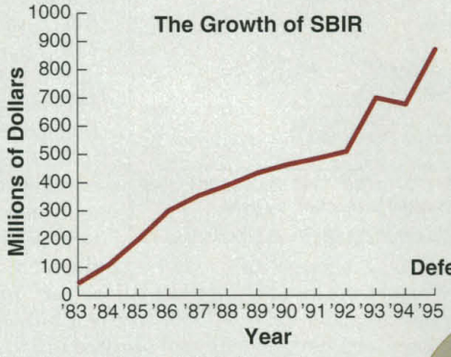
A $1 Billion 'Tax' on R&D Funds

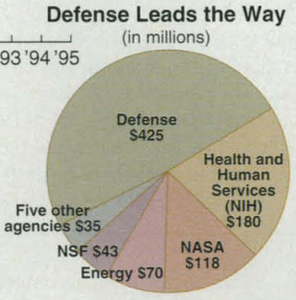
A little-known effort to help small high-tech businesses is under fire from academics who resent its source of funding: a mandatory—and growing—share of federal research budgets

Suppose you wanted to protect a new research program from federal budget cutters. You might start by making it a small piece of a larger pie. You'd probably authorize it for several years. And if you were clever, you'd insert a provision for automatic, incremental growth. But even if you built in all these provisions, you'd certainly never expect to see the program's budget leap by almost 25%, to more than $1 billion, in the same year that individual research agencies are trying to stave off deep cuts. But that's exactly what's happening to the Small Business Innovation Research (SBIR) program.

SBIR may well be the biggest secret in the federal research establishment. Created in 1982 to help small companies commercialize their ideas with a slice of the federal R&D pie, the SBIR program is fueled by a small tax on the budgets of the 11 federal agencies that spend more than $100 million a year on extramural R&D. As a result of a mandated increase in that tax, this fall the program is expected to grow by more than $200 million, to $1.1 billion. This increase is, however, finally lifting the veil of obscurity from the program (see next page).

Some academic research groups are taking aim at SBIR's growing budget and the quality of the research it supports. "The SBIR program is a prime example of how a congressional set-aside is having an adverse impact on support of science," says Robert Rich, president of the American Association of Immunologists and dean of research at Baylor College of Medicine in Houston. The group is a member of the Federation of American Societies for Experimental Biology (FASEB), which is leading the charge. And their complaints have been heard by an influential lawmaker who oversees NIH's budget.





SOURCE: SMALL BUSINESS ADMINISTRATION

By the numbers. SBIR's budget comes from a rising share of each agency's R&D spending.

However, any curbs on SBIR will have to overcome bipartisan support on Capitol Hill and in the White House, which likes SBIR's relatively even national distribution of awards. The program is fiercely defended by the powerful small business lobby, which is quick to cite success stories of individual companies. But hard data on the impact of SBIR awards—up to $100,000 for Phase I, which tests the feasibility of an idea, and up to $750,000 for Phase II, aimed at moving the technology closer to the marketplace—are hard to come by. One problem is teasing out the influence of a relatively small SBIR award among the myriad factors that affect the commercialization of research results. Even the definition of success remains elusive, although a recent academic study questions whether the program, by itself, contributes to the nation's overall R&D effort (see box).

The program was initially viewed by individual agencies as a loss of independence and by scientific organizations as a raid on funds for university-based researchers. That opposition died down, however, in part because the program took a comparatively small slice of a growing R&D budget. The 1982 law began with a 0.2% tax on agency budgets that grew to 1.25% in 1989.

The program began to take a more noticeable bite, however, after Congress passed an 8-year reauthorization in 1992 and stipulated

Does SBIR Increase the R&D Pot?

Winning an SBIR award appears to have a negative effect on the size of a company's R&D budget, and no effect on its ability to create jobs or increase sales. This surprising finding, from a new study of how the SBIR program affects small businesses, runs counter to the widely held notion that the awards are a much needed catalyst for growth in R&D spending.

The unpublished study, completed last summer by Scott Wallsten, a graduate student at Stanford University, uses publicly available data to compare 513 companies that received SBIR awards from 1990 to 1992 with 185 companies whose proposals were rejected, and 79 that were eligible but did not apply for an award. It found that the more SBIR awards a company received over that period, the less its R&D budget was likely to grow. In fact, the difference was exactly the same as the size of the SBIR award. "I was very surprised to find basically a dollar-for-dollar crowd-out effect," says Wallsten, who is spending this year at the White House Council of Economic Advisers before returning to Stanford this fall to complete his graduate degree under technology policy guru Roger Noll.

