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Introduction

For more than 100 years, the National Institutes of Health (NIH) have been at the forefront of innovative biomedical research. Employees of the NIH have won four Nobel Prizes and 12 Lasker Prizes; the NIH has sponsored the work of over 70 Nobel laureates and more than 60 members of the National Academy of Sciences are affiliated with NIH.[1] The NIH is also expensive. Of the federal government's $50 billion annual research and development budget, the NIH receives approximately $7–8 billion. The majority of Congress and the scientific community believe that this money is well spent. While the U.S. has slipped from its position as world leader in numerous areas, it maintains preeminence in the area of biomedical research. For decades, the NIH has attracted leading scientists from around the nation because of its unique mission of performing basic biomedical research. At NIH, investigators, unlike their colleagues in academia or industry, have been able to do research without the external constraints of teaching, grant acquisition or profit generation. In 1983, then Secretary of Health and Human Services, Margaret Heckler, commented that "NIH is an island of objective and pristine scientific research excellence untainted by

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1 Palca, *Privatization not the Answer to NIH Problems,* 336 NATURE 22 (1988). *See also,* Kosterlitz, *Bust Up a Winning Team?* 20 Nat'l. J., Jan. 9, 1988, at 70.

commercialization influences."[2]

Governmental initiatives during the past four years have rendered this statement false. As a response to the mounting budget deficit and America's declining competitiveness in world markets, the federal government has crafted a policy designed to encourage federally funded scientists to develop the fruits of their research commercially.

On October 20, 1986, President Reagan signed the Federal Technology Transfer Act (FTTA).[3] In a subsequent report, Secretary of Commerce, Robert A. Mosbacher, stated that, although the Act challenged[4] "long-held views on the proper role of Federal laboratories and scientists," he believed that, in retrospect, it would be regarded as "one of the seminal developments in the history of federal efforts to put technology to work for the taxpayers who paid for it."[5] He cited dissatisfaction over the return on the nation's research and development investment as justification for the FTTA:[6]

> Many in Congress and the Executive branch believed that this investment, however vital for federal programs, was not returning to the taxpayers sufficient dividends in terms of new products, new processes, new jobs, and enhanced international competitiveness.... A common complaint heard was that the U.S. wins Nobel Prizes while other countries walk off with the market.

While the FTTA has broad implications for federal research

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2 Culliton, *NIH, Inc.: The CRADA Boom,* 245 SCIENCE 1036 (1989).

3 The Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified at 15 U.S.C. § 3701 (1986)). *See also,* Executive Order 12591, Facilitating Access to Science and Technology, dated April 10, 1987. Implementation at NIH is addressed in NIH/ADAMHA-INDUSTRY COLLABORATION DIRECTORY (October 1989) (available from NIH Office of Invention Development).

4 R. MOSBOCHER, THE FEDERAL TECHNOLOGY TRANSFER ACT OF 1986: THE FIRST 3 YEARS, REPORT TO THE PRESIDENT AND THE CONGRESS FROM THE SECRETARY OF COMMERCE, July 1989 (available from Department of Commerce and NIH Office of Invention Development).

5 *Id.* at 2.

6 *Id.* at 3.

facilities, this article will focus on its effects on the NIH. As implemented there, the development of a new and useful medical product will most likely occur pursuant to a cooperative research and development agreement (CRADA). This arrangement is likely to result in a government grant of an exclusive license to a private sector participant in exchange for continued governmental research use and, perhaps, payment of royalties to the agency and inventor. Under the NIH CRADA policy,[7] "inventors share 25 percent of the first $50,000 of cumulative gross royalties on a licensed invention, 20 percent of the second $50,00 and 15 percent of the royalty income over $100,000."[8]

In four years under the FTTA, various aspects of research performed at NIH has changed appreciably. As of October, 1989, in what some commentators have called "the CRADA boom" or "CRADA fever",[9] NIH scientists had entered into 101 CRADAs, and the overwhelming majority of these involved a partner from the corporate sector.[10] Reid G. Adler, Director of the NIH Office of Invention Development, reported that his goal was "to make the mechanics of negotiating a CRADA drop out of sight as NIH-industry collaborations become business as usual"[11] and projected that, by the end of 1989, NIH would be a party to approximately 200 CRADAs.

