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Jordan J. Cohen; Elisa K. Siegel

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Academic Medical Centers and Medical Research

The Challenges Ahead

Jordan J. Cohen, MD

Elisa K. Siegel, AB

THE PRESENT ERA OFFERS MORE promise for progress in medical research than ever before. Contemporary science has deciphered the human genome, discovered some of the potential of stem cells, and unleashed the power of information technologies. Any one of these 3 historic scientific achievements would have the potential to effect a fundamental transformation in medicine; their confluence has created unprecedented opportunity for spectacular breakthroughs in human health.

Ironically, the present era also presents more daunting challenges for the conduct of medical research than any previous generation of investigators has likely had to face. Consider the need to manage high (and often unreasonable) public expectations for lifesaving discoveries, the need to maintain public trust despite the suspicions aroused by financial conflicts of interest, the need to sustain the cultural norms of academe while partnering with industry to promote technology transfer, the obstacles to recruiting and retaining physician-scientists to pursue translational research, the widening gap between the costs of research and available funding sources, the unfunded mandates with which investigators and institutions must comply, and the need to transform an academic reward structure built to encourage individual scientists to pursue their own ideas into one that fosters teams of collaborating investigators to pursue “big science.”

Although the present era offers more promise for medical research progress than ever before, academic medical centers also face more daunting challenges for the conduct of medical research: high expectations by the public for a steady stream of lifesaving discoveries, news about financial conflicts of interest and scientific misconduct by researchers that threatens to erode public trust in academic institutions, tensions between the cultural norms of academe and industry that cloud their growing partnerships, obstacles to recruiting and retaining physician-scientists, constrained funding sources and increasing costs of research, and the need to transform the academic reward structure and culture to encourage collaboration and adapt to the new “team science.” The interconnectedness of these challenges magnifies their difficulties and importance. Maintaining academic medicine’s integrity and effectiveness in pursuing its vital research mission will be a crucial challenge for medical schools and teaching hospitals in the years ahead.

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This article will explore each of these challenges and suggest ways that the academic medical community can meet them.

Promoting Public Understanding

Managing public expectations and promoting public understanding about the promise and the reality of medical research is an age-old challenge. The complexity of modern science and the seeming proximity of powerful new approaches to improving human health have heightened the need for the academic community to address this challenge effectively. Having raised expectations with tantalizing promises of scientific breakthroughs, the research community has an obligation to help the public understand the process of medical research and the often uneven and incremental pace of progress that characterizes most medical discoveries.

Raising expectations of medical breakthroughs is a tried and true way to spark public support that has worked well as a strategy for increasing the national investment in medical research. The returns on this investment will surely come, but the dangers of hyping the pace of progress and overselling the impact of the advances can only result in public cynicism in the long run. A 2004 Association of American Medical Colleges (AAMC) opinion poll indicated that half of the congressional staff and registered voters surveyed expected the recent doubling of the National Institutes of Health (NIH) budget to result in new innovations and cures within the next 3 to 10 years.¹ Should those expectations not be realized, continued public support for hefty

Author Affiliations: Association of American Medical Colleges, Washington, DC.

Corresponding Author: Elisa K. Siegel, AB, Association of American Medical Colleges, 2450 N St NW, Washington, DC 20037 (esiegel@aamc.org).

taxpayer investments in medical research could well decline.

Managing public expectations is made more difficult because the public receives most of its information about medical research progress through the filter of the news media. Because the media has a strong tendency to sensationalize reports, the latest discovery is often hailed as a medical breakthrough, and new information that contradicts previous understandings is often highlighted as a controversy. Although the former can lead the public to overinterpret the significance of new medical discoveries, the latter tends to portray scientists as vacillating and uncertain. Ultimately, contradictions can lead to public confusion about a particular area of research, and left unaddressed, confusion can spiral into anger and, ultimately, distrust.²

Perhaps nowhere is the need for circumspection greater at the present time than in the area of stem cell research. The news in May 2005 that South Korean scientists had developed an efficient way to produce individual-specific embryonic stem cell lines³ understandably excited the hopes of patients and the imagination of scientists around the world. But little effort was made to balance that excitement with cautionary reminders about the tremendous amount of work still to be done before the promise of stem cell cures becomes a reality.