"It's a nice piece of work—extremely thorough and thoughtful," says Harvard University economist Joshua Lerner, who has studied the impact of venture capital on high-tech companies. Lerner has found that SBIR award winners grow significantly faster than nonwinners when situated in regions with substantial sources of venture capital.

The Wallsten study found that successful companies tend to be older and larger, and hold more patents—a frequently used measure of a company's level of innovation—than companies whose applications were rejected. And it found that some firms are very successful at winning SBIR awards: The average successful company won six awards over the 3-year period, and 25 firms received more than 20 awards. But Wallsten found that the SBIR program doesn't correct what economists view as a chronic problem of underinvestment in R&D by industry. "In fact," he says, "the SBIR program could be making the problem worse by reducing private R&D spending while public spending holds steady."

–J.D.M.

three additional increases. Last year, the program spent $869 million, 96% of which came from the five largest federal R&D agencies—the Departments of Defense and Energy, the National Institutes of Health (NIH), NASA, and the National Science Foundation (see pie chart). And another jump, from 2% to 2.5%, kicks in on 1 October 1996. The increase prompted a group of federal agencies last fall to ask that the program be held at 2% in their 1997 budget request. But White House officials nixed the idea.

Still, the impact of the rise on flat budgets was enough to put the program in the cross hairs of the 44,000-member FASEB. The federation hopes to shoot down the mandated growth of the program next year at NIH, which in 1995 gave out 830 SBIR awards worth $132 million. It is marshaling two arguments: The quality of the work is lower than in the awards given for basic research, and the program prevents NIH from putting limited funds to the best use. "A set-aside is inherently anti-quality, [and quality] should be the basis for NIH's decisions," says Rich.

One of FASEB's biggest objections is that the typical scores given to funded SBIR proposals are significantly higher—on a 100 to 500 scale in which lower is better—than those for R01s, NIH's bread-and-butter grants to individual investigators. "I can tell you that supporting research proposals with scores [above] 200 is a misuse of federal dollars," Rich said.

Rich, along with FASEB President Ralph Bradshaw, raised this argument in testimony this spring before the House subcommittee that oversees NIH, and it seems to have struck a chord. Representative John Porter (R–IL), chair of the appropriations panel, is drafting language in his upcoming spending bill that would block expansion of NIH's share of the program. "We've heard testimony that some SBIR grants do not meet NIH standards for quality, and that's of great concern to us," says Porter. "We certainly don't want to fund proposals that don't meet those standards."

However, his words are likely to be a call to arms for the powerful small business lobby. "I understand the attitude of the academic community at a time when R&D budgets are flat," says Robin Risser, CEO of Picometrix Inc. of Ann Arbor, Michigan (which makes photodetectors to work with lasers), and an advocate for small, high-tech businesses. "If they want an all-out war, then we're ready."

Porter may also have to reckon with the House Committee on Small Business, which held a March hearing on SBIR and a related university-based program featuring Risser and other supporters. "People are always talking about a diminution in quality, but we've had two GAO [Government Accounting Office] reports that say there's no diminution," says a committee staffer. "We think Congress took the right step in ramping up the program and tying it to overall R&D budgets. The scientists just want to change the law so it doesn't apply to them."

Scientists involved in both the review process and in research funded by SBIR also defend the program, saying that the comparison of SBIR and R01 scores is flawed. "You're comparing apples and oranges," says molecular geneticist Richard Kouri, who served for 10 years as chair of a special study section that reviewed SBIR proposals. He and others point out that SBIR reviewers deliberately use the entire range of possible scores, while scores for R01s are clustered at the low end of the scale because of a well-meaning effort by reviewers to give good proposals the best chance at limited funds. In fact, this so-called "score creep" became so pronounced in the mid-1980s that NIH converted to a percentile ranking for R01s.

"We take these proposals very seriously, and we're just as hard on them as on R01s," says Kouri, who is chair of the board of BIOS Laboratories in New Haven, Connecticut (which has received several SBIR awards), and chief scientist for a second New Haven company, called Gene Logic, that has not sought SBIR funding. "Nobody wants to tell a professor at Harvard—who may also be a friend—that he got a 250. He'd go crazy. But a 250 doesn't mean the same thing for an SBIR applicant."

