

Scientists Play 'Grantsmanship' Game To Win Multimillion-Dollar Awards

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Inside the old brick walls of a former hospital in Belleville, N.J., researchers at the nonprofit Garden State Cancer Center test antibodies designed to detect or fight the disease. Most of the center's funding comes from U.S. taxpayers, courtesy of the National Institutes of Health. Leading the research is the center's founder and president, an experimental pathologist and immunologist named David Goldenberg.



David Goldenberg

Just 24 miles away, in a sleek, glassy building, employees of **Immunomedics Inc.**, a publicly traded biotechnology company, make the antibodies clinically tested at Garden State. The company gets first crack at this research. In charge: the same Dr. Goldenberg, who is the founder, chairman and chief executive of Immunomedics.

Dr. Goldenberg, who owns a 13% stake in Immunomedics worth more than \$100 million, stresses that his two entities are independent. "The company does not depend on the center for anything," the researcher says in a brief interview.

He has a powerful incentive to maintain the separation: millions of additional dollars in grants from the NIH, which controls the government's richest pool of scientific research funds, are more likely to flow to a scientist applying in the name of a nonprofit organization, rather than a for-profit company.

NIH's annual budget has surged 57% over the past five years, and members of both parties in Congress are seeking to push it up another 50%, to about \$27 billion, by 2003. Eyeing that gusher of money, entrepreneurial scientists have become adroit at using private nonprofits to obtain government grants -- and then using the money to fund research that helps their own for-profit biotechnology ventures. In case after case, scientists closely linked to profit-making companies are applying in the name of nonprofit institutes to obtain multimillion-dollar NIH grants.

In some instances, the same person runs both a nonprofit institute and a for-profit company, and the entities share lab space, equipment and employees. Often, the two entities study the same diseases and drugs, with the nonprofit handling the basic research and the for-profit doing product development.

Dr. Goldenberg's Immunomedics said in a filing with the Securities and Exchange Commission last year that without the nonprofit Garden State center, the company

"would have to make alternative arrangements ... which could significantly delay and increase expenses" of testing potential pharmaceuticals.

From his office in San Diego, biochemist Richard Houghten runs an NIH-supported nonprofit institute and -- just a few steps down the hall -- a company that stands to benefit from the institute's research. In Salt Lake City, Don Olsen heads a nonprofit institute using NIH money to test an artificial-heart device. The heart is being developed by a for-profit company Dr. Olsen helped found. The institute and the company, in which he owns stock, are in the same building.

"This is the paradigm for getting things done in the future," says Steven Reed, who helped found two linked Seattle outfits, a nonprofit infectious-disease institute and for-profit **Corixa** Corp., both of which receive NIH grants. "With a good relationship between the two, all the work you do can be developing into something that gets put into a bottle."

Differing Explanations

Some scientists engaged in commercial activity explain that seeking NIH funding in the name of their nonprofits is merely a savvy form of grant-application strategy, or "grantsmanship." Others, including Dr. Goldenberg, maintain that since their nonprofits are independent from their companies, there is nothing to explain at all.

For-profit companies may apply for their own NIH funding. But entrepreneurial scientists are very much aware of the strong tradition of government research money generally going to academic and nonprofit institutions. This tradition creates a strong motivation for researchers involved in commercial activities to seek government grants in the name of their nonprofit enterprises.

The NIH does little to deter this maneuvering. The agency, like many branches of government, encourages cooperation between nonprofit and for-profit concerns to prevent taxpayer-funded research from languishing on laboratory shelves. And this effort to move products to market more quickly has helped stock America's medicine cabinets with better drugs and devices.

Asked why scientists involved in hybrid operations -- those with both commercial and nonprofit activities -- are allowed to seek grants as if they were pure nonprofits, Wendy Baldwin, the NIH's supervisor of grants, says that "there is no legal reason to ban" such applications. "We fund the best science from qualified applicants," she says. "All qualified applications are subject to a peer-review system."

Dr. Baldwin and her boss, NIH Acting Director Ruth Kirschstein, decline to comment on any specific grant or recipient. But Dr. Baldwin says agency officials "are aware of the changes taking place in relationships between NIH grantees and private industry." The agency, she adds, would become concerned if relationships between taxpayer-supported nonprofits and businesses compromised "certain principles," such as objectivity in research and freedom for scientists to communicate their findings.

Universities, colleges and medical schools received nearly three-quarters of the \$12.86

billion in NIH funds awarded in the fiscal year that ended Sept. 30, 1999, the most recent for which figures are available. Nonprofit institutes received 9.8%, or \$1.26 billion. Awards to such institutes have increased 53% over the five years that ended Sept. 30, 1999.

