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COMMERCIALISM IN SCIENTIFIC RESEARCH

• • •

Scientific research has never been entirely insulated from the incentives provided by the profit motive and the need to secure financial support. Scientists have always required funding, whether it be from personal funds, patrons, universities, or industry. Similarly, opportunities for scientific entrepreneurship have always existed. Since the early 1800s, however, scientific research has both required increasing amounts of capital investment and promised progressively greater financial returns. Consequently, scientists have been forced to rely on a broader range of funding sources and have become more willing to involve themselves in the financial implications of their work. This incremental "commercialization" of science has increased markedly since the early 1980s and poses challenges for both society and the research community.

Well into the early nineteenth century most scientists were indifferent to the commercial potential of their work and typically did not pursue large-scale or external financial support. Research then did not require huge expenditures, and many researchers believed that scientific research was the work of disinterested amateurs devoted to the pursuit of truth. In the mid- to late nineteenth century the development of the large-scale laboratory in Europe and ultimately in the United States increased the costs of research and foreshadowed the decline of the solitary, amateur researcher. At the same time, a variety of connections between industry and science developed. Many businesses employed their own scientists, but an increasing number established relationships with universities and employed academic scientists as consultants and researchers. While this trend continued in the early twentieth century, industry-sponsored research typically focused on applied-science projects. Basic research areas had yet to be viewed as fruitful areas of investment (Etzkowitz).

In the last half of the twentieth century, several developments enhanced the commercial aspects of science. The cost of basic science research continued to soar, requiring sophisticated equipment and resources, larger laboratories, and more staff. Basic research therefore has become increasingly dependent on financial support from either the government or the private sector. Scientific research, especially in the biomedical fields, promises to generate tremendous profits for those who control new discoveries. Moreover, the gap between basic and applied science has narrowed, so that discoveries can be translated into usable and profitable products with less energy and over a shorter span of time (Etzkowitz).

Commercialization, the Ideals of Science, and the Public Good

Despite the need for broad-based and generous funding and the right of scientists to reap rewards for their efforts and ingenuity, financial incentives may create conflicts of interest that can undermine and corrupt the ideal of disinterested scientific inquiry. A conflict of interest exists when any professional judgment or activity relating to a primary interest (e.g., intellectual honesty, validity, openness, or objectivity), equivalent to the scientific norms articulated by Robert K. Merton and others, may be influenced by secondary interests (e.g., financial gain, profit, position, or fame). The mere existence of a conflict of interest does not mean that unethical behavior has occurred; the scientist may honor the primary interests and refuse to be influenced by the secondary interests. Conflicts of interest instead signal cases in which the danger of unethical behavior is increased. In some cases the conflicts can be managed by restricting the secondary interests; in more extreme cases ethical outcomes can be assured only if the secondary interests are entirely removed (Thompson; Merton; Cournand).

Conflict of interest may exist at an individual or at an institutional level. For example, one primary interest of a university is to serve the public good. Financial incentives may induce researchers and institutions to behave in ways

detrimental to society (Angell). For example, a scientist may forgo research on an important project in favor of another that is more profitable. Comprehensive ethical policies would ideally address both possible levels of conflict, though they require different forms of remedies.

Industry Investment in Academic Research

Private investment in university research may take a number of forms. Companies may offer universities large grants in exchange for patent rights to anticipated discoveries or establish lucrative consulting arrangements with faculty members who provide sponsoring corporations with priority access to valuable research. Faculty members sometimes own equity interests in biotechnology firms related to their work, or they may found their own corporations. And in what is so far a rare agreement, a corporation may provide an academic research institute generous payments in exchange for the right to market all the institution's discoveries. These secondary—financial—interests threaten to undermine the university's primary interests of advancing basic knowledge, promoting the open exchange of ideas, providing a source of expertise for society, and training future scientists (Etzkowitz; Ashford).

In 2003 Justin E. Bekelman, Yan Li, and Cary P. Gross provided a systematic review of the extent and nature of commercial influence on biomedical research. The researchers found that about one-fourth of biomedical scientists at academic institutions receive research funding from industry, while two-thirds of academic institutions hold equity interests in biotechnology firms. According to the survey findings, it is likely that such relationships bias scientific outcomes because published studies sponsored by industry are substantially more likely than nonindustry studies to reach conclusions favorable to the sale of the sponsors' products. Faculty sponsored by industry are more likely than other faculty to report that publication of their research results was delayed, and more than half of the firms surveyed reported that their contracts typically demand delays in publication of more than six months. Between 12 percent and 34 percent of investigators reported that they had tried to obtain and had been denied access to research results by industry sponsors.

