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## United States Senate

COMMITTEE ON SMALL BUSINESS  
WASHINGTON, DC 20510-6350

November 19, 1999

The Honorable Aida Alvarez  
Administrator  
U.S. Small Business Administration  
409 Third Street, S.W.  
Washington, D.C. 20416

Dear Administrator Alvarez:

Under the Small Business Act, the Small Business Administration (SBA) has the responsibility to survey and monitor the operation of Small Business Innovation Research (SBIR) programs within participating Federal agencies. The Office of Inspector General (OIG) of the Department of Health and Human Services recently released a report on the administration of the SBIR program at the National Institutes of Health (NIH), a copy of which is attached for your review (Report). The Report details the NIH's failure to ensure that SBIR grantees comply with invention reporting requirements and its failure to evaluate the success of SBIR grantees at commercializing products developed under the SBIR program. It is apparent that the problems addressed in the Report are symptomatic of a larger issue: the failure of the SBA to oversee properly the SBIR program and ensure that Federal agencies with SBIR programs are complying with the Small Business Act and SBA's policy directives relating to that program.

In the Report, the OIG independently reviewed 100 phase II grants awarded in fiscal years 1994 and 1995. The OIG verified that 12 patents were granted as a result of such awards. The NIH, however, was only aware of one of the patents. This lack of awareness is alarming. The Federal government must know about such inventions so that it may exercise its rights regarding them, including, but not limited to, its right to a nonexclusive, nontransferable, irrevocable and paid-up license to utilize the particular invention. These intellectual property rights and the associated invention reporting requirements are clearly set forth in 35 U.S.C. § 202.

The primary reason given for NIH's ignorance of existing patents is that the NIH has not been providing clear information to SBIR grantees regarding invention reporting requirements or the intellectual property rights of the Federal government that arise from such inventions. The SBA's own policy directives to SBIR agencies specifically require that "each funding agreement under the SBIR program shall include provisions setting forth the respective rights of the United States and the small business concern with respect to intellectual property rights . . ." It is the SBA's responsibility to ensure that SBIR agencies are complying with the SBA's directives and to take appropriate action when they do not. From a fair reading of the report, it does not appear that the SBA fulfilled its responsibility in this instance. In fiscal year 1998 alone, the Federal government awarded approximately \$1.1 billion to small business concerns under the SBIR program. If neither the SBA nor the SBIR agencies make an effort to track what small businesses do with these funds, the Federal government may wrongfully be subject to liability for royalties in patent infringement suits and inadvertently be paying royalties when procuring inventions that have been licensed to third-party manufacturers.

Hon. Aida Alvarez

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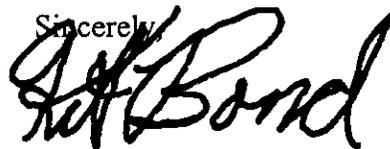
Unfortunately, this appears to be only the latest example of unsatisfactory record-keeping and oversight relating to this program. The Report also finds that the NIH does not have a system in place to evaluate the commercialization activities of SBIR grantees and had little information in that regard. According to the Report, NIH officials indicated during the review that they did not need to evaluate commercialization activities because the SBA does not require SBIR agencies to obtain this information and that the SBA and the General Accounting Office (GAO) have performed their own commercialization studies in the past. I understand, however, that the SBA does not maintain data on the commercialization success of SBIR grantees in its SBIR database. While I understand and appreciate the benefits that arise from the SBIR program other than the commercialization of products, the failure to maintain regularly information regarding commercialization activities precludes the SBA from evaluating an important indicator of success of the SBIR programs at the Federal agencies.

Moreover, the Committee received disturbing information regarding the data the SBA maintains on SBIR awardees. Specifically, the Committee learned that the GAO, in preparing its reports on the SBIR program in 1998 (RCED-98-132) and 1999 (RCED 99-114), spent substantial resources correcting and updating information in the SBA's SBIR database. Although the GAO referenced in its 1999 report that it had concerns about the reliability of the information in SBA's database and had to correct the data, the Committee only learned the full extent of GAO's efforts in this regard through conversations with GAO staff. Please be advised that it is not the responsibility of the GAO to create an accurate database on the SBIR program. The SBA receives appropriated funds to conduct its core activities, such as oversight of the SBIR program. The fact that the GAO was compelled to undertake this task is evidence that the SBA is, at a minimum, neglecting its SBIR oversight responsibilities.

To ensure that other agencies are not ignoring SBA's directives, please provide the Committee, by December 8, 1999, a letter describing how the SBA intends to ensure that each Federal agency with an SBIR program provides clear instruction to SBIR grantees regarding the Federal government's intellectual property rights and invention reporting requirements and a timeline for SBA's actions in this regard. Moreover, so that the Committee can ensure that the SBA is appropriately maintaining a database on SBIR grantees, please include in the letter an explanation of the data fields that the SBA is maintaining on SBIR grantees, the extent to which the Federal agencies are providing sufficient data to the SBA in a timely manner, the length of time that the SBA has been collecting such data, and how often the database is updated.

Thank you for your prompt attention to this serious matter. If you have any questions, please contact me or David Bohley of the Committee's staff at (202) 224-5175.

Sincerely,



Christopher S. Bond  
Chairman