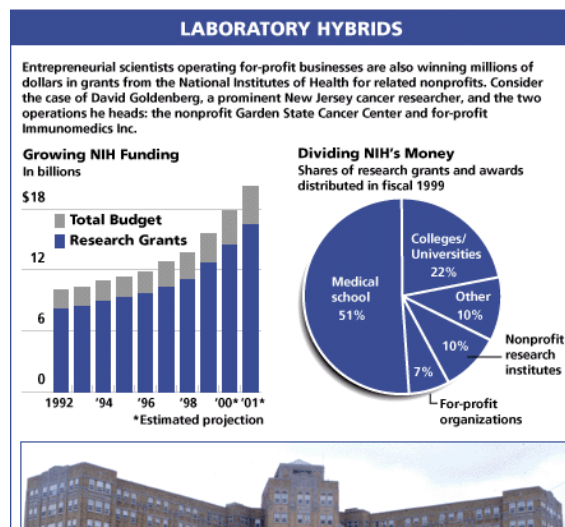
Nonprofit institutes began working closely with the private sector after the enactment of a federal law in 1980 that freed grant recipients to license their NIH-funded discoveries. At the time, universities and nonprofits scrambled to cut deals. The number of nonprofits receiving NIH funds has grown by 18%, to about 180, since 1985.

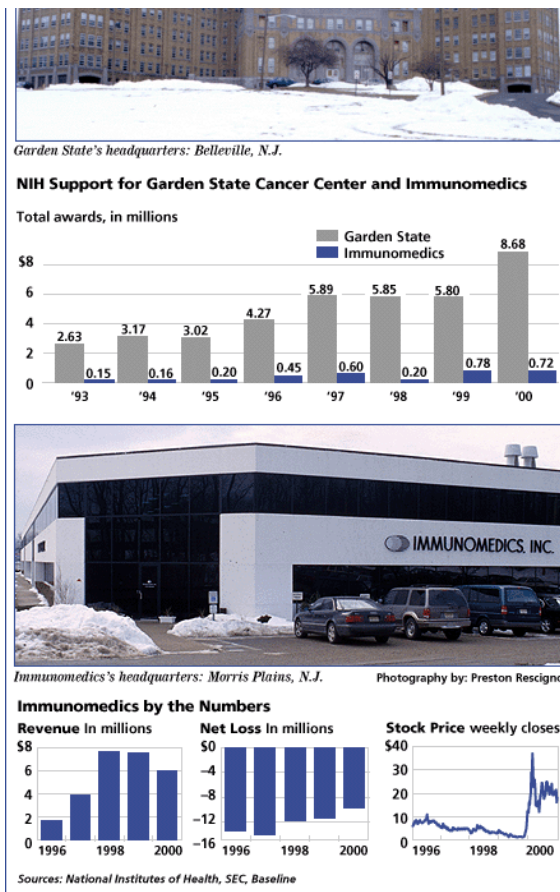
The role of these nonprofits has received little scrutiny. One exception was a public controversy that followed a 1992 deal in which Sandoz Pharmaceuticals Corp., now a part of **Novartis** AG, agreed to pay \$300 million over 10 years to the NIH-funded Scripps Research Institute in La Jolla, Calif. In return, Scripps agreed to give Sandoz first option to license most of the institute's biomedical research, as well as what the NIH ultimately concluded was too much influence over the nonprofit. The controversy caused the deal to be scaled back, and in 1994, the NIH issued guidelines for nonprofit grants.

The 11-page guidelines say that nonprofit recipients should be careful to "maintain their independence to pursue their own mission without undue influence or restraint" by corporate allies. Nonprofits shouldn't give companies "the ability to direct" their research agendas, the guidelines say.

But the NIH doesn't actively enforce these guidelines, says Dr. Kirschstein, the acting director. "We are not a regulatory agency," she explains. Instead, she adds, the NIH relies on nonprofit institutes to police themselves.

In an extreme case, a nonprofit recipient using an NIH grant for something other than the approved research could be prosecuted for violation of federal fraud laws. But what is striking about NIH grants to nonprofit institutes that have ties to for-profits is what agency officials and many scientists consider standard, appropriate grant-seeking practices.





Capitalist Awakening

Dr. Houghten of San Diego, the 54-year-old son of a physicist, wears jeans and sandals to the office. He talks about the "absolute turn-on of taking this chemical and that chemical and putting them together to make something else." Early in his career in the 1970s, he says, he shared a view common among scientists that pursuing knowledge for profit amounted to "intellectual prostitution."