If free exchange through traditional scholarly mediums of conferences and publications is blunted, scientists will be unable to examine and replicate experiments, and scientific progress may be endangered. Some contractual agreements with industries specifically require scientists to withhold submission of their findings to professional journals until the corporation has determined if the information warrants patent protection. After patent protection is secured, the findings can be released to the general scientific community. The propriety of these arrangements depends in part on the length and impact of the delay of release of scientifically important information and varies from contract to contract. It is possible that much of the research that is withheld from the scientific community as trade secrets has little intrinsic scientific value or applicability and is limited to information such as scientifically unimportant formulas for products, scientific instrument calibrations, or engineering tolerances (Snapper).

Commercial considerations can distort academic life in other respects. Researchers may be tempted to devote time earmarked for the university to their commercial projects and to use university resources, including graduate assistants and laboratory staff, for their own financial benefit. Graduate students are particularly vulnerable to the availability of funds; the entire course of their careers may be guided by the source of their mentors' grants (Porter 1992a; Blumenthal). The prospect of large infusions of money into a cash-starved university might make an institution less scrupulous when evaluating potential research projects. For example, an institutional review board (IRB) might be less likely to point out problematic aspects of an experimental study if they believe that the corporate sponsor will withdraw its funds and go elsewhere with the proposal. An existing or potential grant might influence a university's decision on the composition of its faculty, the structure of a department, and the granting of tenure (Nelkin and Nelson). Financial incentives have encouraged some university researchers to redirect their work toward projects that are more likely to yield financial rewards. Such a redirection of research might encourage researchers to value applied projects with clear commercial ends and patentable uses over basic science projects whose practical applications are uncertain. While society benefits from applied research, fundamental breakthroughs and scientific progress are predicated on a strong commitment to basic research.

Despite these caveats, private funding of university research serves as an effective and essential supplement to government funding. Some reports demonstrate that, in general, industry-funded scientists publish more, produce more patentable discoveries, and still manage to teach as much and to serve as many administrative roles as colleagues without corporate financial support (Blumenthal). Industrial subsidies allow universities to support a more talented and larger faculty and to improve their facilities. Therefore, some authors argue that the danger of increased commercial presence in universities must be weighed against the positive contributions made by industry funding (Blake).

Conflicts and Scientists' Social Duties

Professional researchers are the public's and policymakers' most important source of scientific expertise. Government agencies that evaluate biomedical proposals and projects must rely on scientists to analyze the safety and efficacy of research and products. Scientists also serve as reviewers for governmental grant applications and as authors, editors, and referees for professional publications. Conflicts of interest arise when industry, regulatory agencies, government committees, and editors all seek out the same individuals—a likely prospect when many of the most talented researchers have already-established commercial interests (Culliton).

Few scientists will purposely present biased conclusions, but researchers' commercial interests may influence their professional life in other respects. Scientists might be hesitant to participate in the evaluation of an industry with which they maintain a financial connection. Following a large oil spill on the California coast in the late 1960s, for example, government investigators found it difficult to recruit scientists willing to testify against the oil companies. Most qualified scientists had commercial ties to the industry (Kenney). When a medical journal sought independent reviewers to judge the quality of a research study showing the lack of benefits of a popular drug—a study whose publication the company manufacturing the drug was attempting to suppress on the grounds that the study was badly designed—the editors discovered that virtually all scientific experts in that field had existing financial ties to the company (Rennie). Corporations frequently employ researchers as consultants to determine if their facilities meet governmental health standards or if their new product induces disease. A researcher's desire to please the employer and to preserve the potential of future affiliations may influence the study design and methodology selected for the investigation. A study that monitors employee health for only a short time, for example, would be less likely to uncover an occupation-related disease with a long latency period. A corporation facing liability for a suspect drug would prefer its researchers to find that the product presented no danger and was not responsible for the maladies suffered by current users (Ashford; Porter, 1992a, 1992b).

