The changing norms of the life sciences

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New institutional relationships, sources of funding, collaborations, and career paths are arising in the rapidly evolving field of life sciences. Concerns about eventual product development resulting from scientific work are increasing in importance, whereas open publication of data is not. We contend that current practices in the life sciences do not conform to a Mertonian analysis of scientific value. Moreover, we propose that active investigation of the process of evolution of the life sciences should be a priority and concern to its scientific practitioners and the publics who fund, purchase, or are affected by its products.

A clash of cultures

The past 20 years have witnessed a marked realignment of the institutions in which biological research is conducted. Although the boundary between pure and applied has never been as distinct as many scientists and bioethicists claim, the development of biotechnology served as an important benchmark in bringing 'public' scientific discovery and 'private' product development into more overt and explicit contact. Both critics and advocates of these changes agree that something important has taken place[1]. The venture capital market, the growth of biotechnology startups, and the convergence of university and industry in areas of scientific labor and technology transfer have built a robust infrastructure linking the laboratory directly to commercial outlets[2,3]. Indeed, contemporary experimentation in the life sciences, whether conducted in university, industry, or medical settings, is thoroughly dependent on a diverse array of sophisticated and expensive tools sold by private industry.

The critical distinction is no longer between the production of knowledge and the development of commodities, but between different modes of organizing research that in all cases require massive capital outlays to function[4]. There is a new milieu, a new ecology of market and research, one in which a seemingly inescapable mutual interdependence exists. The interdependence, however, is a dynamic one; it requires fresh self-reflection by those who are directly involved as well as those who consider themselves exempt from its influences.

These transformations in molecular biology and biochemistry raise important questions about what it means in practical terms to lead a life of science. The new norms that structure the life sciences—from aggressive marketing to the pursuit of proprietary interests—will fundamentally shape how science and society interact in the coming decades. Although many observers have noted the ethical implications of the changing modes of scientific production, few have examined their impact on science as a vocation and a way of life. Greater self-examination by scientists and biotechnologists could yield important insights into the future practices of science. Proper scientific governance will require that members of the life science community take a more active position in public debates surrounding these changes.

The public vs. private dichotomy

The widely publicized discussion of federal funding for research on human embryonic stem (ES) cell lines has highlighted several key features of change in the biosciences. First, private initiatives dominate the basic science on stem cells. Paralleling important developments in other research areas, a substantial portion of basic ES cell research has been conducted by biotechnology companies, such as Geron (Menlo Park, CA) and Advanced Cell Technology (Worcester, MA), as well as by privately funded university scientists.

Second, the proprietary knowledge they produce is exempt from political controls. Despite US President Bush's executive order, attempts by the US National Institutes of Health (NIH; Bethesda, MD) to acquire the approved stem cell lines have been complicated by material transfer agreements that assign ownership of these biologics and their by-products to the original patent holders[5].

Third, far from exhibiting a singular 'public' whose uniform interest is at stake, the stem cell debate is characterized by a plurality of competing social groups—including antiabortion activists, patients' groups, scientists, bioethicists, and federal policymakers—asserting their agendas in media outlets and the floors of Congress. Traditional distinctions between the motives and practices of actors in the public and private spheres are no longer self-evident. This suggests that the categories that frame the life sciences—such as 'science,' 'public interest', and the 'market'—need to be reviewed and more adequately qualified.

From the commercial takeoff of the biotechnology industry in the 1970s onward, innovations in the field have been the products of an intricate and shifting alliance between academy and industry. In its early stages, university researchers used both their intellectual and material capital to build much of the private landscape. Though not as dominant as in the early days, this trend of prestigious academic scientists leveraging their research accomplishments has carried on, from the founding of Genentech (S. San Francisco, CA) by Herbert Boyer at the University of California, San Francisco in 1976, to the creation in 1999 of the Institute for Systems Biology (Seattle, WA) by Leroy Hood and colleagues at the University of Washington (Seattle, WA). At five California universities alone, former and current faculty members have founded over 300 biotechnology companies[6]. Academia has supplied the bulk of expertise for the commercial biosciences, as demonstrated by the proximity of businesses to public research centers in such cities as Boston, San Francisco, and San Diego.

