Chapter 2
What Are the Promises and Challenges of Scientific Integration?

Elias A. Zerhouni, M.D., Director, National Institutes of Health

Dr. Zerhouni leads the nation's medical research agency and oversees the NIH's 27 Institutes and Centers with more than 18,000 employees and a fiscal year 2006 budget of $28.6 billion.

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Could you address the challenges and opportunities you see in terms of Integrated Science and the National Institutes of Health?

When future historians look back upon our era, they will see it as a pivotal moment, with humanity at a crossroads. Poised between nature, science, and a multiplicity of societies, we – the actors of tomorrow's historical accounts – look out upon an exciting but uncertain horizon. The completion of the Human Genome in 2003 has placed within our grasp a map of our own architecture – the "book of life." Computer technologies allow us to process unimaginably large amounts of data and share the results with each other, instantaneously, almost anywhere on the globe. In these and so many other instances, we live in a world "made flat" by our knowledge. [1] Yet, we need not look far to see that our successes have given rise to new challenges. Technologies that allow modern civilization to thrive are also warming the planet. World populations, too, are on the rise – particularly in places that economic "flattening" has neglected. All around the world, chronic diseases are becoming epidemic, and infectious diseases stubbornly resist our best efforts at containment. Our knowledge has, in the prophetic words of Francis Bacon, given us power: for better, and for worse.

Today, poised at a historic crossroads, we are finally in a position to actualize the second, if lesser known, part of Bacon's famous phrase: "Nature to be commanded must be obeyed." To preserve Nature – be it the environment, or human nature – we must follow Nature's rules. We may still have some way to go in our efforts to understand those rules in general, and the rules of living systems in particular. Yet, we appreciate more fully than ever before the complexity of those systems. We are beginning to recognize that we cannot simply follow the traditional paths of science – as successful as they have been – if we hope to understand nature and effectively address the many challenges we face. We must chart a new course, forge new paths. An integrated approach to science must be our guide.

In the effort to forge these new, integrated paths for biomedicine, the National Institutes of Health is uniquely situated to take a pioneering role. NIH is the world's pre-eminent medical research center and the steward of medical and behavioral research for the Nation. With a $29 billion dollar Federal budget, NIH supports peer-reviewed research at universities, medical schools, hospitals, and research institutions throughout the U.S. and the world. It conducts research in its own laboratories, trains research investigators, and disseminates science-based health information. Only a single institute in 1930, NIH evolved, with Congressional directives, to the 27 Institutes and Centers of the present day. NIH breakthroughs have transformed medicine, and NIH trainees or grantees have garnered 122 Nobel prizes.

NIH's achievements have been grounded in its successful adaptation of modern biomedicine's finest principles and practices. Each of its 27 Institutes and Centers focuses on a set of diseases, disorders, or bodily systems that reflect society's most

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[1] Thomas L. Friedman, *The World is Flat: A Brief History of the Twenty-First Century* (New York: Farrar, Straus and Giroux, 2005).

pressing medical concerns. Within this "intramural" program, NIH researchers conduct cutting-edge, often long-term, research. Many draw upon the NIH Clinical Center – the Nation's largest hospital devoted entirely to clinical research – in their efforts to bring the latest laboratory discoveries to bear on a variety of intractable patient conditions. Moreover, the NIH extramural grants program, now in its 62nd year, relies on its unparalleled peer review system to determine the most promising research projects outside NIH, and to fund those projects with few constraints. The NIH peer review system, which continues to be a model the world over, has periodically been retooled to better fit changing times. Yet, at its heart, it continues to adhere to one of modern medicine's greatest lessons. In the words of Vannevar Bush – echoing Louis Pasteur: "The history of medical science teaches clearly the supreme importance of affording the prepared mind complete freedom for the exercise of initiative." [2]

Clearly, this bedrock of biomedical progress must be preserved. At the same time, today, efforts to prevent, detect, and treat disease demand that we better understand the dynamic complexity of the many biological systems of the human body and their interactions with our environment at several scales – from atoms, molecules, cells, and organs to body and mind. A dizzying array of parts participates in intricate and interwoven pathways that, together, contribute to health. Research is just beginning to converge on unifying principles that link apparently disparate diseases through common biological pathways and therapeutic approaches. Today, and in the future, biomedical research must reflect this new reality. Advanced technologies, including sophisticated computational tools and burgeoning databases, likewise span diseases and disciplines. The scale and complexity of our multi-faceted biomedical research problems increasingly demand that scientists move beyond the borders of their own disciplines and apply new organizational models for team science.

The fit between this emerging biomedical reality and traditional biomedical research – the latter resting as it does on individual researchers, distinct diseases, independent disciplines and institutions, and a curative approach to disease that intervenes only *after* symptoms have become manifest in a patient – is far from perfect. How, then, can NIH integrate these related but still divergent perspectives? Upon becoming the NIH Director in 2002, I devoted myself to working with my colleagues to find solutions. These solutions have taken the form of the NIH Roadmap for Medical Research.

How was the Roadmap constructed?

The NIH Roadmap began with a series of conversations: with directors of NIH Institutes, Centers, and programs; with legislators and members of the American public, who had supported a 5-year doubling of the NIH budget (completed in the 2003 fiscal year [FY]); with patient advocacy groups; and with scientific leaders at

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[2] Vannevar Bush, *Science, the Endless Frontier* (Washington, D.C.: U.S. Government Printing Office, 1945).

institutions around the country. These conversations underscored the need for NIH to reexamine its portfolio, with a goal of identifying critical scientific gaps that it might help fill. Among these gaps was the difficulty that NIH itself faced when it sought to support cross-cutting research programs that fell outside the scope of any one NIH Institute or Center. More conversations – and discussions – followed. My colleagues at NIH and I consulted with hundreds of nationally recognized leaders in academia, industry, government, and the public. Where, we asked, should biomedical research be headed? What were the roadblocks that obstructed its path? In answer to these questions, we introduced the NIH Roadmap in the fall of 2003.[3]

The Roadmap was organized around three major themes: New Pathways to Discovery, Research Teams of the Future, and Reengineering the Clinical Research Enterprise. The three themes are mutually reinforcing and, as they develop, become increasingly convergent. Working groups, each led by Institute directors and with input from the NIH Council of Public Representatives and the Advisory Committee to the Director, determined an array of potential initiatives related to these themes. Their suggestions were further refined and, from them, we chose the initiatives that would represent the first round of Roadmap initiatives in FY2004. We strongly believed that their successful implementation would allow NIH to more effectively support innovative and high-risk research, incubate new ideas, and stimulate the development of transforming strategies that could benefit the entire scientific community.

Initially, each NIH institute contributed 1% of its budget to fund the Roadmap. In December, 2006, Congress, recognizing the initial success and future promise of the Roadmap, responded to these integrative efforts by authorizing a "Common Fund" within the Office of the Director to provide stable support for Roadmap programs. President Bush signed the "NIH Reform Act of 2006" into law in the following month.

Teams

One of the Nation's most pressing challenges is to generate and maintain the trained and creative biomedical workforce necessary to tackle the converging and daunting research questions of this century. NIH is actively experimenting with building research teams of the future through the Roadmap.