Similarly, reviewers of grant applications may have commercial interests that unconsciously lead them to undervalue a potential competitor's proposal. Journal referees may denigrate articles or reports that threaten their commercial interests or their industry employer. A researcher with a consulting arrangement or an equity interest in a new development might tend toward findings that would laud the benefits of the innovation. In one egregious case, a researcher who owned over 500,000 shares of biomedical stock altered a study design to delay the release of negative findings until he could sell his holdings for a tremendous profit (American Medical Association). Physician-researchers with commercial interests in innovative treatments or research protocols bear additional responsibilities. A central tenet of medical professionalism holds that the welfare of the patient be placed before any benefit to the physician. If a physician-researcher is testing an experimental therapy, the patient must be protected from risks of undue harm from either the experimental drug itself or from withholding standard therapy. Physician-researchers with financial interests in their protocol might tend to recruit subjects aggressively, playing down the risks and exaggerating the benefits associated with the research. In a highly publicized case in which a young man died during experimental gene therapy, both the investigator and the university had financial interests in the biotechnology firm that planned to market the drug if it proved successful, and it was charged that substantial, known risks were not disclosed to the subject (2001).

During the 1990s a considerable change in pharmaceutical research funding occurred in the United States. Companies began to shift research grants away from universities and toward for-profit contract-research organizations (CROs). The CROs promised quicker research results and hence faster licensing of new drugs, compared to the more cumbersome, bureaucratic university system. Between 1991 and 1998, the portion of pharmaceutical industry research funds going to academic medical centers fell from 80 percent to 40 percent (2000). For-profit commercial IRBs sprang up to service the CROs, creating questions as to the adequacy of ethical review when both the IRB and the investigating organization had such strong financial incentives to speed the progress of research and to produce positive results (Lemmens and Freedman). As research funds were shifted to the private sector, university investigators had to compete more vigorously for the remaining funds, increasing the likelihood that both institutions and individuals would ignore serious conflicts of interest in their eagerness to secure funding.

Remedies and Safeguards

The integrity of individual researchers is clearly the most important guard against the malevolent potential of conflicts of interest. But honesty alone may sometimes be insufficient, as damage can occur from unconscious bias and error as well as from conscious falsification. While all conflicts of interest have the potential to undermine a scientist's or an institution's primary goals of truth, objectivity, and openness, all conflicts do not pose the same degree of danger or require the same response. The danger of a particular conflict of interest depends both on how likely the

arrangement is to corrupt the scientist's professional duty and on how much damage that corruption is likely to cause. Larger financial payments, and longer and closer relationships between researchers and business, will typically pose greater dangers than small financial incentives and one-time contacts with corporations (Thompson). While supervisory and regulatory measures can usually be tailored to the degree of the risk, there may be some situations in which the danger of harm to scientific integrity and society is so high that no protective measure can remedy it.

Universities might limit the amount of support they accept from industry, limit the amount of time that faculty may devote to outside endeavors, or prohibit particularly suspicious arrangements. In addition, research institutes can require the disclosure of all commercial links and interests and establish prospective administrative review of all proposals for outside funding (Varrin and Kukich; AAMC, 1990). Disclosure rules not only assist university officials and peers in policing conflicts of interest but may also make researchers more scrupulous in evaluating the potential bias in their own work. Researchers sometimes end or eschew questionable relationships rather than disclose them to the academic community. Some have argued, however, that today's institutional policies tend to advocate, inappropriately, disclosure alone, treating it as if it were a panacea. A number of prestigious universities and organizations in the United States proposed stringent conflict of interest policies in the early 2000s (Kelch; Kassirer). Many focus on individual conflicts of interest to the exclusion of institutional-level conflicts. By contrast, a group of Canadian authors, stimulated by widely publicized cases in their country of egregious institutional violations of academic freedom, have proposed elements of a conflict of interest policy that offers remedies for both levels of conflict (Lewis et al.). A policy on institutional conflicts of interest proposed in 2002 by the Association of American Medical Colleges (AAMC) locates responsibility for policing potential conflicts of interest within each university, whereas the Canadian group suggested that an appellate process involving a national group independent of any one university would be desirable (Lewis et al.; AAMC 2002). After developing a policy considered one of the most stringent in the nation, Harvard Medical School came under pressure to loosen its requirements, lest some of its most prestigious researchers move elsewhere (Angell). Bioethics programs in universities are part of the research enterprise and, according to some, should have policies to prevent conflicts of interest. Concerns have been expressed about paid consulting relationships between bioethics faculty and industry (Brody et al.).

