

Harnessing Openness to Transform American Health Care



A Report by the Digital Connections Council of
the Committee for Economic Development

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Digital Connections Council

Harnessing Openness to Transform American Health Care

Preface by the CED Research and Policy Committee

CED's Digital Connections Council (DCC), a group of information technology experts from CED trustee-affiliated companies, was established to advise CED on the policy issues associated with cutting-edge technologies. This report, concerning "openness" in healthcare, is the third of its products. CED appreciates greatly the efforts of the members of the Council, and in particular, the work of DCC Chair Paul Horn, Senior Vice President, Research (retired), IBM Corporation, and Distinguished Scientist in Residence, Stern School of Business, Courant Institute of Mathematical Sciences and the Graduate School of Arts and Science, New York University, for his leadership in bringing this report to completion. Special thanks are also due to Elliot Maxwell, CED's project director and consultant, to Charles Johnson and Daphne McCurdy, CED Research Associates, for assistance with research, editing, and publication, and to Elliot Schwartz, CED's Vice President and Director of Economic Studies.

This report is the work of the Digital Connections Council. We welcome this report and recommend it to readers as an excellent analysis of how the system of healthcare in the United States, and importantly health outcomes, can benefit from the application of greater openness through digital technologies. The recommendations of this report, along with those of CED's policy statement, *Quality, Affordable Health Care for All: Moving Beyond the Employer-Based Health-Insurance System*, can transform healthcare in the United States by making it significantly more efficient, accessible, and responsive.

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Executive Summary

The Digital Connections Council (DCC) of the Committee for Economic Development (CED) has been developing the concept of openness in a series of reports.¹ We have analyzed information and processes and attempted to determine their openness based on their qualities of “accessibility” and “responsiveness.” If, for example, information is not available or available only under restrictive conditions it is less accessible and therefore less “open.” If information can be modified, repurposed, and redistributed freely it is more responsive, and therefore more “open.” Based on their accessibility and responsiveness, information can be placed on a continuum of openness, stretching from fully open to fully closed.*

The Council has found that an increased degree of openness often leads to greater innovation because it allows contributions to a work from more individuals whose differing insights and experiences can add considerable value. But greater openness is not always appropriate or desirable. In some cases, such as an individual’s personally identifiable information, the last thing one would want would be to enable someone to modify the information without the appropriate authorization.

In other cases greater openness creates new problems. We can, for example, be overwhelmed by the amount of information available on the Internet if we lack the proper tools to evaluate it. It is therefore important to determine, in a particular case, the degree of openness likely to bring the greatest benefit, and the most appropriate way to deal with the problems that greater openness may bring.

Our goal in this report is to bring the DCC’s expertise in information and communications technology and electronic commerce to bear on those aspects of

healthcare that have been or can be changed by the Internet, the continued growth in computing power and data storage capacity, and the increasing digitization of information. These technological changes, and the greater openness that they enable, are visible in areas that range from biomedical research and the disclosure of research findings, through the process of evaluating drugs and devices, to the emergence of electronic health records, and the development and implementation of treatment regimes by caregivers and patients. Bringing greater openness to different parts of the healthcare production chain can lead to substantial benefits by stimulating innovation, lowering costs, reducing errors, and closing the gap between discovery and treatment delivery.

We have not exhaustively cataloged the healthcare arenas that could benefit from greater openness. We have simply tried to show potential benefits which can be achieved with or without a fundamental restructuring of healthcare in the United States or the achievement of universality of healthcare insurance. We hope others can build upon this work.

Biomedical Research

The report focuses first on the area of biomedical research. This realm is being transformed by the success of the Human Genome Project (HGP). By mapping the human genome, the HGP demonstrated the possibilities of mass collaboration and the beneficial results of allowing data to be accessed immediately and manipulated by researchers around the world.² The progeny of the HGP have adopted this open model and are flourishing by sharing data, applications, and even network resources. **The Council recommends that the federal research agencies push further by enunciating clear policies favoring openness,**

* The accessibility aspect of openness is closely related to “transparency” but openness as we are using it has the additional aspect of responsiveness—permitting people other than the creator to contribute, modify, reuse, repurpose, and redistribute the work.

funding further work on standards for protocols, formats, terminology and nomenclature that allow the sharing and manipulation of data, and supporting experiments with differing levels of openness to determine the optimal level for research under various scenarios.

Clinical Trials

Questions about the openness of clinical trials have been raised vigorously over the last decade. Although the Food and Drug Administration (FDA) had long required the registration of clinical trials involving life-threatening interventions, there have been disputes as to the completeness of these registrations—and about the lack of registration of other clinical trials. Advocates of greater openness here and around the world have been concerned not only about registrations, but also about access to trial results and, perhaps more important, to the data that underlie the results—and whether the data will be available in a computable form.

Because clinical-trial populations do not reflect the broader populations that will later use the intervention—or the length of time that they will use it—many adverse effects are unlikely to be discovered through clinical trials, raising questions about drug safety and the processes for monitoring drug impacts after approval. Amendments to the FDA's enabling legislation in 2007 addressed these issues in part, but there are additional ways in which greater openness can improve clinical trials and post-approval surveillance. **Most important for improved healthcare research is to make the trial results and the data underlying trials more accessible more quickly in a form that is searchable and computable using common standards. In addition, applicants for FDA approval should be required to submit all studies they have conducted on the intervention with any safety-related results being made publicly available.**

The system would also be improved by further strengthening the protections for trial participants, ending split federal oversight of trials, and clarifying the laws regarding tissue donations. The Council joins a long list of groups recommending far more comparative testing of drugs to supplement clinical trials that simply compare an intervention's effects with those of a placebo.

Disclosure of Results and Underlying Data

Common to both basic research and clinical trials are issues surrounding what results and what data are made public and when? A new concern is how data will be published or disclosed, given the rise of new disclosure models, ranging from the filing of human genome sequences in the open GenBank to new open-access scientific and technical journals and open-access archives. These outlets pose a serious challenge to the traditional model of publishing research in subscription-funded, paper-based scientific and technical journals owned by commercial or not-for-profit publishers.

The Council recommends federal support for earlier and expanded accessibility to results and data, and, more specifically, the passage of legislation that would mandate public access to results of most unclassified government-funded research no later than six months after publication. Major government funders of research should also be receptive to requests for funding for the publication of research results in open-access journals.

Electronic Health Records

The emergence of electronic health records (EHRs) raises new openness issues. Utilizing such records, caregivers at any location would have access to a patient's medical history. Results of tests and treatments could be added easily as they become available, thereby improving treatment, preventing duplicative testing, and reducing medical errors. Eventually, EHRs could be constructed including family medical histories, genomic and pharmacogenomic data, environmental exposures, lifestyle and other information, easing the way toward the "personalization" of treatment. The aggregation of such records, and others, could then facilitate the achievement of a genuine "evidence-based" medical system. Such records provide far richer data than clinical trials, and could serve as the basis for predictive models similar to those used in other scientific domains. **The Council recommends that federal efforts to develop standards for an interoperable, national EHR system should be given high priority.**

Privacy and Security

But the openness of the EHR that allows more efficient collection of more data and permits improved caregiver access raises fundamental issues of privacy and security that will tend to limit openness. Who will have access to these records and under what circumstances? How will the information be used? Who will make these decisions? Whether patients agree to participate in an EHR system may well depend on whether these questions are answered to their satisfaction.

The Council returned to the theme of the importance of greater federal support for the infrastructural aspects of openness—in this case the development and implementation of standards that would facilitate the creation and exchange of data—as well as incentives for the adoption of EHRs. To protect privacy, new rules will need to be extended to any entity that handles patient-identifiable healthcare information, and new resources will be needed to support vigorous enforcement of privacy and security rules. **In order to foster comparative testing of drugs and treatments, strengthen drug and device safety monitoring, and spur development of evidence-based medicine and the generation of clinical-practice guidelines that would bridge the gap between discovery and treatment, the Council calls for a public-private partnership to create large databases made up of EHRs, health-insurance-claims data, and clinical-trial data, etc., appropriately de-identified to protect patient privacy.**

New Sources of Information for Patients and Caregivers

The Council also looked at aspects of openness related to new sources of information for patients and caregivers. Patients are now able to search through a vast store of health-related information on the Internet (some good, some bad, much irrelevant) and even provide their caregivers with current research. They can customize their own treatment through shared decision making with their caregivers, and continuously contribute data through the use of remote-monitoring equipment. With greater access to information about the quality and costs of procedures and practitioners, patients can become more responsible healthcare

consumers; good caregivers should benefit as poorer performers are weeded out. But information can be used in harmful ways such as the adverse selection of sicker patients or of talented, but less cost-conscious, caregivers. Both patients and caregivers can benefit from having vastly expanded access to data, but may also be overwhelmed without appropriate support tools.

The Council recommends that the federal government move aggressively to disclose data on the cost and quality of healthcare providers and procedures, and to monitor and provide financial incentives for compliance with evidence-based, clinical-practice guidelines. Given the explosion of caregiver-affiliated enterprises that provide patient testing or treatment, conflicts of interest by caregivers need to be disclosed. In order to avoid disincentives for the use of remote monitoring and telemedicine, the federal government should review its reimbursement policies and work with the states to address conflicting state licensing and malpractice rules.

Public Health

The global public health system depends on data sharing and worldwide collaboration; without it, as seen in the Severe Acute Respiratory Syndrome (SARS) experience, the lives of millions are threatened. **With lower-income countries showing reluctance to share data and physical evidence, the Council recommends greater attention to ensuring that all countries benefit from discoveries that result from the global sharing of data related to the emergence of new diseases.** Better electronic linkages among public health agencies, both globally and locally, and a willingness to develop new detection methods, are also necessary when diseases can spread at the speed of a jet plane.

Medical Devices

Greater openness in software-controlled medical devices creates new opportunities and challenges. The history of practitioner innovation in scientific instruments and the infinite malleability of software suggest the potential for a dramatic increase in practitioner-driven customization of such devices. At the same time, the FDA continues to have responsibility for assuring the safety and efficacy of these devices and has

justifiable concerns about post-approval changes made to them. **The Council recommends that the FDA begin an examination of how to benefit from the user-driven innovation while maintaining appropriate oversight for safety and efficacy.**

Conclusion

One point should be made explicit. Some readers might approach this report thinking it is about health-care and information technology—and there have been a number of excellent reports on that subject.³ But openness, while facilitated by information technology, should not be equated with it. The benefits of greater openness can be found when a caregiver is more attentive to a patient’s story and does not stop listening prematurely in order to narrow down potential diagnoses. Greater openness is what allows us to

improve the evaluation of interventions in clinical trials through patient-outcomes reporting. When game hunters in Cameroon provide samples to public health researchers on the lookout for disease outbreaks we are witnessing greater openness. Openness is ultimately about an attitude that sees the opportunity for many to benefit from greater access to information, as well as to contribute much to the benefit of us all.

Greater openness is likely to become increasingly important in more and more areas driven by the relentless progress of information and communications technology. We offer these recommendations with the hope that modest changes based on greater access to information by more people, and more possibilities for them to contribute based on their own expertise and energy, can help improve healthcare in the United States and around the world.

Introduction

The progress of scientific and technological knowledge is a cumulative process, one that depends in the long-run on the rapid and widespread disclosure of new findings, so that they may be rapidly discarded if unreliable, or confirmed and brought into fruitful conjunction with other bodies of reliable knowledge.”

- Paul David⁴

For the last several years the Digital Connections Council (DCC) of the Committee for Economic Development (CED) has been documenting the growing impact of the Internet on innovation. Its first report, *The Digital Economy: Promoting Competition, Innovation, and Opportunity* (2001), provided an early gauge of how strongly the Internet was affecting the economy a few years after the development of the World Wide Web and the release of the first commercial browser.

The Council's second report, *Promoting Innovation and Economic Growth: The Special Problem of Digital Intellectual Property* (2004), addressed an important consequence of the increasing digitization of information and the global spread of Internet connectivity: the tension between the virtually free copying and distribution of information products enabled by digitization and the Internet and the growing concern among intellectual property rights holders over the misappropriation of their works. Because of this tension—and proposed legislation and regulatory responses to it—the Council began to look more deeply at the process of innovation in the increasingly digital environment of the early 21st century.

Innovation, the Council noted, involves both first creators and follow-on innovators, with the latter vastly outnumbering the former. But first creators are almost always follow-on innovators to some previous first

creators—they too, as Sir Isaac Newton wrote, “stand on the shoulders of giants.”^{*}

The cycle of innovation is thus continuously sustained. An equitable and effective intellectual property system must take into account both first creators and those who come later to build upon their work.

The U.S. intellectual property system allocates rights between a first creator and those who would utilize that creation for another work. Economists have pointed out that if the rights of the first creator are extended too far there may be too little room left for follow-on innovation which falls outside the first creator's control. This would result in the “underproduction” of follow-on innovation. If the rights of first creators are reduced too much, there may be too little financial incentive to spur additional creative activity, resulting in the underproduction of first creations.

The Council noted that for over 200 years the United States has been able to maintain a reasonable balance between the rights accorded first creators and follow-on innovators. The first creator has more rights in the early years after he or she creates the work. Eventually the scales are tipped toward follow-on innovators when the work enters the public domain, freely available to all. The Council found that the Internet, even with the capabilities it provides for misappropriation of works, has not so changed the environment as to justify a dramatic expansion of the rights of first creators (with a concomitant lessening of the rights of follow-on innovators). After reviewing the technology and the law, the Council concluded that the existing balanced allocation of rights had proven itself sufficiently flexible to accommodate the emergence of new technologies such as the player piano, phonograph, radio and television broadcasting, and tape and CD recording,

^{*} Hundreds of years before Newton, Bernard of Chartres made the same point when he remarked, “We are like dwarfs standing upon the shoulders of giants, and so able to see more and see farther than the ancients.”

and that it should also be able to accommodate the rise of the Internet. The Council therefore rejected a call for vastly greater protections for rights holders and opposed technological mandates that would seek to enforce those rights in every manner of digital device.

In its next report, *Open Standards, Open Source, and Open Innovation: Harnessing the Power of Openness* (2006), the Council documented the growing importance of open standards in the information and communications technology arenas and their value in increasing competition and stimulating innovation. Through an analysis of the operations of the open-source software development community, the Council showed the many different motivations that lead individuals to voluntarily contribute their time and effort and to share their creative acts.

The Council also recognized the emergence of a theory about how sharing one's creation freely with others provides a means of adding value to it. Traditional theories of intellectual property identify the principal incentive for creative activity as coming from the economic returns that might be obtained by the creator. To obtain these returns, the rights holder must be able to control the creation so as to be able to charge for access and obtain compensation for the creative effort. The system of intellectual property rights and licenses provides the means for such controls.

The open-software movement also utilizes intellectual property rights and licenses. The underlying premise of open software, however, is the mirror image of the traditional view that value is based on allowing control by the rights holder and facilitating the exclusion of others. Open-source licensing is designed instead to *facilitate* creative acts by *others* based on the assumption that the value of the original work can be increased most by encouraging the greatest number of follow-on innovators to contribute to it. Open-source intellectual property licenses *prohibit* anyone from restricting access to, or preventing the modification of, the original work.

This theory of value based on sharing focuses on follow-on innovators. It is closely connected to the rise of the Internet, which allows more efficient access to the first creation and more efficient contribution of suggested modifications. This ability to have access and to make changes (responsiveness) is how we define what we call "openness."

The Council concluded that both theories of value—one based on exercising control and restricting access, the other based on encouraging access and modification—have places in the system of innovation. It noted that follow-on innovators had historically played an important role in innovation—such as in developing many of the popular modifications of the first automobiles—and that the open-source software movement, with its emphasis on follow-on innovation, was consistent with a long history of innovation in America and around the world. What the Internet has changed is the ability to provide access and responsiveness, and therefore to stimulate global collaboration on a mass scale. This capacity to allow millions of people to work together and to contribute their own expertise has been observed by others who have labeled it an "architecture for participation," the "read-write Web," or "Web 2.0."

For this report, the DCC decided to look at how "openness" was being or might usefully be employed in the healthcare arena. This area, which now constitutes approximately 16-17 percent of GDP, has long frustrated policymakers, practitioners, and patients. It was the Council's desire to bring its expertise in information and communications technology to bear on issues in healthcare using the "lens" of openness to complement other work on healthcare being done under the auspices of the CED.* Thus, the aim of this report is to identify areas where greater openness is likely to increase innovation, minimize costs, improve treatments, reduce errors, and shorten the interval between research and discovery and the development of clinical practices based on research results. The following report is the result of the Council's deliberations.