Interdisciplinary Research

To lower artificial organizational barriers and advance science, the Roadmap established a series of awards that makes it easier for scientists to conduct interdisciplinary research. These new awards support an array of initiatives. They promote, for example, the training of scientists in interdisciplinary strategies, the creation of specialized centers that help scientists forge new, more advanced disciplines from

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[3] Elias Zerhouni, "The NIH roadmap," *Science* 302 (2003): 63–64; 72.

existing ones, and the planning of forward-looking conferences with the potential to catalyze collaboration among the life and physical sciences – important areas of research that historically have had limited interaction.

The largest component of the Roadmap's interdisciplinary research program is the Interdisciplinary Research Consortia. Launched in 2007, the Consortia employ interdisciplinary approaches to medical problems that have proved resistant to solutions from single-, or even multi-disciplinary approaches. (Whereas *multi*disciplinary research involves teams of scientists approaching a problem from their own discipline, *inter*disciplinary research *integrates* elements of a wide range of disciplines so that all of the scientists approach the problem in a new way.) [4] Each consortium adopts one general medical problem for particular attention. Presently, Consortia members are investigating problems that range from ways to preserve fertility in women with cancer and methods for deciphering the basis of neuropsychiatric disorders to strategies for devising a coordinated and systematic approach to regenerative medicine and obesity. In addition to addressing these particular medical problems, Consortia members are contributing to the development of a medical culture that is more open to interdisciplinary teamwork.

In addition to funded initiatives, the Interdisciplinary Research initiatives include non-funded projects that aim to change NIH policies and procedures. Chief among these is a reconsideration of how NIH should best recognize leadership of collaborative projects. We have seen that NIH has followed the traditions of modern medicine by singling out one "Principal Investigator" (PI) as the guiding mind behind each award. This policy, however, effectively acts as a roadblock to funding truly interdisciplinary team projects. In response, NIH has moved toward recognition of *multiple* PIs for any award. Moreover, interdisciplinary research tends to resist fair evaluation by review groups that have largely been cast along standard disciplinary lines. Consequently, we have analyzed review strategies that are better able to assess interdisciplinary research proposals. These Roadmap projects have also helped inform the larger, recent NIH-wide effort to reconsider how we conduct the scientific review of all NIH grant applications.

Director's Pioneer and New Innovator Awards

At the same time, traditional review groups have on occasion displayed conservative tendencies that discourage certain kinds of *individual* investigators: particularly, those who propose pioneering projects considered to be high-risk, and those who are new to the field and consequently lack detailed substantiating data and a proven track record. The work of both groups is essential to the future of biomedical research and must be preserved and encouraged. Therefore, the Roadmap offers two

[4] Committee on Facilitating Interdisciplinary Research and the Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, Institute of Medicine of the National Academies, *Facilitating Interdisciplinary Research* (Washington, D.C.: The National Academies Press, 2004).

programs designed to achieve this end: the NIH Director's Pioneer Awards and the New Innovator Awards.

Winners of the highly selective Pioneer Award are scientists of exceptional creativity who propose highly innovative approaches to major contemporary challenges in biomedical research. By bringing their unique perspectives and abilities to bear on key research questions, these visionary scientists may develop seminal theories or technologies that will propel fields forward and speed the translation of research into improved health. Since the program started in 2004, there have been 47 awardees; already, their work is producing impressive, and potentially transformative, results. One awardee is using a multi-disciplinary approach to understand the principles governing T cell-mediated autoimmunity. The research could lead to new ways to predict or preempt autoimmune diseases such as multiple sclerosis or type 1 diabetes. Another is employing antigenic cartography to map differences in seasonal influenza strains worldwide: knowledge that could significantly improve our ability to track the influenza virus and select proper strains for vaccine preparation. [5]

The Director's New Innovator Awards support exceptional new investigators who have not yet received an NIH R01 grant, but who take particularly innovative approaches to biomedical or behavioral research. One Innovator awardee is researching the role of the *in utero* environment on the development of childhood obesity. Using state-of-the-art biological analysis technology, another Innovator awardee is developing a method for personalized diagnosis of a form of brain cancer known as glioblastoma multiforme. If validated, this technology could guide therapy decisions to the agents that would be most effective for the individual patient.

The creative scientists we recognize with NIH Director's Pioneer Awards and NIH Director's New Innovator Awards are well-positioned to make significant – and potentially transformative – discoveries in a variety of areas.

Public–Private Partnerships (PPPs)

Another way the Roadmap encourages the creation of teams that cut across traditional boundaries is by fostering Public–Private Partnerships (PPPs). PPPs offer an opportunity to integrate several critical aspects of science capable of moving us into the future. Indeed, the vision of a personalized medicine – medicine that is able to promote health by personalized risk assessment and prevention, ameliorate disease by timely and effective interventions, and avoid toxic or morbid side effects of treatment by sensitive prediction – can only be promoted by combining the resources, insights, and tools of the public and private sectors.

Why partnerships? Scientific research is increasingly expensive, and PPPs allow for cost sharing across sectors. Science is increasingly complex, and PPPs permit early and substantive sharing of planning and implementation inclusive of scientists, clinicians, regulators, manufacturers, and the public. In this way, PPPs – properly

[5] NIH Roadmap for Medical Research, "Science News About Pioneer Awardees," http://nihroadmap.nih.gov/pioneer/AwardeeScienceNews.aspx

configured – facilitate faster and more efficient scientific work, thereby hastening the translation of discovery to benefits in public health.

Cost sharing can be understood in terms of leveraging the considerable public investment in research and promoting the effective translation of government-supported discovery to clinically available therapeutics and interventions. Examples of translation via technology transfer are numerous. They include the development of breast cancer drugs such as Taxol (whose use in this tragically common and important disease was developed in NIH's intramural research program) and the development of coated stents for use in angioplasty. The cost of commercialization and of meeting regulatory requirements was undertaken by private companies, thus making these benefits available to the public.

PPP: The Biomarkers Consortium

Another advantage to PPPs is that their multi-sector teams generate a unique form of synergy. Such synergy can offer novel solutions to vexing clinical problems, including the assessment of individual patients, the development of effective drugs, and the complications of navigating the regulatory review and approval process. The Biomarkers Consortium is a PPP that promises to generate just such synergistic solutions.

Biomarkers are measures of some aspect(s) of health or disease. "Biomarkers" comprise a wide array of biological indicators that can serve to identify risk, define diagnosis, stratify patients, predict outcomes, or signal response to therapy or progression of disease. Similarly, they can be measured by a wide variety of methods and platforms, including, for example, biochemical measures of protein or nucleic acid; images such as those collected from X-rays, MRIs or molecular imaging; and functional measures of immune system response or past exposures. Applying biomarkers in clinical practice or drug development requires the coordination of a wide range of basic, clinical, and regulatory scientific principles and processes. There must be a body of agreed upon standards for collection, measurement, and interpretation in specific contexts. A consortium including all such expertise, working within a coordinated and collaborative framework, facilitates the discovery, development and regulatory qualification of biomarkers.

