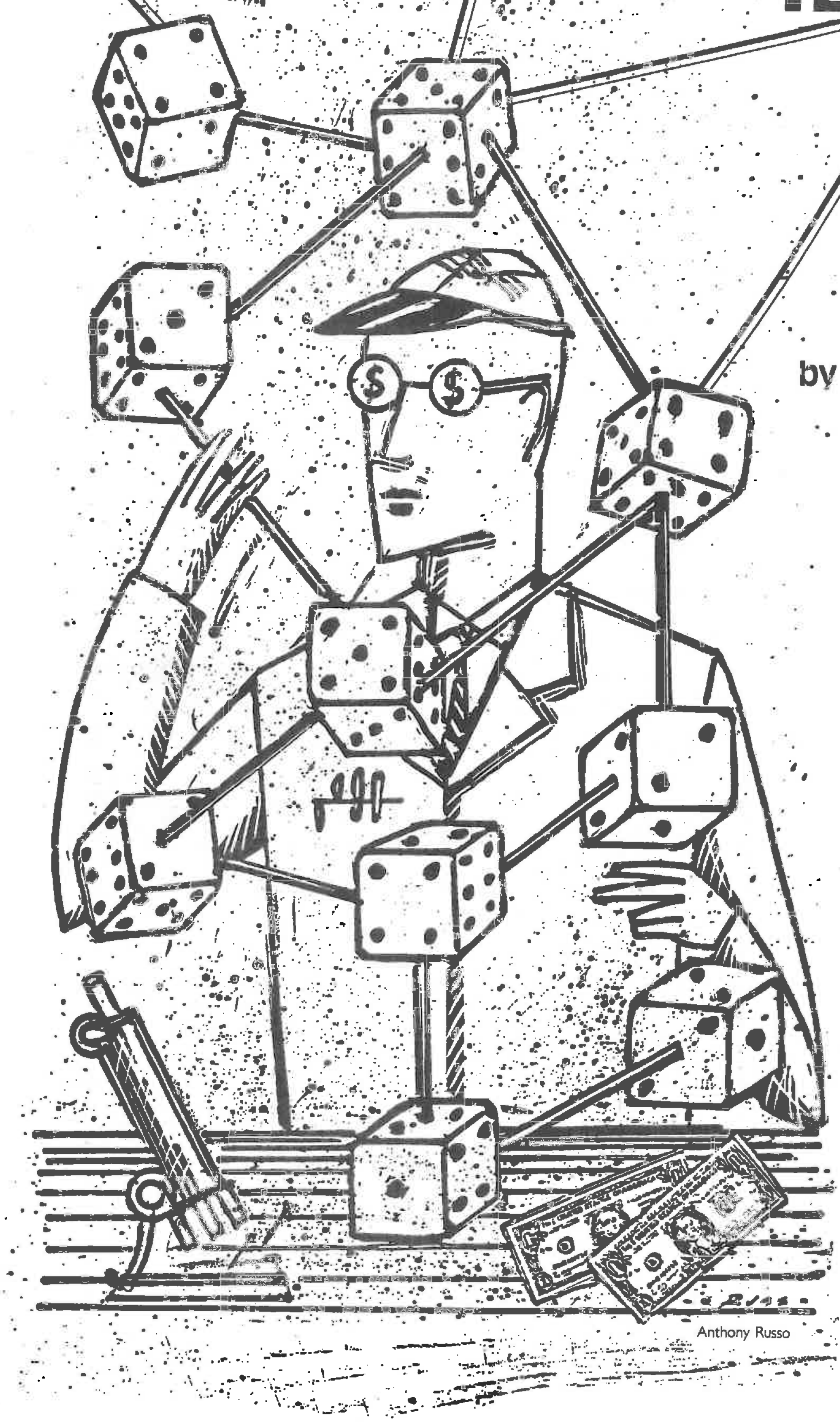
THE CORPORATE CAPTURE OF GENETIC TECHNOLOGIES



Anthony Russo

Scientists' Corporate Affiliations Surveyed

by Sheldon Krimsky

Commercial applications of molecular genetics and cell biology have resulted in a flurry of entrepreneurial activities among academic biologists and universities eager to cash in on the financial side of the biotechnology revolution. The situation is not unique to biology, but is following the path of other academic disciplines that have formed close partnerships with industry, such as nuclear and petroleum engineering, computer sciences, nutrition, electronics, and chemistry. Nevertheless, the current debate that has centered around the commercial ties of academic biologists has been more widely publicized than at any time in the past.