* Committee for Economic Development, *The Employer-Based Health-Insurance System is Failing: What We Must Do About It* (Washington D.C.: CED, 2007).

Chapter 1: The State of U. S. Health Care

The patient is in crisis.

The symptoms are clear.

But there is no widespread agreement on how to proceed.

That is healthcare in the United States in 2007 when:

- We spend far more than any other industrialized nation—according to the OECD more than twice as much as the median of its members—while having the lowest longevity rate;⁵
- Little more than one-half of patients receive care based on best medical practices;⁶
- Less than one-half of physicians practice using recommended processes for care;⁷
- Only one-quarter of medical practices are based on adequate evidence of their efficacy;⁸
- \$3.5 billion a year is wasted on medication errors, while 1.5 million patients are hurt by them;⁹
- Most drugs prescribed in the United States today are effective in only 60 percent of treated patients;¹⁰
- 30 percent to 40 percent of every healthcare dollar—some two trillion of them or roughly 16-17 percent of GDP—is spent on costs associated with “overuse, underuse, misuse, duplication, system failure, unnecessary repetition, poor communications and inefficiency;”¹¹
- We spend six times as much for administration as any other nation.¹²

Healthcare in the United States in the 21st century is pre-industrial in organization. It is a combination of leading-edge science, practitioners organized in guilds similar to those of the Middle Ages, operating within jurisdictional boundaries determined in the 18th and 19th centuries with a 20th century payment system.

There have been many reports on what is wrong with healthcare in the United States. What follows are not suggestions for radical change. They are examples of specific and limited reforms that, in their cumulative impact, could be transformative. They are changes that are occurring, or could occur reasonably easily, utilizing the power of the Internet and an approach that looks at all procedures and processes for improvements based on two considerations: 1) will this be improved by providing greater access to information; and 2) will this be improved by allowing a broader group to be able to add their contributions through the modification, repurposing, and redistribution of information? In other words, are there ways in which we can make parts of healthcare more “open” and allow the power of openness to affect it as it is affecting—and benefiting—almost every other aspect of our world?

There are several reasons why we have not seen more openness in healthcare. As many have remarked, we have no healthcare “system.” The marketplace is extraordinarily fragmented among individual and institutional players. The player that pays almost half of the costs, the federal government, does not fully exploit the data it possesses and rarely exercises its power as a payer to improve the quality of healthcare. Increased access to information is viewed as threatening by those who now control the information, criticized by others for allowing adverse selection to maximize profits, and condemned as potentially compromising patient privacy and security. Some licensed professionals may resist greater participation by others they consider less qualified. The tensions between the need for intellectual property protection and controlled access to stimulate innovation and the potential gains from the widespread availability of information are becoming increasingly clear when the consequences may be life or death.

We may have assumed in the past that information should be held tightly unless there was a good reason

to provide access to it. As a thought experiment we might instead assume that information can be shared and improved unless there is a good reason for restricting access or controlling modifications. What follows is an exploration of how such greater openness might benefit healthcare in the United States and the world in 2007 and beyond.

Chapter 2: The Genome Era—Openness in Biomedical Research

Just weeks before the 50th anniversary of Watson and Crick's article describing DNA's double-helix structure, scientists produced a finished sequence of the human genome, launching "the genome era."¹³ The mapping of over 3-billion base-pairs was an extraordinary accomplishment that at the same time demonstrated the power of an open and collaborative model of discovery that has become a paradigm for modern database-oriented biomedical research.

The Human Genome Project's Open Model

Like the race to discover DNA's structure, the search for the human genome sequence was very competitive. Celera, a private-sector firm led by Craig Venter, sought to be first to establish the sequence while, as was the norm, keeping much of its data private, to be made available on commercial terms to other researchers. In contrast, the publicly funded Human Genome Project (HGP) followed an open model making its data publicly available and welcoming input from around the world. HGP pushed participating researchers to disclose their findings as quickly as possible.¹⁴ While Celera made important contributions to the sequencing, it was the HGP's model of discovery that has transformed the research process by reducing "transaction costs and secrecy that may impede follow-on research."¹⁵

The HGP researchers not only put raw sequencing data into the public domain, but as the "data were being produced, an open-source software program known as the distributed annotation system (DAS) was set up to facilitate collaborative improvement and annotation of the genome."¹⁶ This allowed any researcher to choose the annotation they wanted to view and enabled the ranking of annotations by the number of researchers that used them, something akin to Google's methods for ranking search results.¹⁷

This open model is now being used in a federally funded international effort to create a map of

haplotypes (HapMap), which describe variations in the human genome that tend to occur together in "neighborhoods" or haplotypes.¹⁸ Data about the genotype of the individual haplotypes is being released publicly as soon as it is identified. The openness of the HapMap effort is reinforced by its use of a licensing system that is "self-consciously modeled on the 'copy-left' system of open-source software licensing" and which prevents those who utilize the data from attempting to close it to others via patents.¹⁹

Utilizing the results of the HapMap process, a public-private partnership, the SNP Consortium, is identifying panels of a few hundred thousand single-nucleotide polymorphisms (SNPs) that can be used to identify common variants in an individual's entire 3-billion base-pair genome that might be associated with a disease.²⁰ As with the HapMap project, participants in the consortium have agreed to put the data they produce in to the public domain.²¹

In the reasonably near future, according to Dr. Francis Collins, leader of the National Human Genome Research Institute (NHGRI) in the National Institutes of Health (NIH), the HapMap should help make practical case-controlled studies using SNP's to identify gene variants that "contribute to diabetes, heart disease, Alzheimer disease, common cancers, mental illness, hypertension, asthma, and a host of other common disorders."²² That future seems nearer than ever today with scientists finding correlations between diseases such as multiple sclerosis and breast cancer and specific genetic variations.²³

In the area of "chemical" genomics the National Institutes of Health (NIH), as part of its "Roadmap" process, has established a network of chemical genomics centers available to all researchers, as well as a new database, PubChem, that makes much of the data generated by the centers freely accessible. Today's drugs target only about 500 of the more than 20,000 genes in the human genome considered "druggable"

even though pharmaceutical researchers have created libraries of hundreds of thousands of potentially useful compounds.²⁴ The open tools established by NIH should help researchers identify new targets for research.

Among the legacies of the HGP are the development of pharmacogenomics, the study of the relationship between pharmacological substances and genomic data and epigenomics, the study of proteins that control gene activation.²⁵ Eventually research in these areas will help determine which patients will benefit from which drugs as well as those likely to have adverse reactions, enabling practitioners to give the right medicine at the right time in the right amount to the right patient. We are already benefiting from improved predictions of the need for chemotherapy in certain breast cancers and the potential for adverse reactions in particular patients to warfarin, a commonly used medicine to prevent blood clotting.²⁶ Such research has also identified a drug that had been written off for most lung-cancer patients but which now appears to be potentially lifesaving for a small number of patients with a particular genotype.²⁷

The velocity of discovery is likely to revolutionize the development and use of pharmaceutical agents. Most drugs prescribed today have positive impacts on fewer than 60 percent of those receiving them.²⁸ If we knew more about who would benefit and who would be harmed, we could provide more effective therapies with less risk, reduce the length, size and expense of clinical trials (all of which are tied to the risk of adverse events), and get more valuable treatments to market sooner.²⁹ The value of pharmacogenomics will only increase as the cost of sequencing an individual's genotype continues to decline, the number of cost-effective diagnostic tests increase, and genomic data become part of medical records as is now happening in some leading-edge healthcare providers such as the Mayo Clinic and the Kaiser-Permanente system.³⁰

Reflecting the openness of the HGP, the National Institute of General Medical Sciences has funded grants intended to make "resources available for independently funded scientists to form research teams to solve a complex biological problem that is of central importance to biomedical science...and that would be beyond the means of any one research group."³¹ The Alliance for Cell Signaling, one of the grantees,

is publishing its data on the Web; all the participants have agreed to disavow intellectual property rights in their research.³²

Similarly the National Cancer Institute (NCI) of the NIH has established caBIG, the Cancer Biomedical Informatics Grid—a network for cancer research made up of over 50 cancer-research centers and 30 other organizations that voluntarily share data, tools, applications, and infrastructure.³³ It has also established, among other initiatives, the Cancer Gene Data Curation Project which has created a database of associations between genes and diseases and genes and drug compounds, the National Cancer Imaging Archive which provides an image archive to assist in the development of tools to detect and classify lesions, and is planning a Clinical Research Information Exchange as a common electronic infrastructure linking those developing biomedical therapies and those overseeing the drug development and approval process.³⁴ NCI is also addressing the underappreciated need for the creation of standards necessary for data exchange by supporting the development of a standardized clinical vocabulary for cancer.

Among international organizations, the World Health Organization has created www.TDRtargets.org, a publicly accessible Internet-based clearinghouse of genetic information on such diseases as malaria and African sleeping sickness. The clearinghouse is providing this genetic data on often-neglected diseases to assist researchers in identifying genetic targets for new interventions.³⁵

These more open approaches stand out in contrast to a tendency in biomedical research to become "increasingly proprietary and secretive" because of the importance of such data for potential commercial applications or because of competition among academics for prestige and career progress based on journal publication.³⁶ In response to this "privatization of data," and to harness the power of openness to speed the development of medicines and vaccines for less lucrative commercial markets, the Bill & Melinda Gates Foundation is now conditioning its grants to require researchers to share their results promptly so that rival teams can build on successes, avoid pitfalls, and eliminate redundancy.³⁷

There is growing agreement on the value of increased openness in pre-competitive research; the broad

participation of for-profit and not-for-profit entities in the SNP consortium is an example of open pre-competitive research at work.³⁸ But there remains a considerable tension between those who seek intellectual property protection for research results and those who advocate greater disclosure. The disputes are not theoretical. Many genes have already been patented. A number of biomarkers are tied up by restrictive patent-licensing agreements.³⁹ And patents cover tools critical for future research.⁴⁰

The HGP dealt with the patent issue from the top down and participants agreed to forego patent protection. Other collaborative efforts have chosen different paths including defensive patenting (with non-exclusive licensing to prevent other parties from appropriating research results and using them in patent applications) and defensive publishing to thwart patent claims.⁴¹

Some Limits on Openness

Complete openness of data is neither easy to accomplish nor necessarily the best answer in all cases. Much work still needs to be done to establish standards for protocols, formats, terminology and nomenclature that will allow data to be combined easily. The integrity of existing data must be protected. There may be privacy issues that limit accessibility as well as disputes over ownership and control of data. There are public policy questions about the wisdom of allowing free-and-open access to, for example, databases of pathogens.⁴² And there are contentious issues to be addressed about the effects of openness and sharing in different parts of the production chain on incentives to develop commercially viable products. Given all these issues it is not surprising that models with varying degrees of openness are being tested.

Not all of the NCI's program participants, for example, provide all their data to any and all comers. Certain materials produced with NCI support are shared only with participating cancer researchers. In other cases, where participants in NCI programs are reluctant to give up control over data they have collected or generated, an innovative solution has been

crafted under which the data holder agrees to respond to queries from qualified researchers utilizing the data they control but will not share.

It is clear, however, that the open model of progress through sharing has found great resonance in the biomedical research world. Even Craig Venter of Celera, a vigorous proponent of the privatization of genomic data, has recognized this. He literally has been sailing the seven seas gathering and classifying organisms. Rather than charging for access to the data, he is making it available to all through the open-access Public Library of Science (PLOS).⁴³

Recommendations Regarding Openness in Biomedical Research

The leading federal research agencies should continue their support for open models of research, whether entirely publicly funded or in public/private partnerships, such as the Human Genome Project, the HapMap Project, or the SNP Consortium, and should enunciate policies with a strong preference for utilizing the most open models, particularly in pre-competitive research.

Experiments with differing levels of openness should continue as appropriate, but greater openness should be preferred absent strong countervailing interests.

Because the absence of agreed upon standards for protocols, formats, terminology, and nomenclature undercuts the ability of researchers to share data in its most usable form, the leading federal research agencies should increase their support for the development of these infrastructural underpinnings of openness.

The leading federal research agencies should continue to require data-sharing agreements from recipients of federal support and should, to the greatest extent possible, encourage recipients to share results and underlying data generated by the research.

Chapter 3: Openness Regarding Clinical Trials and Post-Approval Surveillance

In 2003 Andrew von Eschenbach articulated the challenge of closing the gap between basic research and the development of clinical and public health interventions. We have seen the impact of greater openness in basic research. How could the processes of approving drugs and devices and the monitoring of the effects of these interventions after approval benefit from being made more open?

The Societal Bargain Underlying Clinical Trials

To obtain U.S. Food and Drug Administration (FDA) approval for a drug or device, the intervention must be tested on humans as part of a multistage-clinical trial in which the intervention is compared for safety and efficacy with a placebo. A clinical trial such as this is considered “the gold standard” for human testing and generates the evidentiary basis for applications for FDA approval. Some 10,000 clinical trials are conducted every year.

Approval by the FDA does not require that the intervention be without risk. Both risks and benefits must be considered, as the FDA’s decision can have profound consequences. When approval is denied or delayed those who might have benefited are harmed; when approval is granted, or granted before the risks are understood, those who can benefit from the intervention are rewarded but some suffer adverse effects. The FDA attempts to find the right balance, but given the state of our knowledge, the attempt is as likely to resemble art as much as science.

Until 2007, FDA rules required the registration of clinical trials only for interventions dealing with serious or life-threatening illnesses.⁴⁴ (Many trials that did not meet these criteria have been registered at the same location: www.clinicaltrials.gov.) The registration requirement was not only pragmatic—other researchers should know whether a drug or other intervention has been studied—but principled.

Our society recognizes a moral obligation not to do harm to others. Any intervention on a participant in a clinical trial presents some level of risk, so some offsetting benefit is expected. Society will thus authorize an entity to conduct a clinical trial, with its inherent risks borne by the individual participants, in exchange for the potential benefits from the drug or device as well as the knowledge that is gained from the trial. The value to society as a whole is directly related to the knowledge generated and its availability.

This societal bargain does not always work as intended. Over the last decade, many questions have been raised about the registration of trials, the transparency of their conduct, as well as the accuracy and accessibility of their results and the data they produce. Recent headlines, for example, reveal examples of fraudulent results and raise questions as to whether results have been selectively reported with negative, even life-threatening, evidence suppressed.⁴⁵ Research has shown a strong publication bias favoring the disclosure of favorable results and disfavoring the disclosure of negative trials or negative outcomes.⁴⁶ Studies reveal that research results and disclosures appear to be affected by the financial interests of researchers and sponsors; research supported by entities with a financial interest in the outcome reported significantly higher positive outcomes than research supported by neutral parties.⁴⁷

Registration of Clinical Trials

Registration of clinical trials in the United States has been very uneven, despite the FDA’s regulatory requirements; there is little evidence that the FDA has made any significant effort to determine if its requirements were met.⁴⁸ In some cases, requirements for registered trials were met only 3 percent of the time.⁴⁹

In an attempt to address the incompleteness of clinical-trial registrations, the editors of some of the world’s most prestigious biomedical journals jointly published

a statement in September 2004 that their journals would not publish findings based on clinical trials that were not registered. Analysis following the editors' announcement demonstrated a spike in compliance with registration requirements, at least arguably due to the importance, both scientifically and commercially, of publication in these journals.⁵⁰ (We discuss issues regarding publication/disclosure in Chapter 4.)

An extensive examination of the issues surrounding clinical-trial registrations, including what data should be disclosed and when, has taken place over the last several years in Geneva under the auspices of the World Health Organization (WHO) International Clinical Trial Registry Platform.⁵¹ The WHO began an effort to establish a universal set of minimum data requirements for clinical trials based on the need of researchers to have access to the broadest possible array of compatible data and to increase the efficiency of clinical research by preventing unnecessary duplication.⁵² The WHO also sought to provide guidance to lower-income countries facing an increasing number of clinical trials within their jurisdictions and lacking well-developed regulatory structures. At the same time, major private-sector sponsors of clinical trials were attempting to harmonize clinical-trial reporting requirements around the world in order to reduce the costs of complying with differing regimes.