The Biomarkers Consortium (BC) – one of the first partnerships supported by the Roadmap's PPP program – was established in October, 2006. The Foundation for NIH serves as the managing partner of this large and complex PPP; founding partners include NIH, FDA, and PhRMA; as well as CMS, BIO, numerous drug and biotechnology companies, academia, patient advocacy groups, and professional societies. Much care was devoted to developing a consortium structure and policies attentive to concerns about protecting the public health, working in a pre-competitive fashion, and developing public biomarker resources. Moreover, BC polices explicitly addressed ways to protect the public, and partners, from conflicts of interest and antitrust issues.

The BC's initial projects are currently under way; they include qualification studies relating to the use of FDG-PET imaging in non-small cell lung cancer and

lymphoma. Projects evaluating the use of carotid MRI in atherosclerotic disease and in assessing the role of adiponectin as a marker of treatment response in diabetes are about to begin. Some 30 to 40 additional projects in areas of oncology, neuroscience, immunity and inflammation, and metabolic diseases, have been approved; still other specific project plans and associated agreements are being developed.

The promise of the BC lies not only in the anticipation of having a wider array of available qualified biomarkers for clinical and regulatory uses, but also in its role as a template for large multi-sector partnerships promoting cross-disciplinary science in a speedy and efficient manner. Partnerships are not likely to serve all purposes: basic discovery, for example, is not a reliable investment for industry, and its utility for specific diseases cannot always be predicted. For activities representing shared aims and goals, and where alignment of business principles and practices can be arrived at, PPPs offer a powerful approach to leveraging partners' investments through synergy.

The growing ties between academia and industry are leading to productive collaborations and innovations in healthcare. Academic stars routinely turn entrepreneurial, and private industries and venture capitalists constantly seek potentially valuable basic science breakthroughs worthy of support. These exciting trends also pose a serious challenge: how do we manage the conflicts of interest created when researchers develop economic stakes in their research? Conflicts of interest can undermine public confidence in scientific data and policy recommendations. They have also been shown to subtly influence even the most honest of people. For the Federal employees at NIH, we have adopted stringent restrictions on conflicts of interest. But for our grantees in universities and institutes around the country, we take a more nuanced approach.

The biomedical research community recognizes that some of the most knowledgeable experts in many fields have experience in both the public and private sectors. "Wearing both hats" may grant them unique insights into how to translate basic research into viable healthcare interventions. Further, one could argue that allowing great researchers to benefit financially from their own discoveries may not only be fair, but may also provide incentives to increase productivity. The risks of *excluding* more entrepreneurially inclined scientists from the research enterprise may well outweigh the risks of letting them continue to conduct research. However, the relative risk depends on how well the biomedical research enterprise can identify and manage conflicts. We are working diligently with scientists, universities, stakeholder groups, the Institute of Medicine, and policy makers to develop strategies to appropriately deal with conflicts of interest – to optimize the balance between maintaining the public trust and maximizing the public benefits of NIH research.

Tools

Of course, all the teamwork in the world would not take biomedicine very far if its teams weren't equipped with the tools needed to translate ideas into actions. In today's biomedical research labs, tools and technologies are being imported from

an impressive spectrum of sciences, and finding new applications in the process. At the same time, biomedical needs are helping to shape new technologies. "Necessity" and "invention" play mutually reinforcing roles in the advance of today's biomedicine. The NIH Roadmap encourages this process by supporting the development of tools that will facilitate cross-cutting biomedical research and quicken the pace of its translation into clinical applications.

Nanomedicine

Nanomedicine offers a striking example of the Roadmap's support of research tool development. "Nano" refers to a unit of measure: one nanometer equals one billionth of a meter. It is the scale applied to atoms and molecules. "Nanomedicine" is an offshoot of nanotechnology, which is based on fundamental discoveries in physics and chemistry that now allow us to manipulate atoms and molecules in order to create nanomaterials. Because of their small size, nanomaterials often have quite different properties than do their larger counterparts. These novel properties have promising biomedical relevance. Over the past few years, NIH established eight Nanomedicine Development Centers across the U.S. These collaborative centers are staffed with multidisciplinary teams including biologists, chemists, material engineers, clinicians, mathematicians, and computer scientists. Breakthroughs in nanomedicine are already being achieved as experts team up to devise novel nanomaterials that aid in drug delivery, serve as tissue scaffolds, or enhance imaging scans in patients.

Structural Biology

A healthy mind and body require the coordinated action of billions of proteins – molecular workers that build our cells and even allow us to think, smell, eat, and breathe. Proteins have unique three-dimensional shapes that allow them to accomplish their particular tasks. A protein's shape is so essential to its ability to function properly that a structural error in even one protein can have major health consequences. How, then, can medicine help ensure that such errors do not occur?

Answering this question has proven to be as difficult as it is critical. Efforts to study the structures of protein membranes have been only occasionally successful. A limiting step in determining protein structures is our inability to produce purified samples of the proteins in quantities sufficient for analysis. Proteins that are tightly bound to the membranes of our cells have been the most difficult to study. Yet, membrane proteins not only account for about 30% of the proteins in a cell, but they also turn out to be one of the most important classes of proteins for health. Moreover, they are major drug targets for the development of disease treatments. These proteins were therefore chosen for special Roadmap attention.

The Structural Biology Roadmap program is a strategic effort to create a "picture" gallery of the molecular shapes of proteins in the body. This will require the development of rapid, efficient, and dependable methods to produce protein samples that scientists can use to determine the three-dimensional structure of a protein. Once developed, these methods will streamline and systematize research efforts,

producing a routine that will help researchers clarify the role of protein shape in health and disease.

During the first phase of the Structural Biology Roadmap (FY2004–2008), the NIH Roadmap funded two Centers for Innovation in Membrane Protein Production that enabled interdisciplinary groups of scientists to develop innovative methods for producing large quantities of membrane proteins. In addition, a number of small exploratory (R21) and regular research grants (R01) were awarded to individual investigators to broaden the base of innovative ideas under development.

These investments have already produced considerable advances in methods and in solved structures. Most notably, researchers determined the structure of the beta-2 adrenergic receptor. This receptor, which is adrenaline's target, is also the target of numerous drugs. Moreover, it is a prime example of a large family of important cell regulatory molecules known as G-protein coupled receptors (GPCRs). GPCRs mediate our interactions with the world outside our bodies by detecting sensory perceptions such as light and taste; they are also essential to the maintenance of our internal environment, acting as relays for molecules such as neurotransmitters and hormones. So significant was this discovery that *Science* magazine listed it among its top ten breakthroughs for 2007. [6]

Thus far, however, most work has been done on relatively *simple* membrane proteins. Many membrane proteins are complex biological machines consisting of several interlocking proteins working together. To understand how these machines work – and to learn how to fix them when they don't – researchers need to view the protein complexes in several different orientations, mimicking the way these assemblies twist and bend inside living cells. NIH anticipates that scientists will require about a decade of intense work to achieve the project's most ambitious goal: the ability to routinely predict the shape and action of a biological machine from its DNA script. The next phase of the NIH Structural Biology Roadmap (FY2009–2013) will be devoted to developing the means necessary to achieve this goal.