He had an awakening in the mid-1980s. As a researcher at the Scripps institute, he found a faster way to make synthetic peptides, the strings of amino acids used in pain relievers and other drugs. He called his invention the "T-bag method" and used it to start a company in his garage. The company thrived. "Hey," Dr. Houghten recalls thinking, "this business stuff is a pretty good thing."

He left Scripps in 1989 and moved the T-bag company to rented space in an industrial park. He started a second company at the site, which later became known as **Trega Biosciences Inc.** And he launched the nonprofit Torrey Pines Institute for Molecular Studies, located in the same industrial-park building.

Dr. Houghten says he started Torrey Pines primarily to serve as the recipient of NIH grants he had been awarded at Scripps. It was easier, he explains, to redirect the money flow to another nonprofit, rather than to a for-profit company.

The arrangement, he says, has allowed him to combine academic-style intellectual freedom with the ability to usher his inventions to market and the possibility of a financial payoff. It also has permitted Torrey Pines to collect a total of \$11.2 million in NIH research awards -- money that would have been more difficult to obtain through his for-profit businesses.

Dr. Houghten's commercial and nonprofit activities have been intertwined in many ways. Torrey Pines awarded the company that became known as Trega first rights to license institute research, in exchange for annual payments of about \$1.5 million. In 1997, the contract between the two outfits said that, if Dr. Houghten were unable to continue running Torrey Pines, his successor "must be acceptable to" the company.

During the contract's duration from 1990 to 1997, Torrey Pines scientists made more than 80 significant findings of drug-discovery techniques and potentially therapeutic compounds, says Dr. Houghten. "Probably all" of them were at least partly funded by the government, he says. Of those, Trega licensed about half.

Trega went public in 1996. In 1998, Dr. Houghten left the company, and he later sold his stock for about \$2 million, he says.

In 1999, Dr. Houghten started another company, a drug-discovery outfit called Mixture Sciences Inc., which shares quarters with Torrey Pines. Showing a visitor around his operation, he strides past Torrey Pines labs that reek of chemicals. He passes through a doorway and announces, "This is Multiple Peptide Systems," his original T-bag company. "Down here is more Torrey Pines, and Mixture Sciences has some space at the end of this hallway."

He sold Multiple Peptide in 1999, personally receiving \$3.5 million. He remains its scientific director. "I never, ever envisioned this level of success," he says.

Mixture Sciences now has preferential access to Torrey Pines research, paying \$600,000 a year for first-option rights to about two-thirds of the institute's results. In the year ended June 30, 2000, 67% of Torrey Pines's revenue of \$6.2 million came from the NIH and other government agencies.

Torrey Pines, which has about 65 employees, currently is working under a five-year, \$7.2-million NIH grant to research new cancer drugs and vaccines. Mixture Sciences has first dibs on the institute's research in this area, but it also has its own NIH grant to investigate cancer vaccines. One Torrey Pines researcher is working under both the institute's and the company's grants in this area.

The company received its \$501,000 cancer-vaccine grant under a special program that sets aside 2.7% of the NIH's grant money for "small" businesses, with up to 500 employees. Last fiscal year, the agency funneled \$373 million to small businesses. Most of these grants are too small to fund a major project by themselves. Large companies rarely seek or receive direct NIH research funding.

Asked to explain why it's appropriate to seek grants in the name of his nonprofit when

his operation includes a substantial commercial component, Dr. Houghten rejects the premise that his enterprises are effectively blended: "They are separate and distinctly different organizations and have separate and distinctly different environments."

NIH grants to Torrey Pines support basic researchers, who need to explore freely, he explains. For-profit scientists at Mixture Sciences have to be more practical, because companies "live and die based on their financial bottom line," he adds.

He acknowledges that he wears multiple professional "hats" while running his various science shops. But he says he prevents his corporate entities from dictating what goes on at his nonprofit. "Mixture Sciences can't say one word about what we do [at Torrey Pines] -- period," says Dr. Houghten. He owns about 80% of Mixture Sciences and is its CEO.

When Torrey Pines and Mixture Sciences routinely renegotiate their contract, Dr. Houghten says, he removes his nonprofit hat and represents the company. Peggy Totzke, the chief financial and administrative officer of Torrey Pines, represents the institute.

"Peggy and I don't always agree," Dr. Houghten says. He calls Ms. Totzke into his office to confirm this.

"A tiebreaker goes to the institute -- always," she says.

'Part of the Grantsmanship'

Dr. Olsen of Salt Lake City, one of the nation's foremost artificial-heart researchers, retired from the University of Utah in 1999 to start the nonprofit Utah Artificial Heart Institute. The institute so far has received a four-year \$4.2 million grant from NIH. The grant is being used to fund testing of a new artificial heart being developed by MedQuest Products Inc., a for-profit company which Dr. Olsen helped found seven years ago. He says he owns shares and options that, if the options were exercised, would give him about a 12% stake in the company.