Although the aims of the WHO were broadly shared among the various stakeholders, and the final list of twenty data elements to be required for registration were largely agreed to, the various stakeholders were ultimately unable to reach agreement as to when trials would have to be registered and when certain data elements would have to be disclosed. The principal argument against early disclosure was that "premature" disclosure would stifle innovation. Premature disclosure, it was argued, would alert competitors who might use the data for their own patent applications. It would hinder companies in their efforts to obtain intellectual property protection and to commercialize the products being tested, thus reducing their incentives for research.⁵³ Private-sector trial sponsors suggested postponing registration until the initiation of larger, later-stage trials (stages III and IV), and placing the data that is generated in escrow with an independent third party to be disclosed at the time of the approval of the drug or device.⁵⁴

Proponents of earlier disclosure noted that many trials never progress to these later stages; there were good reasons to disclose the results of early stage trials, even those deemed to have "failed."⁵⁵ There is no convincing justification, they argued, to waste scarce research resources on work already done, and there may well be important data gathered on the safety (and efficacy) of interventions in the earliest stages.⁵⁶ Proponents of early and full disclosure point to the peer-reviewed *Journal of Negative Results in Biomedicine* and *PLoS Clinical Trials*, which publishes trial results irrespective of the outcomes, as proof of the scientific value of learning from what does not work.⁵⁷ (One can imagine that at least some participants in clinical trials would have second thoughts about their participation if they knew that the results might be kept secret.)

After completion of its consultation, the WHO's International Clinical Trials Registry Platform rejected the arguments for delayed disclosure, noting the wide variation in disclosure practices about trials among trial sponsors and the availability of information about the trials from other sources.⁵⁸ It called for the "registration of all interventional trials, including early-phase uncontrolled trials in patients or healthy volunteers" and for "full public disclosure of all registration data items at the time of registration and before recruitment of the first participant."⁵⁹

It is beyond the scope of this paper to answer definitively the core questions as to the impact of the data-disclosure requirements proposed by WHO's International Clinical Trials Registry on innovation and how the impact might vary based on the timing of the disclosures. A number of countries adopted the WHO requirements, although the United States initially took a different path, with the FDA arguing that it did not have the authority to impose such requirements.⁶⁰

Congress recently passed and the President has signed the Food and Drug Administration Amendments Act of 2007 (hereinafter referred to as the 2007 Amendments) which requires the registration of all clinical trials and the filing of all results in a results database; the FDA is to study what disclosures should be required.⁶¹ Given the complexity of the issue, it would be helpful if a neutral and expert party such as the National Academy could conduct a public study, specifically with input from the FDA and NIH, on the optimal timing

of disclosures of registrations and results, considering the potential impacts on innovation, the progress and efficiency of biomedical research, and patient safety.

The 2007 FDA amendments did not resolve all of the important issues about openness in clinical trials. We believe that the following steps would further improve the utility, safety and efficacy of clinical trials:

- The existing registry, www.clinicaltrials.gov, should be continued and strengthened, as it is the largest and most advanced clinical-trial registry in the world. Any results database should build upon this infrastructure and existing trial records.
- Each trial should be issued a unique identifier so that the trial can be tracked through various reviews and over time. As more and more trials are taking place internationally a solution that has each registry issuing its own unique identifier is unlikely to be the best long-term solution. A more appropriate solution might be found in the WHO's plan to issue a Universal Trial Reference Number for all trials worldwide; another possible solution would be to use some variant of the Internet's domain name registry system.
- Companies seeking FDA approval for an intervention are not required to file all the studies that they have conducted regarding that intervention, just those conducted for purposes of obtaining approval. The vast majority of other, non-filed, studies are never published. All company studies of the agent should be made available to the FDA, decreasing any incentive to submit only the most favorable; any study relevant to the agent's safety should be publicly available. Similarly the FDA should consider providing access to any FDA studies it conducted during the approval process.
- There is still much to be learned about how to measure trial outcomes. NIH is now building a pilot results database with information from NIH-funded trials. The National Library of Medicine is funding TrialBank, which will provide open access to computable trial results.⁶² Based on the experience with these databases, it should be possible to make more informed judgments about what data should be made available and when, and what conditions would maximize the utility of the data.

Data Integrity in Clinical Trials

There have recently been allegations of fraudulent data being incorporated into reports on clinical trials and of abuse of clinical data by sponsors.⁶³ Such actions fundamentally undercut the value of clinical trials and strike at the heart of the drug and device approval processes. Although present regulations appear to permit the reporting of fraudulent data to be delayed until approval is sought for the drug or device being trialed, legislation should make clear that evidence that would lead a reasonable researcher to conclude that it is likely that clinical trial data has been fraudulently altered should be reported immediately.⁶⁴

To further safeguard the integrity of clinical trials, any agreements that limit the ability of researchers to freely discuss their findings, particularly with respect to potential problems, should be disclosed. The legitimate goal of protecting proprietary information can not justify a "gag order."

Conflicts of Interest in Clinical Trials

Recent research strongly suggests that the conduct and reporting of clinical trials can be affected by financial interests.⁶⁵ With private sector funding playing a larger role in support of research, and with growing ties between academic researchers and commercial enterprises, it is important to disclose potential conflicts so that those who rely upon these studies can make more informed judgments about them. Here, as in other areas, "sunlight is the best disinfectant."⁶⁶

Access to Data Produced in Clinical Trials

Even more contentious than the issues surrounding registration of clinical trials and reports of results is the issue of access to the underlying data generated by the clinical trials. Such data are not generally available even after the trials are completed and the drugs or devices approved; in fact, the data can be protected by law for an additional period of time after the FDA has acted.⁶⁷

These data may well still be of value to the trial's sponsor. But their value to the research community at large is likely to be even greater. Moreover, even if the data are disclosed the sponsor does not lose all of its benefits having had a multiyear head start in analyzing the data and preparing itself to act upon that analysis.⁶⁸

The Need for Usable Data

Researchers now *read* journal articles about the *results* of trials in hard copy or in Microsoft Word or PDF files and generally lack access to the underlying data. But, as one student of clinical trials has noted, computers don't read journals, they process data. Imagine the added value to a researcher of access to the underlying data from a journal article. Then imagine the added value to society of a searchable database containing the aggregated data underlying multiple clinical trials.

The present situation is in stark contrast. Most of the data from applications to the FDA lies in a "bottomless pit," and "is not cataloged, tagged, or in any usable form that would allow it to be found."⁶⁹

In the past, the FDA has not required that applications be submitted in electronic form or specified data formats.⁷⁰ Ultimately, policymakers will have to determine what types of data from clinical trials ought to be disclosed and when, but it is increasingly important that if data are made available they should be in a searchable computable form—interoperable at both a semantic and syntactical level—allowing for interpretation both statistically and medically.⁷¹ This is no easy task. It will require significant efforts to reach agreement on the appropriate standards, but the potential gains are enormous.

Informed Consent for Participation in Clinical Trials

No matter how important the trial, the protection of the patient must be a central concern. To ensure that the rights of patient participants in clinical trials are protected, it is important that they have access to and understand the conditions of participation, the risks involved, as well as the potential benefits, and any potential conflicts of interest. There are no general rules that apply to clinical trials and, surprisingly, there is no single federal agency with authority over them.⁷² Given recent examples that suggest that participant consent has been less than informed, it would be helpful for expert federal agencies to help craft generally applicable rules regarding consent.⁷³ In addition, those who recruit participants should make clear any financial stake they have in such recruiting.

The website www.clinicaltrials.gov now provides useful information for those seeking to identify relevant

clinical trials in which they might participate, as well as providing information that can help them make decisions about whether to enroll. This resource should continue to be enhanced as the 2007 Amendments are implemented.

Informed Consent for the Use of Tissue Samples in Clinical Trials

Almost three-quarters of trials submitted to the FDA are based on the use of patient-tissue samples.⁷⁴ The willingness of patients to provide such samples in the future is crucial for the success of biomedical research, and there are signs of a growing reluctance on the part of individuals to provide samples without compensation when the samples might be used by others for commercial purposes without any benefit for the donor.⁷⁵ Here too there are no general rules, and the law is unclear. The expert federal agencies should make recommendations as to the appropriate balance between the rights of donors and the needs of researchers, including what kinds of disclosures of risks and benefits are required, and what would constitute informed consent.

Ideally the patient should be informed of all the uses that will be made of the donation. But it is obviously difficult to predict *all* the uses—remember that scientists recently used tissue samples obtained during the great flu epidemic of 1918 to better understand the potential for future pandemics. Even so it is important to be open about existing plans and to consider carefully whether additional consent should be required in the future, and under what circumstances.

Given the extraordinary pace of developments in genomics, pharmacogenomics and related fields, the FDA should consider whether DNA samples should be requested as a matter of course from all clinical-trial participants, especially as the cost of sequencing an individual's genome falls. Eventually, it seems likely that genomic data will be an important component of the data produced by any well-conducted clinical trial.

Privacy and Clinical Trials

Participants in clinical trials have important privacy interests and should be confident that information about them is not disclosed to unauthorized parties or used for purposes to which they have not consented.

Expanded collection of genomic data would only increase the privacy stakes. Recent litigation raises the issue of whether privacy protections can be maintained when the results of clinical trials are subpoenaed.⁷⁶ Policymakers should carefully examine how to protect the privacy of clinical-trial participants while ensuring that appropriate information is made available in related litigation. If personally identifiable information is disclosed, either to unauthorized parties or pursuant to legal order, trial participants should be notified.

Post-Approval Surveillance

While properly conducted and reported clinical trials are the “gold standard” for determining the effect of an intervention on the trial population during the trial period, clinical trials have important limitations. They are very expensive. They take a substantial amount of time to complete. More important, it is not clear whether they are truly generalizable or effective in predicting safety and efficacy over longer periods of time by larger groups of users.

Clinical-trial populations have been justifiably criticized for not adequately reflecting the much larger populations, particularly minority and older populations and those with multiple medical conditions, who will ultimately use the intervention if it is approved.⁷⁷ The relatively limited durations of trials do not allow them to predict long-term adverse results or demonstrate long-term effects.⁷⁸ It is not surprising then that the exposure of a drug or device to a much larger population with much greater individual variation for a much longer period of time will sometimes lead to unpredicted consequences; these include not only adverse events not foreseen at the time of approval but also the development of evidence of efficacy in treating conditions that had not been the subject of the trial.

Recognizing these limitations of clinical trials, the FDA has often required, as a condition of approval, post-authorization follow-up studies. The agency has also established a system, MedWatch, to receive reports on post-approval adverse events.⁷⁹ In response to reports of adverse events, the FDA has convened expert advisory councils to make recommendations about changing drug labels, imposing new conditions on use, or even ordering drugs off the market.

These processes have not always worked as intended. As many as thirty-five percent of the post-approval studies mandated by the FDA may never have been filed or completed as required.⁸⁰ The Inspector General of the Department of Health and Human Services (HHS) reported that the FDA did not know the fate of these studies and made little effort to follow up.⁸¹ The Institute of Medicine has called for a better system of adverse-event reporting.⁸² And more major drugs have been withdrawn from use in recent years than at any time since 1990.⁸³

The 2007 Amendments greatly increase the availability of information regarding post-approval surveillance monitoring. They grant new powers to the FDA regarding post-approval studies—such a study, for example, served as the basis for the 2007 re-evaluation of Avandia—as well as post-authorization reporting.⁸⁴

Some 449,000 adverse events were reported in 2006. Many experts believe this represents only a small percentage of actual problems.⁸⁵ The 2007 Amendments direct the FDA to contract with private-sector entities, such as healthcare providers or insurers, to use massive databases (100 million records or more) of patient records to identify possible safety issues related to drugs and devices.⁸⁶ Advocates for such a use of massive databases believe that it will facilitate the earlier discovery of adverse effects from drugs such as Vioxx.⁸⁷ (We will discuss the use of such databases in evidence-based medicine in Chapter 5.)

Additional steps may be desirable. The FDA should consider creating incentives for the reporting of adverse events, broadening the means by which interested parties can report them, and increasing access to the reports that are received.⁸⁸

Greater disclosure raises issues such as the potential for misinterpretation of reports and the gaming of FDA processes by competitors. But these possibilities are outweighed by the gains from having the active participation of patients and practitioners who experience adverse reactions on medicine’s front lines.⁸⁹ Practitioners are already seeing the benefit of using the Internet to share such reports with each other, without waiting for FDA action, in order to improve their own practice of medicine.⁹⁰

Comparative Testing

As one expert put it, for a new drug to be approved by the FDA it “must merely be slightly better than (the) placebo in achieving a surrogate outcome over a few months, in modest numbers of highly selected patients.”⁹¹ Is this really all we need to know?

Billions of dollars are spent each year on groups of drugs that act in similar ways. For caregivers and patients to make more informed decisions, they need to know whether one intervention is superior to another for a particular patient or group of patients. Such information does not normally emerge from the FDA’s drug approval process. Individual companies are unlikely to undergo the expense of conducting rigorous comparative trials. If healthcare resources are not infinite and if better, more cost-effective care is the goal, we should identify the best possible sources for comparative testing and fund them accordingly.

HHS’s Agency for Healthcare Quality and Testing and the NIH Center for Transitional Medicine may be equipped to conduct such studies but they are inadequately funded to undertake such efforts. In a recent report the CED suggested the creation of a new entity, the Institute for Medical Outcomes and Technology Assessment, which would “assess the effectiveness, cost, and overall value of health interventions and practices.”⁹² Whatever the vehicle, rigorous comparative assessments are both critical and largely unavailable to caregivers and patients alike.

Recommendations Regarding Clinical Trials and Post-Approval Surveillance

Support for the government’s leading clinical trials database (www.clinicaltrials.gov) should be enhanced so that it will include all clinical trials in the United States, whether publicly or privately funded, as well as information useful for individuals searching for relevant clinical trials and guidance for those seeking to participate in them.

The United States should work to promulgate a universal clinical-trial reference-number system so that clinical trials may be more readily tracked globally.

NIH should continue its work to increase the availability of the results of clinical trials, starting with the results of trials funded by the federal government. This work should inform any FDA decision on the appropriate conditions for disclosure of data generated by clinical trials as well as on standards to improve the utility of such data for biomedical research.

To assist the FDA in setting requirements for clinical trials and approving drugs and devices, the National Academy should be commissioned to conduct a study and prepare recommendations as to the nature and timing of clinical-trial registrations and disclosures of data generated by clinical trials and other submissions to the FDA, based on the impact on innovation, the progress and efficiency of biomedical research, and patient safety.

The National Academy should be commissioned to conduct a study on the state of the existing law regarding the rights of patients and the use of their tissues or fluids in biomedical research, including issues of consent, privacy, and payment, and make recommendations as to whether changes are required.

The FDA should review existing requirements as to patient consent to participate in clinical trials and make changes as appropriate. The bifurcated authority in this area should be ended.

Those recruiting participants for clinical trials should be required to disclose any financial interest in the recruitment.

The FDA should consider whether to require DNA samples to be taken of participants in clinical trials when the price of individual sequencing declines to a level where mass sequencing can be done cost effectively.

The FDA should require electronic filing for all drug and device approvals. The Agency should set standards for and require the filing of data in a form that allows subsequent machine aggregation, search, and manipulation.

The FDA should require the filing of all studies that an applicant has commissioned on a drug or device that is being submitted for approval, whether or not the study

was commissioned as part of the application. Any studies reflecting safety issues should be made public.

The FDA should consider making public any studies that it conducts in the course of a drug or device approval.

Those conducting clinical trials should be required to report to the FDA, upon detection, any instances that would reasonably suggest the use of fraudulent data.

The FDA should require disclosure of any limitations on researchers' ability to comment on clinical trials with which they are involved.

The FDA should require reporting on the progress of all required post-approval studies.

FDA should broaden the means by which post-approval adverse events can be reported and should make the reports more widely available.

The FDA should encourage the disclosure of post-approval data indicating the efficacy of interventions for non-approved purposes.

The federal government should dramatically increase its efforts to directly compare the safety and efficacy of similar drugs and devices.

Chapter 4: Encouraging Openness in Publication/ Disclosure of Research Results

Scientific and Technical Publishing

Scientific and technical journals are the traditional vehicles for disclosure of results of basic research and clinical trials. Scientific-and-technical publishing is a major commercial activity with industry revenues upward of \$7 billion annually.⁹³ It is estimated that some 2.5 million research articles are published each year in over 24,000 peer-reviewed journals.⁹⁴ Most of these journals are owned by commercial publishers, although some of the most highly regarded and widely distributed are published by not-for-profit “learned societies” such as the American Chemical Society.

