790.0	2	9/1/1999
CytoLogix Corporation	46,850.0	5	5/29/2002
Cytomation, Inc.	14,293.0	2	6/8/2001
Cytac Corporation (FKA: Generitech Corporation)	35,154.9	4	5/1/1995
Dharmacon Research, Inc.	5,700.0	1	8/23/2002
Digirad Corporation (FKA: Aurora Technologies)	75,320.0	9	4/24/2002
DiscoverRx Corporation, Ltd.	28,406.0	5	2/20/2007
Discovery Laboratories, Inc.	13,211.0	2	6/20/2003
Displaytech, Inc.	70,225.1	5	3/12/2006
Edenspace Systems Corporation	5,250.0	1	4/23/2007
EKOS Corporation	85,900.4	8	6/27/2007
Endocyte, Inc.	60,700.2	4	3/23/2007
Epicyte Pharmaceutical, Inc.	22,200.0	4	4/16/2001
EpiGenesis Pharmaceuticals, Inc.	35,956.2	4	3/7/2007
Epoch Biosciences (FKA:MicroProbe Corporation)	30,030.2	13	7/1/1993

First Round Date	Status	Ticker Symbol	Last Known Date	Annual Revenue (Millions of Dollars)	Number of Employees	Profit/Loss
11/29/2000	private			0.1	1	
3/31/1999	private					
10/1/1996	private					
8/1/1992	NASDAQ			6.2	52	(43.6)
1/1/1998	NASDAQ			84.2	314	(28.5)
7/1/1981	private			19.4	150	
4/1/1983	private			4.6	65	
10/1/1986	Sold					
10/1/1995	Out of business		2003			
1/1/1986	Sold					
3/7/2002	Out of business					
12/1/1992	Out of business		2002			
10/1/1987	NASDAQ	CEPH		18,641.1	2,895	144.8
12/1/1988	Out of business					
1/6/1989	private			0.2	3	
7/1/1997	private			17.0	175	
2/1/1989	Sold					
8/1/2001	Out of business					
4/1/1996	private			6.7	28	
9/1/1987	Sold					
8/22/2000	Sold		2005	17.2	26	
3/16/1988	Sold		2002			
12/2/1994	Sold		2005			
5/1/1988	AMEX	COR		1.2	26	(16.2)
5/1/1982	NASDAQ	CRIS		16.7	68	(8.8)
1/1/1986	NYSE	CRY		81.3	363	0.4
1/1/1988	private			2.5	25	
9/1/1992	NASDAQ	CBST		194.8	410	(0.4)
3/1/1997	NASDAQ	CRGN		39.6	666	(59.8)
1/1/1997	private					
5/1/1997	Sold					
1/1/1987	Sold		2006	608.0	1,500	139.5
8/23/2002	private			10.1	120	
5/30/1995	NASDAQ	DRAD		71.9	601	(6.3)
2/1/1999	private			3.3	40	
11/5/2002	NASDAQ			0.0	160	(46.3)
4/11/2000	IPO		2002	3.2	47	
4/23/2007	private			0.7	10	
10/1/1996	private			9.5	99	
7/1/2001	private			3.3	40	
7/1/1996	Sold		2004			
10/1/1997	private					
3/1/1986	Sold		2004			

continued

Company	Venture Capital (Thousands of Dollars)	Rounds	Last Round Date
EraGen Biosciences, Inc. (FKA: Sulfonics, Inc.)	32,647.0	3	3/15/2007
Exogene Corporation	7,115.1	5	7/1/1993
Fluorous Technologies, Inc. (AKA: FTI)	3,650.0	2	5/23/2003
Genaera Corporation (FKA: Magainin Pharmaceuticals)	18,106.0	5	10/1/1998
Genaissance Pharmaceuticals, Inc.	75,749.9	4	11/4/2004
Genelabs Technologies, Inc.	34,949.4	8	6/29/2006
GeneMedicine, Inc.	8,900.0	2	7/13/1994
Genetic Therapy, Inc.	13,989.0	8	7/1/1994
GenPharm International, Inc.	18,989.1	8	2/29/2000
Geron Corporation	42,074.8	5	1/1/1996
Gilead Sciences, Inc.	32,060.0	6	8/1/1992
Gliatech, Inc.	32,596.1	7	6/1/1995
Hauser Chemical Research, Inc.	1,893.0	3	12/7/1990
Hawaii Biotech, Inc.	16,500.0	5	12/26/2006
Houston Biotechnology, Inc.	3,240.0	2	5/1/1986
Hypres, Inc.	39,841.0	20	12/31/2002
Icagen, Inc.	96,700.7	7	2/1/2007
Illumigen Biosciences, Inc.	7,950.0	8	7/6/2007
Illumina, Inc.	36,567.0	2	11/1/1999
Immtech Pharmaceuticals, Inc. (FKA: Immtech International)	2,509.0	3	2/14/1994
ImmuLogic Pharmaceutical Corporation	29,844.0	5	2/22/1993
Immunicon Corporation	106,800.4	7	6/29/2005
ImmunoGen, Inc.	21,934.0	7	1/1/1989
Immusol, Inc.	23,500.0	2	9/24/2003
IntraTherapeutics, Inc. (FKA: Cardia Catheter Company)	32,224.2	8	3/31/2000
Invitrogen Corporation	15,000.0	1	6/20/1997
Iomai Corporation	80,570.0	9	10/25/2006
Irvine Sensors Corporation	2,650.0	3	6/10/2003
Isis Pharmaceuticals	17,490.0	6	8/11/1994
Isolab, Inc.	2,744.0	2	6/28/1990
ISTO Technologies, Inc.	25,725.0	5	8/3/2007
Kurzweil Applied Intelligence, Inc.	26,122.1	13	1/1/1993
Large Scale Biology Corp. (FKA: Biosource Genetics Corp)	11,675.1	6	3/1/1998
Laser Diagnostic Technology, Inc.	13,310.9	5	11/30/2001
Laserscope	24,045.4	8	9/1/1987
LeukoSite, Inc.	32,613.1	8	7/1/1998
LifeSpan BioSciences, Inc.	19,000.0	1	4/17/2001
Linguagen Corporation	20,212.0	4	5/23/2006
Lucent Medical Systems, Inc.	6,700.0	2	9/25/1998
Lynx Therapeutics, Inc.	72,200.4	5	9/25/2003
Markwell Medical Institute, Inc.	882.0	5	5/1/1987
MediChem Research Inc.	35,000.0	1	6/28/1999
Medinox, Inc.	21,199.8	2	1/8/2002