The early connections that existed between university laboratories and firms, however, were for the most part unofficial and considered dangerous for the functioning of science[7]. This position was striking, given the extensive research conducted by the US National Academy of Sciences for defense, and how previously even radicals had felt comfortable taking money from 'tainted' sources. Whatever the reasons, it took a new set of institutional rules and incentives to develop techno-economic coordination in the life sciences.

With the end of the Cold War, public R&D priorities in the United States shifted from national security to the international competitiveness of key industries[8]. The new climate brought initiatives to promote government and university cooperation

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with biotechnology companies. Federal programs like the Small Business Initiative Research and the Small Business Technology Transfer initiatives placed commercial success at the top of criteria for government grant allocation. The Bayh-Dole Act of 1980 opened these ties to new forms of articulation by permitting universities and nonprofit organizations to retain intellectual property rights to federally funded inventions. The Reagan Administration also created tax incentives for private investment in university R&D through the Research and Development Limited Partnership and the Economic Recovery Tax Act of 1981 (ref. 9).

The effects were remarkable. In the period since Bayh-Dole, more than 150 universities have developed patent portfolios and become aggressively involved in the business of technology transfer. More than 2,000 companies have been formed directly through university licenses during this same period10. Corporations now account for over half of all national funding for biomedical R&D, and supply as much as 14% of the money for academic research in biotechnology-intensive areas[11,12]. Studies suggest that more than a quarter of life science faculty participate in industry relationships, and the estimates are 39% for genetics researchers in clinical departments[13,14].

New configurations

Public-private partnerships have not only proliferated, they have also taken on increasingly innovative forms. Biotechnology business incubators, such as Connect and BioSTAR in the University of California system and the Austin Technology Incubator at the University of Texas, support startups with capital, marketing, and other services in the early stages of high-risk ventures. The end goal of these alliances is not so much basic research, but product development and the preparation for clinical trials.

Many of the most innovative projects now involve collaboration between pharmaceutical companies and academic laboratories. Examples of this include the SNP Consortium and the sequencing of mouse and *Drosophila melanogaster* genomes. Voluntary health organizations have also connected to private industry to translate basic science into disease treatment. The Cystic Fibrosis Foundation (Bethesda, MD) announced in May 2000 that it would enter a five-year, $30 million agreement with biotechnology company Aurora Biosciences (San Diego, CA) to identify and develop cystic fibrosis therapies.

These relationships defy traditional commercial models. Research in the laboratory, when it is brought into contact with the private sector, has not often translated into health care commodities. Besides the five largest players—Amgen (Thousand Oaks, CA), Biogen (Cambridge, MA), Chiron (Emeryville, CA), Genentech, and Genzyme (Framingham, MA)—which account for over one-third of industry revenues, most of the 2,000 biotech companies worldwide have yet to generate a substantial revenue-generating product[15]. Basic research in genetics draws its commercial value primarily from the knowledge and information it produces, rather than directly marketable goods[13,14].

Scientific norms in question

New imperatives and normative structures hold together the contemporary life sciences. As the distribution of rewards within the field reveals, the marketing of bioscience research has become an institutionalized goal of universities and federal laboratories. Suzanne Sandmeyer, professor of microbiology and molecular genetics at the University of California, Irvine, has claimed that "corporate support … has enhanced our ability to get National Institutes of Health funding because I no longer have to wave my hands and argue that our work is relevant. I can simply list on my grant support that I'm funded by a gene therapy company to look at the applications … the NIH finds that to be a compelling argument."[16] This contrasts with NIH directives of the 1980s, which once proposed forbidding government scientists to disclose information to industry that was not in the public domain.