National Technology Centers for Networks and Pathways

In the human body, all biological components – from individual genes to entire organs – work together to promote normal development and sustain health. This amazing feat of biological teamwork is made possible by an array of intricate and interconnected pathways that facilitate communication among genes, molecules, and cells.

Limitations of proteomics technologies often force investigators to treat dynamic systems as either static or as binary options between static states. As with early photography, current approaches to proteomics involve long exposures that capture broadly defined "images" such as "normal vs. diseased," "the yeast interactome," or "the nuclear pore complex." We are largely blind to the dynamics of systems which we know are not static but which must be treated as such at present because of

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[6] "Breakthrough of the year: the runners-up," *Science* 318 (2007): 1844–1849.

inadequate tools. Transient interactions, rapid changes in protein activity or location, and post-translational modifications control critical regulatory steps in biology, yet they are like a bird flying through the frame of a carefully composed long exposure: invisible.

New strategies complementary to conventional proteomics are necessary to help us determine the rapid, dynamic changes that control physiology. The National Technology Centers for Networks and Pathways (TCNPs) create technologies to measure the dynamics of protein interactions, modifications, translocation, expression, and activity, and to do so with temporal, spatial, and quantitative resolution. The program is intended to bridge the quantitation and interaction aspects of proteomics, breaking out of the artificially static view of complex systems. [7] Five independent centers cooperate in a networked national effort to develop instrumentation, biophysical methods, reagents, and infrastructure for temporal and spatial characterization of complex biochemical pathways and networks of protein interactions. The centers are also tasked with providing broad access to the technologies, methods, and reagents they develop, as well as providing appropriate interdisciplinary academic and peer training for biomedical researchers.

National Centers for Biomedical Computing

Clearly, biomedical research is rapidly moving beyond the microscopes, test tubes, and Petri dishes that have been its defining tools. Sophisticated techniques adapted from physics, chemistry, and engineering enable scientists to use computers and robots to separate molecules in solution, read genetic information, reveal the three-dimensional shapes of natural molecules, and take pictures of the brain in action. All of these techniques generate large amounts of data, and there is no way to manage these data by hand. Biology is fast changing into a science of information management. What researchers need are computer programs and other tools to evaluate, combine, and visualize their voluminous data.

The NIH Roadmap program called the National Centers for Biomedical Computing was created to generate the software and data management tools to serve as fundamental building blocks for 21st century medical research. In this program, "big science" and "small science" work hand-in-hand to develop a system that will ultimately resemble the integrated software packages for office tools installed on most home computers today. This system will allow information to be traded seamlessly and cooperatively analyzed. It will allow our best minds to work together effectively to tackle unsolved mysteries – such as the role of heredity in individuals' different responses to medicines and the complex interplay of genetic and environmental factors in common diseases such as Alzheimer's disease, heart disease, cancer, and diabetes.

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[7] Douglas M. Sheeley, Joseph J. Breen, and Susan E. Old, "Building integrated approaches for the proteomics of complex, dynamic systems: NIH programs in technology and infrastructure development," *Journal of Proteome Research* 4 (2005): 1114–1122.

Patient Translations

The NIH's mission extends beyond the laboratory – even beyond laboratories boasting the latest technology and the most integrated approaches to science – and to the improvement of human health. In this still-young century, scientific discoveries have blended with the recent doubling of the NIH budget, justly raising public expectations for rapid progress in fulfilling this mission. Clinical research is a vital component of progress toward improving America's health. But while clinical research helps ensure that new treatments are safe and effective, it is a lengthy and sometimes inefficient process. Growing barriers between clinical and basic research, along with the ever-increasing complexities of conducting clinical research, are making it more difficult to translate new knowledge to the clinic – and back again to the bench. These challenges are limiting professional interest in the field and hampering the clinical research enterprise at a time when it should be expanding. The Roadmap supports an array of programs that aim to accelerate and strengthen clinical research by adopting a systematic infrastructure – from tools and training to discipline-building – that will better serve the evolving field of scientific discovery.

RAID and PROMIS

One roadblock to the safe and effective production of new therapeutic interventions lies in the limited availability of key resources. Two Roadmap initiatives – the NIH Rapid Access to Interventional Development (RAID) Pilot Program and the Patient-Reported Outcomes Measurement Information System (PROMIS) – have been devised to increase the availability of two key resources: funding and related support, and a uniform way of understanding and assessing patients' symptoms.

RAID provides funding and support for the development of novel therapeutic interventions for the treatment of uncommon disorders. While the translation of such interventions is sometimes facilitated by public–private partnerships, high-risk ideas or therapies for uncommon disorders frequently do not attract private sector investment. Where private sector capacity is limited or not available, public resources can bridge the gap between discovery and clinical testing so that more efficient translation of promising discoveries may take place. RAID is a pilot program that will make available, on a competitive basis, certain critical resources needed for the development of new small molecule therapeutic agents. Projects in both the early and late stages of pre-clinical development are suitable for NIH-RAID applications.

The PROMIS initiative is helping to overcome our limited ability to assess the symptoms that patients experience in response to therapeutic interventions for a wide array of disorders. Patient-reported outcomes (PROs), such as pain, fatigue, physical functioning, emotional distress, and social role participation, have a major impact on quality of life. Clinical measures of health outcomes, such as x-rays and lab tests, may have minimal relevance to the day-to-day functioning of patients with chronic diseases. Often, the best way patients can judge the effectiveness of treatments is by changes in symptoms. The goal of PROMIS is to improve the reporting and quantification of changes in PROs by developing a rigorously tested

measurement tool that uses recent advances in information technology, psychometrics, and qualitative, cognitive, and health survey research. In the process, the initiative is creating new paradigms for how clinical research information is collected, used, and reported.

Clinical and Translational Science Award Program

Aimed at generating new drugs, devices, and treatment options, the NIH "bench to bedside to community" enterprise is designed to break down the historic walls separating basic scientists, clinical researchers, and community practitioners. The reengineered home for these translational teams is supported through the Clinical and Translational Science Award (CTSA) program. Led by NIH's National Center for Research Resources, the CTSA program creates a definable academic home for the emerging discipline of clinical and translational science at institutions across the country. To create this home, the program encourages local flexibility, allowing each participating institution to determine whether to establish a center, department, or institute in clinical and translational science. In its first year, 2006, the program made awards to 12 academic health centers. When fully implemented in 2012, approximately 60 institutions will be linked together to energize the discipline of clinical and translational science. [8]

The members of this CTSA consortium are expected to serve as a magnet that attracts basic, translational, and clinical investigators, community clinicians, clinical practices, networks, professional societies, and industry to facilitate the development of new professional programs and research projects. We anticipate that these new institutional arrangements, coupled with innovative advanced degree programs, will foster the development of a new discipline of clinical and translational science – one that will be much broader and deeper than the classical domains of translational research and clinical investigation have been on their own. [9]

Expanding the Roadmap

The NIH Roadmap is intended to act as an *incubator* for innovative and interdisciplinary research. As such, it provides this research with an opportunity to grow, thrive and, eventually, to lead an independent existence. Initiatives are constantly reviewed and, over time, will be cycled out of the Roadmap. Consequently, NIH is continuously evaluating new directions for future initiatives. We recently added the Human Microbiome Project, which uses genomic technologies to illuminate the role of our resident microbes in health and disease. We are also funding a new initiative in epigenomics. Whereas epigenetics focuses on processes that regulate how and when certain genes are turned on and turned off, epigenomics studies epigenetic changes across many genes in a cell or entire organism. The epigenomics initiative

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[8] Clinical and Translational Science Awards Consortium, http://www.ctsaweb.org/

[9] Siri Carpenter, "Carving a career in translational research," *Science* 317 (2007): 966–967.

will build upon our knowledge of the human genome and help us better understand the role of the environment in regulating genes that protect our health or make us more susceptible to disease.