There is a hierarchy of scientific-and-technical publications. For researchers in both the for-profit and not-for-profit sectors, publishing in a leading journal is important for advancement as well as to gain attention for one’s work.

Most journals only publish articles that have survived a “peer-review” process with the most prestigious being the most selective. The peer-review process has anonymous experts in the appropriate field review a submitted manuscript and make recommendations as to whether it merits publication and, if so, what changes would improve it.

This process has a long history and many admirable attributes. At its best it provides free and valuable assistance to journal editors, allowing them to receive an unvarnished critique from an expert in a field about which they may know little. It may detect analytic or methodological errors, raise design issues, challenge assumptions, point to overlooked research, prevent duplication, and discourage cronyism by the editors.

On the other hand, the process, as applied, has significant limitations that are sometimes overlooked.⁹⁵ It does not serve as an independent check on the integrity of the underlying data or the processes by which data are collected. It may not reveal even extensive fraud.⁹⁶ (Only access to the data and a chance to replicate

the research itself would allow outright fraud to be caught.)

A recent explosion of corrections and retractions in leading journals confirms these limitations. A *New York Times* headline captures the problem: “For Science Gatekeepers, A Credibility Gap.” The article which bears this headline roots some of the problems in both organizational and very human terms: “economic pressures for journals to avoid investigating suspected errors, the desire to avoid displeasing the authors and the experts who review manuscripts, and the fear that angry scientists will withhold the manuscripts that are the lifeline of the journal putting them out of business.”⁹⁷

Limits on Openness in the Present Model

There are, from the standpoint of openness, three serious problems with the traditional journal-publishing system. The first is that the costs of subscriptions or licenses have been rising, putting them out of the reach of many subscribers.⁹⁸ Prices for subscriptions have climbed four times faster than the rate of inflation in the recent past, increasing some 300 percent over the last twenty years, leading some institutions to cut back on their subscriptions, thus reducing access to cutting-edge research results.⁹⁹ Researchers in poorer countries are most at risk, having to rely on the generosity of others, including the WHO’s HINARI program, which provides free or almost-free access to journals for many poorer countries.¹⁰⁰ If researchers do not have access to the results of others’ work, it is far more likely that they will duplicate it, and it is a certainty that they cannot build upon it.

The second problem is that the intellectual property rights that protect the content and underlying data of many of the journals prevent those researchers who do have access from doing what researchers are most skilled at—adding to, revising, modifying, repurposing, and reusing the content to generate new

knowledge. Some of these actions might be possible under today's intellectual property rules, but researchers without access to underlying data may be prevented from making use of new and powerful computational techniques such as machine aggregation and manipulation of data.

Finally, as has been true in other areas where information is being digitized, journals are increasingly providing electronic versions under license. These licenses may cut off a subscriber's access immediately and even limit access to older collections, include some, but not all, of the journals that had previously been available, and prevent researchers from transferring journals to new institutions if they change employers. The practice that some large multi-journal publishers employ of providing discounts to subscribers who take a "bundle" of publications to ensure access to one or two "must-have" journals tends to increase the larger-publishers' share of an institution's subscription budget, threatening smaller-journal publishers and learned societies.

New Open Alternatives Emerge

But digitization and the Internet have done more than create the opportunity for publishers to put journal content in a digital lockbox. They have created new means for providing "open access" whether via open digital archives or alternatives to the traditional-journal regime in the form of "open-access" publishing.

In 1991, Paul Ginsparg created "arXiv" as an open digital archive for preprints (now often called e-prints) in physics.¹⁰¹ Submissions poured in. ArXiv has expanded to include mathematics, computer science, and, most recently, quantitative biology and now holds over 400,000 e-prints.¹⁰² Some academics, particularly those outside of physics and mathematics, have resisted posting their materials to arXiv and other open archives because of a concern that journals might not accept their manuscripts if the materials had already been deposited in an open archive; ironically, by not posting they substantially delayed wider access to their findings.

In 1994, Stevan Harnad broadened the debate about open-access science. His "subversive proposal" rested on an obvious fact—researchers, particularly academic researchers, have a tradition of sharing, and want to get their results to as many of their colleagues as possible

as quickly as possible (for many reasons, both public spirited and private-interest enhancing). Harnad showed how electronic archiving could achieve these aims. Researchers would no longer have to rely exclusively on intermediaries such as journal publishers but could—and should, according to Harnad—create publicly accessible digital archives of their own works.¹⁰³

The potential for open-access publishing—moving beyond depositing preprints into archives to Web-based publications unconstrained by subscription requirements or paper-based publishing formats—was bolstered by pioneering journals from the Optical Society of America in 1997 and the Institute of Physics in 1998 and later by the larger-scale and more ambitious Public Library of Science. Open-access publishing has increasingly been endorsed by academics and policy makers. As the Budapest Initiative put it in 2002, "An old tradition and a new technology have converged to make possible an unprecedented public good."¹⁰⁴

The Advantages of Openness

There is no generally agreed-upon definition of open-access publishing but some elements are constant—the removal of cost barriers imposed by subscription and licensing fees, and any other conditions on access.¹⁰⁵ Proponents of open-access publishing claim that more than 2,500 open-access journals now exist, providing clear benefits over traditional subscription-based paper publications.¹⁰⁶ In launching the Public Library of Science's open-access journal *PLoS Biology*, Patrick Brown, Michael Eisen, and Harold Varmus explained why they believed they were making the information they would publish more valuable:

Freeing the information in the scientific literature from the fixed sequence of pages and the arbitrary boundaries drawn by journals or publishers—the electronic vestiges of paper publication—opens up myriad new possibilities for navigating, integrating, 'mining', annotating and mapping connections in the high-dimensional space of scientific knowledge. Consider how the open availability and freedom to use the complete archive of published DNA sequences in the GenBank, EMBL, and DDBJ databases inspired and enabled scientist to transform a collection of individual sequences into something incomparably richer.

With great foresight, it was decided in the early 1980's that published DNA sequences should be deposited in a central repository, in a common format, where they could be freely accessed and used by anyone. Simply giving scientists free and unrestricted access to the raw sequences led them to develop the powerful methods, tools, and resources that have made the whole much greater than the sum of the individual sequences. Just one of the resulting software tools—BLAST—performs 500 trillion sequence comparisons annually! Imagine how impoverished biology and medicine would be today if published DNA sequences were treated like every other kind of research publication—with no comprehensive database searches and no ability to freely download, reorganize, and reanalyze sequences. Now imagine the possibilities if the same creative explosion that was fueled by open access to DNA sequences were to occur for the much larger body of published scientific results.¹⁰⁷

The Public Library of Science, an admittedly interested party, has published several papers attempting to compare the performance of open-access models with those of traditional publishing. These studies found that there were higher rates of citation for online open-access materials during the early months of availability when only subscribers to traditional journals would have had access to non-open access articles. More encouraging to open-access advocates were the findings that the positive gap in citation rates continued after six months when formerly restricted articles were made more broadly available.¹⁰⁸ The research also suggests that a broader, more cross-disciplinary audience used the open-access materials.¹⁰⁹ This is particularly encouraging because research has found that scientists working together with those in different fields are more likely to solve scientific problems.¹¹⁰

Certain advantages are inherent in open-access publishing. Open-access publishing can reach more people because more people have access. More people can reach open access materials more quickly than can reach articles available only in traditional journals.

One traditional-journal editor criticized open-access publishing because “substandard science could be widely circulated without being subjected to more rigorous peer review.”¹¹¹ Greater openness does raise

important issues. But this is not one of them. Open-access journals, like traditional journals, *are* typically peer reviewed. And to the extent that open-access journals provide access to data underlying their articles they provide a means superior to traditional peer review for replicating research and detecting fraud.

Open access in fact can provide new methods for evaluating materials. Having material available to anyone creates a vastly greater number of potential “reviewers” in the form of readers of the article. All of these potential “post-publication peer reviewers” can track comments and changes, and comment accordingly, thereby creating an annotated version that would not otherwise exist.¹¹²

Openness and Government-Funded Research

A special case of open access concerns disclosure of the results of government-funded, non-classified research. The OECD Ministerial of 2004 focused on this issue; this led to a 2007 OECD Recommendation Concerning Public Access To Research Data from Public Funding, which notes the benefits of improved access to, and sharing of, data in terms that could be applied well beyond publicly funded research:¹¹³

- Reinforces open scientific inquiry,
- Encourages diversity of analysis and opinion,
- Promotes new research,
- Makes possible the testing of new or alternative hypotheses and methods of analysis,
- Supports studies on data-collection methods and measurement,
- Facilitates the education of new researchers,
- Enables the exploration of topics not envisioned by the initial investigators, and
- Permits the creation of new data sets when data from multiples sources are combined.¹¹⁴

The OECD Recommendation, citing a U.S. National Research Council Report, states: “The value of data lies in their use. Full and open access to scientific data should be adopted as the international norm for the exchange of scientific data derived from publicly funded research.”¹¹⁵ Open access should be “easy,

timely, user-friendly, and preferably Internet based.”¹¹⁶ Such a regime, according to the Recommendation, not only “helps to maximize the research potential of new digital technologies and networks, but provides greater returns from the public investment in research.”¹¹⁷

Following the OECD’s lead, the European Commission has agreed to provide millions of dollars in funding to support the creation and maintenance of an open-access digital repository.¹¹⁸ CERN, Europe’s leading high-energy physics organization, announced that it will *only* publish the results of its supercollider trials in open-access publications.¹¹⁹

In the United States, the National Institutes of Health have taken the lead in pushing for broader disclosure of the fruits of government-funded research. NIH has “recommended” that funding recipients “submit an electronic version of the author’s final manuscript upon acceptance for publication,” although NIH policy does allow the author to designate a timeframe for public release anytime within 12 months of final publication.¹²⁰ This recommendation, explicitly *not* a requirement, has largely been ignored, with fewer than 5 percent of grantees complying.¹²¹ Like NIH, the NSF requires that grantees provide a data-sharing plan but has not required “open access” to the results of its funded research.¹²²

The proposed Federal Research Public Access Act, introduced in 2006 with both liberal and conservative support, would require that unclassified research funded by any U.S. government agency that makes research grants totaling more than \$100 million annually would have to be made public within six months of publication.¹²³ Conservative supporters of the legislation who might have been expected to champion private-sector publishers argued that the research was paid for by taxpayers who should not have to pay twice by having public institutions pay for journal subscriptions. The House and Senate appropriations bills (funding NIH) include a similar provision for access within 12 months, but passage of the Public Access Act would highlight the policy of greater openness with respect to government-funded research.¹²⁴

Differing Models for Openness

Just as there is no agreement as to the precise definition of open access, there is no one open-access

publishing model. In addition to the pure open-access journals, the principles of open access are being implemented in journals that provide open access to some articles and not others (hybrid open-access journals), or that provide open access after some delay following publication (delayed open-access journals). Open-access principles are also being furthered in different forms in blogs, wikis, e-books, listserves, and file-sharing systems. An Autism Wiki, for example, managed by adults with autism and Asperger’s syndrome, publishes information on autism and related conditions.¹²⁵

There are also many economic models being proposed to support open-access publishing.¹²⁶ The most common funding model is that of the author paying the journal the cost of publication. Fee waivers would be possible for those unable to pay. Wellcome Trust advocates a variant of the “author-pays” model, under which the funding organization would pay for publication with disclosure/publication being considered as simply another phase of the research project.¹²⁷

It is not yet clear whether incorporating the cost of disclosure/publication into research grants would, as critics charge, reduce the total amount of research that is supported in the long run; running PubMedCentral costs NIH approximately 0.02 percent of its budget. But it is possible that if NIH grant budgets were declining, adding even small amounts of publication costs into grant budgets might cumulatively reduce the number of NIH grants.

Other models include foundation support, advertiser support, and subscription support by research-oriented institutions, which would allow researchers from the subscribing institution to publish in the journal—a form of “co-op” journal.¹²⁸ Another model would have commercial entities charged for access while maintaining open access for not-for-profit entities and independent researchers. Like the open-source software community, the open-access publishing community is exploring a wide range of activities to support its mission, ranging from print sales and value-added research services to the conduct of related conferences and the establishment of electronic marketplaces.

Among the many unknowns about the relatively new area of open-access publishing is whether any of these models are economically sustainable. There are

conflicting analytic studies. The Wellcome Trust, a long-time open-access champion, commissioned several studies that showed that open-access publishing was 30 percent cheaper than traditional publishing.¹²⁹ Indeed, most open-access publishers have reduced costs by embracing “lean-publishing” methods and free open-source publishing tools.¹³⁰ Traditional publishers have countered with other studies showing that open-access publishing is at least as costly, if not more so, than traditional publishing. Elsevier has argued that higher education in the United Kingdom would have to pay 30 percent to 50 percent more to cover the costs imposed by author-pays publishing models, given the growth of research.¹³¹ These disputes about sustainability are likely to be resolved only by the passage of time.

Another argument raised against open-access publishing is that it will eventually reduce the volume of research as publishers, particularly learned societies, will reduce or eliminate their publishing activities. Many learned societies depend on journals to support their other activities and might be forced to find other revenue streams or cut back their activities. Whether competition from open-access journals will force the closing of these journals is yet to be seen. But research good enough to be published in learned-society journals seems likely to find a place in new journals or expanded old journals, open access or not.

Openness and Academic Advancement

A more important issue today may be that of prestige. For academic researchers, many rewards—appointments, promotions, tenure, access to research support, reputation within their scholarly community—depend on publication. The greatest rewards usually go to those who publish in the most prestigious journals. While academic researchers may support the goal of advancing science and may obtain personal satisfaction from working collaboratively with their peers, they understand the realities of academic advancement. They realize they are competing with others for future publication glory and, like all of us, want recognition of their work.¹³²

Some academics, particularly more junior ones, may well be concerned with the effect of publication in an open-access journal (as opposed to a traditional one)

on their career prospects. Will some peer-reviewed, open-access journals (such as those of PLoS) achieve the prestige of *Nature* or *Science*?¹³³ Will they be shown to have a high impact in their field? How will tenure committees, made up of senior academics (who may play major roles in learned societies), react to a colleague’s choice to publish in an open-access journal? Will new models of recognition for scholarship—based on the number of citations, number of times downloaded, BioMed Central’s “most viewed” designation, or the amount of data generated or annotated—begin to substitute for more traditional methods of judging an article’s worth? Will scholarly journals and tenure committees give recognition to work in database science which utilizes immediate web posting of data? (Currently researchers who immediately post their results must forego traditional publishing because traditional journals generally do not accept already-disclosed work.)

Arti Rai, who has written widely on the issues surrounding open science, has suggested that a major step forward would be for a prestigious peer-reviewed journal in the biomedical arena to confront the issue of academic competition by committing not to discriminate against articles analyzing data already made publicly available.¹³⁴

Traditional Publishers Respond to New Open Models

Traditional journals have responded in differing ways to the new open-access models. Some are becoming open-access hybrids, providing authors, whom they would otherwise have published under traditional rules, with the option to pay the cost of publication and eliminate any period of exclusivity.¹³⁵ Some, such as *Nature*, and publishers Blackwells, Oxford University, and Springer, have shortened the period of exclusivity that they impose, sometimes to as little as six months.

Even six months may be conservative. In 2001, the American Society for Cell Biology began providing free access to all articles published in their journal, *Molecular Biology of the Cell*, two months after initial release based on an analysis that showed that the first two months were the critical period for citations of the article, and thus should be the period of exclusivity.¹³⁶

Other traditional publishers are actively hostile to the open-access publishing model and appear committed to fighting it—even for publicly funded research. As one publishing executive noted “We’re like a firm under siege.”¹³⁷ An article in Nature.com, quoting from the minutes of a meeting of a committee of the American Association of Publishers (AAP), noted that AAP members need to pay special attention to PubMed Central, whose work “threatens our livelihoods.”¹³⁸ It was suggested that members should raise the issue of censorship against PubMed Central. “When any government funding agency houses and disseminates for public consumption only the work it itself funds, that constitutes a form of selection and self promotion of that entity’s interests.”¹³⁹

Such a response implies that we must choose between open-access and closed-proprietary models. This is not the case. There are many different models that occupy disparate places along the broad continuum of “openness.” As Paul David has written: “Considered at the macro-level, open science and commercially oriented R&D based upon proprietary information constitute complementary sub-systems. The public-policy problem, consequently, is to keep the two sub-systems in proper balance by public funding of ‘open-science’ research, and by checking the excessive intrusions of claims to private property rights over material that would otherwise remain in the public domain of scientific data and information.”¹⁴⁰

The Future of Open Publishing and Disclosure

In the coming years open access may well continue to pressure more-traditional models. More institutions are following MIT’s lead and creating digital archives.¹⁴¹ Proponents of open access are attempting to educate their academic colleagues about their intellectual property rights and the opportunities to provide access to their works; Science Commons is attempting to create a system by which authors can easily modify traditional copyright transfer agreements to ensure that they retain sufficient IP rights to archive their works.¹⁴² Whether academic institutions ever adopt Stevan Harnad’s suggestion to mandate self-archiving—“Publish or perish, self-archive to flourish”—it is likely that we will see new models emerging to provide greater openness.¹⁴³ Harnad himself supports self archiving of even “closed materials” if

meta-data—subject, author etc.—are made accessible through bibliographic databases so that others can learn of the works.