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These changes represent a "seismic shift in presumption," as Michael Phelps, chair of molecular and medical pharmacology at the University of California, Los Angeles, has claimed. Skepticism toward industry-sponsored research is now widely disregarded. Thus, it is not uncommon to see someone like Richard Atkinson, the president of the University of California, express confidence that commercial involvement can "be designed to be beneficial to the industry and at the same time be consistent with universities' fundamental principles."[16] Such optimism should be viewed as premature at best. Trends indicate that faculty with corporate sponsorship are more likely to produce favorable findings and to withhold data from the scientific community to protect proprietary interests[17].

Dealing effectively with the new patterns of bioscience demands a more complete knowledge of the changing alliances and complex interdependencies among government, universities, and industry. The consequences of these arrangements have yet to be fully elaborated or examined. There is a need to address real health outcomes, appropriate safety regulation, and expanded public input and consumer knowledge. Responding to public concern means addressing the broad contexts, including equity in access to health care and growing power inequalities[18].

What do these new relationships mean for the values of science? Back in 1942, Robert Merton wrote of four principles composing the normative structure of science: "universalism," denoting the impersonal character of knowledge claims; "communalism," or common ownership of discoveries; "disinterestedness," the commitment to truth for its own sake; and "organized skepticism," referring to the suspension of judgment until conclusive evidence appears. "Property rights," he wrote, "become whittled down to just one: the recognition by others of the scientist's distinctive part in having brought the result into being."[19] Thus, for Merton, prestige is the reward in this hierarchical view of science. One is reminded of Max Weber's claim that science is not a democracy but an "aristocracy" of merit[20]. What drove such a system was neither brotherliness nor solidarity, but agonistic combat. Winning was its own reward. The competition revealed in James Watson's *The Double Helix* is illustrative of this point.

Merton worked in an era dominated by the prestige of physics and chemistry, when knowledge could more easily be situated in a value hierarchy in which instrumental goals were deemed to be inferior to pure research. That Merton wrote his essay during the Second World War, when physics and chemistry had close ties with the pharmaceutical and defense industries, underscores the degree of idealism with which these claims were invested.

Clearly, Merton's norms never adequately captured the conflicting values embedded in scientific practice. Common access to information was always balanced by rules of secrecy, in that the latter served as a protective device against the appropriation of one's ideas by competing scientists. Personal reputations, as much as objective criteria of evaluation, have guided academic recognition. Likewise, the ability to raise funds from private and public donors has always been a gateway to scientific prestige[21].

Scientists themselves would be wise to revisit the meaning of "science as a vocation" in light of the shifting commercial and political conditions. Despite the much-publicized advances, as well as promises and prophecies, the supposedly traditional core principles and values of biomedicine have been scarcely publicly re-examined from within the field. We say "publicly" because nearly every scientist and technician today has faced practical decisions about where and how to situate themselves in this new mode of production.

Conclusions

At the turn of the millennium, life science's application in the marketplace has produced neither the revolution in medicine that its optimists hoped for, nor all of the bioethical crises its critics feared. But debates over such issues as human cloning, artificial reproductive technologies, and genetic engineering (applied to plants, animals, and humans) indicate an increasingly contested terrain. The marketing of biomedical knowledge has raised moral apprehension and regulatory demands[18]. The 'lay public' is no longer simply acquiescing to the opinions of experts and is more actively voicing its concerns and articulating agendas so as to shape, or at least inflect, how science is practiced, understood in the broadest terms[22]. This active role of the citizenry is itself a product of the new formation of science and commerce, as citizens exert pressure as investors (e.g., mutual funds) and consumers (in response to direct marketing) upon both public and private scientific direction.

A new framing of the biosciences is arising from the combination of dialogue and conflict among scientists, government agencies, and social groups over the proper scope of public oversight and the vital directions for future research and development. Such a development has the potential to benefit all parties concerned and to become an important determinant of the future of the life sciences.

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