First Round Date	Status	Ticker Symbol	Last Known Date	Annual Revenue (Millions of Dollars)	Number of Employees	Profit/Loss
10/6/2005	private					
10/1/1988	Sold		1996			
6/20/2000	private			2.0	15	
3/1/1988	NASDAQ	GENR		0.9	46	(21.2)
8/1/1998	Sold		2005			
10/1/1984	NASDAQ	GNLB		11.2	66	(8.7)
10/1/1992	private			14.9	110	
8/1/1988	private			1.0	15	
2/29/2000	Sold					
7/10/1992	NASDAQ	GERN		3.3	90	(31.4)
8/1/1987	NASDAQ	GILD		3,026.1	2,525	(1,190.0)
7/1/1988	Sold		2000			
4/1/1988	Out of business					
6/7/2002	private			5.1	65	
10/1/1985	Sold					
7/1/1983	private			8.0	33	
10/1/1995	NASDAQ	ICGN		8.4	72	(24.8)
5/1/2000	private			1.5	10	
11/30/1998	NASDAQ	ILMN		184.5	277	40.0
12/21/1992	AMEX	IMM		4.3	27	(11.3)
5/1/1987	Out of business		2002			
7/1/1988	NASDAQ	IMMC		8.7	107	(24.0)
6/1/1981	NASDAQ	IMGN		38.2	192	(19.0)
6/1/2001	Sold					
10/7/1991	Sold		2001			
6/20/1997	NASDAQ			1,263.5	4,835	(191.0)
1/1/1998	NASDAQ	IOMI		1.5	66	(31.8)
10/1/1997	NASDAQ	IRSN		30.8	166	(8.5)
2/1/1989	NASDAQ	ISIS		24.5	258	(45.9)
5/1/1987	Foreign					
3/1/2000	private			1.6	24	
5/1/1984	private					
12/1/1987	private			0.8	20	
1/1/1994	Foreign					
3/1/1983	Sold		2006			
9/1/1994	Sold		1999			
4/17/2001	private			3.3	40	
12/30/2003	private					
7/1/1997	private			0.5	7	
2/15/1994	Sold		2007			
6/1/1981	Out of business					
6/28/1999	private					
6/15/1999	private					

continued

Company	Venture Capital (Thousands of Dollars)	Rounds	Last Round Date
MediSpectra, Inc.	58,970.0	8	7/21/2006
Meridian Instruments, Inc.	3,557.0	4	10/1/1993
Message Pharmaceuticals, Inc.	11,142.5	8	4/14/2004
MIICRO, Inc.	6,840.0	4	9/26/2001
MIDI	2.0	8,250	5/3/2004
Moberg Medical, Inc. (AKA: Moberg Research, Inc.)	5,473.8	6	4/1/1997
Molecular Dynamics, Inc.	22,717.0	7	7/1/1994
Myogen, Inc.	191,452.8	6	10/13/2004
Nanosphere, Inc.	80,130.1	5	5/16/2006
NeoGenesis, Inc.	22,999.9	1	6/21/2001
Nereus Pharmaceuticals, Inc.	127,345.6	8	8/9/2007
NeuroControl Corporation	22,800.0	9	1/4/2001
Neurocrine Biosciences, Inc.	21,499.9	6	5/23/1996
Neuron Therapeutics, Inc. (FKA: ICTUS Pharmaceuticals)	28,717.0	4	12/7/2001
NimbleGen Systems, Inc.	73,250.5	8	1/2/2007
Nimbus Medical, Inc.	9,635.1	3	7/1/1986
Octagen Corporation	4,800.0	2	3/6/2000
Ontogen	24,945.0	5	10/13/2000
Onyx Pharmaceuticals, Inc.	70,200.2	6	5/9/2002
Organ Recovery Systems	13,999.8	1	7/29/2004
Orquest, Inc.	42,814.8	5	10/16/2001
Palatin Technologies	45,700.0	3	1/30/2004
Panacos Pharmaceuticals, Inc.	26,550.0	3	6/28/2007
Perlan Therapeutics, Inc.	5,227.0	3	12/27/2001
Pharmacoepia Drug Discovery, Inc.	8,472.0	1	8/11/2005
PharmaSonics, Inc.	22,700.0	4	6/30/2002
Pharmavene, Inc.	13,044.0	3	6/1/1996
PHT Corporation (AKA: Personal Health Technologies Corp.)	48,250.2	6	10/18/2004
Phylos, Inc.	25,100.0	1	11/30/2000
Physical Optics Corporation	3,337.0	4	8/1/1990
Physical Sciences, Inc.	492.0	2	7/1/1995
Premier Laser Systems, Inc	6,145.0	4	1/1/1997
Progenics Pharmaceuticals, Inc.	21,448.0	2	12/27/2005
Promega Corporation	5,250.0	4	5/27/1993
PRP, Inc.	384.0	2	1/1/1996
Proteome, Inc.	8,100.0	1	12/1/1999
Quantum Dot Corporation (AKA: Q Dot)	39,150.0	3	8/10/2005
Quantum Magnetics, Inc.	3,800.0	3	7/1/1997
Replidyne, Inc.	126,500.1	6	8/17/2005
Repligen Corporation	12,234.0	3	5/1/1985
RiboGene, Inc. (FKA: Transgene)	48,233.2	15	2/1/1997
Sangamo Biosciences	16,950.0	3	12/31/2001
Sangart, Inc.	50,353.0	2	4/4/2007