This article will consider several potentially detrimental effects of

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7 COLLABORATION DIRECTORY, *supra* note 2.

8 *Implementation of the Federal Technology Transfer Act: Hearings before the Subcomm. on Science, Research, and Technology*, 101st Cong. 1st Sess. 104 (1989) (testimony of Reid G. Adler, Director, Office of Invention Development, NIH)

9 *See* Culliton, *supra* note 2, at 1034.

10 *Supra* note 7.

11 *See* Culliton, *supra* note 2, at 1034. *See also*, 54 F.R. 38905 (Sept. 21, 1989), announcing the second annual NIH-ADAMHA Collaboration forum for Oct. 3, 1989.

such government/industry cooperation.

Does the FTTA Subsidize Industry?

Secretary Mosbacher has explained that one of the primary goals of the FTTA was to insure that taxpayers who contribute more than $63 billion each year to federal research and development are the principle beneficiaries of those expenditures.[12] Among tangible benefits to taxpayers resulting from successful transfer of technology from federal laboratories to the private sector, he cited the generation of new products, processes, industries and jobs.[13]

Such efforts predate the FTTA.[14] For example, the Orphan Drug Act[15] fosters such cooperation in developing products which have a limited market (i.e. treatment of rare diseases). This is in the public interest if such products would not otherwise be developed or would be substantially delayed.

However, the price of drugs is a concern. Representatives of the industry argue that the prices of drugs are justified because substantial investments are needed to bring them to market. Thousands of products show promise, but, after millions of dollars are spent on research, only a handful make it to the market.[16] Lisa Raines, Director of Government Relations for the Industrial Biotechnology Association, maintains: "If you want to limit the profits a company can reap from an invention, then

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12 *Supra* note 4, at 1-2.

13 *Id.* at i.

14 *See, e.g.*, Government Patent Policy Act of 1980, P.L. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200–212 (Supp. 1990)). For a discussion of the controversy predating that legislation, *see, e.g.*, vanRavenswaay, *Government Patents and the Public Interest*, 19 IDEA 331 (1978).

15 P.L. 97-414, 96 Stat. 2049 (1982) (Codified at 21 U.S.C.A § 360aa et. seq. (Supp. 1990).

16 *See generally, e.g.*, Field, *Pharmaceuticals and Intellectual Property...*, 31 IDEA 3 (1990).

the federal government should be willing to pick up the cost of the development."[17]

Conversely, if the government *does* pick up part of the costs, the same level of profits may not be warranted. E.g., Representative Harry Waxman, Chairman of the House Subcommittee on Health and the Environment, has observed:[18]

> Through the auspices of the National Institutes of Health, government has developed AIDS and cancer drugs and turned them over to private industry, which has exercised little or any restraint in charging sick people.... We shouldn't ask sick people to subsidize one of our nation's most profitable industries — the drug companies.

Also, Dr. Sidney Wolfe, Executive Director of Public Citizen's Health Research Group objects to exclusive licenses granted without governmental consideration of pricing:[19]

> When you're talking about something involving AIDS or cancer that's used by tens of thousands of people here and worldwide, I don't believe an incentive is needed... as there's too much money to be made to discourage several companies from participating.

For example, AZT, first shown by government scientists to be useful in the treating AIDS, initially cost patients more than $10,000 per year and still costs approximately $6,500.[20] Spokespersons for Public Citizen point out the multiple folly of such a system: Taxpayers pay for the development of the drugs, and the subsequent grant of exclusive licenses to pharmaceutical companies drive up prices due to a lack of competition. Further, the government often pays for the treatment:[21]

> It's... an extreme example of robbing Peter to pay Paul,

17 Kornblum, *Controversial Partnerships*, Newsday, Aug. 22, 1989 (Discovery Section), at 6.

18 *Id.*

19 *Id.*

20 Gladwell & Specter, *Changes Asked On Licensing Of AIDS Drug*, The Wash. Post, Oct. 27, 1988, at A 3.

21 *Supra* note 17

> because what the government is doing is failing to clamp down on the prices of these drugs that evolve from government-funded research and then out of the other pocket paying tens or hundreds of millions of dollars more.