Both open access and traditional journals can be more open by being more rigorous in ensuring that authors disclose potential conflicts of interest. Similarly, both open access and traditional journals should expand the availability of standardized data that can be aggregated, searched, and manipulated.

Finally, whether research results are disclosed through traditional or open-access publication, or via archiving, the time interval between disclosure and incorporation into clinical-treatment regimens is tragically long. According to research cited by the Agency for Healthcare and Quality Research and the National Cancer Institute, it takes from 13-17 years to get 14 percent of research into healthcare practice.¹⁴⁴ Those who study, fund, and utilize healthcare-related research need to identify and address the problems inhibiting the dissemination of research results and their implementation in treatments.¹⁴⁵ To continually improve healthcare we will need to ensure that the extraordinary discoveries of creative researchers do not remain “academic” but rather reach those in need more quickly.

Recommendations Regarding Openness and Publishing and Disclosure of Research Results

The explicit policy of the federal government should be to promote the broadest possible access to research results in the healthcare arena, particularly government-supported research.

The principles of the proposed Federal Research Public Access Act should be enacted into law.

The federal government should not discriminate among models for publication/disclosure.

Those federal agencies supporting research should positively respond to requests for funding to pay for publication/disclosure of sponsored research.

In evaluating applicants for research funding, federal agencies supporting research should recognize the scientific value of database science and scholarly work that may be validated by means other than traditional scholarly publication.

Federal agencies supporting research should require that sponsored researchers disclose potential conflicts of interest in any publications/disclosure of the sponsored research.

Federal agencies supporting research should target efforts to reduce the interval between publication/disclosure of research and its implementation in accepted treatment regimes.

Chapter 5: Openness Regarding Electronic Health Records and Evidence-Based Medicine

The Vision of Electronic Health Records

Over the last decade the United States has been lurching toward implementing a system of electronic health records (EHRs). What is being sought in the EHR would not merely replicate, in electronic form, today's patient record, but could include, in addition to the individual's medical history, other information such as his or her family medical history, as well as genomic, pharmacogenomic, and nutrigenomic data, environmental exposures, dietary and exercise practices etc. It would be the key to "empower individual patients to assume a much more active, controlling role in their own health care; improve access to timely, effective, and convenient care; improve patient compliance with clinician guidance; enable continuous monitoring of patient conditions by care professionals/care teams; and enable care providers to integrate critical information streams to improve patient-centered care, as well as to analyze, control, and optimize the performance of care teams."¹⁴⁶

From the standpoint of openness the EHR would be a major step forward in both accessibility and responsiveness. The Health Insurance Portability and Accountability Act (HIPAA) today guarantees a patient the right to access his or her records, although anecdotal evidence suggests that it is a right that is rarely invoked.¹⁴⁷ Ideally, the EHR would be easily available and more valuable, with electronic access for patients and other authorized users anytime and anywhere. It would be far more responsive than today's medical record, capable of electronically receiving data regarding treatments, lab results, hospital-discharge information, prescription records etc. from any authorized user who deals with the patient anywhere and anytime. And it could arguably be made more secure with greater protections for patient privacy than today's paper records, which do not seem to be easily protected from the gaze of those interested, for example, in a celebrity's medical status.¹⁴⁸

Having access to more complete and accurate information would allow caregivers to offer better and more personalized treatment; HHS data show, for example, that one-seventh of primary-care visits are affected by missing data.¹⁴⁹ The improvement in data access would be particularly marked if the patient moved, or if the patient's records were physically destroyed, or if the patient came to an emergency facility that had not previously provided treatment, or if the patient were comatose—in the aftermath of Hurricane Katrina all of these conditions might have been simultaneously met for a single patient. An EHR would be extremely useful when a patient is being treated by multiple healthcare providers for multiple ailments and when healthcare information is scattered across multiple facilities—which is often the case for chronically ill patients who generate a disproportionately large proportion of healthcare costs. It would, if comprehensive and accurate, help avoid duplicative testing, conflicting prescriptions, and redundant treatments. It could, as one observer put it, improve a caregiver's ability to deal with misinformation, missing information, mishandled information, mislabeled information, and misfiled information.¹⁵⁰

An EHR could serve as a platform for writing prescriptions and having them filled, ordering tests, scheduling appointments, providing reminders, and issuing alerts.¹⁵¹ By recording prescriptions and reactions it could provide useful inputs for an expanded FDA post-authorization surveillance system. And having data in standardized electronic form could potentially reduce health spending. RAND researchers estimate that EHR implementation costs could total \$8 billion per year over 15 years.¹⁵² But the same RAND study predicts that annual savings from health IT would average \$81 billion over 15 years.¹⁵³ HHS estimates that the widespread adoption of EHRs could reduce health spending by 7.5 percent to 30 percent, and further cut administrative costs, which constitute one-third of all healthcare expenses.¹⁵⁴ (Because an EHR would be created, maintained, and utilized by real and

fallible people, the chance that it would completely fulfill all these goals approaches zero—but it offers the opportunity for enormous advances.)

The Reality of Electronic Health Records

EHRs might be characterized today as an extremely slowly developing success story. In 2004 President Bush set a goal of having an electronic medical record for every American in 10 years—by 2014.¹⁵⁵ At present only a quarter of U.S. doctors utilize electronic records although that is a 30 percent increase from 2001 (By contrast 98 percent of physicians in the Netherlands utilize electronic records, 92 percent in New Zealand, and 89 percent in the United Kingdom. These electronic records, however, do not necessarily have all the characteristics of the EHRs described above.)¹⁵⁶

In early 2007 four HHS-funded prototype electronic-records systems linking healthcare systems from around the country were showcased in Washington.¹⁵⁷ At almost the same time a consortium of employers led by Wal-Mart and Intel announced that it would establish an EHR system managed by a not-for-profit third party and covering their 2.5 million employees who would be given control over access to information about themselves.¹⁵⁸ The Veterans' Administration, acknowledged as the government leader in EHRs, is rolling out MyHealtheVet, a system for its 7.6 million enrollees, which will gradually be extended to include treatment records, appointments, chemical and blood tests, allergies and immunizations, and hospital discharge records; the Department of Defense and the Veterans' Administration have agreed to a process for a seamless real-time exchange of data between themselves, although completion of this process is many years away.¹⁵⁹ IBM and the Mayo Clinic are collaborating on a system for the Clinic's 4.4 million records which will include personal histories, imaging, tissue analyses, as well as biochemical and genetic data.¹⁶⁰

There are a number of major obstacles to the attainment of the EHR vision. The balkanization of healthcare has resulted in very diverse participants using many different legacy systems with few areas of consistency across the country. Attempts to share information between different systems now produce a mosaic with too many missing pieces, as different

systems utilize different standards and procedures and are not designed to be interoperable.

Moreover, any major information technology project can be daunting and contains some risk of failure. A series in the *Los Angeles Times* demonstrated how even leading healthcare organizations such as Kaiser Permanente, which have embraced information and communications technology, are struggling to overcome technical problems in accomplishing their EHR goals.¹⁶¹

The lowest take-up rate for EHRs is in physician's offices consisting of one or two physicians—and 50 percent of U.S. physicians practice in such settings.¹⁶² The use of information technology in these practices, beyond billing and lab-based tests, is not a matter of course.¹⁶³

There are few clear incentives for a small medical practice to convert its records. It would bear the relatively high costs—researchers estimate a cost of \$33,000 per physician to adopt EHRs—but the real benefits would go to the healthcare system as a whole.¹⁶⁴ There is a need to demonstrate real gains in results and efficiency to caregivers, particularly if the most immediate impacts may be from fewer patient visits and fewer authorized tests. Even major institutions that are already benefiting from the improvements made possible by the use of EHRs may be reluctant to share data if sharing increases the likelihood that they will lose patients.

While the cost of establishing an EHR system is high, there is no ready source of funding for the effort. One regulatory step, permitting hospitals to donate medical-record systems to physician practices, has been taken.¹⁶⁵ Various bills have been introduced in the Congress to address the cost issue by means such as grants and loans to smaller medical practices, increasing depreciation rates for health IT investments, and bonuses for those connecting and providing Medicaid reporting electronically.¹⁶⁶

Several innovative responses are already addressing the cost issue. On the local level, New York City is planning to provide free software to 1500 large and small practices that have a substantial percentage of Medicaid eligible patients.¹⁶⁷ On a larger scale, the National E-Prescribing Patient Safety Initiative is offering “free

electronic prescribing software to every physician in the United States.”¹⁶⁸ World VISTA, an open-source software system for EHRs, modeled on the Veterans Administration’s VISTA patient-record system, has been created and is available to all.¹⁶⁹ It appears likely, however, that further financial incentives to encourage and support adoption of EHRs will be necessary to meet the 2014 goal; even with such incentives there is virtually no chance that all existing records will be converted due to the cost and the quality of the records themselves.¹⁷⁰

Two additional obstacles to the establishment of an interoperable national EHR system are the lack of standards necessary for interoperability, and the lack of agreement on how to achieve acceptable levels of privacy and security.

Standards

A broadly based, joint public-private effort, led by HHS, is attempting to develop the necessary standards to allow data in one part of the healthcare system, when authorized, to be available for access for clinical, administrative, payment and research purposes. Standards would cover how the messages that update the EHR would be sent and accepted as well as the content of the messages.¹⁷¹ The present schedule for standards development calls for this work to be completed by 2008.¹⁷²

There is some dispute over the progress of the standards development process which, even under the very best of circumstances, would be difficult, given the number of standards involved and the fragmentation of the healthcare industry. Compounding the problem are the myriad disputes over intellectual property that competing vendors would like to have included as part of the standards.

One small but illustrative example: There are three proprietary systems for describing allergenic reactions to penicillin. It would obviously be preferable to choose one system so that data on allergenic reactions to penicillin can be fed into the EHR in a standardized format, but in a consensus-based process this is not always easy—and the 2008 deadline for this standard is looming. Even if one proprietary system is chosen, issues might arise over royalties.¹⁷³ To keep the standards-development process on track, the federal

government will have to play a major role; as the party that pays roughly half of the healthcare costs in the United States, it can exercise enormous leverage should it choose to do so or if it is perceived as willing to do so.

Technology will also surely play an important role in facilitating interoperability. For example, just as the Extensible Business Reporting Language (XBRL) www.xbrl.org, was developed for financial reporting purposes, new languages may provide semantic harmonization of the many legacy systems that today exist in the healthcare sector.¹⁷⁴

Privacy and Security

Probably the most contentious issue is the impact of EHRs on patient privacy—an area where total openness is certainly not the goal. We need thoughtful efforts to reconcile the benefits of openness made possible by an effective EHR system with the requirement that we close the system by restricting access sufficiently to protect privacy. The EHRs of the future that we have been describing would raise the stakes for privacy and security solutions dramatically, as they would vastly increase the amount and kinds of sensitive data available.

Studies by the Markle, Pew, and California Health Foundations have shown that while most Americans are enthusiastic about improving how their healthcare information is shared among their caregivers, they are concerned about the potential for abuse of privacy regarding that information.¹⁷⁵ Underlying that concern is the belief that the leak of a patient’s medical condition or genomic attributes or other sensitive information could result in great harm to the patient including loss of employment, loss of access to insurance, or other possibly irrevocable consequences.¹⁷⁶ (For similar reasons, few Americans, for example, have expressed a willingness to undergo genetic testing. This may change given the broad bipartisan support in Congress and the White House for legislation forbidding discrimination based on genetic information. Some prominent individuals are, however, already making their genetic profiles public.)¹⁷⁷

Unauthorized disclosure may also increase the growing problem of “medical identity theft” (called the most underreported and poorly documented of identity crimes) spurred by the high cost of medical care

and the large number of uninsured or underinsured people.¹⁷⁸ Victims of medical identity theft may not only be charged for someone else's treatment, exposed to inappropriate treatment based on medical records that reflect another person's medical condition, but also may face the loss of their own health insurance.¹⁷⁹ They may wind up with mixed records including information about themselves as well as somebody else.

All stakeholders in the efforts to create an interoperable national EHR system stress their commitment to protecting the privacy and security of the system. The Acting Coordinator of Health Information Policy has emphasized the Administration's commitment in calling for a system that would give "people the capability to decide how they view, store and control access to their own information. A person could say how that information flows to specific entities or completely block the flow of information."¹⁸⁰

But a gap exists between the professions of commitment and the efforts required for the difficult task of creating and implementing generally acceptable privacy and security protections. The Government Accountability Office has been highly critical of the Administration's privacy efforts.¹⁸¹ The chair of a panel providing advice to HHS on health-information policy accused the Administration of lacking "a sense of urgency" about privacy and resigned.¹⁸²

Today's National Healthcare Privacy Law—HIPAA

HIPAA is the controlling federal law governing the privacy and security of patient medical records. There are many additional laws at the state level which reflect varying levels of privacy protection. (The patchwork nature of these laws serves as an additional barrier to the implementation of an interoperable national EHR system.)

The application of current HIPAA regulations, which took several years to draft and were quite contentious, is not acceptable to many stakeholders. For example, HIPAA does not cover many parties likely to have access to EHRs.¹⁸³ The American Health Information Community's "Confidentiality, Privacy and Security Workgroup" has recommended that every party that participates in an electronic health-information exchange of individually identifiable health information

be subject to enforceable privacy and security criteria at least equivalent to the relevant HIPAA requirements.¹⁸⁴ The National Committee on Vital and Health Statistics has made a similar recommendation regarding any entity that creates, stores, transmits or uses personally identifiable health information.¹⁸⁵

There is, moreover, considerable skepticism about the enforcement of even current rules. Over thirty thousand complaints have been filed pursuant to the regulations, but there have been few enforcement actions and fewer sanctions imposed.¹⁸⁶ Thousands of complaints remain unresolved.¹⁸⁷

According to a recent *CIO Magazine* survey, only 39 percent of companies surveyed believed that they were fully HIPAA compliant; the survey showed that, on the whole, HIPAA compliance today is lower than in earlier years.¹⁸⁸ Another poll showed that three out of five people interviewed do not trust HIPAA to protect their privacy.¹⁸⁹

Recent Privacy Initiatives

An enormous amount of work has been done over the last five years to try to resolve issues of healthcare privacy and security. The Markle Foundation has led a group of over 100 organizations in an effort over the past several years to develop a "Common Framework"—a set of technical and policy standards—for health information exchange.¹⁹⁰ Health information, under this "federated" model, would remain under control of the parties that collect it, leaving judgments about who should and should not see patient data in the hands of the patient, the physicians, and the institutions that are directly involved in providing treatment. This federated model aims to avoid a large, centralized database which might be more vulnerable to privacy and security breaches. The system would be based on common, open technical and policy standards that could work with existing hardware and software, and would rely on model business contracts to govern the exchange among organizations holding the data.¹⁹¹ It would support variation and innovation to respond to local needs and would contain feedback mechanisms to fix faulty data.