From Crossroads to Future Horizons

The NIH Roadmap for Medical Research was conceived in response to the challenges and opportunities of our time; and it has been forged by the ideals of integrated science. The broad outlines of its destination are evident. For biomedicine in particular, however, the Roadmap's ultimate destination is nothing short of effecting a new paradigm for medical practice.

Ever since the days of Hippocrates, medical practice has been driven by a goal of *curing* disease: symptoms develop, and a person, who has become a patient, seeks medical intervention to cure those symptoms. (If one counts the intervention of deities, the curative paradigm far predates the Hippocratic physicians.) Present-day scientific advances suggest that we can – and should – aspire to a new medical paradigm. In this paradigm, medical practitioners will use their deep understanding of living systems and disease processes to *predict* the course of disease in individual patients before symptoms ever strike. These practitioners will then *personalize* their (pre-symptomatic) interventions to fit the particular genetic, social, and environmental needs of each patient. This approach will only work if patients actively *participate* in their own healthcare – and if communities link people to clinical trials and medical institutions in a network of mutual support. Ultimately, this predictive, personalized, and participatory approach will usher in a new era of medical care: an era in which our knowledge will give us the power to *preempt* symptoms before they ever transform people into "patients." In other words, these "4 Ps" will bring about a shift from a *curative* to a *preemptive* medical paradigm. An integrated approach to science will be a fundamental driver of this shift.

I believe these advances in the life sciences will have applications that extend even beyond the improvement of human health. They will have significant applications to the interrelated ailments – from crop growth and energy supply to global warming – that threaten our planet. We must do all we can to pave the way for these advances – and we must do it now. If we succeed, those future generations of historians will look back upon us as sage stewards of our planet. Seen in this light, our failure cannot be contemplated.

James J. Duderstadt, President Emeritus and University Professor of Science and Engineering at the University of Michigan

Dr. James J. Duderstadt served as the President of the University of Michigan from 1988 to 1996. He currently chairs a number of national commissions related to federal science policy, higher education, information technology, and energy sciences and holds a university-wide faculty appointment as University Professor of Science and Engineering at the University of Michigan and as Director of the Millennium Project, a research center exploring the impact of over-the-horizon technologies on society.

Many have suggested that academic science, industry, and government should work together to find solutions to broad social problems. Dr. Duderstadt, how would you describe recent trends of convergence between the efforts of the academy, federal and state government, and industry?

The efforts of universities and faculty members to capture and exploit the soaring commercial value of the intellectual property created by research and instructional activities create many opportunities and challenges for higher education. Clearly

there are substantial financial benefits to those institutions and faculty members who strike it rich with tech transfer. In the 1980s, it was the "red Ferrari in the parking lot" syndrome, as the first signs of faculty wealth from tech transfer began to appear. In the booming days of the dot-coms, the more typical story is of the young assistant professor of computer science telling his department chair, "I'm going to take a one year leave of absence to start up a company. If I'm successful, I probably won't return, but at least you may get a million dollar gift out of me. If I'm not successful, then I'll return and see if I can get tenure." Or yet another faculty member, who informs his chair that he has set up a small foundation financed by his recent IPO, apologizing that his first gift will be only $10 million, but he expects his contributions to rise rapidly.

Each of these stories is true (although the Ferrari belonged to the wife of a professor who had struck it rich from a best selling textbook). But there are also many signs that the commercialization of intellectual property has its downside as well. Today scientists sign agreements requiring them to keep both the methods and the results of their work secret for a certain period of time. More than a quarter of US geneticists say they can't replicate published findings because other investigators will not give them relevant data or materials. There is growing evidence suggesting that industrial sponsorship actually influences the outcome of scientific work.[10] Universities are encountering an increasing number of conflict of interest cases, stimulated by the exploding commercial value of intellectual property and threatening not only institutional integrity but even human life in conflicted clinical trials.

In recent years, many universities seem to have adopted the attitude that "What is good for General Motors – or rather, consistent with the Bayh-Dole Act – is good for the country."[11] They recognize and exploit the increasing commercial value of the intellectual property developed on the campuses as an important part of their mission (and part of their reward as well, I might add.) This has infected the research university with the profit objectives of a business, as both institutions and individual faculty members attempt to profit from the commercial value of the products of their research and instructional activities. Universities have adopted aggressive commercialization policies and invested heavily in technology transfer offices to encourage the development and ownership of intellectual property rather than its traditional open sharing with the broader scholarly community. They have hired teams of lawyers to defend their ownership of the intellectual property derived from their research and instruction. On occasions, some institutions and faculty members have set aside the most fundamental values of the university, such as openness, academic

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[10] "Data Hoarding Blocks Progress in Genetics", *Science*, Vol 295, January 25, 2002, p. 599.

[11] Editor's Note: Enacted on December 12, 1980, the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs. This legislation was co-sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas.

freedom, and a willingness to challenge the status quo in order to accommodate this growing commercial role of the research university.[12]

But what is the public interest here? As Donald Kennedy has noted, " 'Public interest' has two translations. In the more technical, political science sense, it refers to those attributes of a venture or an organization that supports the larger society, benefiting the welfare of all the people. More colloquially, it can also mean what the public cares about, what it is interested in."[13]

Do you see an increase in the commercial activities of academic institutions, at either the federal or state level?

The Association of University Technology Managers[14] estimate that during FY2000 universities and their faculties collected more than $1 billion in royalties, created 368 spin-off companies, filed for 8,534 patents, and executed 3,606 licenses and options. While this royalty figure is some 40 percent higher than in FY1999, it includes several one-time events such as $200 million paid by Genetech to UCSF to settle a patent dispute and several universities cashing in their equity interest from earlier spin-off activities. Furthermore, it is also true while some universities benefited greatly from these commercial activities, most received less than $1 million in royalties, which was frequently not even sufficient to cover the costs of their technology transfer activities. Actually, from the earliest days of the Bayh-Dole Act of 1980, only a few inventions and discoveries have struck it rich for universities (e.g., recombinant DNA at UCSF and Stanford, Lycos at Carnegie-Mellon, carboplatin at Michigan State, and, of course, Gatorade at the University of Florida). In contrast, many individual faculty members have benefited considerably from equity interest in spin-off companies through IPOs and other financial events as my anecdotes in the introduction suggest.