Yet, as one NIH official has observed, without granting exclusive licenses to private companies, numerous potentially valuable products would never make it to market:[22]

> Most of the time it's like pulling teeth to get something commercialized...[, and] there's no way to tell whether research will lead to an invention and whether someone knows what to do when they invent something. Most of the time they're just happy that someone is willing to take the second step.

While these are difficult problems, there are others which pose a bigger risk to basic research at the NIH.

The FTTA and NIH Funding

The very existence, development and maintenance of the NIH is a testament to the fact that American society values basic scientific research. While its research does not always present immediate financial benefits, it does generate advances in knowledge and technology which enrich society beyond measure. Yet, the federal salary structure for scientists conducting basic biomedical research reflects a notion that good scientists will labor for nothing more than the love of knowledge.

Traditionally, NIH scientists have been willing to accept lower salaries because of their ability to do pioneering research free of teaching responsibilities and the necessity to seek grants. However, the disparity between public and private sector pay is wide and growing wider. A recent publication by the National Academy of Sciences Institute of Medicine reported that, within the last five years, 42 senior scientists left NIH to work at other institutions.[23] These researchers, earning

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22 *Id.*

23 Specter, *Panel Opposes Turning NIH Into Private Institution*, The Wash. Post,

between $77,000 and $99,500, were among the highest paid at the NIH. The average base pay for leading researchers at medical schools exceeds the top federal pay level by 45–70%.[24] Dr. William Raub, Deputy Director of NIH, reports that within the last ten years NIH has lost 28% of its senior work force because of transfer to academia and industry.[25] Dr. Robert Gallo, believes that NIH "is in a semi-crisis.... It's just too wide a [salary] gap now.... We're living next to people making too much money".[26]

Samuel O. Thier, President of the National Academy of Sciences Institute of Medicine suggests, "biotechnology has reduced that chasm between what you're doing and what they're paying you to do it."[27] Also, Nobel laureate Joshua Lederberg has said:[28]

> I see nothing wrong with losing top people if other institutions are prepared to support them. There are many other things that need to be done that don't have that faddish appeal.

Dr. Lederberg's comments are valid assuming that the federal government is committed to maintaining a strong, federally supported, independent basic research establishment. Director Wyngaarden has suggested a need to "throw money at it."[29] The question is: Where is the money to come from?

Philip Chen, Associate Director for Intramural Affairs at NIH, suggests that collaborations with the private sector are simply a

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Dec. 20, 1988, at A 14.

24 *Id.*

25 Thompson, *The "No Pay Raise" Blues*, The Wash. Post, Feb. 14, 1989, Health Section, at 2-27.

26 Okie, *Fauci Seen As Leading NIH Slate; But Heart May Lie With Aids Post*, The Wash. Post, Sept. 1, 1989, at A 25.

27 Kosterlitz, *supra* note 1, at 72.

28 *Id.* at 74.

29 Garrett, *Health Center in a Crisis Of Its Own*, Newsday, June 21, 1988, (Discovery Section), at 1.

mechanism to satisfy the political policy objective of transferring technology.[30] Some, however, believe otherwise. The FTTA could potentially get more money into the hands of researchers: Annual royalties may be as high as $100,000 as a result of collaborations with the private sector. Dr. Anthony Fauci, for example, has expressed concern that this private support may result in withdrawal of federal funds and noted that "It would be naive to think otherwise."[31]

Such a proposal was contained in a 1987 Office of Management and Budget draft which suggested that the Bethesda campus should be operated like a private university.[32] However, this generated strident objections and has not received serious consideration. Nevertheless, during the past five years, private sector influence at the NIH has significantly increased.

Distinguished NIH researchers are involved in the following work with private companies: the study of retroviral-mediated gene transfer for AIDS therapy with Genetic Therapy, Inc.; research directed at developing a vaccine for the prevention of AIDS with British Biotechnology Limited; and a project involving AIDS vaccine development with IMMUNO.[33]

While such CRADAs have been accepted by the NIH administration, having research intertwined with industrial objectives means that NIH scientists have a pecuniary interest in the commercial development of their inventions. Thus, the quality of basic research at NIH will decline as the focus turns to applied research. Although the proponents of the FTTA may be correct in asserting that the transfer of technology from the federal laboratories to the private sector will result

30 *See* Booth, *NIH Scientists Agonize Over Technology Transfer*, 243 SCIENCE 20, 20-21 (1989).