Academic medical centers, as sources of much of the advances in medicine, have a special role to play in managing the public's expectations and can do so by ensuring that public communications about their research developments are tempered with realistic assessments of their practical impact. For example, when announcing news of medical discoveries, scientists and institutional press officers should make every effort to explain the finding in understandable terms, resist the temptation to overstate the importance of the discovery, and attempt to place the discovery within a broader context so that journalists who report the news have less cause to sensationalize it.

Sustaining Trust

The successful conduct of medical research in a free society depends on trust between the scientific enterprise and the public, trust in the integrity of the discovery process, and especially trust in the safety of patients and healthy volunteers who participate in the process. In recent years, this essential trust has been shaken by a number of highly publicized events: tragic deaths of patients enrolled in clinical trials,⁴ high-profile allegations of financial conflicts of interest,⁵ and scientific misconduct by a few investigators.⁶ In an effort to shore up public trust, medical schools and teaching hospitals,^{7,8} government regulators, and patient advocacy groups have implemented a number of actions throughout the past decade to improve and strengthen the protection of human subjects who participate in medical research and to strengthen the management of financial conflicts of interest.

Protection of Human Subjects in Clinical Research

Maintaining strong safeguards for the safety of human subjects in medical research is a paramount obligation of clinical investigators and their institutions. Institutional review boards (IRBs) are the heart of the protection regime; they are responsible for reviewing all clinical and translational research conducted at their respective institutions and for making ethical determinations that risks to human subjects have been minimized to the greatest extent possible; risks are reasonable in relation to anticipated benefits, if any; and the risks, benefits, and alternative options are clearly communicated to the potential participants in the informed consent process.

Since 2002, institutions have had the opportunity to participate in a voluntary accreditation process and, thereby, to have their human research protection programs, including IRBs, assessed against rigorous national standards.⁹ To date, nearly 80% of medical schools are preparing, have applied for, or have achieved accreditation of their

human research protection programs (Marjorie Speers, oral communication, June 9, 2005 [AAMC is a founding member and financial supporter of the Association for the Accreditation of Human Research Protection Programs]).

Although this willingness to be scrutinized by accreditors clearly evidences a commitment to "doing it right," academic medical centers nevertheless find themselves challenged by a costly, heavily prescriptive IRB process that consumes substantial amounts of limited faculty time and that requires substantial education of IRB staff, IRB members, and investigators. The importance of sustaining an unflagging commitment to the IRB process cannot be overestimated, yet the where-withal to do so is likely to be a continued struggle for the research community. As calls increase for rapid translation of scientific discoveries into human benefit, ensuring that research on human subjects is conducted within a rigorous ethical framework that is transparent and credible has never been more urgent.

Managing Financial Conflicts of Interest

Financial conflicts of interest on the part of investigators and their institutions have the potential both to undermine the integrity of the scientific process and to compromise the safe conduct of human research. Concerns about how well the research community monitors and manages financial conflicts of interest have flared in the past year, sparked by media reports and congressional unhappiness about the financial dealings of several prominent NIH scientists and administrators. The recent publication of several books documenting conflicts arising in the relationships between universities and industry, focusing particularly on academic medical centers,¹⁰⁻¹² attests to the public's interest in maintaining the independence of academic institutions and their faculties from inappropriate financial influences.

Although institutions conducting federally funded research have been required for years to comply with conflict-

of-interest regulations,^{13,14} several organizations have recommended more stringent guidelines for this purpose.¹⁵⁻¹⁸ According to a 2004 AAMC survey,¹⁸ the academic medicine community has made substantial progress in moving beyond the minimum requirements prescribed by federal regulations to strengthen the safeguards against conflicts of interest in human research. However, this survey also revealed that the academic medicine community still has more work to do to establish a uniformly robust set of policies and procedures. For example, not all institutions have adopted a “rebuttable presumption” standard by which an investigator is presumed to be ineligible to conduct human subjects research in which he or she has a significant financial interest, unless that investigator is uniquely qualified to do so, and even then, only under carefully monitored conditions. Similarly, not all institutions explicitly prohibit payments for particular research results.¹⁸

Sustaining public trust in the medical research enterprise will, at minimum, require continued efforts to identify and address ways to improve the protection of human research subjects and to buttress the management of financial conflicts of interest.