At the level of the states, governments are sending public research universities clear signals to commercialize their discoveries in an effort to stimulate local economic development.[15] Nearly one-third of the governors have called on legislatures to pump money into campus research and tech transfer programs.[16] Several states

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[12] Eyal Press and Jennifer Washburn, "The Kept University", *Atlantic Monthly*, March, 2000, pp. 39–54.

[13] Donald Kennedy, *Academic Duty* (Cambridge: Harvard University Press, 1999).

[14] *Annual Survey of Technology Licensing Activity*, FY2000, Association of University Technology Managers; see also Goldie Blumenstyk, "Income from University Licenses on Patents Exceeded $1 Billion", *The Chronicle of Higher Education*, March 22, 2002.

[15] Peter Schmidt, "States Push Public Universities to Commercialize Research" *The Chronicle of Higher Education*, March 29, 2002.

[16] Here it is worth noting that my own state, Michigan, committed $50 million per year from their tobacco settlement payments to support biomedical research in a "Life Sciences Corridor" stretching from Detroit to Grand Rapids. However, it is also worth noting that Michigan was one of only three states choosing not to deploy any of the tobacco funds for their stated intent, to ameliorate teenage smoking.

have changed their laws to eliminate barriers to public-private collaboration, including giving for-profit companies unprecedented access to public university research facilities, while encouraging public universities and their employees to hold a financial stake in companies. Even conflict of interest and freedom-of-information laws have been throttled back to protect proprietary activities in nearly half of the states.

What about the effect of the market in influencing the direction of the university?

Today our society is evolving rapidly into a post-industrial, knowledge-based society, a shift in culture and technology as profound as the social transformation that took place a century ago as an agrarian America evolved into an industrial nation.[17] Industrial production is steadily shifting from material- and labor-intensive products and processes to knowledge-intensive products and services. A radically new system for creating wealth has evolved that depends upon the creation and application of new knowledge.

In a very real sense, we are entering a new age, an age of knowledge, in which the key strategic resource necessary for prosperity has become knowledge itself, that is, educated people and their ideas. Unlike natural resources, such as iron and oil, that have driven earlier economic transformations, knowledge is inexhaustible. The more it is used, the more it multiplies and expands. But knowledge is not available to all. It can be absorbed and applied only by the educated mind. Hence as our society becomes ever more knowledge-intensive, it becomes ever more dependent upon those social institutions such as the university that create knowledge, that educate people, and that provide them with knowledge and learning resources throughout their lives.[18]

This increasing economic value of the university and its products, along with other factors such as changing social needs, economic realities, and rapidly advancing technology, have created powerful market forces acting upon and within higher education. Even within the traditional higher education enterprise, there is a sense that the arms race is escalating, as institutions compete ever more aggressively for better students, better faculty, government grants, private gifts, prestige, winning athletic programs, and commercial market dominance. Faculty members, as the key sources of intellectual content in both instruction and research, increasingly view themselves as independent contractors and entrepreneurs, seeking ownership and personal financial gain.

With the emergence of new competitive forces and the weakening influence of traditional regulations, the higher education enterprise is entering a period of restructuring similar to that experienced by other economic sectors such as health care, communications, and energy. Higher education is breaking loose from the

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[17] Peter F. Drucker, "The Age of Social Transformation," *Atlantic Monthly*, November 1994, 53–80; Peter Drucker, "The Next Society: A Survey of the Near Future," *The Economist*. (3 November 2001) 356(32): 3–20.

[18] Derek Bok, *Universities and the Future of America* (Durham: Duke University Press, 1990).

moorings of physical campuses, even as its credentialing monopoly begins to erode. It appears to be evolving from a loosely federated system of colleges and universities serving traditional students to, in effect, a global knowledge and learning industry driven by strong market forces.

As our society becomes ever more dependent upon new knowledge and educated people, upon knowledge workers, this global knowledge business must be viewed clearly as one of the most active growth industries of our times. Today it is estimated that higher education represents roughly $225 billion of the $665 billion education market in the United States.[19] But even these markets are dwarfed by the size of the "knowledge and learning" marketplace, a convergence of education, communications, information technology, and entertainment sectors, estimated in excess of $2 trillion.

This perspective of a market-driven restructuring of higher education as an industry, while perhaps both alien and distasteful to the academy, is nevertheless an important framework for considering the future of the university. These social, economic, technological, and market forces are far more powerful than many within the higher education establishment realize. They are driving change at an unprecedented pace, perhaps even beyond the capacity of our colleges and universities to adapt. There are increasing signs that our current paradigms for higher education, the nature of our academic programs, the organizations of our colleges and universities, the way that we finance, conduct, and distribute the services of higher education, may not be able to adapt to the demands and realities of our times.

As each wave of transformation sweeps through our economy and our society, with an ever more rapid tempo, the existing infrastructure of educational institutions, programs, and policies becomes more outdated and perhaps even obsolete. It is clear that no one, no institution, and no government, will be in control of the emergence and growth of the knowledge industry. It will respond to forces of the marketplace. And perhaps this is the most serious threat of the emerging competitive marketplace for knowledge and learning: the danger that it will not only distort but erode the most important values and purposes of the university. In a highly competitive market economy, short-term commercial opportunity and challenges usually win out over long-term public interests.

Given the potential positive outcomes associated with such industry-driven research, can you enumerate any concerns?

In the past, the public purposes of our universities were determined primarily by public policy and public investment. Today the marketplace may be redefining these roles. The ties between universities and the corporate world have proliferated and changed over recent decades. There has been a shift in the priorities of the university, away from the pursuit of knowledge and the education of the next generation and instead toward responding to the commercial lure of the marketplace.

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[19] Michael T. Moe, *The Knowledge Web* (Merrill-Lynch, New York, 2000).

While partnerships between universities and industry have existed for many years, in the past they tended to rely on traditional relationships such as the hiring of graduates, the use of faculty consultants, or the sponsorship of research. Financial associations with private industry were largely confined to companies awarding grants to academic institutions for research in areas of mutual interest. Companies played no part in designing or analyzing the studies; they did not house the data, and they certainly did not write the papers and control the publications of results.

Things have changed dramatically in the past decade. Arm's length relationships are a thing of the past, and financial arrangements go far beyond simple grant support. In some research universities, the conflict of interest policies have been designed primarily to comply with federally funded research, while the increasing flow of privately funded research is eroding university-wide compliance with the spirit and letter of the federal guidelines. New forms of hybrid institutions have emerged to facilitate joint industry-university collaborations that are not formally covered by faculty policies. The increasing trend for students at the graduate and undergraduate level to be involved in proprietary work with sponsoring corporations can create conflicts for which most university government committees have few policies and sometimes no oversight.