In addition, say study section chairs, the applications are often not as polished as R01s, and the principal investigators are usually less familiar to reviewers and have a less impressive track record. And an SBIR pro-

House Panel Wants Bigger Bang for Buck

Biomedical scientists aren't the only ones raising questions about the Small Business Innovation Research (SBIR) program (see main text). A bill to authorize the 1997 defense budget contains a provision to tailor the Department of Defense's (DOD's) half-billion-dollar investment in SBIR—the largest amount spent by any agency—more closely to the military's needs. The committee has also requested a study by the General Accounting Office of the quality of the proposals coming in to DOD.

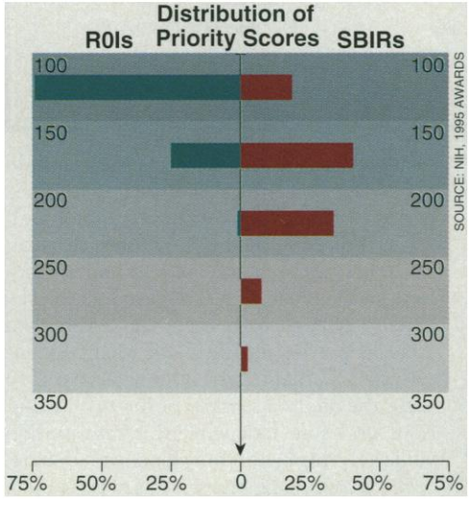
These moves are prompted by the growing scale of SBIR funding. "It's getting to be a lot of money," says a House staffer who follows the program. "The question is whether the [defense] technology funded by SBIR is making a transition into military programs or whether it's simply going to gee-whiz technology." In particular, the legislative language would give DOD program managers with research budgets of $20 million or more the authority to manage the SBIR program as they see fit.

These changes don't sit well with SBIR's supporters. Representative Jan Meyers (R–KS), chair of the Committee on Small Business, says the bill "would fundamentally disrupt" the governmentwide program and weaken DOD's SBIR activities, which she feels already serve the department's mission. Meyers missed the chance to defeat the provision in this week's floor debate on the bill, but hopes to mount an attack next month after the Senate passes its own authorization bill.

Ironically, DOD managers have already begun experimenting with ways to make it easier for companies to move from the research to the development phase of SBIR projects. Last summer its department began what it calls a Fast Track pilot project that would reduce the amount of time that small businesses must wait between Phase I and Phase II awards. In return, companies must lay out their strategy for commercializing the promised technology, including pledges of third-party support.

Some National Institutes of Health (NIH) institutes are taking a similar tack. This spring, NIH launched a pilot project, with the same name, that would treat Phase II awards much like the successive years of a regular research grant. Companies are to be eligible for continuous funding at the end of Phase I if they are making satisfactory progress. To qualify, companies must also submit a detailed product development plan, although NIH does not require pledges of outside funding.

–J.D.M.



What's the score? Funded R01s get better scores on average than SBIR grants.

posal is inherently riskier than an R01, says Harry Tyrer, a University of Missouri computer scientist and chair of a special SBIR study section, because it's examining the commercial feasibility of an idea. "The whole point is to see whether the idea works or not," he says.

But Rich insists that the difference in scores reflects an imbalance in quality. "Reviewers know what a 150 [score] means, even if it is in a different context," he says. "I don't buy for a second that a 150 on an R01 means the same thing as a 250 does on an SBIR." And quality isn't the only issue. Rich and other FASEB officials also feel that NIH shouldn't be in the business of moving new discoveries from the bench to the drug counter or supply catalog. "If it's such a good idea, then the private sector will pick it up," he says.

However, that's not the way the world works, explains physicist Gerd Muehllehner. Muehllehner took a sabbatical from the University of Pennsylvania in 1988 to start UGM, a small Philadelphia company that makes million-dollar positron emission tomography scanners. But he says he would have headed back to academia if he had failed to obtain an SBIR award. "We tried to go the venture capital route, but they wanted to see a prototype. And big companies rely on small companies to do innovation," says Muehllehner, whose company now markets its products through General Electric.

Muehllehner admits that it took longer than he expected to get his company on its feet. But this month he's adding four scientists to his 11-person staff, and he no longer has second thoughts about his decision: "I spent 15 years of my life developing this idea, and now we're having an impact on the market. And we wouldn't exist without SBIR."