First Round Date	Status	Ticker Symbol	Last Known Date	Annual Revenue (Millions of Dollars)	Number of Employees	Profit/Loss
6/1/1996	private			1.6	21	
5/1/1983	Sold					
1/1/1998	Out of business		2004			
10/31/1997	private			1.6	20	
5/19/2005	private			1.3	25	
1/1/1992	private					
9/1/1987	Sold		1998			
10/5/1998	Sold		2006			
1/25/2000	NASDAQ	NSPH		1.1	50	113.0
1/9/2001	Sold		2005			
7/29/1998	private			9.3	29	
3/3/1994	private					
9/25/1992	NASDAQ	NBIX		39.2	588	(107.2)
10/1/1998	private					
9/1/2000	Sold					
3/1/1988	Sold		1996			
4/1/1998	private					
5/19/1992	Out of business		2003			
4/24/1992	NASDAQ			0.3	125	(92.7)
1/20/2003	private			2.4	27	
6/8/1994	Sold		2003			
11/1/1996	AMEX	PTN		14.4	85	(27.8)
11/4/2000	NASDAQ	PANC		0.3	32	(38.1)
6/4/1999	private			1.2	14	
8/11/2005	NASDAQ	PCOP		16.9	150	(27.8)
2/1/1997	Out of business					
4/1/1993	Sold					
11/3/1999	private			8.4	80	
11/30/2000	private			1.7	18	
8/1/1987	private			30.0	150	
5/9/1995	private			12.4	150	
4/1/1994	Out of business					
12/1/1995	NASDAQ	PGNX		69.9	149	(21.6)
10/1/1982	private			175.0	850	
4/1/1996	private			6.8	130	
12/1/1999	private					
1/1/1999	Sold		2005			
10/15/1995	Out of business					
2/21/2002	NASDAQ	RDYN		16.0	85	(29.3)
11/1/1981	NASDAQ	RGEN		14.1	45	(0.9)
1/1/1990	Sold		1999			
6/1/1996	NASDAQ	SGMO		7.9	62	(17.9)
10/31/2004	private			7.3	35	

continued

Company	Venture Capital (Thousands of Dollars)	Rounds	Last Round Date
Scios Nova, Inc.(F.K.A Scios Inc)California Biotechnology)	5,425.0	1	6/1/1982
Secretech	800.0	2	10/1/1990
Selective Genetics, Inc. (FKA: Prizm Pharmaceuticals, Inc.)	56,867.0	14	12/1/2003
Sepracor, Inc.	16,892.0	8	2/22/1993
Signal Pharmaceuticals, Inc.	44,543.7	10	12/1/1999
Spire Corporation	3,750.0	3	1/1/1987
Stratagene Cloning Systems	1,873.0	2	12/31/1992
Structural Bioinformatics, Inc.	46,371.7	4	3/22/2000
Sunesis Pharmaceuticals, Inc. (FKA: Mosaic Pharmaceutical)	163,338.1	8	5/30/2007
Synaptic Pharmaceutical Corporation (FKA:Neurogenetic Corp)	89,772.2	7	9/5/2001
T Cell Sciences, Inc.	3,634.0	3	10/1/1989
Targeted Genetics Corporation	46,450.0	4	6/28/2007
TechniScan Medical Systems, Inc.	6,400.0	1	2/5/2007
Tegic Communications, Inc. (AKA:T9 Text Input)	15,000.0	2	5/4/1999
Telefactor Corporation	450.0	3	12/31/1998
Telios Pharmaceuticals, Inc.	30,530.0	7	1/1/1993
Third Wave Technologies, Inc.	78,064.2	5	7/26/2000
TraceDetect, Inc.	1,600.0	2	11/17/2003
TransMolecular, Inc.	42,364.3	4	2/20/2004
Trimeris, Inc. (FKA: SL-1 Pharmaceuticals, Inc.)	38,283.0	6	9/1/1999
United Biomedical, Inc.	9,000.0	1	7/1/1997
UroCor, Inc. (FKA: CytoDiagnostics, Inc.)	16,600.1	5	7/1/1995
VaxGen, Inc.	29,449.0	2	3/1/1997
Vertex Pharmaceuticals, Inc.	13,538.0	5	10/1/1996
VueSonix Sensors	4,600.0	3	7/30/2004
Xeotron Corporation	9,000.0	1	5/1/2001
Xeyex Corporation	3,267.0	2	6/30/1999
Zynaxis, Inc.(FKA: Zynaxis Cell Science/PKH Labs)	37,581.0	8	1/1/1995
Martek Biosciences Corporation	35,167.1	8	1/1/1986
Vestar, Inc.	34,509.1	15	7/1/1981
Vical, Inc.	17,850.0	7	6/1/1987

NOTE: Hoover's data reflect current data available through Hoover's Small Business Database as of September 2007.

SOURCES: Data on VC investments are from VentureSource; data on current and historical firms status are from Hoover's Small Business Database (<<http://www.hoovers.com>>).

First Round Date	Status	Ticker Symbol	Last Known Date	Annual Revenue (Millions of Dollars)	Number of Employees	Profit/Loss
6/1/1982	Sold					
9/1/1989	Out of business					
6/12/1992	private					
1/1/1984	NASDAQ	SEPR		1,196.5	228	184.6
1/1/1993	private			48.5	134	
11/1/1979	NASDAQ	SPIR		20.1	118	(8.1)
4/1/1987	Sold					
11/1/1996	Sold					
2/17/1998	NASDAQ	SNSS		13.7	138	
1/1/1987	Sold					
4/1/1985	Out of business					
6/1/1992	NASDAQ	TGEN		9.9	95	(34.0)
2/5/2007	private					
1/22/1998	Sold					
12/31/1997	Sold		2000			
1/1/1986	Sold					
6/30/1995	NASDAQ	TWTI		28.0	154	(18.9)
3/15/2002	private			1.4	12	
9/30/1997	private			1.2	18	
2/12/1993	NASDAQ	TRMS		37.0	90	7.4
7/1/1997	private			13.8	285	
7/1/1987	Sold					
4/10/1996	private					
1/1/1989	NASDAQ	TRTX		216.4	320	(206.9)
6/9/2000	private					
5/1/2001	Sold		2004			
1/1/1997	Out of business					
6/1/1988	Out of business					
2/1/2005	NASDAQ	MATK		270.0	582	14.9
7/1/1993	Out of business		2000			
3/10/1993	NASDAQ	VICL		14.7	155	(23.1)

Appendix E

Analysis of the Evidence Submitted by BIO

In response to requests from the NRC, BIO has submitted testimony about the impact of the SBA venture capital ruling on its membership. The testimony summarizes several surveys conducted by BIO as well as information about six company cases.