The company says the NIH grant will pay roughly a quarter of the cost of developing the heart to the point that it would be ready for clinical trials. Although he isn't a MedQuest employee, Dr. Olsen works closely with its heart developers.

He acknowledges that MedQuest itself could have applied for the \$4.2 million grant. But without a well-known researcher like himself on staff, he says, the company probably wouldn't have qualified.

"We felt that there was nobody in MedQuest that had the name recognition, the experience and the [reputation] to justify the award of a grant of that size and complexity," he says. Asked why he didn't just become an employee of MedQuest and then seek the grant, he explains that the company "was a little start-up" without the resources to pay his salary.

Applying to the NIH through the institute "was part of the grantsmanship," he adds. The NIH, he says, "would prefer to fund a nonprofit university or research institute over a corporation."

Shared Offices, Employees, Gear

In 1981, immunologist David Katz started the nonprofit Medical Biology Institute in La Jolla. Seven years later, he founded its corporate partner, for-profit **Lidak Pharmaceuticals**.

MBI's budget came mostly from the NIH. Since it started, the institute has received at least \$40 million to pursue several lines of basic health research. Lidak, which went public in 1990, had a written agreement with MBI that gave the company "a right of first preference" to commercialize MBI research. In return, the institute received stock and cash from Lidak and a promise of future royalty payments on any commercialized products. The two entities shared office space, equipment and employees.

MBI did basic research, Dr. Katz says, while Lidak did applied research that sometimes was related. Explaining why he didn't unify the operation and have the company apply for basic research grants in its own name, Dr. Katz says, "that wasn't the conventional way things were done." He adds that he suspects that the NIH wouldn't have looked as favorably on basic applications from for-profit Lidak, compared with those from MBI.

In 1998, Dr. Katz left his posts heading MBI and Lidak, and the two entities ended up in state-court litigation in San Diego. MBI accused Lidak of, among other things, sitting on diagnostic and therapeutic technologies developed at the institute, in part with NIH funds. Taxpayer dollars hadn't promoted the public good, MBI contended in court papers. Under its contract, the institute couldn't offer those technologies to other potential partners. Lidak denied the allegation.

The two sides settled their dispute in August 1998 and divided the rights to various research results. Lidak has since been renamed Avanir Pharmaceuticals. MBI has closed its doors, and Dr. Katz now works as a consultant.

Tapping Two Kinds of Funding

At Seattle's nonprofit Infectious Disease Research Institute, "we're very, very product-oriented," says Dr. Reed, the founder. "You can study things and write a paper, but if you don't end up with a new test, you don't end up helping people."

He launched the institute in 1993. It has received a total of \$3.6 million from the NIH and now has 18 employees. Its research sometimes helps Corixa, the for-profit developer of drugs and vaccines Dr. Reed co-founded in 1994. He is now the company's executive vice president and chief scientific officer. An agreement between the institute and Corixa gives the company first negotiating rights for research findings at the institute.

The institute has performed research related to five potential products developed by Corixa, Dr. Reed says. One of the five, a vaccine for leishmaniasis, a skin and visceral disease that annually kills more than 500,000 people world-wide, stemmed directly from NIH-funded research, he says. The vaccine is still in development. The other four research programs were helped indirectly by the nonprofit's NIH support, he adds.

Both the institute and Corixa have received funding from the NIH for studying leishmaniasis. Overall, Corixa has received more money directly from the NIH -- about \$10 million, most of it in small-business grants.

The leadership of the institute and Corixa have been tightly interwoven. From late 1994 through early 1997, all of the members of the institute's board were affiliated with Corixa or one of its largest investors, Silicon Valley venture capital firm Kleiner Perkins Caufield & Byers. For two additional years, a majority of the board members had these affiliations. Today, one of the institute's six board members is Cynthia Healy, a consultant to Kleiner Perkins, which still owns 9.6% of Corixa's common stock.

Even though Corixa and the Seattle institute are closely affiliated, Dr. Reed says, applying for some grants in the name of the nonprofit, and others in the name of the company, helps maximize NIH funding. "The marriage between [the institute] and Corixa -- or the engagement -- is a great way to tap into both kinds of funding," he says.

A Beer-Industry Tie

In one of the more unusual nonprofit alliances with business, **Kirin Brewery Co.**, the big Japanese beer company, helped start the nonprofit La Jolla Institute for Allergy and Immunology in 1988.