Success stories like Muehllehner's make a powerful political statement. Moreover, before Porter can limit SBIR's growth at NIH, he must get authority to modify the existing law. If he succeeds, the debate would then shift to the value of the program itself. Regardless of which side wins, one of the government's least known billion-dollar research programs is about to get some attention.

–Jeffrey Mervis

CLINICAL RESEARCH

UCSF, Stanford Hospitals to Merge

Like pressure that builds along a fault before a big quake, tension is rising at some of the nation's top medical research centers as their leaders plan for restructuring. Across the nation, teaching hospitals are preparing to streamline, downsize, and forge alliances with old competitors in order to cut costs. Some medical specialties and research projects may feel the impact, and already one national medical group is trying to anticipate the size of the jolt.

A preview of the kind of change that will affect these academic centers came last year in Boston, where the Harvard-affiliated Massachusetts General Hospital merged with Brigham and Women's Hospital (*Science*, 19 May 1995, p. 968). This spring, the action is heating up on the West Coast, where demands for efficiency are driving the teaching hospital of the University of California, San Francisco (UCSF), into the arms of Stanford University. The UC regents were planning to review a merger proposal this week, and Stanford's trustees are scheduled to consider it in early June. Other medical schools around the country are talking about consolidation, and the list of those reported to be in the market for mergers seems to grow every month (see table).

TEACHING HOSPITAL MERGERS
(Actual and Potential)

Boston	
Massachusetts General	Brigham and Women's (completed)
Beth Israel	Deaconess and Mt. Auburn hospitals
Boston City Hospital	Boston University Medical School
Tufts NE Medical Center	Caritas Christi hospitals
San Francisco	
UC San Francisco	Stanford (expected 1997)
New York	
Mt. Sinai	New York University (?)
Columbia University	St. Luke's Medical Center (?)
Indianapolis	
Indiana University	Methodist Hospital

Driving this reorganization of academic medicine is the demand by health care financing systems that academic health centers match the efficiency of nonresearch hospitals. Funds for research are likely to get caught in the squeeze, says Paul Griner, former director of Strong Memorial Hospital at the University of Rochester. The magnitude of the effect is hard to predict, he notes. But he estimates that as much as 20% of research funded at institutions belonging to the Association of American Medical Colleges (AAMC) has been paid for in the past by hospital charges and faculty fees for medical services—funds that will be tighter in the new world of cost-cutting megahospitals.

Officials at UCSF and Stanford began their talks last summer, and in November, they publicly acknowledged that the process was going forward. In recent weeks, they've begun briefing medical service employees and faculty members on how the union could affect individual departments. According to spokespersons for both universities, the Stanford-UCSF alliance could be finalized this year. Although the specifics are still under negotiation, the broad plan has been described by Peter Van Etten, president and CEO of Stanford Health Services, and by UCSF Medical Center chief William Kerr. The objective is to unite the medical services of the two institutions under an independent administration while keeping the teaching functions separate.

By reorganizing, the schools hope to put a lid on operating expenses, including salaries. Van Etten has said that the schools expect to gain additional savings through joint purchasing deals, combined administration, joint capital investment, and elimination of overlapping clinical specialties. UCSF medical school Dean Haile Debas conceded recently that the new structure would mean some loss of control for medical school officials, but said that "we emphatically believe that a combined organization would be in a stronger position to continue, over the long term, to provide competitive salaries, benefits, and jobs than either UCSF or Stanford would be by attempting to survive on its own in the new managed-care environment."

Independent auditors are now combing the books of both schools, searching for functions that need to be stitched together or cut out. One of the big issues that remains obscure is how much money the cost cutters will allow for research. But Stanford medical school Dean Eugene Bauer stressed the positive, saying he hopes that the merger will make it easier to collaborate on research projects.

Similar questions are likely to come up elsewhere, says Griner: The merger of UCSF and Stanford, "is a good example of the things that have occurred elsewhere and are likely to occur in large-volume markets" around the nation. The AAMC has set up a special unit to keep an eye on these changes and collect data as mergers get under way. The project began to take shape about 6 months ago at AAMC headquarters in Washington, D.C., under Griner's direction. Griner has now finished hiring members of a team that will monitor a "sentinel network of 15 to 18 diverse and representative" medical schools.

The next regions likely to be swept by mergers, predicts Griner, are New York, where several academic health centers are already in pursuit of business partners, and Chicago, where at least six major teaching hospitals compete for patients. The full impact of the quake hasn't hit the clinical research labs as yet, Griner says, but "we are all predicting that it will be significant."

–Eliot Marshall