Maintaining Academic Values

The interactions between academic medicine and industry have grown more numerous and more complex in recent decades. These interactions have been stimulated by growing public demands for the benefits of scientific discovery and by the increasing gap between the escalating costs of research and the availability to academic institutions of more traditional funding sources. By calling on the complementary expertise of both academe and industry, the resulting partnerships have greatly accelerated the translation of scientific discoveries into useful products and services and have provided much-needed additional financial support to the academic research enterprise. As an ancillary benefit, they have also exposed students, trainees, and

faculty to the unique talent and resources available in industry.

These academic-industry relationships can, however, have undesirable consequences. They can seriously distort academic values and directly threaten the integrity of research if they are not carefully managed and if policies for ensuring freedom from inappropriate influence are not rigorously enforced. Examples of the potentially damaging effects of academic-industry relationships include real or perceived pressures to relax scientific standards, inducements to become advocates (or shells) for industry, suppression of nonoptimal research results, incomplete or misleading descriptions and interpretations of trial results, and premature termination of clinical trials. Some academic institutions continue to accept contract language restricting traditional academic prerogatives in return for industry support of faculty research.

Much of the interaction between academic medical centers and industry has been encouraged by state and local governments, which view university campuses as venues for attracting new, high-technology industries. In addition the federal 1980 Bayh-Dole Act¹⁹ permits universities to retain title to patentable inventions developed with federal funds and gives universities further incentive to patent and license new technology. The Association of University Technology Managers recently reported that surveyed universities received a total of \$1.31 billion in licensing revenues in 2003, up 6.1% from 2002.²⁰ Under Bayh-Dole’s provisions and university policies, these funds are reinvested in institutions’ research and education programs. But even these welcome resources pose a challenge to universities, namely, that the incentives to patent and license new technologies do not result in a stifling of open scientific communication or impede the sharing of materials and data among academic colleagues. The NIH has demonstrated admirable leadership by prohibiting NIH-funded investigators from placing undue restric-

tions or requirements on access to research tools or other materials.²¹

Another growing concern related to academic-industry relationships is the potential for bias in the reporting of industry-sponsored research, which has led the editors of major journals to issue stringent standards for reporting clinical trial results and to affirm authorial accountability.²² Some editors have called for a mandatory clinical trials registry,^{23,24} and the NIH has finalized its proposal for enhanced public access to NIH-sponsored health-related research information.²⁵

Remaining faithful to the core academic values of objectivity, openness, and independence while engaging in industry-sponsored research is likely to become even more challenging, especially as academic institutions increasingly partner with community-based and ambulatory sites. Academic medical centers and their industry partners must be willing to adopt more uniform, more robust, and more transparent standards governing their relationships if the mutual benefits of those relationships are to be sustained.

Strengthening the Clinical Research Workforce

The relative paucity of physician-scientists has long been recognized as a significant bottleneck in the progression from the discovery of new knowledge to the clinical application of that knowledge. Given the accelerated rate of scientific developments, there is an urgent need to recruit, train, and retain a much larger number of physician-scientists. In responding to this need, however, medical schools and teaching hospitals must find ways to overcome the numerous obstacles known to discourage young physicians from pursuing careers in clinical and translational research. These obstacles include the increasing demand for clinical faculty to provide patient care services; the decreasing support from institutional or departmental sources to offset foregone clinical income; the uncertainty of sustained funding from the NIH or other sources; the ever-

increasing complexity and time required for regulatory compliance; and the perceived lower stature of clinical research in the academic culture, with consequent doubts about academic advancement.

In response to the report of the NIH Director's Panel on Clinical Research in 1997,²⁶ the NIH implemented initiatives to attract more physicians into clinical research careers. These initiatives included substantial investments in training and career development awards and new educational loan repayment programs for clinical investigators. Recognizing that these steps are insufficient by themselves to engender a robust clinical and translational research enterprise, the NIH recently announced its desire to work with the academic community to fashion a "transforming" initiative that will "provide the academic home and integrated resources needed to advance the new intellectual discipline of clinical and translational sciences, create and nurture a cadre of well-trained investigators, and advance the health of the nation by transforming patient observations and basic discovery research into clinical practice."²⁷

Medical schools and teaching hospitals have a responsibility to partner with the NIH and other federal agencies to provide the supportive institutional environment and rigorous training necessary to maintain high-quality clinical and translational research and to produce and nurture physician-scientists. The AAMC has launched a new taskforce (Clinical Research Task Force II) to formulate recommendations to academic medical centers and the NIH about the organization, funding, infrastructure, training, and community involvement of clinical and translational research that will best meet these goals.