One of the reasons for this may be historical accident. The commercialization of biology occurred on the heels of a widely publicized debate over the safety of recombinant DNA technology. The confluence of debates over the social, ethical, health and environmental impacts of genetic engineering served to focus considerable attention on the commercialization of this science. Another probable reason is that, unlike other scientific and engineering fields that have developed linkages with the private sector, biological re-

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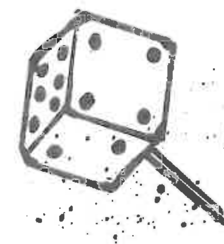
search has been closely associated with public health. The public expectations for this area of research are greater than they are for such areas as chemistry or computer science. Moreover, since the preponderance of funding for biomedical research comes from social resources, academic entrepreneurs in the biomedical sciences tend to be held accountable for their commercial activities in ways that other scientists are not.[1]

An additional factor that helps to account for the vehemence of this issue is that our society, in the post-Watergate period, has become more sensitive to conflicts of interest and to allegations that public funds are being misused or that private interests are exploiting social resources. Further, and lastly, the types of university-industry relationships in biology are more varied, more aggressive, more experimental, and more indiscreet than they had been in similar historical circumstances. Unlike the microelectronics field, for instance, which spawned firms direcly from industries that were recipients of Department of Defense contracts, a significant number of new firms in biotechnology have sprung directly out of academia.

The Current Debate

Much of the debate on the commercial ties of university faculty has centered around a number of issues which highlight the conflicting missions of business and academia. These include the control of intellectual property, openness and accessibility of scientific and technical knowledge, the pooling of public and private funds, the ownership of tangible research property, the use of public research funds for private business interests, and the influence of entrepreneurial faculty on the education of students. These are serious issues and they have been aired to some extent in the media, university debates, and congressional hearings.[2] Several leading universities have already issued guidelines for faculty pursuing commercial interests and have established policies on contractual agreements between the university and the private sector.[3] OTA, 1984).

However, an even more important issue is raised by the role that universities and their faculty play as a national resource in the analysis and formulation of public policy. If a sufficiently large and influential number of scientists or engineers become financially involved with industry, problems raised by the commercial applications of the particular areas of science/engineering are likely to go unaddressed. New values emphasizing science for commerce become internalized and rationalized as a public good, and the scientific community becomes reluctant to raise questions about the social impacts of science. Incrementally, without conspiracy or malice, the disciplinary conscience becomes transformed. Scientists or engineers with a stake in the commercial outcome of a field cannot, at the same time, retain a public interest perspective that gives critical attention to the perversion of science in the interests of the market.



A sizeable academic-industrial association will slowly change the ethos of science away from social protectionism and toward commercial protectionism.

When the number of faculty involvements are small, the effects on public interest science are not likely to be important. As long as a sufficient number of scientists remain free from corporate influence, there will be a disinterested intelligentsia to whom the public can turn for critical evaluation of technological risks, goals, and directions. This suggests that the *individual* instances of faculty-industry ties are far less important than both the aggregate corporate penetration into an academic discipline and the degree to which the major institutions and leading faculty in that discipline are involved. It is thus critical that we develop quantitative information about the degree of corporate-academic interaction in order to assess the reality of this problem.

Scientific Objectivity and Industrial Interests

Public policy formation in a highly industrialized society such as ours is a complex affair. It frequently involves input from experts from many fields. Scientists serve on a labyrinth of public advisory committees, review boards, and risk assessment panels throughout all levels of government. How do we insure objectivity in the contributions of scientific experts to public issues particularly when consensus is difficult to find? Recently the Office of Technology Assessment (OTA) issued a report on biotechnology which posed the argument that the dual affiliation of scientists in the academic and commercial worlds is actually more desirable from a public policy standpoint when expertise is needed.