The Southern California institute has since received a total of more than \$29 million from the NIH to conduct research, more than 80% of that in the last five years. Kirin's U.S. drug-discovery subsidiary, Gemini Science Inc., has right of first refusal to "substantially all" of La Jolla's research findings, in return for annual injections of cash, which last year came to \$6 million, according to the institute.

In 1998, Kirin opened a new laboratory in the same building as the institute, designed specifically to "maximize the transfer of commercializable technology to Kirin," says Jun Yamaya, a senior executive with the Gemini subsidiary. So far, none of the institute's research has resulted in marketable products.

However, "to suggest that the institute has been a vehicle for Gemini to obtain NIH funding is an insult to" the institute's leadership, Mr. Yamaya adds. "I have never thought of [Gemini's] relationship with the institute as a way of obtaining NIH funds," he says.

Dr. Goldenberg's Garden State

Immunomedics, the Morris Plains, N.J., biotech firm, told the SEC last year, "Our product development is dependent upon our continued relationship with" the nonprofit Garden State Cancer Center.

Still, Dr. Goldenberg, who heads both organizations, says in his brief interview that multiple safeguards preserve the center's autonomy. Its board of trustees, for example, makes decisions regarding its relationship with Immunomedics without his participation, Bruce Baird, Dr. Goldenberg's lawyer in Washington, says in a written statement responding to questions.

Garden State "had importance to the company" in the 1980s, when the two entities were young, Dr. Goldenberg says. Today, "it has none."

Mr. Baird, to whom Dr. Goldenberg's office refers all follow-up questions, isn't quite so dismissive. He acknowledges, "The loss of Garden State's research capacity would be an inconvenience for Immunomedics, and might cause delay and increase expenses, but it would not be a disaster." As for the SEC filing in which the company said its product development is dependent upon a relationship with the institute, Mr. Baird explains that this is "cautionary language" that "may well be overly conservative."

The institute recently received its largest NIH award ever -- \$17 million over five years. A large portion of the money is allocated for clinical trials of an Immunomedics antibody that may prove to be a potential treatment for ovarian, breast and medullary thyroid cancer. The antibody, known as hMN-14, is one of the two most-advanced therapeutic products in the for-profit company's developmental pipeline. Promising results from the NIH-funded studies at the nonprofit could help Immunomedics convince the Food and Drug Administration to approve more-advanced clinical trials or, eventually, marketing of the product. Mr. Baird points out, though, that Immunomedics would have to do many more studies to win FDA approval.

Apart from Garden State's NIH-supported research on hMN-14, Immunomedics is sponsoring its own research on the antibody's effectiveness against cancer. Mr. Baird writes that it is nevertheless appropriate for grants to be sought in the name of the nonprofit: "Only if both nonprofit organizations and commercial entities are allowed to deal with each other and attempt to make profits from the development of scientific discoveries, can government funding of such studies result in a benefit to mankind."

Immunomedics does seek its own NIH support. The company has collected \$3.3 million in small-business grants since 1990. Over the past dozen years, the NIH has funded about 30 Garden State projects with a total of about \$50 million. From mid-1996 through mid-1999, the last year for which tax returns are available, 86% of the institute's total revenue has come from the NIH and other government agencies.

Dr. Goldenberg, 62, made his name in the late 1970s, researching antibodies attached to radioactive substances that can help physicians diagnose cancers too small to be seen by other methods. The NIH has called him an "outstanding investigator."

To further his antibody research, and commercialize some of it, Dr. Goldenberg founded two organizations in 1982. One was the nonprofit that later became known as Garden State. The other was Immunomedics. The importance of the relationship between the two was evident even in this early period. Immunomedics said in a 1985 SEC filing that its affiliated nonprofit would seek government and private "grants that would be unavailable to a for-profit corporation such as the company."

Beyond Garden State's NIH-supported research on Immunomedics antibodies, the two organizations today are linked by a licensing contract. Immunomedics has the first right to commercialize 20% of any products that might be developed and tested independently by Garden State, although no such products have been created so far. In return, Immunomedics pays the institute \$200,000 a year.

Mr. Baird also points out that Garden State benefits from its relationship with Immunomedics. The company, for example, supplies specialized antibodies that Garden State scientists use to further their own research. "While some of what Garden State does undoubtedly benefits Immunomedics, Garden State does a good deal of work having nothing to do with Immunomedics at all," and "Immunomedics also does things that benefit Garden State," the lawyer explains.

Dr. Goldenberg's 13% stake in Immunomedics was worth about \$115 million at Monday's closing price of \$17.38 in Nasdaq trading. His family and companies he owns hold another 10%.

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