Of particular concern is the attention paid within the university research community to the commercialization of technology and discoveries, sometimes with the potential for very large financial rewards to individual faculty members under prevailing technology transfer policies and practices. The traditional belief of universities that proprietary claims were fundamentally at odds with their obligation to disseminate knowledge as broadly as possible fell by the wayside with the Bayh-Dole Act of 1980. This legislation obliged those receiving federal funds for research to make strong efforts to promote the commercialization of their discoveries. From that time forward, faculty researchers were expected to be aware of the potential commercial value of their work and their institutions were obliged to create the infrastructure that would facilitate patenting, marketing, and licensing their faculty's discoveries. It didn't take long for universities to realize that the Bayh-Dole mandate had the potential for becoming a "cash cow" for the institution and the faculty. Universities invested heavily in technology transfer and licensing offices with the missions of developing, protecting, and marketing of intellectual properties.

Did the federal government favor industry-driven research at academic institutions, and if so, how?

The federal government played a major role in stimulating and sustaining the American research university through the government-university research partnership first articulated in Vannevar Bush's *Science, the Endless Frontier* report.[20]

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[20] Vannevar Bush, *Science–The Endless Frontier* (National Science Foundation, Washington, 1945).

It has similarly triggered the explosion in campus activities designed to capture and exploit the commercial value of the intellectual property created by federally sponsored research through federal policies such as the Bayh-Dole Act of 1980. This legislation allows universities to retain the ownership of commercially valuable intellectual property produced in government-sponsored research. Universities have responded by providing strong incentives to their faculty and creating technology transfer offices to identify, protect, patent, license, and spin-off commercially valuable products and companies. As one data point, prior to the Bayh-Dole Act of 1980, universities produced roughly 250 patents a year (most of which were never commercialized). In 2000, universities filed for 8,534 patents and spun off 368 companies.

Prior to the Bayh-Dole Act, technology transfer occurred primarily through publication in scientific journals, technical consulting, continuing education and extension services, and the employment of trained graduates. To this array, Bayh-Dole added the transfer of a property right as the result of ownership of the intellectual property generated during the conduct of research, as manifested by patents, copyrights, trademarks, trade secrets, or a proprietary right in the tangible products of research. Fundamental to Bayh-Dole was the certainty that if the universities were the owners of inventions from research, they could grant exclusive licenses stimulating the private sector to invest in development.

The underlying tenant of the Bayh-Dole Act is that inventions resulting from federally funded research should be owned by universities and provided to exclusive licenses to industry for commercial development in the public interest. The act was based on the belief that a non-exclusive licensing policy simply is not effective in technology transfer. It is the incentive inherent in the right to exclude conferred upon the private owner of a patent that is the inducement to development efforts necessary to the marketing of new product. What is available to everyone is of interest to no one. Proponents of Bayh-Dole note that when the government held title to inventions under the policy that the inventions should be available to all, much the same as if the invention had been disclosed in a publication, the patent system could not operate in the manner in which it was intended.

But is this true? Although the recent increases in university patenting and licensing are widely assumed to be the direct consequences of Bayh-Dole, empirical evidence suggests that the impact of this activity on the content of academic research has been modest.[21] The growing importance of biomedical research, much of which relied on federal support that expanded significantly during the 1970s, was at least as important as Bayh-Dole in explaining increased university patenting and licensing after 1980. Other factors also encouraged the growth of university patenting in this and other areas such as judicial decisions that declared that "engineering molecules" were patentable. It seems clear that an array of developments in research,

[21] David C. Mowery, Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis, "The Effects of the Bayh-Dole Act on U.S. University Research and Technology Transfer", in *Industrializing Knowledge*, ed. L. Branscomb and R. Florida (MIT Press, Cambridge, 1999).

technology, industry, and policy combined to increase US universities in technology licensing, and Bayh-Dole, while important, was not determinative.

Furthermore, the Bayh-Dole Act represents an application of the "linear model" to science and technology policy, assuming that if basic research results can be purchased by would-be developers, thereby establishing clear potential for the commercial development of these results, commercial innovation will be accelerated. The earlier concept of a linear progression of basic research to applied research to commercial development to marketable products, a fundamental assumption of the *Science, the Endless Frontier*[22] policies that have governed university research for the past half century, has been replaced by a nonlinear process in which basic and applied research, development and commercialization are mixed, a la Pasteur's Quadrant[23] (or Jeffersonian science).

The theory behind Bayh-Dole (that companies need exclusive patent rights to pick up, develop, and commercialize the results of university research) seems in conflict with the fact that patents tend to restrict use of scientific and technological information and open publication, which facilitates wider use and application of such inventions and knowledge. Are patents or restrictive licenses really necessary to achieve application? Should such licenses be negotiated by universities, institutions not known for their commercial expertise? Does the presence of a university-assigned patent and the requirement for licensing delay and narrow technology transfer? There is as yet little empirical evidence in support of this principle.

There are still other challenges to the conventional Bayh-Dole doctrine. Are universities' patenting efforts increasing or reducing the social returns to the results of the publicly funded research performed on their campuses? Are universities' expanded efforts to patent inputs into the scientific research process impeding progress? It is certainly true that with the increasing emphasis on disclosure, patenting, and licensing, more of what universities naturally would have produced and placed in the public domain now is subject to more complex administrative procedures. These policies may raise the costs of use of these research results in both academic and non-academic settings, as well as limiting the diffusion of these results.

Donald Kennedy made an excellent further point in a recent editorial in *Science*. He suggests that just as Vannevar Bush's *Endless Frontier* changed fundamental science from a venture dependent on small privileged elites into a vast publicly owned enterprise, Bayh-Dole and related federal policies is driving university research toward the private sector, fueled by the mobilization of philanthropy and corporate risk capital. Continuing the frontier motif, he suggests we might regard the current framework characterizing technology transfer as the "Great Enclosure." Just as the Homestead Act of 1862 transformed the American frontier from public land into a checkerboard of individually owned holdings by allocating land virtually free to

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[22] Vannevar Bush, *Science–The Endless Frontier* (National Science Foundation, Washington, 1945).

[23] Donald E. Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation* (Brookings Institution Press, Washington, 1997).

those who would promise to live on and improve it, the largely public domain of basic research is now moving into private hands by yet another federal act, Bayh-Dole, that allows universities or individual scientists to claim ownership of the intellectual property created by federally sponsored research. Interestingly, these enclosure revolutions came about in the same way: both were implemented by purposeful government intervention, accomplished through statute.

Kennedy contends that while this has brought some major benefits, it has also been accompanied by significant costs. New problems of conflict of interest, royalty distribution, and the propriety of commercial relationships have arisen for faculty members and university administrators alike. The contemporary enclosure of the Endless Frontier is replicating the history of the Homestead Act, yielding patent disputes, hostile encounters between public and private ventures, and faculty distress over corporate deals with their universities. Sometimes government action is unintended, such as the recent Executive Order on stem cell research that promises to transform a major public program into the private sector. Many observers, noting these costs, advocate policies for reversing privatization.

Would you suggest that these trends may ultimately lead to a major change in the fundamental mission of the academy?