> An argument could be made that because the public has supported research in universities, it has a right to know whether a particular university faculty member who is giving testimony, for example, has a consulting relationship with a company that manufactures a particular harmful chemical. The negative side of the disclosure policies is that 'objective' information may be judged 'subjective' because of guilt by association. If a faculty member's consulting arrangement with industry is declared openly, it is not necessarily the case that his or her testimony is biased. In fact, the expert may have a more objective view because he or she understands both the research and development aspects of the technology.[4]

There are two arguments here. The first is that when a scientist is testifying before a governmental body, a veil of confidentiality about commercial affiliations prevents bias against the individual's presentation. According to OTA, if the disclosure is required, testimony would not be taken on face value but would be dismissed for reasons of association. The second argument interprets objectivity to mean "multidimensionality." The implication is that the more affiliations a person has, the more objective that person can be.

The OTA analysis confuses objectivity with eclecticism. There are many advantages in having faculty link up with the private sector. Those advantages include a greater awareness of the full life cycle of science, from discovery to manufacture. But OTA makes a serious error when it describes the financial involvement of academic scientists in commercial ventures as a contributor to objectivity. The argument fails because of the financial interests; only a form of eclecticism that is independent of pecuniary interest could indeed enhance such objectivity. Our conflict of interest laws are based upon assumptions of human frailty as exemplified by the aphorism "Don't bite the hand that feeds you." Although it is a mistake to view conflict of interest in terms of conspiracy or conscious design, it is my hypothesis that a sizable academic-industrial association will slowly change the ethos of science away from social protectionism and toward commercial protectionism.

The economic determinants of research and their influence on the latitude of inquiry are both pervasive and subtle. Sometimes this influence manifests itself in the distortion of science. Other times it is expressed in the control of information. Most frequently it is felt by the kinds of questions that are pursued in the areas where science and social policy intersect. Let me begin with a simple illustration of my thesis.

Imagine that you are heavily funded by a company to engage in research. Is it likely that you would publicly embarrass the company by revealing information or posing questions about its technological direction? Most scientists with a conscience would make their viewpoints known to the firm's directors. But who would want to jeopardize his or her funding by making an issue public? The closer the relationship one has to a firm, the greater the chance that propriety and self-interest dictate that one keep criticisms within the corporate family.

A few years ago I supervised a policy study involving the chemical contamination of a town's water supply. The parties involved included a multinational corporation, town, state, and federal officials, a public advocacy group, and technical people. I chose to do the study for three reasons. First, it served the public interest. Second, it was a useful case for instructional purposes. Third, from a public policy standpoint, it represented a milestone for the implementation of a major federal law. If I had been funded by the corporation in question, however, that research study would never have entered my mind because of the likelihood that the company would not be shown in the best light. If my department had been heavily funded by the company possibly including graduate student stipends and multi-year grants it is extremely doubtful that any faculty member would have chosen to study how the department's corporate benefactor was implicated in the contamination of a water supply, unless there was reasonable assurance that the outcome would not be an embarrassment.

When our policy study on the chemical contamination of the town's water supply was complete, a vice president of the corporation made a personal visit to the president of my university and asked to have the study suppressed or totally disassociated from the university. It is gratifying to report that my university made no efforts to restrict my academic freedom.

However, the economic determinants of research and their influence on the lattitude of inquiry are far more pervasive and subtle. Sometimes this influence manifests itself in the distortion of science. Other times it is expressed in the control of information. Most frequently it is felt by the kinds of questions that are pursued in the areas where science and social policy intersect.

Scientists and the Public Trust

Periodically, a story appears in the media about an academic scientist who expresses sympathetic views to an industry position on a controversial health or environmental policy. The article might then mention the financial association between the scientist and the company that has a stake in the outcome.

Given the choice, the public sector would place its trust in scientific experts who are not linked to industry financially; problems arise when the pool of unaffiliated experts becomes scarce.

Considering the amount of industry consulting that takes place, the public only learns about the proverbial "tip of the iceberg" of the associations. While the numbers of documented cases may be small, there is no clear way of knowing the total effect these associations have on social policy formation. Given the choice, the public sector would place its trust on scientific experts who are not linked to industry financially. Problems arise when the pool of unaffiliated experts become scarce.