31 *Id.* at 21.

32 Beardsley, *Bethesda Brain Drain*, 258 SCI. AM. 34 (June 1988).

33 *See* COLLABORATION DIRECTORY, *supra* note 2.

in more jobs, more products brought to market, and a boon to the economy, such a position is, nevertheless, myopic.

This has given rise to concerns such as expressed by Joseph Rall, Deputy Director for Intramural Research at NIH:[34]

> I'd rather see NIH scientists think about fundamental problems... than [say] "I bet I could improve this technique and that some company could make a million dollars and I could make $10,000."

By institutionalizing the scientific researcher's reliance on the private sector, the federal government is, to a great extent, abdicating its role in the support of basic science. If the next paradigm shift[35] in biomedical sciences does not present immediate commercial prospects, the U.S. may lose its position as world leader in basic research. Government policies which exalt the conduct of "normal" science, simply because of its commercial potential, at the expense of science which may generate a "scientific revolution," are unwise and potentially dangerous. If the federal infrastructure for the conduct of basic science is eroded — a distinct possibility under the policies of the FTTA — the U.S. will walk away with neither the markets nor the Nobel Prizes.

Further Challenges

Conflicts of Interest

Scientific researchers in federal and university laboratories have traditionally been subject to pressures arising from the "publish or perish" ethic. While instances of outright fraud are rare, the temptation to "fudge" data to secure publications and grants has been ever present. The effects of such behavior is usually limited because published experimental results are constantly tested for replicability.[36] Still,

34 *Supra* note 30.

35 T. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1970).

36 *See, e.g.*, Opinion Editorial, *How Much Fraud in Science?* The Wash. Post,

leaders of the scientific community, recognizing that allegations of scientific fraud and misconduct are potentially devastating, are vigilant in protecting the integrity of scientific research.

NIH investigations of scientific misconduct have demonstrated its commitment to maintaining public confidence in the integrity of biomedical research. Yet, collaboration with the private sector may increase the temptation to misrepresent research potential in order to increase income or laboratory resources.

Sheldon Krimsky of Tufts University has observed: [37]

> I have heard it said within the scientific community that everyone gains from this marriage of academia and commerce. Nothing could be further from the truth. Not only are there losses, but some of these losses threaten the integrity of our scientific institutions and weaken public confidence in science.

Representative Weiss insists that "all federally funded research should be free of the taint of potential conflicts of interest."[38] Yet, in avoiding this, the NIH is faced with the difficult task of balancing the need to maintain scientific integrity and independence while promoting commercialization under the FTTA.

That such concerns are well-founded is illustrated by an October 1988, report in the Boston Globe of an NIH grantee, who was simultaneously testing an experimental drug on hundreds of patients and setting up a company to produce and distribute it.[39] Although the drug ultimately proved ineffective, the researcher and his family earned in excess of $1 million from the sale of the company stock.

July 6, 1989, at A 16. *Compare* W. BROAD & N. WADE, BETRAYERS OF THE TRUTH 60 (1982).

37 Bass, *Privately Funded Research may Breed Conflicts*, United Press Int'l, June 13, 1989.

38 Gosselin, *Flawed Study Helps Doctors Profit on Drug*, Boston Globe, Oct. 19, 1988, (National/Foreign Section), at 1.

39 *Id.*

Also, in the fall of 1988, several published reports indicated that as many as twelve government funded scientists, while conducting clinical trials on TPA, a clot-dissolving drug manufactured by Genentech, owned Genentech stock. The fact that Genentech was in competition with another company that manufactured streptokinase, a similar drug, raised questions regarding the reliability of their safety and efficacy data.[40]

In attempting to avoid such difficulties, the NIH, in December 1988, conducted a two day retreat with 42 legal and scientific experts to discuss conflict of interest. On June 22 and 23, 1989, an open meeting was held, and proposed guidelines to regulate conflicts of interest were published, with a request for comments, on September 15.[41]