Transferring university-developed knowledge to the private sector fulfills a goal of federally funded research by bringing the fruits of research to the benefit of society. With this important technology transfer comes increasingly close relationships between industry and universities. While this provides benefits to society, it also increases the risk of academic research being compromised by constraining open publication of research methods and results while diverting faculty from more fundamental research topics not so directly linked to commercial outcomes. Ironically, it has been the freedom of universities from market constraints that is precisely what allowed them in the past to nurture the kind of open-ended basic research that led to some of the most important (and least expected) discoveries in history.

There remains considerable uncertainty concerning just how universities should approach the commercialization of the intellectual property associated with campus-based research and instruction. Beyond the traditional triad of teaching, research, and service (or in more contemporary language, learning, discovery, and engagement),[24] it is useful to consider the "products" of the university as educated people, content, and knowledge services. Yet content, that is intellectual property, cannot be bottled and marketed like other commercial products. It exists in the minds of people, the faculty, staff, and students of the university. As such, it can simply walk out the door.

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[24] *Kellogg Commission on the Future of State and Land-Grant Universities*, Renewing the Covenant. (National Association of State Universities and Land-Grant Colleges, Washington, 2000).

So how do universities handle content? Traditionally they have used the library model, that is, they distribute knowledge freely through open publication (and then, occasionally, are forced to buy it back in the form of expensive journals from commercial publishers). In the wake of Bayh-Dole, they have swung to the other extreme by attempting to capture, patent, and license the intellectual property resulting from their scholarly and instructional activities, relying on armies of lawyers to defend this ownership (much as the NCAA attempts to capture and control all of the riches generated by college sports). The past two decades have seen technology transfer shift from the "library" toward the "NCAA" model, in which private profit has become a stronger motivating force than public interest.

Of course, although the federal government has encouraged and facilitated this shift through policies such as Bayh-Dole, it certainly does not require it. Indeed, the National Institutes of Health state quite clearly that "Universities have no duty to return value to shareholders, and their principal obligation under the Bayh-Dole Act is to promote utilization, not to maximize financial returns. It hardly seems consistent with the purposes of the Bayh-Dole Act to impose proprietary restrictions on research tools that would be widely utilized if freely disseminated." Furthermore, while disclosure, patenting, and licensing intellectual property may be appropriate for some areas such as the product-orientation of biomedical research, it may not be an effective mechanism for very rapidly evolving areas such as information technology or instructional content.

Let me suggest an even bolder approach. Suppose that in return for strong public support, the nation's public universities could be persuaded to regard all intellectual property developed on the campus through research ... as in the public domain. They could encourage their faculty to work closely with commercial interests to enable these knowledge resources to serve society, without direct control or financial benefit to the university, perhaps by setting up a "commons" environment adjacent to the campus (either geographically or virtually) where technology transfer was the primary mission. This might be just as effective a system for transferring technology as the current Bayh-Dole environment for many areas of research and instruction. Furthermore, such an unconstrained distribution of the knowledge produced on campuses into the public domain seems more closely aligned with the century old spirit of the land-grant university movement.

What kind of changes do you believe are necessary to balance the goals of the University and the demands of industry in terms of technology transfer?

It is important in such discussions to always keep in mind the fundamental purposes and values of the university. In preparing for this discussion, I read back over the technology transfer policies of the University of Michigan, which begin with the statement: "The mission of the University is to generate and disseminate knowledge in the public interest. Essential to this mission are two fundamental principles: open scholarly exchange and academic freedom." And, of course, this is the issue in a nutshell: the degree to which the increasing commercialization of the academy is threatening its most fundamental mission and values.

As Henry Rosovsky put it at a recent meeting of American and European educators, the marriage between universities and industry is "against nature."[25] It represents a symbiotic relationship, between two unlike organisms with vastly different characteristics and objectives. The values of the university involve freedom of inquiry, the open sharing of knowledge, a commitment to rigorous study, and a love of learning. The goals of the marketplace are return on investment and shareholder value.

What is the public interest in the transfer of knowledge from the campus to society through commercial avenues? How are the rules and expectations characterizing the interaction between the university and the commercial marketplace changing? Is there an appropriate balance of public and private interests in today's universities? How are policies, practices, and dialog concerning the relationship between the university and industry affecting the traditional scholarly mission and sense of community on the campuses? Do universities and faculty have the necessary tools to manage the complexity of new relationships with industry? These are the questions that remain before us, and these are the issues that should be addressed through further dialog both on the campuses and with those served by the university.

The market forces driven by the increasing commercial value of the knowledge produced on our campuses are powerful indeed. Yet, if they are allowed to dominate and reshape the higher education enterprise without constraint, some of the most important values and traditions of the university will likely fall by the wayside. Will higher education retain its special role and responsibilities, its privileged position in our society? Will it continue to prepare young students for roles as responsible citizens? Will it provide social mobility through access to education? Will it challenge our society in the pursuit of truth and openness? Or will it become, both in perception and reality, just another interest group driven along by market forces? As we assess these market-driven emerging learning structures, we must bear in mind the importance of preserving the ability of the university to serve a broader public purpose.

The American university has been seen as an important social institution, created by, supported by, and accountable to society at large. The key social principle sustaining the university has been the perception of education as a public good – that is, the university was established to benefit all of society. Like other institutions such as parks and police, it was felt that individual choice alone would not sustain an institution serving the broad range of society's education needs. Hence public policy dictated that the university merited broad support by all of society, rather than just by the individuals benefiting from its particular educational programs.

Yet, today, even as the needs of our society for post-secondary education intensifies, we also find an erosion in the perception of education as a public good

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[25] Henry Rosvosky, "And the Walls Come Tumbling Down" in *The Glion III Symposium*, ed. by Luc Weber and Werner Hirsch, (Paris: Economica, 2002).

deserving of strong societal support.[26] State and federal programs have shifted from investment in the higher education enterprise (appropriations to institutions or students) to investment in the marketplace for higher education services (tax benefits to students and parents). Whether a deliberate or involuntary response to the tightening constraints and changing priorities for public funds, the new message is that education has become a private good that should be paid for by the individuals who benefit most directly, the students. Government policies that not only enable but intensify the capacity of universities to capture and market the commercial value of the intellectual products of research and instruction represent additional steps down this slippery slope.

Education and scholarship are the primary functions of a university, its primary contributions to society, and the most significant roles of the faculty. When universities become overly distracted by other activities, they not only compromise these core missions but they also erode their priorities within our society. The shifting perspective of higher education from that of a social institution, shaped by the values and priorities of broader society, to, in effect, an industry, increasingly responsive to the marketplace only intensifies this concern. While it is important that the university accept its responsibility to transfer the knowledge produced on its campus to serve society, it should do so in such a way as to preserve its core missions, characteristics, and values. In particular, the nature of higher education as a public good rather than simply a market commodity needs to be recognized by higher education and re-established by strong public policy and public investment both at the federal level and at the level of our states and communities, since the future of the university in an ever more knowledge-driven society is clearly a national concern.

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[26] Robert Zemsky, "Rumbling," Policy Perspectives, Pew Higher Education Roundtable, sponsored by the *Pew Charitable Trusts* (Philadelphia: Institute for Research on Higher Education, April 1997).

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