A situation like this occurred in 1969 when close ties between the oil industry and university experts in academic discipline such as geology, geophysics, and petroleum engineering made it impossible for California officials and federal authorities to obtain testimony relating to the environmental problems arising from massive oil leaks of the Union Oil Company's offshore well in the Santa Barbara Channel. According to the report in *Science*:

> California's chief deputy attorney general . . . publicly complained that experts at both state and private universities turned down his requests to testify for the state in its half-billion dollar damage suit against Union and three other oil companies.[4]

The explanation offered by state officials about the difficulty they had in getting testimony from experts is that "petroleum engineers at the University of California campuses of Santa Barbara and Berkeley and at the privately supported University of Southern California indicated that they did not wish to risk losing industry grants and consulting arrangements."

It was reported in *Science* that most petroleum engineers in academia did extensive consulting for oil companies and formed part of the university-industry "oil fraternity:"

> Consulting is regarded not simply as a lucrative prerequisite of the profession but as a necessary way to establish and maintain a departmental reputation and create job opportunities.[5]

Another obstacle facing public officials hoping to obtain objective advice from experts who serve on public service panels is that many own stock in the companies that are affected by their decisions.

The lesson illustrated by this case is not that petroleum engineers did not testify. They were probably acting ethically in not testifying since their corporate ties might have compromised or cast doubt on their objectivity. The real problem was the scarcity of academic experts who were not affiliated with the oil industry and who could provide a potentially disinterested perspective.

In some situations, research is so highly specialized that only a few scientists in the entire country may have the information necessary to render a decision on the health and safety of a new substance. Several decades ago, it was common practice for scientists to sign restrictive publication agreements with companies. It is still done today in the biotechnology industry. In one important case, information withheld from publication could have prevented a toxic pesticide from being marketed. In the 1950s, a clinical professor of occupational and environmental medicine at the University of California at San Francisco was engaged in toxicological research on the pesticide dibromochlorapropane (DBCP) for the Shell Development Corporation. In the course of the research, he discovered that the chemical caused severe cases of testicular atrophy in test animals. As was common practice at that time, research results were kept out of print to protect trade secrets. While a brief abstract of the toxicological study was published in 1956, the full results were held back from publication until 1961, *six years* after the pesticide was approved for marketing.

In the late 1970s, workers in a DBCP plant were monitored, and unusually high incidence of male infertility was reported. At state hearings on DBCP, it was noted that the scientist who studied the pesticide testified at public hearings on other environmental health matters without disclosing his consulting work with firms that had a financial interest in the subject matter under investigation. The chairman of the panel stated:

> It is difficult to know in the cases of [such scientists] with 30 years of dual relationships with the university and with Shell where advocacy on behalf of private interests ends and where responsibility as an 'objective' professor begins.[6]

A special feature of the journal *Business and Society Review* reported cases where the public received expert testimony from scientists with undisclosed relationships to companies that stood to gain from the recommendations. Michael Jacobson, Executive Director of the Center for Science in the Public Interest described conditions in the field of nutrition.

> In the area of food safety and nutrition . . . a large percentage of experts has received industry money. Rare is the expert who accepts such funds as an ardent defender of the public's interest.[7]

Similar examples can be found in nuclear engineering, occupational health and medicine, and ecology.

Ultimately, it is socially desirable that there be a balance in the academic community. For any discipline that has a commercial offspring, it is vital that a critical mass of experts remain disassociated from industrial ties in areas related to their field of expertise. And when scientists maintain such ties, it is essential that the public understand the nature of the relationships when their expertise is sought in setting policy. But just how extensive is the problem in biotechnology?

It is critical that we develop quantitative information about the degree of corporate-academic interaction in order to assess the reality of this problem.

Academic-Corporate Linkages in Biotechnology: Some Quantitative Results

For the past year, I have been quantifying the linkage betweenthe academic and commercial/industrial sectors in biotechnology. What follows is a report on the preliminary findings of this research.

The key questions underlying the current study are:

1. As a baseline, what number of academic scientists are formally involved in commercial biotechnology?
2. What is the growth profile of new firms created in the biotechnology industry?
3. Of the scientists involved in the commercial/industrial activities, how many are members of the National Academy of Sciences (NAS); what are their demographics; what percentage serve on study panels or public advisory committees to the National Science Foundation (NSF), the National Institutes of Health (NIH), and the U.S. Department of Agriculture; and what percentage of the specialized sections of the NAS in the biomedical sciences are comprised of dual-affiliated scientists?