SURVEYS

BIO conducted telephone and Internet surveys of its “emerging company” membership—defined as firms with fewer than 350 employees and no marketable products. A 2006 Internet survey indicated that 50 of 267 responding firms had been refused SBIR funding at NIH based on the venture capital exclusion.¹ Of these, nine were able to find alternative funding.

A smaller telephone survey in 2007 indicated that about two-thirds of the respondents² would use SBIR awards for preclinical or discovery work; 84 percent indicated that they would apply for SBIR funding if they were eligible. The latter of course is no indication either of the importance of the funding or its strategic value to the company.

Finally, another 2007 survey indicated that about half of respondents³ would not use SBIR funding to support their lead product, and a further 18 percent

¹BIO provided no additional background information about the surveys; however, it appears that the merging company membership totals 650 companies, about 85 percent of BIO’s total membership. We can assume that all surveys attempted to contact all 650 firms. For this survey, the response rate was about 41 percent.

²n=144, or about 22 percent of the total emerging company population.

³n=167, or about 26 percent of the total emerging company population.

would use it to discover other applications for their lead product. This supports the case study analysis which suggests that venture capital-funded companies tend not to use SBIR for lead product support.

CASE STUDIES

BIO provided six case studies. We can summarize this evidence as follows:

- Two are now apparently funding the excluded research from venture capital or other funds. One of these received substantial funding from the venture arm of Novartis, a large pharmaceutical company.
- Two have been acquired (and hence may no longer be eligible for the SBIR program on other grounds).
- Two reflect only the information provided by BIO, which claims that the NIH-funded research has been abandoned. It is worth noting that for both, the abandoned research was not the primary product line.

ANALYSIS OF BIO EVIDENCE

The Case Studies

The six case studies are all designed to show that promising lines of early-stage research have been abandoned or delayed as a result of the ruling. They do not provide counterfactual evidence based on products that were funded prior to the SBA ruling, which would have been excluded by the ruling. This would have added power to the cases.

The six companies do not provide a clear picture of the ruling's impact. Two firms appear to be using venture capital funding to continue the research—in one case, funds were at least partly provided by Novartis Venture Funds. Two have been acquired. The remaining two did not appear to be working in the affected areas any more—which may be a direct result of the ruling.

As BIO claims, it also appears to be true that for five of the firms, the affected research did not involve their lead product. This raises questions about the likelihood that this research would have led to any commercial result, if only because data from the NRC survey and NRC case studies indicates that such outcomes are less likely than commercialization of lead products.

The Surveys

The surveys provide a somewhat more compelling picture. They suggest that a large majority of responding biotech companies would apply for NIH funding absent the ruling, and that most would not use the funds for their lead product.

Two-thirds of the proposed research was reported to be focused on preclinical or discovery stages.

Limitations of the survey data. The surveys themselves were all limited to BIO members—a membership more likely on average to have received venture capital funding. This is, therefore, necessarily not a representative sample of the industry (nor was it presented as such).

This point is buttressed by a comparison between the BIO survey and the NRC Non-participant Survey. About 18 percent of BIO respondents—or 8 percent of BIO’s emerging company membership—reported that they had been excluded as a result of the SBA ruling, while about 2 percent of NRC respondents indicated that venture capital ownership was the primary cause of their non-application to the program.⁴

Moreover, details of the surveys and the methodologies used for them have not been provided by BIO, so it is not possible to determine whether the survey process itself inadvertently introduced biases into the results.

Conclusions. Overall, it seems fair to conclude on the basis of the BIO testimony that for a limited but still substantial number of firms, the SBA ruling has blocked access to a source of NIH funding that was in the main used for research on potential new products and applications that were not the company’s lead focus. In some cases, this led to delays or to the abandonment of the research.

The testimony did not however provide compelling evidence that the size of the problem was substantially greater than estimated by the NRC survey.

It did show that some research had been negatively impacted, and in some cases eliminated altogether. However, BIO provided no evidence to suggest that this research was more valuable than the research supported through the diversion of SBIR funds away from venture capital-funded companies to other companies. Nor did BIO present any evidence that SBIR supported research at venture capital-funded companies was more likely to reach the market than other SBIR-supported research at NIH, or more likely to have a major impact.

⁴It is worth noting that according to the third quarter 2007 PWC Moneytree survey, approximately 100 investments per quarter are made in the biotech sector. <<https://www.pwcmoneytree.com/MTPublic/ns/nav.jsp?page=notice&iden=B>>.

Appendix F

SBA Administrative Ruling on Appeal of Cognetix, Inc.

Cognetix, Inc., No. 4560 (May 29, 2003)
Docket No. SIZ-2003-04-28-26

UNITED STATES OF AMERICA
SMALL BUSINESS ADMINISTRATION
OFFICE OF HEARINGS AND APPEALS
WASHINGTON, D.C.