Central to the Common Framework is a set of principles to protect privacy and security that would be embodied in the technology. These principles are:

- *Openness and Transparency:* Individuals should be able to know what information exists about them, where it is, and who can access it;
- *Purpose Specification and Minimization:* The purposes for which information is collected should be specified when it is collected. Subsequent use should be limited to those purposes, or if used for other purposes, those purposes must be specified;
- *Collection Limitation:* Personal health information should only be collected for the specified purposes, by lawful and fair means, and where possible, with the knowledge or consent of the data subject;
- *Use Limitation:* Personal data should not be disclosed or otherwise made available for purposes other than those specified;
- *Individual Participation and Control:* Individuals should control access to their personal information. They should be able to obtain a response from any entity that controls personal health information about whether that entity has personal health information about them. They should be able to obtain that information in a reasonable time in an understandable form for a reasonable price. They should be able to have that information amended. They should be able to appeal denial of access;
- *Data Integrity and Quality:* Personal data that is collected should be relevant to the purposes specified, current, complete, and accurate;
- *Security Safeguards and Controls:* Personal data should be protected by reasonable security safeguards against such risks as loss or unauthorized access, destruction, use, modification or disclosure;
- *Accountability and Oversight:* Entities in control of personal health data must be held accountable for implementing these principles;
- *Remedies:* Legal and financial remedies must exist for security breaches or privacy violations.¹⁹²

These principles would provide a sound basis for an EHR system. They put the focus clearly on the patient and his or her role in controlling access. Although they do not definitively establish who “owns” personal health information, they would establish obligations for any entity that collects such information, and

would leave data collections decentralized. They provide for data minimization and cleansing, auditing of data use, as well as remedies for breaches of privacy and security.

But agreement on principles still leaves many difficult issues to be resolved. Rules must be developed about who is allowed to have access to what information and under what conditions. Then the system must be able to verify that the party requesting access is authorized to have access, and can be identified and authenticated as the appropriately authorized party.¹⁹³ These authorization, identification, and authentication issues are being addressed in other domains that deal with sensitive information, such as banking and finance and homeland security; healthcare will surely benefit from efforts to find answers in other sensitive areas.

There are obviously a myriad of other questions that will have to be decided. Will there be national standards for privacy and security preempting state rules or will national standards create baselines for privacy and security protections? How will the system deal with circumstances that do not readily allow a patient to authorize access to information? (Studies on how to improve emergency care show how contentious issues of consent can be.) What, if any, are the appropriate limits on patient control of access? How will exceptions be dealt with? How will disputes be resolved? How will the system be structured so that the patient-centered processes for controlling access to information do not impede the delivery of services—so that practitioners, wary of anything that gets in the way of their providing quality patient care, will not reject or undercut the system? How will public health needs, such as in the case of a pandemic, be balanced against patient privacy rights? What will be done in the case of unauthorized access to patient information? Will patients be able to opt out of the system, or will the system, as one leading expert suggests, gain support by requiring that patient’s opt-in?¹⁹⁴ And given researchers’ concerns (it has been argued that the famous Framingham Heart Study could not be conducted now under today’s less rigorous HIPAA regime), will a system designed to protect patient privacy be flexible enough to allow the use of EHRs for research purposes? The questions go on and on.

And even if we feel confident that the major questions have been answered, there are very substantial

challenges to implementation. For example, the business contracts between organizations that the Common Framework foresees as necessary for the exchange of information are not in place and will not come into being without great effort. Much of the data that exists in today's records are inaccurate and should be corrected but it is easier and cheaper to avoid cleansing records; much information is missing and will be expensive and time consuming to fix. There is little evidence that sufficient resources and commitment will be available to enforce new privacy and security rules.

However great the difficulties, if EHRs are likely to provide the benefits described earlier, we should be able to find solutions. We must recognize that no system is born perfect or ever achieves perfection, but any EHR system must have the capacity to evolve. No massive system for exchanging information exists that will guarantee absolute confidentiality. There will be violations and breakdowns, so there must be strong provisions to protect privacy and efficient and effective mechanisms to deal with violations. Patients and practitioners alike must feel confident that their interests are adequately reflected in the rules; both must feel that the benefits outweigh the costs.

Andy Grove, formerly of Intel, has predicted that the United States will transform its healthcare system through the use of information and communications technology as has occurred in other sectors of the economy, "only after the next pandemic." To prove him wrong and bring an interoperable, nationwide, efficient, patient-centered, and privacy-respecting EHR system to fruition will require a strong commitment by the federal government with its role in healthcare-funding and national perspective.

Electronic Health Records and the Development of Evidence-Based Medicine

EHRs are important in their own right, being the key to personalized patient treatment. EHRs are also likely to play an important role in monitoring drug safety. But perhaps their greatest potential lies in furthering the development of evidence-based medicine.

Little hard evidence exists to demonstrate that many of today's medical treatments are based on reliable data.¹⁹⁵ As the Institute of Medicine described it, we face a "structural inability of evidence to keep pace

with the need for better information to guide clinical decision making."¹⁹⁶ Clinical trials, as we have seen, provide such data but they are expensive, time consuming, limited in scope and "fraught with questions of generalizability."¹⁹⁷

We can do better. Imagine if we were able to construct collections of appropriately de-identified EHRs that have been bulked up with genomic, pharmacogenomic, proteomic, epigenomic, and nutrigenomic data, supplemented with environmental-exposure information, diet and exercise data, and family medical histories. What if we added insurance claims data and the data underlying clinical trials and research funded by governmental agencies?

Building such databases, providing appropriate access, (perhaps in some cases limited to professional researchers as opposed to anyone and everyone), and ensuring privacy and security are, of course, not easy tasks. Some goals may not be achievable, such as a perfectly de-identified system. (The inadvertent disclosure of supposedly de-identified AOL search data and the relatively quick identification of AOL users illustrate the difficulties.) Some goals remain in tension; researchers generally prefer more information to be available for correlation in developing clinical guidelines while privacy advocates generally prefer less.

But around the world we are seeing important steps forward. In Europe, Asia, and the United States, researchers are recruiting hundreds of thousands of people to participate in biobank initiatives that compile an individual's genetic, health and lifestyle information, and track it over time through electronic health records.¹⁹⁸ Biobanks seek to better understand the linkages between these and other factors to improve the prevention and treatment of myriad disabling and life-threatening diseases—including cancer, heart diseases, diabetes, arthritis and types of dementia.

Biobanks are not a new phenomenon, although these biobanks aren't your grandfather's or even your father's biobanks. (Fifty years ago, Sir Richard Doll followed the health of 50,000 doctors and ultimately unveiled the link between smoking and lung cancer.)¹⁹⁹

But for all of the possibilities to prevent and cure disease, biobanks remain controversial. Some medical experts worry that "volunteers will be asked to donate their DNA without really knowing how it's to be

used or who's going to use it."²⁰⁰ Others worry about whether private companies will be permitted access to the sensitive data.²⁰¹ And these worries say nothing of the technical hurdles that computer scientists must overcome to ensure that the data generated by biobanks can be structured to respond to queries that may change in unexpected ways over time. How these issues are resolved will undoubtedly shape the direction of biomedicine and the healthcare industry generally, for years to come.

Beyond these new biobanks, sponsored by governments and not-for-profits such as the American Cancer Society, there are existing data collections which are being used in new ways. While they contain only a small portion of the possible data sources, even at this early stage they provide a far richer data environment than even the best clinical trials. Both the VA and Kaiser-Permanente, with roughly 8 million patient records apiece, have patient-record collections including more cancer patients than have participated in all the cancer clinical trials ever conducted.²⁰²

As part of its Research Program on Genes, Environment and Health, Kaiser's Northern California Division is sending a detailed survey to each of its two million adult subscribers asking for information on their habits and family medical histories.²⁰³ (The risk that a woman will develop breast cancer, for example, is inextricably linked to family medical histories.)²⁰⁴ A year from now Kaiser plans to solicit genetic samples from its patients to test and add to their records.²⁰⁵ Kaiser's long-term vision, similar to that of the VA, the Mayo Clinic, and others, is to use its vast record holdings to determine the optimal treatment regime for each patient. A consortium of health insurance providers and several medical-practice associations are exploring collaborations to the same end.²⁰⁶

While such efforts are dominated by large groups, even sophisticated smaller institutions are moving in the same direction. Geisinger Health, for example, is attempting to utilize its relatively stable patient population in central Pennsylvania to build a database rich in extended-family histories, and is supplementing these with U.S. Geological Survey data on local water supplies to determine environmental exposures.²⁰⁷

Large-cohort studies can usefully supplement other databases, such as those from clinical trials that may not

be representative of the U.S. population. Some cohort studies of women and children, traditionally funded by the federal government, were cut back in recent years because of budget pressures. The announcement in the fall of 2007 of a National Children's Study targeting 100,000 children from birth to age 21 by the National Institute of Child Health and Human Development of the NIH is therefore very good news.

Think of what we could learn if researchers could have access to all this information. Not only would we be able to personalize treatments and monitor drug safety, but we could be increasingly confident that recommended treatments actually are based on evidence, not anecdote or habit. As more data are added, and as data mining improves, researchers will be able to create predictive models and test these against the aggregated data and through better-targeted clinical trials. We will also be better able to compare the efficacy of various interventions which we do all too little today.

Perhaps in no other sector of the economy do we spend so little effort to measure and improve performance. HHS's Agency for Healthcare Research and Quality has a relatively small budget of \$500 million to conduct studies of comparative effectiveness of procedures. But comparing this \$500 million with the \$2 trillion dollars in healthcare expenditures (0.025 percent) validates what one noted physician author has written: "The scientific effort to improve performance in medicine—an effort that gets only a pitifully miniscule portion of scientific budgets—can arguably save more lives in the next decade" than all the basic breakthroughs that we hear about in the news.²⁰⁸

Eventually we will be able to identify and extract the right data. Eventually we will be able to perform the right comparisons. Eventually we will find the right balance between efficient, standardized care which serves most patients well, and individualized treatments based on less common attributes in a patient which is likely to be much more expensive.²⁰⁹ In the future we might, for example, see fewer blockbuster drugs—like any other manufacturer, a pharmaceutical company searches for a product useful for the largest possible group in order to maximize revenues and amortize costs over the largest number of users—and more targeted therapeutic regimens. (But the individualized pill is likely to remain an expensive and distant dream.²¹⁰)

The mining of these databases should continually generate new clinical best practices. There are hundreds of guidelines already in the Agency for Healthcare Research and Quality's Guidelines Clearinghouse but with over 10,000 various medical conditions we still have a long way to go.²¹¹ And we still need to ensure that those clinical best practices inform the work of clinicians. Without effective monitoring and rewards for their use, however, they will be an empty tribute to our ability to gather and manipulate data. We would have demonstrated that access to information is not sufficient, but that improved healthcare will result only if we incorporate our more sophisticated understandings into real world actions.

The issue of potential conflicts of interest is particularly acute when recommended-treatment regimes are being created. These regimes should be based solely on the best possible scientific information. Any potential for the skewing of these recommendations based on financial interest must be avoided. Strenuous efforts should be made to ensure that participants in the process are not subject to potential conflicts and strict disclosure requirements should be in effect.

Recommendations Regarding Electronic Health Records and the Development of Evidence-Based Medicine

The federal effort to develop standards for an interoperable, national EHR System should be given high priority and sufficient support, including a strong commitment by the federal government to use its leverage to obtain timely agreement on standards. Legislation should promote the establishment of national health data standards and an interoperable national EHR system.

Individuals and groups providing and funding healthcare should institute appropriate incentives for the adoption of information and communications technologies (including EHRs) to reduce healthcare's burdensome administrative costs.

New rules designed to ensure the privacy and security of healthcare records must be adopted to provide assurance to patients and practitioners. These must cover all entities involved in the handling of individually identifiable health-related information. The federal government must demonstrate a commitment to enforcement of these rules and provide sufficient funding to do so.

The federal research agencies should increase their support for the development of the very large databases necessary for progress toward evidence-based medicine including the necessary data standards. Support should also be provided for research on how such data should be structured to facilitate the varying queries necessary to develop evidence-based clinical treatment practices, to compare the safety and efficacy of various treatments, and to allow the development of predictive models of diseases and treatments.

The National Academy of Sciences should undertake a study of de-identification techniques that might be applied in the creation of large databases to protect the privacy of patients in order to provide guidance to federal policymakers.

Strict requirements on the disclosure of conflicts of interest should be applied to those participating in the development of recommended clinical practice regimens.

Congress should provide additional support for long-term cohort research for groups underrepresented in existing biomedical research results.

HIPAA should be amended to require that those parties who hold a patient's medical records must provide the patient with the opportunity to receive copies of those records pursuant to HIPAA in digital form.²¹²

Chapter 6: Expanding Openness for Patients and Caregivers

Biomedical research and evidence-based medicine are cases where the increased access to information and the ability to manipulate data reveal the value of greater openness. This Chapter will focus on the impact of providing more and better information to patients and caregivers, and being more responsive to the unique contributions they can make.

The kinds of openness described in this section—such as allowing patients to evaluate the interventions being tested on them in clinical trials or increased attentiveness by caregivers to patients' stories—are not treated by economists as precisely the same as the openness that enhances the research process. But they can be understood using the same characteristics of accessibility and responsiveness described earlier, and can provide significant benefits, particularly with regard to disease prevention and treatment.

Changing Ideas About the Role of the Patient

In the past, patients were often viewed as passive recipients of health-related information and treatment decisions from their caregiver. Healthcare revolved around meetings between sick patients and their doctors; the patient's role in the "production" of good health was basically to do what an oracular caregiver instructed. Treatments were based on limited data and anecdotal evidence. Patients were given few incentives and little training to take more responsibility for their own well being. One did not look to the mainstream medical community for information on "lifestyle" choices.

Today we live in a world of patient-centered healthcare. We are awash in information. Increasingly, efforts are being made to encourage individuals to take greater responsibility for their own health and to make choices that reduce the likelihood of illness.²¹³ An advertisement for Pfizer sums it up: "Get well soon? We prefer, 'Stay healthier longer.'"

We have learned that the most important drivers of healthcare costs are chronic conditions and serious illnesses that may be prevented or mitigated by patient actions.²¹⁴ Therapeutic encounters between a sick patient and his or her trusted doctor do not dominate healthcare costs; as many of us have experienced, these encounters seem to get shorter and shorter and may involve doctors whom we have never seen before—or even no physician at all.²¹⁵

Under these conditions, how can openness improve a potential patient's ability to prevent problems and to be a better partner in dealing with those that arise?

Patient Access to Healthcare Information

Perhaps the greatest opportunities arise from the increased availability of healthcare-related information via the Internet, including information on prevention, exercise, and nutrition. In 2006, ninety-five million Americans searched the web for information on specific diseases, how to treat chronic illnesses, how to assess a specific health risk, who or where to go to for help, or where to buy health-related products.²¹⁶

Some of the information consumers get from the Web is right, some of it is wrong, and much of it is not sufficiently particularized to be of great value for an individual.²¹⁷ (Here again the double-edged sword of openness is visible. Much more information is available but we lack good tools for evaluation and there is too little transparency about the sources of the information.) There is a tremendous need for evidence-based, comprehensible, consumer-friendly, and relevant healthcare information and for quality measures to allow readers to make better judgments about information from the many players who would like to be their source for healthcare information.

The government is playing a vital role, one that the National Library of Medicine (NLM), in particular, has embraced.²¹⁸ Its MedLinePlus website provides

well-vetted information based on the most current scientific data on everything from conditions such as arthritis and back pain to frequently asked healthcare questions. NLM has consistently worked to make its healthcare information more accessible to individuals. Other governmental agencies also provide excellent sources of healthcare information.²¹⁹

Many valuable sources of information are sponsored by private-sector organizations. The American Cancer Society and the American Heart Association for example, provide high-quality information related to the diseases that they fight. For-profit entities operate healthcare portals such as WebMD, Revolutionhealthcare.com, Everydayhealth.com, and the HealthCentral Network.²²⁰ Microsoft recently purchased Medstory, Inc., a healthcare search engine for consumers, and in October of 2007 released HealthVault, a free and ad-supported portal that will allow individuals to download data from their caregivers or from digital devices such as glucometers, upload data on their diet and exercise routines, and share the encrypted data with others.²²¹ The healthcare portals are all trying to differentiate themselves with additional services—displaying health tips, linking patients with insurers, rating medicines, doctors and hospitals and providing decision-support capabilities. One can even get “second opinions” via the Internet.²²²

As is true in other areas, conflicts of interest due to the role of advertisers or donors may affect the healthcare information provided; patients can, however, find disinterested sources of information at government websites and those of groups such as Consumers Union or the Center for the Study of Services.²²³ Patients themselves are likely to publish ratings of information sources on healthcare, just as they rate other goods and services offerings in today’s Web 2.0 world.²²⁴

Personal Health Records

Some healthcare portals (and many employers and insurers) are building infrastructures that allow an individual to create a web-based “personal health record” (PHR), an individual’s version of the EHR. PHRs are designed to be portable and under the control of the individual. As with EHRs, certain other countries have made greater progress. In Germany, for

example, all patients carry their medical records on a single computer chip.²²⁵

PHRs offer a potentially valuable resource for those individuals who choose to adopt them. They include a wide variety of information such as medical history, present medications, the results of tests and remote monitoring, a patient’s reporting on his or her health, and current treatment regimens.²²⁶ They hold out the promise that patients will change their behaviors if they have more convenient access to their records—something that, unfortunately, does not always follow.