Sustaining Research Funding

Without question, a major reason for the preeminence of biomedical research in the United States has been the availability of generous federal support throughout several decades, largely

through the programs of the NIH. The longstanding, bipartisan commitment to medical research and to the NIH was evidenced as never before in 2003 when Congress completed the doubling of the NIH's budget to nearly \$27 billion.²⁸ Unfortunately, many in Congress now view the completion of the budget doubling as "mission accomplished" for medical research, making it especially difficult at a time of staggering federal budget deficits to argue for continued large increases in funding for medical research. Indeed, since 2003, the NIH's budget has grown by less than the rate of inflation (as measured by the Biomedical Research and Development Price Index),²⁸ and the prospects for the near future appear equally dim. As a consequence, the research community must adjust its expectations and will be hard pressed to take full advantage of the opportunities created by recent investments.

Compounding this restrictive fiscal climate are the increasing costs of modern science and of complying with the ever-increasing burden of government regulations. In recent decades, the federal government has, through legislation and regulation, increased institutional cost sharing by shifting more expenses to awardees and by mandating costly new regulations. Particularly problematic has been the Office of Management and Budget's imposition of an arbitrary 26% cap on the recovery of administrative expenses on research grants to academic institutions,²⁹ despite the additional administrative burdens of meeting ever more demanding regulatory and reporting requirements. Among the requirements are those related to disposal of hazardous waste, increased monitoring of laboratory health and safety, animal welfare regulation, HIPAA (the Health Insurance Portability and Accountability Act), and the Patriot Act and related Homeland Security measures.

A recent survey of 25 academic institutions conducted by the Council of Governmental Relations (COGR) to determine the amount actually required to comply with existing and new regulations projected that the surveyed insti-

tutions would spend approximately \$411 million from 2000-2005, or \$16.5 million per institution, on new "incremental" compliance activities.³⁰ Average incremental expenditures per institution were estimated to have increased from \$1.8 million in 2000 to \$4.1 million in 2005. Extrapolating from their sample, COGR estimated that the compliance-related expenditure would exceed \$1.2 billion for the 100 research institutions that received the most federal funding.³⁰ These findings are consistent with those of an earlier study by RAND that examined facilities and administrative (F&A) costs associated with federally sponsored research. RAND reported that the federal government, because of cost-shifting arrangements, such as the 26% cap, actually provides academic institutions with no more than 70% to 90% of the total F&A expenses otherwise eligible for reimbursement.³¹

In addition to the burden of unreimbursed F&A costs, institutions also must bear the expenses triggered by other federal actions, such as the legislated cap on salary levels reimbursable by NIH grants that is below actual salaries paid to many investigators, including many physician investigators; caps on stipends for predoctoral and postdoctoral fellowships and training grants that are set below the levels many institutions must provide to remain competitive; and limitations on the recovery from federal grants of graduate student tuition costs at levels below that charged by many institutions. The cumulative effect of these actions has been the transfer to awardee institutions of even more of the legitimate costs of conducting federally sponsored research.

The White House Office of Science and Technology Policy and Office of Management and Budget have undertaken a cross-agency initiative to identify more efficient business models and to streamline agency requirements for federally sponsored research,³² giving rise to some hope that the federal government will at least partially restore the balance of responsibility that formerly characterized the historic federal-

academic partnership in the country's research enterprise. If some relief is not forthcoming, some institutions may find it impossible to sustain their sponsored research programs.

Adapting Academic Structures and Culture

A final category of challenges facing academic medical centers is the need to adapt to the changing nature of biology and biomedical research. Arguably the most urgent need is to reconcile the ways in which research institutions recruit and reward investigators with the evolving demands of contemporary science. Traditionally, investigators (in the life sciences, at least) have been valued and rewarded for their success as individuals. The prototypical medical scientist acquired independent funding by competing for investigator-initiated grants and conducted hypothesis-driven experiments in self-contained environments as a leader of a small group of graduate students, postdoctoral fellows, and technicians. The success of this "cottage industry" model is evident in the remarkable achievements of 20th-century biomedical research and is reflected in the deeply rooted cultural norms that now characterize academic medical centers.