SIZE APPEAL OF:)	Docket No. SIZ-2003-04-28- 26
)	
Cognetix, Inc.)	Decided: May 29, 2003
)	
Appellant)	
)	
Solicitation No. PHS 2002-2)	
National Institutes of)	
Bethesda, Maryland)	
)	
)	
)	

APPEARANCES

Michael K. Wyatt, Esq.
Michael J. Vernick, Esq.
For Appellant

Kevin R. Harber, Esq. for the Small Business Administration

DIGEST

The term "individuals" in 13 C.F.R. Section 121.702(a) means only natural persons and does not include venture capital funds, pension funds, and corporate entities for purposes of an SBIR award. Thus, a firm that is otherwise eligible for an SBIR award is disqualified because it is less than 51 percent owned by natural persons.

DECISION

BLAZSIK, Administrative Judge:

Jurisdiction

This appeal is decided under the Small Business Act of 1958, 15 U.S.C. Section 631 et seq., and 13 C.F.R. Parts 121 and 134.

Issue

Whether a firm that is otherwise eligible for an SBIR award is disqualified because it is less than 51 percent owned by natural persons.

Facts

The National Institutes of Health (NIH), National Institute of General Medical Sciences, issued this small business set-aside solicitation on a Phase II proposal for the Small Business Innovation Research (SBIR) program. The title of the Phase II project is "Alpha-Conopeptides: Novel Rapid-Acting Muscle Relaxants." The applicable size standard for the SBIR program, including affiliates, is 500 employees. 13 C.F.R. Section 121.702(b).

On March 5, 2003, the NIH's Contracting Officer (CO) requested a formal size determination from the Small Business Administration's (SBA) Office of Government Contracting, Area VI (Area Office) in San Francisco, California, on Cognetix, Inc. (Appellant), the SBIR awardee. The CO's request stated that Appellant was awarded a grant, but in the course of obtaining additional financial information, the applicant provided statements that raised concern on their organization's eligibility for SBIR funds. [1]

The Size Determination

On April 7, 2003, the Area Office issued its size determination. Based on the documents Appellant submitted, the Area Office made the following factual findings. First, it noted Appellant's size status would be determined as of the date of the SBIR award for Phase II. 13 C.F.R. Section 121.704. The Phase II SBIR award was made on April 1, 2003 - thus, Appellant's size would be determined as of that date. [2]

Second, the Area Office noted Appellant's two largest stockholders are MDS Capital and AIG Global Investments. The documents submitted revealed no entities control or have the power to control Appellant. Appellant's number of employees do not exceed 500 employees. 13 C.F.R. Section 121.702(b).

Third, Appellant provided the Area Office with a stock ownership chart showing its diverse group of investors and the holdings of each investor after outstanding stock options are given present effect. 13 C.F.R. Section 121.103(d) (the present effect rule). Shares of Appellant's voting stock are owned by natural persons, corporations, and non-corporate institutional investors, including venture capital funds and pension funds.

The amount held by natural persons combined with that held by non-corporate institutional investors based in the United States exceeds 51 percent, but the amount held by natural persons alone is less than 51 percent.

Based on the above, the Area Office determined that the majority of Appellant's stock is owned by institutions which, by Appellant's own admission, "are primarily venture capital operating companies, investment companies, and employee benefit or pension plans."

Finally, the Area Office concluded that, although Appellant met the 500-employee size standard mandated by 13 C.F.R. Section 121.702(b), it did not meet section (a) of the rule. That section requires that a business concern to be eligible to compete for an SBIR award must be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in the United States. The Area Office noted in *Size Appeal of CBR Laboratories, Inc.*, SBA No. SIZ-4423 (2001) (CBR), this Office held that the terms "individuals" and "citizens" in the regulation mean only natural persons and not entities such as corporations. Accordingly, the Area Office concluded Appellant is ineligible for the SBIR Phase II award.

Appellant received the size determination on April 11, 2003, and filed its appeal April 28, 2003. [3] On May 2, 2003, the Administrative Judge directed the SBA's Office of General Counsel (OGC) to submit comments on the issues raised in the appeal on or before May 13, 2003. She also gave permission to Appellant to file a reply to OGC's comments on or before May 23, 2003. She ordered the record to close on that date.

The Appeal

Appellant asserts the Area Office erred in applying CBR here. In distinguishing the facts in CBR from those in the instant proceeding, Appellant asserts in CBR, the challenged firm was wholly owned by a single corporation, whereas Appellant here is owned neither by corporations alone nor wholly by any single investor.

Alternatively, Appellant asserts the Area Office erred in interpreting the CBR decision to mean that the term "individual" excludes venture capital funds and pension funds as well as corporations in determining SBIR eligibility. Thus, the Area Office erroneously counted shares held by Appellant's non-corporate institutional investors (pension funds and venture capital funds) as if those shares were held by corporations, rather than by individuals. Appellant asserts its non-corporate institutional investors hold Appellant's shares "on an aggregated basis for individual investors," and thus that stock should be counted as if owned directly by individual investors.

Appellant asserts the Area Office's interpretation of CBR is

contrary to one of the Congressional intents of the SBIR program; that is, to attract to awardees private capital including venture capital funds and pension funds, which are typically organized as limited partnerships and trusts. Moreover, Appellant asserts SBA itself has acknowledged CBR is controversial in its new SBIR Policy Directive, and SBA plans to change it in a forthcoming rulemaking.

As relief, Appellant requests the Administrative Judge either to reverse the size determination or to remand the matter to the Area Office.

OGC's Comments

On May 13, 2003, OGC filed its comments in opposition to the appeal. First, Counsel asserts the CBR decision is not limited to those instances where the applicant is a wholly-owned subsidiary of another firm. Second, CBR expressly stands for the proposition that a firm not 51 percent owned and controlled by natural persons is ineligible for the SBIR program. Pension funds and venture capital funds, as limited partnerships and trusts, are entities, not natural persons. Further, Appellant's approach, to count shares owned by pension funds and venture capital funds as if individuals owned them would undermine 13 C.F.R. Section 121.702(a). Finally, Counsel disagrees with Appellant that Congressional intent favors Appellant's approach, and cites exhaustively from legislative history to support his contention.