The purpose behind the guidelines was "to ensure that NIH- and ADAMHA-supported research is carried out in a completely objective manner, and that the research results are not influenced by the possibility of financial gain...."[42]

Perhaps because NIH officials found themselves between the Scilla and Charybdis, in January 1990, Secretary Sullivan announced the withdrawal of the proposed guidelines.[43] However, a recent announcement sets a meeting for November 30, 1990 to further consider the topic.[44]

> PHS [Public Health Service] is considering issuance of additional rules to promote the integrity of PHS-supported clinical trials where investigators may have financial

40 Okie, *Drug Testers Had Stock in Its Maker; Disclosure Raises Doubts About Studies of Heart Treatment*, The Wash. Post, Sept. 30, 1988, at A 6. *See also*, Viewpoint, *How Can Science Ignore This Conflict of Interest?*, Newsday, Jan. 2, 1989, at 38.

41 NIH/ADAMHA Request for Comment on Proposed Guidelines for Policies on Conflict of Interest, 18 (32) NIH Guide for Grants and Contracts, Sept. 15, 1989.

42 *Id.*

43 HHS News, Dec. 29, 1989.

44 55 F.R. 45815 (Oct. 31, 1990).

> interests that could affect or give the appearance of affecting their objectivity. Before doing so, the PHS... the... NIH and the... ADAMHA will conduct a public meeting to discuss... the issues involved.... The proposed approach... outlined in this notice... has taken into consideration the comments received on the earlier proposed Guidelines published... [on] September 15, 1989.

The announcement addresses general principles and proposes, e.g., that:[45]

> Covered individuals would include investigators responsible for designing, conducting or reporting research and their spouses, dependents and business partners.

Then it sets forth the issues to be considered:[46]

> • The overarching issue is how best to protect the integrity of research while promoting technology transfer.
> • Should the basic regulatory approach (a) require disclosure and allow flexibility for institutions to take appropriate action, (b) state specific prohibitions, or (c) require disclosure and decisions on appropriateness by the funding agency?
> • To what extent should... rules applicable to Federal employees... serve as a model in developing the proposed requirements? (See 45 CFR part 73.)
> • Are there regulatory frameworks not specific to PHS (e.g. Federal Securities Laws) that are applicable to the topic?
> • Who are the most appropriate parties to determine a conflict of interest?
> • Should all forms of financial interests be reviewed, for example, equity, salary, other payment for services, honoraria, and gifts?
> • Are there minimal levels of financial interests which would not create an actual or apparent conflict of interest?
> • Should PHS require submission and approval of institutional policies in order to ensure consistency and provide technical assistance where necessary?
> • Should PHS require disclosure to the funding agency of approved financial interests, if any?

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45 *Id.*
46 *Id.*

- Should there be a requirement for public disclosure of financial interests, for example, in publications?
- Should there be disclosure of the investigators' financial interests as part of the document seeking the research subjects' informed consent to participation in clinical trials? (In this regard, see... Moore v. Regents of University of California..., 19 USPQ2d 1753... 1990).
- Should institutional financial interests be considered?
- What should the remedies be for violations?

Secrecy

More subtle consequences of FTTA implementation are also possible. The proliferation of NIH-industry partnerships creates a situation where researchers involved with similar projects with different private concerns may be reluctant to share information for fear of violating confidentiality agreements.[47] This could undoubtedly impede research progress notwithstanding express objectives of the FTTA.

Such problems are addressed in an NIH CRADA/licensing Policy Statement.[48] In discussing that statement in testimony before Congress on the implementation of the FTTA, Reid G. Adler asserted that NIH has affirmed its commitment:[49]

> to transfer technology within an overall framework that promotes the free exchange of ideas and information by, for example, preserving the freedom of our investigators to publish the results, and attempts to safeguard the collegiality and integrity of as well as public confidence in, the NIH/ADAMHA research programs.

Thus, researchers are admonished to restrict the amount of proprietary information exchanged during execution of a CRADA: [50]

> Although agreements to maintain confidentiality are

47 *See, e.g., supra* at note 33.