Government agencies and professional publications also institute policies to guard against conflicts of interest. The U.S. Food and Drug Administration and the National Institutes of Health require extensive disclosure of all advisers' commercial interests. Some professional journals demand that authors and reviewers disclose any commercial relationships that might be construed as creating conflicts of interest. According to this view, conflicts of interest should not automatically disqualify a reviewer or author, but the revelation will allow readers, editors, and administrators to scrutinize conclusions more carefully (Koshland). Other publications have adopted somewhat more stringent guidelines. The *New England Journal of Medicine,* for example, has required that authors disclose their financial conflicts, that its editors have no financial interest in any business related to clinical medicine, and that authors of review articles and editorials have no financial connection to their topics (Relman). The *Journal* was later forced to admit, however, that many of its authors of review articles had evaded these requirements (Angell, Utiger, and Wood). A few observers warn that excessive concern over conflicts of interest and safeguards may hinder scientific progress and undermine the scientific objectivity that they are designed to preserve. These writers claim that focusing reviewers' and readers' attention on potential outside influences instead of the content of the data, findings, and ideas generates a subjective skepticism unrelated to the objective merit of the work (Rothman). In 2001, however, the editors of thirteen major medical journals decided that the problem was serious enough to demand a unified and even more stringent disclosure policy (Davidoff et al.).

Some observers argue that the physician-researcher's commercial ties should be revealed to the patient-subject through the mechanism of informed consent and to the investigator's institution through a formal reporting mechanism (Finkel). Finally, IRBs can scrutinize protocols that promise great financial rewards for physician-investigators.

Patents and the Public Interest

Patenting is another commercially motivated practice that may create conflicts between the primary interests of good science and the secondary interests created by the profit motive. Patenting is based on the theory that innovators will be more likely to share their knowledge because they know that they will receive remuneration and credit and that entrepreneurs will be more willing to invest in the development of discoveries because they know that they have exclusive or protected access and will recoup their expenditures in profits. Patenting's skeptics, however, argue that the very nature of patenting undermines the traditional scientific norm of openness. Researchers may be tempted to withhold socially valuable information until they are certain

that their pecuniary interests are protected by a patent (Kass; Wiener). Especially in the biomedical fields, a delay in the release of information can lead to postponed development and dissemination and the loss of lives. Others speculate that potentially patentable, lucrative discoveries will lead researchers away from less profitable yet socially important projects. Finally, some critics claim that entrepreneurs who purchase rights to a basic discovery often do not use or develop it in a socially responsible way. Furthermore, their monopoly advantage makes it impossible for the market to force them to distribute the breakthrough in an equitable and useful manner (Goldman).

The federal Bayh-Dole Act of 1980 provided the legal basis for universities to patent genetic and other biotechnology products and discoveries. When passed by Congress, the act seemed uncontroversial, because the public would benefit both from the quicker marketing of the fruits of new research and also from a lower tax burden as universities made more money from patents and licenses. In retrospect, some provisions of the act appear to have had undesirable consequences. Besides the dangers of turning so big a percentage of research funding over to corporate interests, some fear that the ease with which one can patent each separate step of a complex sequence needed to create genetic tests or therapies will actually pose a barrier to future advances, because the manufacture of any gene product may require negotiating license fees with the owners of dozens of patents (Nelkin and Andrews; Merz et al.).

The government can also provide patentlike incentives to encourage the development of products with marginal profitability that are intended to treat a small patient population or that are ineligible for normal patent protection—so-called orphan drugs. Orphan-drug programs might include research grants, investment tax credits, expedited approval processes, and exclusive licenses to produce and distribute the drug. Critics of orphan-drug programs argue that the policy excessively favors drug manufacturers, inflates the costs of lifesaving medications, and delays the development of lower-cost alternatives. Private corporations sometimes reap profits far in excess of their expectations and effort while effectively denying life-sustaining remedies to patients through monopoly pricing practices (Ackiron). Incentives are sometimes overgenerous, and corporations are able to enrich themselves on drugs that serve only a small number of patients and occasionally produce limited benefits (Wagner). It is important to scrutinize the incentive structure of the orphan-drug policy in an attempt to eliminate unnecessary windfall profits for drug manufacturers. Policymakers must balance the cost of the incentives, including monopoly pricing practices and tax abatements, against the benefits provided by the new drug (i.e., the number of people served and the efficacy of the remedy).