On May 23, 2003, Appellant filed a reply to OGC's comments. Appellant disagrees with OGC's brief and reiterates its appeal's assertions that the SBIR Program's legislative history clearly supports Appellant's eligibility for a Phase II award. Appellant reasserts that Congress's intent cannot be questioned and that Congress intended the program to encourage investments from venture capital and other sources of private investment such as pension funds. Finally, Appellant asserts limiting CBR will not create an exception inconsistent with Congress's clearly expressed intent. Appellant repeats its request for either remand to the Area Office or reversal of the Area Office's determination.

Discussion

As noted, *supra*, fn. 3, the appeal is timely filed. On the merits, Appellant has the burden of proving, by a preponderance of the evidence, all the elements of its appeal. Specifically, it must prove the size determination is based on a clear error of fact and law. 13 C.F.R. Section 134.314; *Size Appeal of Rebmar, Inc.*, SBA No. SIZ-4713 (1996).

To reiterate the general elements, to be eligible for an SBIR award, a firm must be "at least 51 percent owned and

controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States." 13 C.F.R. Section 121.702(a). [4] In CBR, after an exhaustive analysis of the pertinent regulation, its legislative history, and the pertinent SBIR Policy Directives, this Office held that the word "individuals" can refer only to natural persons and cannot refer to entities. CBR, at 11-12.

The Administrative Judge rejects as specious Appellant's first argument, that the holding in CBR cannot be applied to any challenged firm not wholly owned by one corporation because the challenged firm in CBR was wholly owned by one corporation. The regulatory requirement quoted above is not premised on any particular ownership structure, and the discussion in CBR clearly considered the broad issue of whether the word "individuals," as used in 13 C.F.R. Section 121.702(a), could have any meaning other than natural persons.

The Administrative Judge also must reject Appellant's second argument, that the stock holdings of non-corporate institutional investors should be treated as if owned directly by individual investors, because the institutions hold them "on an aggregated basis for individual investors." Institutional investors, whether organized as limited partnerships or trusts, clearly are entities and not individuals. Moreover, the Administrative Judge agrees with SBA's Counsel that if the definition of "individuals" in Section 121.702(a) contained an exception for non-corporate institutional investors, for which Appellant argues, this exception would eviscerate the rule.

In the time since this Office issued the CBR decision in January 2001, SBA has revised its SBIR Program Policy Directive. 67 Fed. Reg. 60072 (Sept. 24, 2002). SBA changed its definition of "small business concern" to permit program applicants that are joint ventures. Policy Directive Section 3.y(2), 67 Fed. Reg. at 60084. In discussing ownership, the SBA retained precisely the same language interpreted in CBR, except with respect to joint ventures:

at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States,

Id. at Section 3.y(3); see 13 C.F.R. Section 121.702(a); CBR at 3.

In its preamble to the Policy Directive, SBA addressed a comment regarding the eligibility of wholly-owned subsidiaries by referring to this language, and noting this Office also addressed the issue in CBR. SBA further commented:

At this time, SBA is considering this issue and if SBA determines that a change in the regulation is necessary, it will issue a proposed regulation pursuant

to Notice and Comment rulemaking. If there is a change in the regulation, the Directive will be changed accordingly.

67 Fed. Reg. at 60076. Shortly after issuing this Policy Directive, SBA proposed revisions to the size regulations. 67 Fed. Reg. 70339 (Nov. 22, 2002). Except for new language pertaining to joint ventures, the proposed text of Section 121.702(a) retains the same language as before. 67 Fed. Reg. at 70350. The preamble to the proposed rule states:

The current requirement . . . requires 51 percent direct ownership by individuals who are U.S. citizens or permanent resident aliens in every case. This change is being made to make the size regulations consistent with a recent change made to the SBIR Policy Directive.

67 Fed. Reg. at 70344-45 (emphasis added).

Based on the above, the Administrative Judge concludes that, as of both April 2, 2003, Phase II award date determining Appellant's size eligibility and the present time, this Office's holding in CBR still governs the issue of whether the term "individuals" in 13 C.F.R. Section 121.702(a) must refer to natural persons.

Accordingly, Appellant's arguments to the contrary have no basis of fact or law and, thus, are without merit. In the circumstances, the Administrative Judge affirms the size determination and reaffirms this Office's decision in CBR.

Conclusion

For the above reasons, the Administrative Judge DENIES the instant appeal and AFFIRMS the Area Office's size determination.

This is the Small Business Administration's final decision. 13 C.F.R. Section 134.316(b).

GLORIA E. BLAZSIK
Administrative Judge

1 On May 7, 2003, the CO notified this Office that the grant was suspended pending resolution of this appeal.

2 The Area Office incorrectly stated it as April 2, 2003.

3 The appeal is timely under 13 C.F.R. Section 134.304(a)(1), because Appellant filed the appeal within 15 days of the receipt of the size determination. Because the 15th day was on a Saturday, the following business day (Monday) is the determinative date.

4 The other eligibility criterion, that the challenged firm, including its affiliates, has no more than 500 employees, is not at issue in this appeal.

Posted: June, 2003

Appendix G

Letter from
Elias A. Zerhouni, Director,
National Institutes of Health
to Hector V. Barreto, Administrator,
U.S. Small Business Administration,
June 28, 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

JUN 28 2005

The Honorable Hector V. Barreto
Administrator
United States Small Business Administration
409 Third Street, S.W.
Washington, DC 20416-0001

Dear Administrator Barreto:

I am writing to express concern that current Small Business Administration (SBA) limits on eligibility for Small Business Innovation Research (SBIR) awards, in the context of biomedical and public health research, unduly restrict the ability of the National Institutes of Health (NIH) to fund high quality, small companies that receive venture capital (VC) investment. As a result, NIH must turn away many deserving applicants, and the goals of the SBIR program are being undermined. I ask that you consider a waiver to enable NIH to remedy this problem and look forward to discussing it with you.