I chose to examine formal, long-term ties between scientists and biotechnology firms. To meet this criterion a scientist has to satisfy at least one of the following conditions: serve on a scientific advisory board of a biotechnology firm, hold a long term consultantship with a company, hold substantial equity in a biotechnology firm, or serve in a managerial capacity for a firm. For companies that offer public stock, some of this information is contained in reports to the Securities and Exchange Commission. It is more difficult to obtain information about the scientific consultants and equity holdings of private firms since they are not legally obligated to file reports in the public domain.

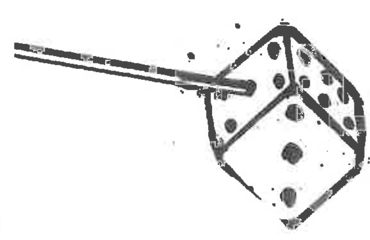
The data base for this study included a list of 212 biotechnology firms, of which 103 issue public stock, 119 are private, and 70 are undesignated. The prospectuses and financial reports have been reviewed for 82 of the largest and most active of the public corporations and a few private companies for information on major stockholders and the composition of their scientific advisory boards. Relevant information from trade literature and media reports of commercial activities in biotechnology brought additional scientific affiliations. The result of this inquiry was a list of academic scientists with formal commercial ties to the biotechnology industry.

Thus far the survey of public firms shows that 393 academic scientists serve on scientific advisory boards of biotechnology firms. The actual number of university scientists with formal ties to the private sector may run several times this number when all public and private firms are reviewed. The quantitative information compiled thus far is summarized in table 1.

An important consideration in interpreting the data is that the number of biotechnology firms has increased rapidly over the past decade. The birth of new firms peaked in the early 1980s and appears to be in a decline (figure 1). The trade magazine *Genetics Engineering News (GEN)* reported that there were a handful of biotechnology companies before 1981. By the next year *GEN* listed 194 firms in its registry. The number climbed rapidly to 220 by November 1983 and current estimates place the number of firms at about 350. The increase in the number of scientists on

TABLE 1. Commercially affiliated academic scientists in biology/medicine/biotechnology. Data base of 393 scientists and 292 biotechnology firms of which 50 were systematically surveyed.

Subclass Category	Number	% Data Base
Membership in NAS	71	17.6
Serve(d) on NIH Public Advisory Committee/ Study Panel, 1982-84	48	13.2
NSF Mail Reviewers, 1983-84	236	64.9
USDA Mail Reviewers	19	5.2



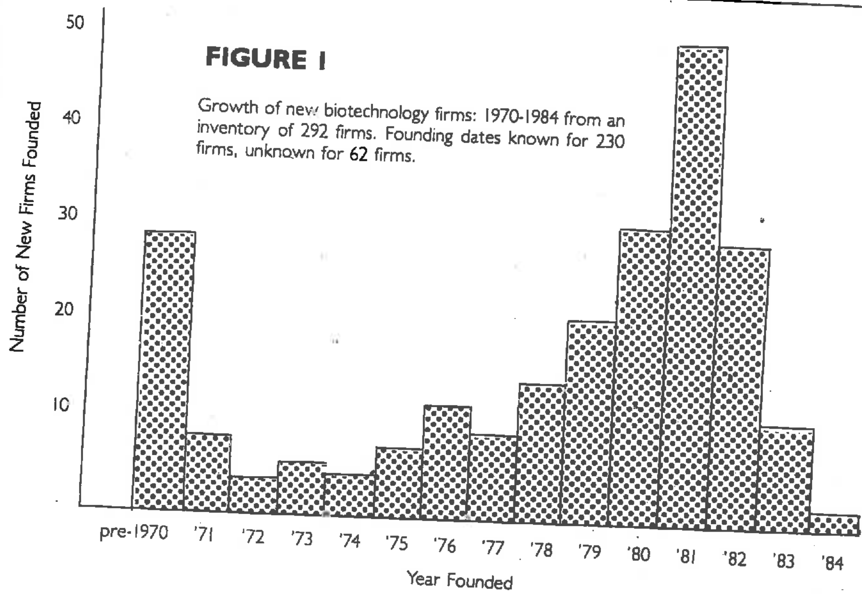


FIGURE 1

Growth of new biotechnology firms: 1970-1984 from an inventory of 292 firms. Founding dates known for 230 firms, unknown for 62 firms.

scientific advisory committees is directly related to growth of the industry. By knowing the number of firms and estimating the average number of scientific advisors on each, it is possible to get an upper bound on the formal linkage between university biomedical scientists and industry.