Marketable Products from Human Sources

Another challenging problem arises when an individual's body parts or cells are transformed into valuable commodities. In one such case, a patient's removed spleen contained unique cells that a physician-researcher cultured into a patented cell line. Should the patient have been apprised, as part of the informed-consent procedure, that the cells had potential commercial value? Fully informed consent would have allowed the patient to evaluate the physician's potential conflict of interests and choice of treatments more effectively. Because society and the law have typically been hesitant to "commodify" the body and do not allow the sale of organs, it might seem inappropriate to grant the patient a share of the profits based on the theory that the tissue is his or her "property." In contrast, the system appears to allow the biomedical entrepreneur to benefit from the sale of body parts. Developers of such innovative products might argue that the resulting cell line is not a body part but rather the result of their labor and ingenuity and that these efforts deserve to be rewarded and encouraged by traditional patents. Even granting this argument, it may be unjust to allow others to benefit from an innovation while the person upon whose existence the development rests receives nothing. Consequently, it seems fair and equitable that individuals receive some benefit from their unique physical characteristics that have been used to create great profits. The amount of remuneration could depend upon the nature of the informed-consent agreement, the degree to which the body tissue contribution was changed by the researcher before it was offered as a product, and the uniqueness of the physical material used (Murray).

Conclusion

It would be unrealistic to expect modern capital-intensive scientific research to thrive entirely without the support and influence of commercial interests and incentives. Similarly, it would be unwise and impractical to suggest that scientists who maintain commercial connections, and therefore have potential conflicts of interest, should disqualify themselves from all advisory duties. The trend toward adoption of explicit and stringent conflict of interest policies suggests a growing consensus that individuals, institutions, and professional groups have all been too tolerant in the past of ethically questionable but lucrative practices. It remains to be seen how effective these new policies will prove in policing the problem. The U.S. public, moreover, may be forced to reexamine the wisdom of allowing so great a

percentage of the total research endeavor to be governed by private commercial interests.

KENNETH ALLEN DE VILLE (1995)
REVISED BY HOWARD BRODY

SEE ALSO: *Conflict of Interest; Corporate Compliance; Pharmaceutical Industry; Private Ownership of Inventions; Profit and Commercialism*

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COMMUNITARIANISM AND BIOETHICS

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In the 1990s, communitarian approaches to bioethics became increasingly common and explicit in the literature. This evolution was the result of the prominence of the communitarian philosophical critiques of liberalism that occurred in the 1980s, particularly works by Alasdair MacIntyre, Michael Sandel, Charles Taylor, and Michael Walzer.

Communitarianism is a neo-Aristotelian philosophy that focuses on the common good and is concerned with the relationship between the good person or good citizen and the good of the community or society. As would be expected, it has much in common with other neo-Aristotelian approaches, such as casuistry and virtue ethics. Communitarianism is both a critique of the dominant Western ideology of liberal individualism and an orientation to ethical problem solving.

Communitarians often argue that the notion of human nature and the concept of the self behind liberalism are insufficient to make possible a shared common understanding of values among members of society. Similarly, communitarians sometimes argue that liberal society is committed to neutrality toward all notions of the good life, and thereby cannot adequately address ethical issues. As a result, communitarians often stress an orientation toward ethical questions that relies on the establishment, or re-establishment, of a shared common understanding, a shared notion of the good life, or a shared notion of the self.

Only a few bioethicists have openly embraced the communitarian label in their writings (Emanuel; Brennan; Loewy; Nelson; Callahan, 1996; Kuczewski, 1997). However, much work in bioethics shares community-oriented assumptions—that healthcare is special and different from market commodities, for example (Daniels), and may be seen as a good that is part of the common good (even by those who do not embrace communitarianism in other spheres of distributive justice) (Jecker and Jonsen). Similarly, many writers take relationships as the starting point of their ethic, rather than the individual (Murray).

Furthermore, even if society tries to remain neutral toward visions of the good life, ethical issues arise within the context of healthcare and require that the public institutions that provide medical treatment and conduct biomedical research somehow address such ethical dilemmas. As a result, pragmatists such as Jonathan Moreno embrace communitarian strands of thought in an effort to resolve such questions through the production of consensus (e.g., the creation of shared common understandings) (Moreno).

Communitarian Critiques of Liberalism

Communitarian critiques of liberalism have an intuitive appeal, and the nature of the critiques determine the kind of solutions that communitarians seek. It is again important to note that these critiques were developed mainly in the philosophical and political-theory literature and then imported to bioethics, often in a compressed fashion. Two different, but related, starting points form the basis of the communitarian criticisms.

LOSS OF SHARED COMMON UNDERSTANDING. Some communitarians, most notably the philosopher Alasdair MacIntyre, claim that liberalism will always fail to settle