But there are significant obstacles to PHR development. Healthcare-related entities are not required by HIPAA to supply information to patients in a digital format. Standards for electronic data exchange are not yet resolved. Concerns about privacy and security are also affecting PHR take-up.²²⁷

Other Sources of Information

The Internet allows access to another source of information—peer groups made up of individuals (or people related to them) who share an interest in the same medical condition. Even more important for group participants than the information provided may be the sense of connection to others facing similar problems—others just like oneself. The information and support are particularly helpful for patients with less-common conditions where an individual’s caregiver may have encountered the condition rarely, if at all. In one well-designed web-based group for sufferers from rare carcinoid cancer, for example, a healthcare expert offers scientifically validated information that helps patients separate fact from fiction.²²⁸

One of the most contentious sources of healthcare information for patients is prescription drug advertising directed to consumers—one of the fastest growing advertising categories. There is no doubt that such advertising plays an important role in informing consumers about various medical conditions and the availability of pharmaceutical treatments, and has triggered countless valuable conversations between patients and their caregivers. At the same time, critics contend, such advertising has been accompanied by growth in inappropriate prescriptions at considerable cost to individual patients and to the healthcare sector in general.²²⁹ Proposals for greater FDA powers over

such advertising were offered but were not included in the 2007 Amendments.²³⁰

Patients as Research Assistants

The abundance of information has begun to change the relationship between patients and caregivers. According to one survey, 52 percent of primary care physicians report that their patients are now arriving with print-outs from web searches.²³¹ Patients are gathering the latest research about a disease or a treatment, finding notices of, and solicitations for, clinical trials, and giving them to their caregivers—along with folk remedies and charlatan's cures.

This may be annoying to some caregivers used to greater patient acquiescence, but thoughtful caregivers recognize that making the patient-caregiver relationship more of a partnership is fundamental to increased patient responsibility and, ultimately, better outcomes.²³² Patient-provided research may also aid in filling the gap between the publication/disclosure of research and its implementation in treatment regimes; patients and their families with their intense motivations to find solutions may prove to be helpful “research assistants” for their caregivers.

Other Patient Contributions

Viewed through the lens of openness, patients are not only the beneficiaries of increased access to information but they are among the most important sources of information for the healthcare system. Patients provide the most direct evidence of what they are experiencing when they tell their stories.²³³ They are also the most immediate source of their own and their family's medical histories.

Patients and their supporters also collectively contribute as they lobby for funding for disease-specific research.²³⁴ The Genetic Alliance, for example, represents over 600 groups of patients with different genetic conditions; the Alliance presses for funding for these conditions and also helps organize donations of tissue samples and solicits volunteers for clinical trials.²³⁵ In some cases patients and their supporters are directly funding research and clinical trials. Private foundations, often disease specific, provided \$5 billion in funding for research last year; in some

cases, individuals actively recruited researchers who otherwise would have been working on different problems.²³⁶

Another way patients, or those who care about them, are stimulating practical research and increased collaboration is via innovation prizes. The use of contests, open to all with large prizes to stimulate creative activity, has a long and honorable history.²³⁷ A \$10 million prize is now being offered, for example, to whomever develops a cheaper, faster, gene-sequencing device, a breakthrough necessary to fully realize the benefits made possible by increased genomic and pharmacogenomic information.²³⁸

Increased patient activism is not an unalloyed good. Patient pressure for new treatments may help speed their development and approval, but there is a risk of rushing out remedies before they have been properly evaluated.²³⁹ Patient persistence may lead to over-prescription or prescriptions for highly advertised drugs that are not as cost-effective as other treatments; one partial explanation for the rise in drug-resistant infections is that many caregivers have acquiesced in the over prescription of antibiotics in response to patient pressure to “do something.” Patient reports about their symptoms are generally valuable, but like all stories may be inaccurate, biased, or at least in conflict with what is considered the best applicable science.²⁴⁰ Patient lobbying can affect healthcare funding in ways that may not reflect the best cost-benefit analysis for the society as a whole. (Although there are legitimate reasons to be concerned about this “politicization” of healthcare research priorities, one can still applaud the efforts by patients and their supporters to increase high-quality research and to speed the application of research to treatments and cures.)

The potential importance of patient input in another setting is just now being recognized. Patient-recorded outcomes (PROs), the patient's view of the impact of an intervention, are increasingly seen as valuable to certain clinical trials. Studies have shown that PROs are, in some cases, better predictors of the effectiveness of an intervention than clinical indicators. In cancer-related clinical trials, for example, PROs provided additional information on outcomes, particularly on how the intervention affected the patient's ability to lead a “normal” life—which is of great interest to patients.²⁴¹

Increased patient involvement has also been shown to have a positive effect in a different way. Greater patient participation in choosing among treatments—so-called “preference-sensitive care”—has reduced the use of the most aggressive, invasive, and expensive treatments by 23 percent over what the healthcare provider would otherwise have chosen.²⁴² Even the attitudes that patients bring to fighting their illnesses can have considerable impact on the success of treatments.²⁴³

Patients are providing vital information in yet another way. More and more data can be, and is beginning to be, collected from patients via remote monitoring. Remote monitoring is being integrated into more treatment regimes in order to increase outpatient treatment while continuing observation and data collection, and to involve the patient more directly in his or her own care.

Increased monitoring is facilitated by expanded Internet access, as well as by the falling prices and greater functionality of communications-capable devices. Cell phones are being sold with glucose monitors and breathalyzers; digital cameras are being used to send pictures of meals for nutritional analysis; implants are communicating their host’s condition to the Web to be remotely scrutinized by his or her caregiver; remote devices that measure blood oxygen are reducing doctor visits and providing doctors with signs of developing problems.²⁴⁴ Devices worn by homebound patients now allow relatives to check if the patient has been immobile too long.²⁴⁵ New radiofrequency identification devices may ultimately allow remote monitors to determine if a refrigerator, or a vial of pills, has been opened, allowing inferences to be drawn about whether patients are eating or taking medications.

Information can be passed both from and to the patient. Remote devices can broadcast reminders for smokers to stop smoking. They can nag patients to take their medications—an important task when 50 percent of prescriptions are never completed as prescribed.²⁴⁶ Such reminders can in fact change behaviors.²⁴⁷

The same progress in information and communications technology that is allowing greater access to information and facilitating remote monitoring is helping to improve rural America’s access to healthcare. Telemedicine is connecting patients far from medical

centers to specialists who can obtain diagnostically relevant data or conduct consults at a distance. The 1996 Telecommunications Act recognized this opportunity and the FCC recently revised its rules to further encourage telemedicine.²⁴⁸ But issues regarding state-based licensing and medical-malpractice regimes still inhibit the growth of telemedicine, and questions about privacy and security, reimbursement for remote monitoring, data standards, and the interoperability of devices have not been fully resolved.²⁴⁹

More Informed Healthcare Consumers

Greater access to information can help harness market forces to improve quality and reduce costs in healthcare. Economists know that it is not possible for a market to function without information about quality and costs, but such information has been in short supply regarding hospitals, procedures, practitioners, and treatments.

Patients often look to their caregivers for information on cost and quality but most caregivers do not have this information. Some limited information is available from the federal government, for example, on the costs of common medical procedures.²⁵⁰ Much more information could and should be made available given the vast amounts of payment data the federal government has accumulated; the total costs associated with a procedure, for example, are rarely disclosed.²⁵¹ (Costs for the same procedures surprisingly vary by up to 400 percent from region to region and the use of procedures can vary remarkably *within* regions, casting doubt on whether clinical-treatment regimes are being consistently followed.²⁵²) There are encouraging signs that, as one leading consultancy wrote, “the federal government and leading private-sector payers are driving providers to make cost and quality data more transparent so that consumers can make better choices.”²⁵³

The Department of Health and Human Service’s website (www.hospitalcompare.hhs.gov) provides comparative information on 19 different quality measures that the federal government gathers on every hospital. It bases its ratings on what is done for the patient. The data are available, however, on only a limited number of conditions and “ignores entire departments and specialties.”²⁵⁴ In February of 2007, HHS announced a plan to create local health-quality

information exchanges that would “collect information on the quality of local healthcare providers based on nationally established standards. That data would then be pooled to create a public, nationwide quality reporting system.”²⁵⁵

Private-sector actors, including web-health portals, see a potentially profitable role in providing quality ratings to the public. Using the same records relied upon by the federal government, Healthgrades (www.healthgrades.com) offers ratings focused on medical outcomes, adjusting them for the severity of the disease and the health of the patient; in addition it computes “patient-safety” ratings.²⁵⁶ Healthgrades charges hospitals for its complete reports and for allowing them to publicize their Healthgrade ratings.²⁵⁷

Experiments suggest that even minimal disclosures can have beneficial results. The release of risk-adjusted mortality data from cardiac-bypass surgery by doctors in New York, for example, had the salutary effect of shining a spotlight on the worst performers, many of whom simply ceased to practice in New York.²⁵⁸

There are reasonable concerns raised about the New York study and its use of mortality data as the basis for the quality metric. There are intense debates about quality measures—as well as a number of initiatives to improve them.²⁵⁹ Care obviously needs to be taken in defining the metrics, avoiding punishing hospitals and other providers that take on more difficult cases, and preventing hospitals and caregivers from “gaming the system” by turning away sicker patients etc. But the efforts to devise better quality measures and to gather and release quality and cost data are easily justified by the potential benefits from unleashing market forces to improve healthcare.

One would expect that many individuals, reliant until now largely on word-of-mouth recommendations, would respond to better information. That assumption underlies the establishment of consumer-directed health plans (CDHP's) which are designed to provide incentives for healthcare consumers to make more informed purchasing decisions. But given present practices in health insurance—limited deductibles, little choice among caregivers in many plans—it would be unduly optimistic to assume that the majority of insured individuals want to, or will soon become, skilled healthcare shoppers.

Greater Openness and Incentives for Improving Healthcare

More important than the voluntary actions of individual consumers will be the actions of employers in forcing the disclosure of cost and quality information and in responding to it. Facing the economic pressures that they do, firms are already working to create incentives for improved medical outcomes and reduced costs, capping their costs, or even dropping health insurance altogether.²⁶⁰ Even more important, given the percentage of the nation's healthcare costs that it pays, will be how the federal government deals with information regarding cost and quality.

Over the long run, efforts by the federal government and employers to harness market forces must go beyond the disclosure of information to more value-conscious healthcare consumers. They will have to create strong incentives for improved care at lower costs.

New clinical practice guidelines are likely to emerge as we strive to move toward evidence-based medicine. But caregivers and institutions will need to be monitored to determine whether they are following new, as well as existing, guidelines. As it is easier for individuals and organization to continue to do what they have been doing—a system at rest remains at rest—incentives are likely to be necessary to increase compliance.²⁶¹

Medicare has recently taken an important step in this direction. Traditionally Medicare has covered the costs of all hospital procedures, even those required to deal with complications resulting from medical errors. Medicare announced in August 2007 that it will no longer reimburse hospitals for additional procedures incurred as a result of “preventable errors.” Medicare will no longer pay, for example, for treatments for hospital-based infections. These are now considered preventable because of the development of guidelines and best practices which have been proven to eliminate their occurrence with little or no increase in costs.²⁶²

State medical-error-reporting systems, which have helped identify the causes of preventable errors such as those that lead to hospital-based infections, provide useful inputs for any system designed to improve quality. But many states do not require the reporting of medical errors. Congress has established a voluntary national patient-safety network for reporting

and analyzing errors but regulations have not yet been issued for its implementation.²⁶³ A mandatory system may well be preferable given the grave consequences of many medical errors and the need to identify errors so that performance-enhancing feedback systems can operate.²⁶⁴

Other information, not directly concerned with specific procedures, drugs, or devices would also be valuable. From the standpoint of improving healthcare and providing greater protection for patients, there seems to be little reason, for example, for any state to withhold information about disciplinary actions taken by its licensing boards against licensed healthcare providers.

Openness and Caregivers

If patients in the past were sometimes seen as passive actors, caregivers were usually accorded great deference as highly educated sources of information and providers of treatments. If patients are now empowered by new sources of information, some caregivers may now feel swamped by new kinds of information, less likely to be knowledgeable about all the interventions that patients have received as more disparate caregivers are involved, more time constrained in their interactions with patients, more burdened by administrative requirements and battles with third-party payers, while receiving less respect and being accorded less status than in the times of Drs. Casey, Kildare and Welby.

Caregivers and New Sources of Information

Caregivers, like patients, can benefit from dramatic increases in genomic, pharmacogenomic, epigenomic and nutrigenomic information and the further evolution of evidence-based medicine. If able to use this information, they will be increasingly capable of personalizing treatments for their patients. But while caregivers are expected to bring order to this information explosion, many may feel information “overload.”²⁶⁵ They are expected to integrate new kinds of information which might not have been part of their medical education with evidence gleaned from massive databases and then determine the right treatment given the patient’s individual and family medical history, his or her symptoms, and the various diseases that this information might suggest.

Proponents of greater openness and more information recognize the dilemma of having too much information and too little time to process it during a meeting with a patient. Kaiser’s “Project Isobel” and similar work at the Veterans Administration and elsewhere are aimed at developing decision-support tools to help providers sort out possible diagnoses.²⁶⁶ Beyond providing possible diagnoses, these tools might suggest additional diagnostic questions, cue relevant tests, and list alternative treatment regimens.

Decision-support systems cannot replace the insights that mark gifted diagnosticians.²⁶⁷ They are not meant to reduce the practice of medicine to a mechanistic process overseen by automatons. But with over 10,000 known conditions and more than 1,900 existing clinical-practice guidelines, decision-support tools are increasingly needed for better and timelier decisions aimed at personalizing treatments in a data-rich environment.²⁶⁸ In theory these tools should be all inclusive, down to patient preferences for generic drugs, but the systems now being constructed have much more limited capabilities.²⁶⁹

Even these limited systems are not easy to build. A much simpler tool, such as a computerized physician-order entry (CPOE) system for drugs, required considerable development and testing efforts and substantial amounts of time before it began to help hospitals reduce medication errors and improve operating efficiency.²⁷⁰

In this new environment, caregivers, like patients, are also turning to their peers, utilizing support groups to exchange information as they do with adverse drug events. Sermo (www.sermo.com), for example, provides an opportunity for registered physicians to exchange ideas and solicit help on difficult medical diagnostic questions.²⁷¹

The Attentive Caregiver

Patients contribute by telling caregivers how they feel. But caregivers may not be as “open” or receptive to what their patients are saying as they should be, or for as long as they should be.²⁷² Observers have noted that many caregivers cease listening to their patients much too quickly, interrupting the patient or prematurely beginning the process of narrowing down potential

diagnoses even before the patient is finished providing his or her story.²⁷³

“Premature closure” is likely to affect diagnostic quality. Estimates of faulty diagnoses range as high as 30 percent; misdiagnoses are the source of almost 60 percent of malpractice claims.²⁷⁴ Increased time pressure on patient-caregiver interactions only heightens this problem

The use of decision-support systems may allow caregivers to spend more time actually listening to patients.²⁷⁵ Similarly, the use of e-mail and other electronic communications tools should, among other effects, enable patients to fill out forms and provide information in advance rather than during the visit, allowing richer and fuller conversations.²⁷⁶

Openness and Information Provided by Caregivers

Caregivers have unique tacit information about their practices—what and how processes work or don’t work, what patients are likely to do in a given situation, and what can or can’t be accomplished under specific conditions. This information is often difficult to codify and transfer, but it is critical for developing effective treatment regimes. Greater involvement in the development of treatment regimes or clinical trials by experienced caregivers would allow tacit, experience-based knowledge to better inform the necessary decisions.

The root of the word doctor is from the Latin *docere*—to teach.²⁷⁷ Doctors have always taught patients about their illnesses. They are increasingly educating them about how to maintain and improve their health. Now they can help patients deal with the information tsunami by teaching them how to evaluate medical information. In doing so, doctors can improve their patients’ performance both as research assistants and healthcare consumers.