The data show that a significant percentage of the academic scientists serving on advisory committees of firms are also members of the National Academy of Sciences. The four sections of the NAS most relevant to biotechnology are: biochemistry, celular and developmental biology, genetics, and medical sciences. The NAS members in the data base of dual-affiliated scientists constitute about 25% of the total membership in the four sections of the Academy. The actual number of dual-affiliated scientists from the data base for each of the four NAS sections is given in figure 2. Some scientists on the NAS list are not classified in specialty areas while other NAS members in our data base are not associated with one of the four sections listed above. Since our survey has analyzed only 28% of the 292 firms inventoried for the study, the number of dual-affiliated scientists who are members of NAS could reach over 50% for certain sections. This is particularly significant because NAS is frequently called upon to render decisions on the social and environmental impacts of science and technology.

In addition to correlations between dual-affiliated scientists and NAS membership, the data base was also examined for affiliations with the National Science Foundation, and National Institutes of Health, and the Department of Agriculture. Nearly 65% of the scientists in the data base served as external reviewers for NSF grant proposals. Although confidentiality in such reviews is a part of the scientific ethic, the flow of commercially useful information to industry resulting from such reviews may be impossible to control, when the reviewers have equity in or strong affiliations with firms. The percentage of dual-affiliated academics on NSF study panels and public advisory groups is considerably lower than those on similar NIH panels and those serving as NSF mail reviewers (table 2). It is not clear whether this is an artifact of no special significance, or whether NSF's conflict of interest procedures for study panel participation screen out those with strong industry ties.

This research is still in progress. Demographic data have not been analyzed. It may be of interest to see which universities have the strongest corporate-academic ties. Considerably more work needs to be done to increase the data base of dual-affiliated scientists by accumulating information on private firms.

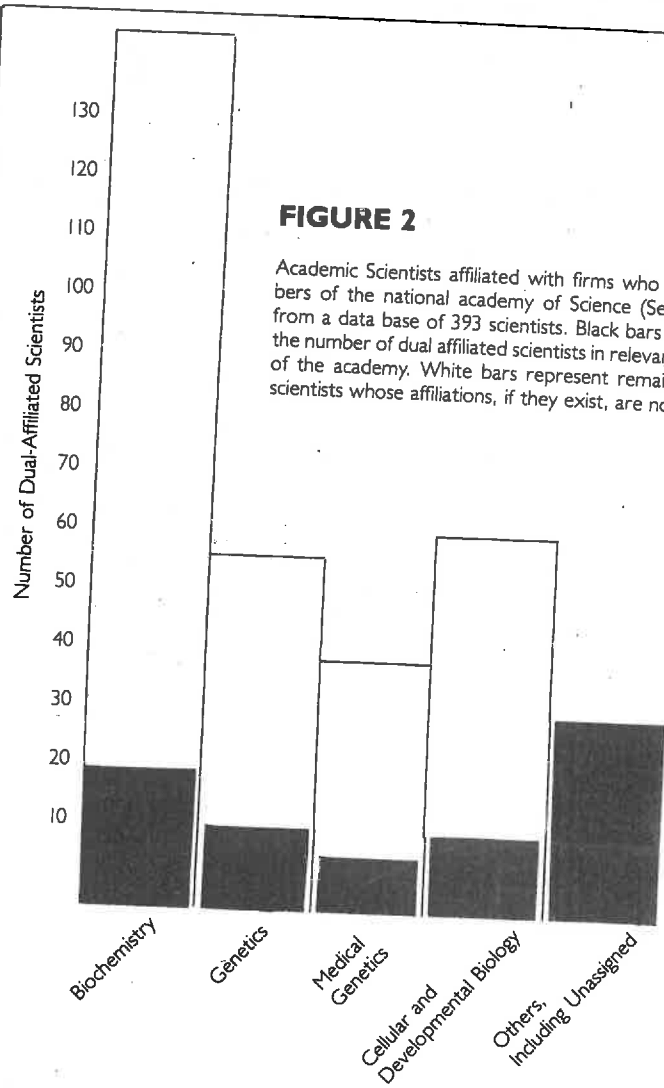
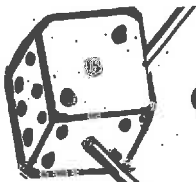