The legislation establishing the SBIR program was signed into law on July 22, 1982, by President Reagan. As stated in the SBA's *SBIR Program Policy Directive*, "the statutory purpose of the SBIR program is to strengthen the role of innovative small business concerns (SBCs) in federally-funded research or research and development (R/R&D). Specific program purposes are to:

- (1) stimulate technological innovation;
- (2) use small business to meet Federal R/R&D needs;
- (3) foster and encourage participation by socially and economically disadvantaged SBCs, and by SBCs that are 51 percent owned and controlled by women, in technological innovation; and
- (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth."

Consistent with these goals, the NIH SBIR program supports a wide array of biomedical and public health R/R&D activities of small, innovative firms. But, in today's high risk biomedical research environment, in areas such as drug development, drug discovery, and therapeutics, fewer than one percent of the innovative, promising projects reach the marketplace. Research in public health and biotechnology is characterized by the following features:

- High and intense capital needs (i.e., up to \$1 billion) to see a product from idea to market;
- Unusually long development time (i.e., 5-12 years);

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- Exceptionally high “burn rate” for investment funds;
- Significant investment by venture capital companies (VCCs), many of whom are not owned at least 51 percent by natural persons;
- Multiple rounds of venture capital financing required; and
- Except for the smallest service-oriented entities, majority ownership and control by natural persons or business concerns majority owned by natural persons is extremely unlikely for R&D companies with significant market potential.

Given that the landscape for small business entities in the public health and biotechnology sector presents unique challenges, NIH is concerned that SBA’s new eligibility rule, while opening the field somewhat, leaves out many small concerns, and, in turn, substantially damages the NIH’s SBIR program. By limiting eligibility to concerns that are owned at least 51 percent by natural persons, or another concern that is itself owned 51 percent by natural persons, the rule disqualifies many highly-deserving small entities. Perversely, this rule dries up Federal funding for early-stage ideas from small concerns that, by attracting substantial VCC funding, show strong signs of likely success. Many of these concerns are the very entities that, with SBIR funding, offer significant promise for progress in improving public health. NIH believes that the current rule undermines the statutory purposes of the SBIR program to “stimulate technological innovation” and to “increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.” Furthermore, it undermines NIH’s ability to award SBIR funds to those applicants whom we believe are most likely to improve human health, which is the mission of NIH.

NIH shares SBA’s commitment to ensuring that only small business concerns receive SBIR awards. To advance this goal, and ensure that NIH also meets its need to support deserving R/R&D in the biotechnology field, I ask SBA to consider a waiver from certain eligibility standards for some concerns. Specifically, in addition to applicants eligible under current rules, the NIH requests that SBA permit it to award funds to small businesses when:

A concern is owned and controlled, at least in part, by a single VCC or multiple VCCs, provided that at least 51 percent of the concern is owned by U.S. individuals and/or VCC(s) that are owned no more than 49 percent by foreign business entities or individuals, and, provided further, that applicable small business affiliation standards are satisfied.

While many details of this proposal remain to be discussed between our two agencies, and its precise formulation may change as we work together, please understand that NIH aims to ensure that small business concerns with substantial VCC support in the biotechnology and public health R/R&D arena are able to receive SBIR awards from NIH. We do not aim to include concerns that are owned and controlled by large companies and believe that adherence to existing affiliation rules will limit this risk.

As additional background, I note that this request is not unprecedented. In the past, SBA waived SBIR program parameters and granted NIH the opportunity to make SBIR awards for certain

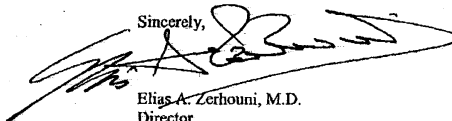
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types of biomedical R&D projects requiring time and dollars above the amounts specified in applicable Policy Directives.

In signing into law the legislation that established the SBIR program, President Reagan stated, *"We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications."* The program was designed *"to strengthen the role of the small, innovative firms in federally funded research and development, and to utilize Federal research and development as a base for technological innovation to meet agency needs and to contribute to the growth and strength of the Nation's economy."*

In keeping with President Reagan's directive, NIIH believes that it must be able to make SBIR awards to many small biotechnology concerns currently excluded from participation. We look forward to working with you on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Zerhouni', written over a horizontal line.

Elias A. Zerhouni, M.D.
Director

Appendix H

Testimony by Steven C. Preston,
SBA Administrator,
to the House Small Business Committee,
March 13, 2008

U.S. Small Business Administration
Statement of Administrator Steven C. Preston
House Small Business Committee
Reauthorization of the Small Business Innovation Research Program
March 13, 2008

Chairwoman Velazquez, Ranking Member Chabot and members of the Committee, the Small Business Innovation Research (SBIR) Program has helped small business to access federal research and development funding.

The SBIR Program was created in 1982 and has been used by small firms to fund research that has fostered technological innovation and commercialization of products. Every federal department with an extramural research and development budget of \$100 million or more participates in the SBIR Program. There are currently eleven federal departments that participate including Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Transportation, the Environmental Protection Agency, NASA and the National Science Foundation. SBA is responsible for promulgating regulations and policy directives to govern the program, while other federal agencies utilize the program to foster innovation.

Eligibility Rules

As a brief background, for a business to be eligible for participation in the SBIR Program, on the date of award they must (1) be organized for profit; (2) be at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States or at least 51 percent owned and controlled by one other for-profit business that is itself at least 51 percent owned and controlled by individuals who are citizens of, or permanent resident aliens in, the United States; and (3) have, including its affiliates, not more than 500 employees. The purpose of these requirements is to ensure that benefits reach only the small business entrepreneurs and that the research and development advances resulting from the SBIR Program remain in this country and benefit the United States.

In 2003, SBA proposed a rulemaking to modify the ownership requirement for SBIR awardees. The Proposed Rule was to add a specific flexibility in the requirements to allow SBIR awardees the option of conducting their innovative SBIR work through a wholly owned and controlled subsidiary. Cases had been brought to SBA's attention where small businesses formed research and development subsidiaries to pursue innovative research with SBIR funding. However, the subsidiaries were unable to receive the funds directly because they were more than 49 percent owned and controlled by another firm. The Proposed Rule was open to public comment from June 4, 2003 to July 7, 2003. Most of the comments were in favor of the proposed change. Some comments argued that the rule need not require 100 percent ownership and control—that less than 100 percent ownership and control by another concern should be allowed.