48 NIH OFFICE OF INVENTION DEVELOPMENT, NIH/ADAMHA PATENT POLICY BOARD POLICY STATEMENT ON COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS AND INTELLECTUAL PROPERTY LICENSING (March 27, 1989)

49 *Supra* note 8.

50 *Supra* note 47, at 3.

> permitted under a CRADA, collaborators should limit their disclosure of proprietary information to the amount necessary to carry out the research plan of the CRADA. The mutual exchange of confidential information, e.g., patent data should be similarly limited. NIH/ADAMHA also recognize that cooperative research may require the exchange of proprietary research materials.... All parties to the CRADA will agree to keep CRADA research results confidential... until they are published in the scientific literature or presented at a public forum.

Yet, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, has said that: "In 21 years at NIH I have never gotten a blank stare before [when asking peers about reagents or enzymes]; [n]ow I am beginning to get blank stares."[51] Also, Samuel Broder, Director of the National Cancer Institute, has said: [52]

> People are worried that if they talk too much about their CRADA research, they may inadvertently disclose too much proprietary information and be sued by the company. The ideal thing to do is file a patent quickly and then fully disclose everything right away.

That solution, while helpful, is unsatisfying. Under such circumstances, a first "inventor" who does not perfect the invention effectively prevent competitors from developing it. Such activity would appear to interfere with public access to the benefits of NIH research and the articulated goals of the FTTA.

Conclusions

Proponents of the FTTA may assert that biomedical technology — the investigation and use of recombinant DNA techniques, genetic engineering, gene therapy, monoclonal antibodies, etc. — is ready for commercial application and should be exploited. However, again, an investigator faced with the choice of continuing along a particular line of

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51 *Supra* note 30, at 21.

52 *See* Culliton, *supra* note 2, at 1036.

research directed toward the improvement of, for example, an in vitro diagnostic assay, or embarking on project with no foreseeable commercial value, is likely to pursue the former. If this is true, the mission of the NIH will shift from long term "conduct [of] biomedical...research that will lead to the better health of the American people"[53] to short term commercial development of products and processes that will lead to the better health of the American people.

Comments that Nobel Prizes represent an inadequate return on tax dollars thus appear to be shortsighted, if not anti-intellectual. A government policy which clearly demonstrates a commitment to support basic scientific inquiry, regardless of its commercial viability, ennobles society. The U.S. basic research establishment, including the NIH, is, as Joshua Lederberg states, "a national treasure."[54] It should not be threatened by unreasonable demands for immediate results of commercial value.

As Thomas Kuhn asserted in his essay, "The Structure of Scientific Revolutions," major scientific advances do not occur in a linear fashion but, rather, occur in a series of quantum leaps or "paradigm shifts."[55] Government officials have failed to recognize an essential aspect of Kuhn's philosophy: The currently dominant biomedical paradigm is not permanent. If policies which encourage (or mandate) scientists to conduct commercially viable research become institutionalized in biomedical science, American society may be perfectly positioned to efficiently exploit this particular subset of technologies, but the machinery for recognizing and developing subsequent paradigm shifts may be irreparably compromised. Present implementation of the FTTA allows for progress in what Kuhn refers to as "normal science" — the

53 *Supra* note 47.

54 Kosterlitz, *supra* note 1, at 70.

55 *Supra* note 35.

development of ideas within a paradigm — but may inhibit the development of "revolutionary" scientific ideas. While stimulation of American industry and trade are legitimate policy objectives, accomplishment of these objectives at the expense of basic scientific research is shortsighted. In the interest of rectifying the budget deficit (created by still other policies which mortgaged the future for immediate benefits) the current governmental policy may create a basic research deficit early in the next century.

Commercializing the fruits of basic biomedical research is not, in and of itself, a dangerous or threatening process, but it must be realized that, while basic science is often the parent of applied research, basic and commercially applied research are two distinct entities. Encouraging private participation in the commercial exploitation of technology developed as an *incident to* research is one thing; encouraging private participation in *directing* basic research is another. Due primarily to the excellence of U.S. basic biomedical research, it has advanced to the point that its fruits have commercial value. To believe that this will continue without support of research unconstrained by the need to show immediate application is naive, and policies which proceed on that assumption threaten to kill the goose that laid the golden egg.