As modern medical research has evolved, the once distinct margins between disciplines have blurred. The individual investigator often is unable to tackle the most promising questions without collaborating with scientists in other disciplines, other schools, even other institutions. A common example is found in modern genetics research. With the availability of methods to clone and sequence DNA, much of genetic research has become dependent on information science and the new discipline of computational biology.^{33,34} Dealing effectively with massive quantities of data demands the expertise of mathematicians, physicists, computer scientists, engineers, and others.

Exploiting the scientific potential of such advances requires collaborative, team-based research strategies.^{35,36} The NIH's recently announced "roadmap"

for medical research, for example, calls for greater emphasis on collaborative research teams to augment the work of individual scientists.³⁷

Evidence suggests that biomedical research is, indeed, moving in the direction of more collaborative, team-based, and interdisciplinary efforts. From 1981-1999, the number of authors per scientific paper increased from an average of 2.8 to 4.3 in biology and from 3.3 to 4.6 in medicine, while the number of university affiliations per scientific paper increased from an average of 1.4 to 2.1 in biology and from 1.5 to 2.0 in medicine.³⁸ Evidence also demonstrates that biomedical research centers and institutes are more interdisciplinary than a generation ago, as measured by the number of departmental collaborations in scientific work and the ways in which investigators interact.³⁹

A challenge for academic medical centers in moving toward greater collaborative and team-based research is how to modify their deeply engrained promotion and tenure processes. In a series of interviews conducted in 2004 by AAMC researchers at 6 research-intensive medical schools, university presidents, provosts, department chairs, and junior faculty members alike cited the academic rewards system as one of the most important barriers in encouraging more team-based and collaborative scientific research. The comments by a vice-dean for research are illustrative: "Many young people on the tenure track are discouraged from collaborating, period, because they have to demonstrate their independence. . . . Most [department] chairs would advise their faculty members not to collaborate until they are established." Junior faculty echoed that viewpoint: "Unless or until I hear from the top that it's good to work across boundaries," said one assistant tenure-track professor, "interdisciplinary research won't happen. I need to hear it from the department and dean level."

As indicated by these results, promotion and tenure committees still typically focus primarily on evidence that an investigator has made substantial in-

dependent contributions to the intellectual fabric of his or her discipline. The conventional wisdom is that evidence of collaboration is often ignored, if not outright disdained.

To face these realities, academic medical centers will have to encourage a cultural shift on the part of deans, department chairs, and tenure review committees to embrace broader pathways of career advancement. Academic leaders and promotion and tenure committees will need to develop methods to identify and recognize important contributions in team and collaborative settings. In addition, as more investigators from medicine, engineering, computer science, physics, and other areas cross disciplinary boundaries, deans and department chairs will need to modify divisional cultures and expectations so that the best multifaceted scientific investigators can succeed and thrive, regardless of the locus of their primary faculty appointment.

The dominant attitude favoring the "independent" investigator over the collaborator within the academic institution is mirrored and reinforced by established practices among scientific journals and funding agencies. Many journals still adhere to the traditional mode of listing multiple authors in a sequence, leaving the reader to surmise that the first or last in the sequence made the principal intellectual contribution. Some journals have begun to describe specific author contributions at the end of an article, a practice that should help promotion committees and others evaluate individual contributions more equitably and that should help reduce the barrier to interdisciplinary collaboration.

Funding agencies have also been slow to adopt practices that encourage collaborative research. Typically, a single principal investigator is assumed to be the dominant driving force behind a grant application. The Office of Science and Technology Policy's recent directive to federal research agencies⁴⁰ to accommodate the recognition of 2 or more principal investigators on research grants and contracts is an en-

couraging sign and should also help reduce the barriers to collaborative research.

Conclusions

Academic medical centers face many difficult challenges in pursuing their research mission, and the interconnectivity of those challenges magnifies the difficulty. The ability to nurture and sustain a vibrant clinical research workforce in the future is heavily dependent on the ability to shift the academic culture and reward system away from the traditional paradigm focused on the individual investigator in favor of one that

is more collaborative, team-based, and interdisciplinary. The ability to sustain financial support for medical research in the face of constrained federal and state budgets is heavily dependent on managing unrealistic public expectations and on maintaining public trust. The ability to benefit optimally from the growing relationships with industry is heavily dependent on remaining true to fundamental academic values, including the safety of human subjects research, the integrity of the scientific process, and the free exchange of research results. The degree to which medical schools and teaching hospitals are suc-

cessful in meeting these challenges will determine the degree to which the historic promise of modern medical science will be realized.

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