After reviewing the public comments, SBA published a Final Rule on this issue in the Federal Register on December 3, 2004 (69 FR 70180). In the Final Rule, SBA made one modification to the ownership requirement set forth in the Proposed Rule. It changed the proposed requirement that the subsidiary be 100 percent owned and controlled by another for-profit business to the requirement that it be at least 51 percent owned and controlled by another for-profit business. Based upon the comments received, the SBA considered its original proposal to be unnecessarily limiting. The Final Rule therefore provides that an SBIR awardee must meet the following requirements: it must be either (1) a for-profit business concern that is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States (as the pre-existing regulations required); or (2) a for-profit business concern that is at least 51 percent owned and controlled by another for-profit business that is itself 51 percent owned and controlled by individuals who are citizens of, or permanent resident aliens in, the United States. The Final Rule became effective January 3, 2005.

During the period that SBA was developing the proposed rule, SBA's Office of Hearings and Appeals (OHA) received an appeal from a company that was found ineligible for the SBIR Program because it was not majority owned by individuals. During the appeal it was argued that the term "individual" in the program's 51 percent ownership requirement should be interpreted to include non-corporate institutional investors such as Venture Capital Companies (VCCs). On May 29, 2003, OHA denied the appeal maintaining the long-standing interpretation that an "individual" is a natural person. This decision reaffirms the eligibility requirements set forth for the SBIR Program.

The 51 percent requirement is there to distinguish between individual owners and owners that are institutional entities to ensure that SBIR funds go only to small, independent U.S. firms. It is important to note that the OHA decision constituted neither a new eligibility rule, nor a new restriction on venture capital financing within the SBIR Program. In fact, based on the new final rule SBA believes this provides further opportunities for venture capital involvement under the SBIR program.

Venture Capital Participation

SBA wants to ensure that the integrity of the program is maintained and that it remains a program for small businesses. VC participation has been allowed and encouraged since the inception of the program. Currently, more than one venture capital company may invest any amount of money into small businesses that receive SBIR awards, with the only restriction that they cannot in concert own more than 49 percent and/or have the ability to control the SBIR awardee. In addition, if a VCC is for profit and is owned at least 51 percent by one or more individuals who are U.S. citizens or permanent resident aliens, it may own more than 49 percent of the SBIR awardee so long as the awardee and its affiliates (including the VCC and its affiliates) have no more than 500 employees in total.

The option of expanding VCC participation raises a number of issues. For example, exempting VC or other institutional investors from affiliation in size determination could

affect the transparency needed to determine program eligibility as well as the intent of the program to benefit businesses that are small. Further, any changes to SBA's size standards could potentially affect SBA's other programs. SBA is unaware of any meaningful distinction between VCCs and other business entities that would allow greater VCC participation in the SBIR program without affecting important ownership restrictions in other SBA programs.

SBA is particularly concerned with possible changes to its affiliation provision. Affiliation is a key concept in defining a small business. Along with a numerical measure of the size of business, the Small Business Act includes the criteria that a small business must also be "independently owned and operated." Without a consideration of affiliation, Federal assistance targeted for small businesses could be inappropriately provided to a business concern that is part of a large business. Accordingly, SBA advises Congress to proceed with the utmost caution in this key concept of defining a small business.

Proposed Legislation

The Administration is concerned with the proposed legislative change to the definition of small business for the purposes of venture capital investment. While recognizing that venture capital investment is crucial to small business growth, the Administration is nevertheless concerned that the committee print offers too broad a definitional change to the affiliation standards. SBA is currently reviewing these rules, and believes that the current change may not reflect the appropriate balancing required in development of size standards. In particular, any redefinition that alters the elements of independent ownership and control that identify small business ownership under current law has the potential for great harm to all small business programs.

It is also of concern that there are certain potential conflicts in the proposed legislation. For instance, SBA has noticed that there is a conflict between the definition of a VCOC which includes patent and licensing organizations affiliated with institutions of higher education and the clause requiring that VCOCs not be controlled by any business concern that is not a small business concern. Under the Small Business Act institutions of higher education are generally not considered small business concerns. Such definitional conflicts present potential inequities and SBA would hope we could work with the committee to clarify this language, consistent with what we believe is a mutual overarching objective: appropriately define the term "small business" in a manner that effectively minimizes *ineligibility* of actual small businesses while also minimizing the *eligibility* of large businesses.

Despite our differences of opinion on the affiliation rules, SBA is committed to the continued improvement and expanded monitoring of the SBIR program. In particular, the Administration would like to work with the committee to create performance goals for the program. These goals and metrics will provide useful information on the successes and strengths and weaknesses of the program in its goal to support innovative research.

For example, the Administration would like to develop quality metrics that can assist agencies in developing standards to limit the perceived effect of so-called “SBIR mills”. In order to understand the issue surrounding multiple award winners it is necessary to have clear data on the issue. Successful awardees should not be penalized provided there is a solid basis for their awards and a clear understanding of the nature of the research’s potential for advancement.

Likewise, the Administration would support efforts to study the commercialization and implementation of research to develop a better understanding of the needs of the Phase III process. While recognizing the historic goal of commercialization in the SBIR program, we believe that further expenditures and programmatic changes should be based on performance data, and we caution Congress to avoid re-focusing the program in a manner that involves direct support for commercialization activities more appropriately performed by the private sector.

The Administration’s clear goal is to further quality research which produces significant results for the Nation. SBA looks forward to working with this Committee as legislation moves forward prior to the sunset date on September 30, 2008.

I appreciate the opportunity to share the administration’s position on the SBIR programs and I look forward to answering any questions you may have.

Appendix I

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