FIGURE 2

Academic Scientists affiliated with firms who are members of the national academy of Science (Sept., 1984) from a data base of 393 scientists. Black bars represent the number of dual affiliated scientists in relevant sections of the academy. White bars represent remaining NAS scientists whose affiliations, if they exist, are not known.



Scientists with a stake in the commercial outcome of a field cannot, at the same time, retain the public interest perspective that gives critical attention to the perversion of science in the interests of the market.

It is also important to study these trends over a long time period to understand how the phenomenon of academic-corporate partnerships evolves as the biotechnology field matures. Until the quantitative assessment of this phenomenon is made we will not be able to fully appreciate the symbiotic nature of industrial partnerships between academe and industry. On one hand we have technology transfer. On the other hand there are changes in the scientific institutions. In particular, it is important to understand how scientists' dual-affiliations affect research programs in molecular biology and change the cultural milieu which has nourished the scientific enterprise.

Conclusion

In conclusion, there is so much that needs to be done to improve the public's attitude toward the role of science in social policy and, particularly, to enhance the image of scientific objectivity. One contribution toward this end is to promote disclosure. The commercial connections of scientists with dual affiliations should be part of their resume and open to the public record when they enter the policy realm or when they serve on public advisory committees. This is not a difficult or burdensome requirement.

A second recommendation which is more difficult to implement would reward scientists who maintain an independence from commercial activities. Such independence might be factored into appointments on prestigious commissions and other policy making activities including service on study panels as well as preference in the competitive grants program.

Without some incentives to reverse the momentum of the phenomenon that is occurring in biotechnology, the pure biomedical scientist may become a vestigial relic of a past generation, with the inevitable results being the foreclosure of an important agenda—the social guidance of a technological revolution–and the increasing erosion of public confidence in scientific objectivity.✭

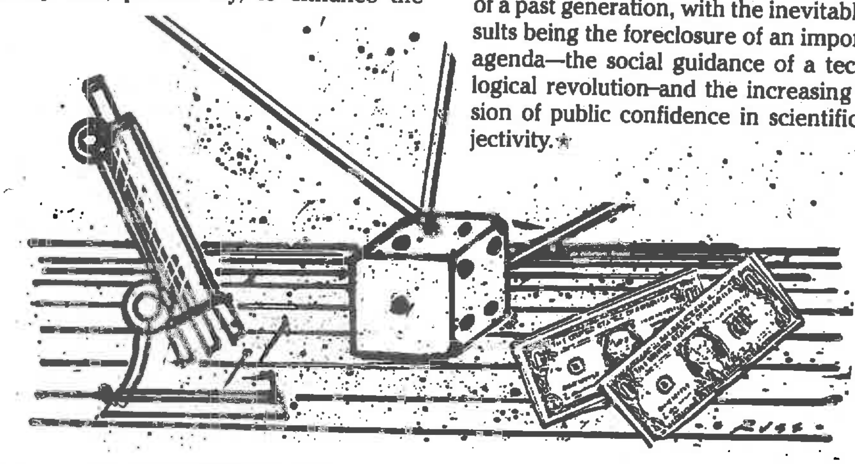


TABLE 2. Dual Affiliated Scientists on NSF Study Sections (FY 1983).

Study Section	No. Scientists in Section on Data Base	No Scientists in Section	% Dual-Affiliated Scientists
Regulatory Biology	0	15	0
Cell Physiology	0	12	0
Cell Biology	0	19	0
Developmental Biology	1	19	5.3
Genetics	1	25	4.0

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