Surveys have shown that 8 percent of caregivers do not provide their patients with a complete range of treatment alternatives based on their own moral views about one or more of the alternatives.²⁷⁸ Eighteen percent of caregivers do not provide their patients with information about doctors whose work they believe is unsatisfactory.²⁷⁹ Other caregivers may not provide information on treatment alternatives that they judge

to be too expensive or inappropriate for the patient for some reason. If shared decision-making between patient and caregiver is desirable, then it follows that patient participants should be aware of any limits set by their caregivers that prevent the patients from fully evaluating the treatment choices available.²⁸⁰

Caregiver Conflicts

Caregivers have traditionally played the principal role in determining what treatment a patient will receive. Recently there has been a dramatic increase in the financial stakes that caregivers have in treatment alternatives.²⁸¹ These financial interests—whether they are in outpatient treatment facilities, hospitals, procedures, etc.—have been demonstrated to affect a caregiver’s objectivity, yet there is little information available to patients regarding such interests.²⁸² Increased openness would require, at the least, that the financial interests of the caregiver in any aspect of treatment be disclosed. Medicare has recognized these conflicts and is cutting back on “self-referrals.”²⁸³

Narrowing the interval between discovery and clinical practice is, as we noted earlier, a major challenge. One way to shorten this interval is to help caregivers stay informed of developments in their field.

Pharmaceutical companies play a crucial role in turning research into treatments. They offer their expertise in new treatments to caregivers and justify visits by their sales representatives to caregivers, in part, on the basis that the representatives help in keeping caregivers current.²⁸⁴ There is no doubt that they do provide useful information.²⁸⁵ But they also often come bearing gifts, including entertainment tickets and free samples; they sometimes stay for (and provide) lunch, and suggest non-FDA approved uses and higher doses for the drugs they represent.²⁸⁶ Research suggests that these visits can affect what caregivers prescribe.²⁸⁷

In 2002, the American Medical Association established a voluntary code governing the receipt of gifts including meals. The Pharmaceutical Research and Manufacturers of America has also established guidelines including, for example, prohibiting gifts of free tickets. Recent surveys show, however, that four out of five doctors would allow pharmaceutical company representatives to buy them meals and 7 percent of caregivers are willing to accept free tickets.²⁸⁸

Policymakers should support other, more disinterested, sources for the continuing education of caregivers.²⁸⁹ More information should be available about the relationship between caregivers and those, other than patients, who profit from their decisions, so that patients can better evaluate treatment alternatives.²⁹⁰

Lawmakers at the federal and state levels have taken steps toward requiring such disclosures. Legislation has been introduced in Congress that would force pharmaceutical companies to report all payouts in excess of \$25 including gifts to physicians to be published in a national on-line registry.²⁹¹

Some states such as Vermont already require drug companies to reveal payouts to physicians but the long-term effects of these laws are not yet known. In the short run they do not appear to have reduced pharmaceutical payments to caregivers; in Vermont payments have increased since 2002 when the disclosure law was passed.²⁹²

Pharmaceutical companies target visits by their sales representatives using state records of prescriptions by caregivers; they focus on caregivers who prescribe the most.²⁹³ Some pharmaceutical companies even provide direct financial incentives via rebates or other means to those who prescribe their drugs most often.²⁹⁴

A number of states have attempted to limit access by pharmaceutical companies to the records of what caregivers prescribe but these restrictions have been challenged.²⁹⁵ Openness generally favors the availability of more rather than less information but there is an argument that caregivers should be able to opt out of these states systems to the extent necessary to prevent the use of their prescribing records for marketing purposes; alternatively a national or state level do-not-call/visit list might be created.

Recommendations Regarding Expanding Openness for Patients and Caregivers

The federal government should increase the provision of consumer-oriented healthcare information based on the best scientific information available.

The National Library of Medicine and other federal healthcare-research agencies should work with private-sector providers of healthcare information and web-search firms to determine if standards or other measures could be implemented to assist users searching for accurate healthcare information.

The federal government should more aggressively move to disclose information on the cost and quality of healthcare procedures with careful attention paid to the development of appropriate metrics and the quality of the available data.

The federal government should lead efforts to monitor compliance with clinical practice guidelines and use financial incentives to encourage compliance. The federal research agencies should support research on the development and evaluation of decision-support systems for caregivers.

The federal research agencies should support research on the appropriate use of patient-reported outcomes and preference-sensitive care.

State governments should provide access to information on disciplinary actions taken by licensing boards regarding licensed healthcare providers.

The federal government should work with state governments and practice groups to reduce barriers to the practice of telemedicine resulting from state-based licensing and malpractice rules.

The federal government should re-examine its healthcare reimbursement policies to determine if changes are necessary to foster the development of appropriate telemedicine practices, to encourage the use of remote-monitoring devices and the evaluation of the data they provide, to reflect efforts by caregivers to help patients monitor chronic conditions, and to compensate caregivers for communicating with patients outside of office hours in order to improve patient care.²⁹⁶

The appropriate federal agencies should work with the appropriate private-sector groups to develop model disclosure requirements dealing with the financial interests of caregivers in treatments they recommend.

Chapter 7: Openness and Public Health

The Human Genome Project demonstrated the power of openness when researchers were collaborating at the microscopic level. The Severe Acute Respiratory Syndrome (SARS) outbreak of 2002-2003 demonstrated the need for openness in public health when even telescopes could not help the global public-health community see an oncoming epidemic.

The SARS outbreak began quietly in China. The Global Public Health Intelligence Network, which gathers information from various sources around the world, helped identify the start of the SARS outbreak from articles published in China about a mysterious illness affecting otherwise healthy people, even before any official reports were received by the WHO.²⁹⁷ As the outbreak gathered momentum it was clear that greater resources were needed—and scientists and public-health workers around the world began an effort to identify the disease and to formulate responses. The WHO helped to coordinate the work of multiple laboratories to ensure the availability of appropriate research materials and to reduce duplication of effort. Eventually the outbreak was contained.²⁹⁸

Lessons of the SARS Outbreak

There are some obvious lessons to be gained about the value of openness in the public-health arena when, given our interconnected world, diseases can be spread at close to supersonic speed. The first is the importance of obtaining and sharing information locally and globally. Even given heroic actions by individual doctors and ordinary citizens to address the SARS outbreak, it was not until authorities in China were prepared to acknowledge that a problem existed and to provide relevant data that the capabilities of the global scientific community could be mobilized.

The Centers for Disease Control and Prevention are now linking public-health laboratories around the world to allow, for example, the rapid identification of food contamination through the comparison of

the DNA fingerprints of the contaminant.²⁹⁹ The Center for Infectious Disease Research and Policy and the Pew Center on the States have created a web site (www.pandemicpractices.org) to allow public health professionals to exchange information and improve pandemic planning.³⁰⁰ On the local level in the United States, though, only 13 states are capable of being interconnected with the Public Health Information Network to be able to share public-health information. The number is expected to grow to 40 by 2012, but there is still much to be done.³⁰¹

The second lesson is that almost any facility designed for collaboration can help in providing an effective public-health response. For example, collaborative search tools developed by Google are being provided to disaster-response organizations to facilitate early detection of potential healthcare disasters.³⁰²

Openness and Contributions from Less Obvious Sources

Other lessons may be less obvious. A corollary to the first lesson is that countries that share information and provide materials essential to identifying a disease and finding a cure—often lower-income countries where new diseases are more likely to emerge—are providing the global health establishment with materials of extraordinary value. They understandably want their contributions recognized. They are increasingly resistant to arrangements that they view as providing the bulk of the benefits, including supplies of vaccines and licensing fees or royalties, to other, more economically advanced countries.

Recent examples of foreign governments withholding sample materials suggest that this issue is likely to become more pressing in the future.³⁰³ In response to these concerns, the WHO is now considering stockpiling vaccines to ensure that poorer countries that provide data and tissue samples but that might not be able to afford costly medicines will be guaranteed

help in dealing with healthcare threats to their own citizens.³⁰⁴

Sometimes the mutuality of benefit can only be recognized over time. It is clear that researchers in sub-Saharan Africa receive substantial benefits today from the WHO's Hinari Project providing them access to scientific literature. What is not yet visible are the contributions that these researchers are more likely to make in the future because of their access today to research journals and better research tools.³⁰⁵

What is also not yet fully appreciated are the potential benefits available to researchers from data collection by, and the tacit knowledge of, individuals in these lower-income countries. Important contributions can come from quite unexpected sources. More-open, more-responsive systems for gathering data should be designed to reflect this. The International Health Regulations, for example, are being changed to allow the WHO to accept disease reports from sources other than governmental officials and, as one observer noted, to empower "ordinary people to notify the right authorities, without getting snarled in politics, commercial interests, or bureaucracy."³⁰⁶ In one extraordinary example of an unexpected source, Nathan Wolfe, an epidemiologist at UCLA, has established in Cameroon a "network of hunters to supply blood samples from themselves and the animals they eat to check for new viruses—[and] to report quickly any novel animal diseases."³⁰⁷ Greater openness in public health, can, and should, be stretched to the ends of the earth.

Public health efforts depend on gathering information from a wide variety of sources, including some of society's most vulnerable populations. It is therefore important to consider who will have access to the data. Should, for example, the information that is gathered for public health purposes be readily available to law enforcement officials? If so, what impact would such access have on the willingness of individuals to provide critical information? Our society has struggled with this question in the context of the HIV Aids epidemic and it is likely that we will continue to wrestle with the issue again.³⁰⁸

Recommendations Regarding Openness and Public Health

The federal agencies should lead efforts to support multilateral surveillance networks and cooperative activities.

The United States should recognize, in material ways, the contributions made by other, particularly lower-income, countries that provide valuable data and samples.

Priority should be given to the electronic interconnection of federal and local public-health authorities.

Chapter 8: Openness and Medical Devices

When proponents of greater openness give examples of its value they rarely point to medical devices. They are more likely to cite innovations in general-purpose personal computers that are the result of individuals “tinkering” with them—making improvements in hardware and software without seeking approval from the government or the manufacturer.³⁰⁹

Changes in Medical Devices

Medical devices are increasingly coming to resemble these computing devices. More medical devices have computational capabilities; more devices are controlled by software that can be modified to cause the device to do new things or to do existing things differently.³¹⁰ At the same time, the open-source movement has demonstrated that software is almost infinitely malleable and that millions of people are willing to suggest ways to improve it.³¹¹

Eric Von Hippel of MIT points out in his book, *Democratizing Innovation*, that “lead users”—those with deep knowledge of their own needs and the resources to satisfy them—have played an important role in innovation.³¹² Von Hippel’s work demonstrates, in particular, that much of the innovation in the area of scientific instruments came from users of these instruments rather than from their manufacturers. Given this history, it would be surprising if “lead users” e.g. caregivers, aren’t tempted to modify their tools, which are medical devices. Moreover, there are situations where the need to customize devices for an individual, such as in the field of prosthetics, seems to invite user-driven innovation.³¹³

The FDA’s Responsibility

At the same time that many medical devices are becoming more susceptible to modification by users, they continue—and justifiably so—to be subject to review by the FDA. FDA jurisdiction over medical devices is designed to ensure that they perform as promised and

do it safely.³¹⁴ If the device is approved by the FDA, it is exempt from state liability rules in the normal course of its operation, reducing the manufacturer’s potential state product-liability exposure.³¹⁵

The FDA approves a device “as is”—with the existing hardware and software. As with warranties from computer, electronics, and automobile manufacturers, the FDA’s approval is voided if “the hood is opened” and changes are made.³¹⁶

Can the potential for greater user-driven innovation in medical devices be reconciled with the FDA’s mission to ensure the safety and efficacy of medical devices? It may not be possible for all of the technically adept caregivers to successfully resist the challenge to hack/improve FDA-approved medical devices. Given this, could and should the FDA provide some form of a “safe harbor” for physicians and physician-directed programmers where they might “tinker” without penalty, similar to the safe harbor the FDA provides for physicians who prescribe drugs for non-FDA approved purposes and for pharmacists who customize a drug compound at the direction of a physician? Could and should the FDA authorize small-scale experiments with modified hardware or software overseen by institutional review boards and based on the informed consent of patients? Could and should the FDA create a less intensive (and less-costly) review process for minor software changes in programmable medical devices analogous to the less-intensive FDA review processes for minor changes in already-approved drugs, while requiring rigorous reporting of adverse events? Could and should the FDA delegate, to a specialized expert body outside of the FDA, the power to review and recommend proposed changes for approval? Or will the acknowledged complexity of software interactions and the critical mandate to ensure patient safety prevent the kind of innovation we would expect when information and communications technologies infiltrate a new area of practice?

One other point might be made about the openness of medical devices. If one examines a device-rich environment such as a hospital intensive-care unit, one is struck by the very large number of devices making critical measurements, with each device providing valuable data. But in many instances the output of an individual device is not in a form that can be captured, recorded, and manipulated together with the outputs of the other devices. Just as the data underlying clinical trials need to be in machine-discoverable, searchable, and manipulatable formats to be of greatest use, the value of the outputs of medical devices would be enhanced if they were standardized in a similar fashion.

Recommendations Regarding the Openness of Medical Devices

The FDA should begin an inquiry into the appropriate long-term regulatory treatment, consistent with patient-safety needs, of software-controlled medical devices given the innovation potential demonstrated by the open-source software movement and the history of user-led innovation in scientific instruments.

The FDA should engage the private-sector medical-device community and the federal research agencies to stimulate greater interoperability among medical devices and greater standardization of data outputs to facilitate the creation and use of integrated data sets.

Chapter 9: Open Business Models

The returns to increased openness in research demonstrate the potential for societal gains from greater openness. But is greater openness compatible with private returns in markets downstream from research?

As the open source software movement has grown, some critics have asserted that the model, which makes computer source code available to all, is incompatible with the profit motive, a threat to investment in “real,” (proprietary) software, and dependent on the altruism of programmers.³¹⁷ Altruism is among the many reasons that programmers participate in the open-software movement and that other individuals contribute their time and effort to other “open” products. But it is not the only reason.

Openness, in the open-source software movement, and in other manifestations we have described, results from many different motivations and is compatible with the creation of private value. It reflects a newly emerging theory of how value can be created.³¹⁸

The creation of private economic value via innovation has long been linked with the ability of a creator to control his or her creation. The creator can then monetize the value of the creation by charging others for the right to access, replicate or modify it. Openness, on the other hand, assumes that the public and private value of a creation can be increased by sharing the creation as broadly as possible, so that others with different experiences, knowledge, insight, and incentives can contribute to and improve it. This idea of how to create value is the mirror image of creating value through control.

We do not always have to choose one model or the other. But given the long history of more-closed business models, it is noteworthy that the idea that greater openness, appropriately applied, can help build better businesses is gaining wider acceptance.³¹⁹

Henry Chesbrough, of the University of California at Berkeley, in his book, *Open Business Models*,

describes several business models that companies can embrace to increase their openness and improve their performance.³²⁰ He analyzes two “syndromes”—“Not Invented Here” and “Not Sold Here”—that have inhibited organizations from becoming more open by drawing upon innovations from outside the organization and from profiting by sharing their own innovations with others.³²¹

Not Invented Here

We all have experienced the rejection of ideas or suggestions because they were “not invented here.”³²² It is not hard to understand why this syndrome has such power. By definition, an innovation from *outside* an organization cannot reflect an intimate understanding of the organization. Such an understanding is only possible *inside* an organization. An innovation from outside arguably cannot be as good because it has not passed the internal approval screens to which an inside innovation is subject. If an outside innovation is significant, the fact that it came from outside may be taken by others as a sign that the organization’s own vehicle for innovation is underperforming or even unnecessary.

Over the years, some of the most prominent and innovative organizations encouraged a “not-invented-here” attitude. Proctor and Gamble (P&G), for example, built a widely admired product development process closed to outsiders. But more recently P&G has recognized the vast amount of creative work done outside of its R&D units and the potential gains available from tapping into knowledge and creativity dispersed globally—both in terms of the costs of development and the time required to bring a product to market.³²³ Instead of “not invented here” P&G is urging its researchers to find innovations that can be labeled “proudly developed elsewhere” and “reapplied with pride.”³²⁴

Even large pharmaceutical companies that traditionally have sought to develop their own drugs and protect them with a barricade of patents rather than relying on the creative work of others are exhibiting greater openness. As the CEO of Novartis stated, “we can’t possibly do it all ourselves.”³²⁵ The CEO of Glaxo SmithKline announced that managers will be rewarded for nurturing products whether developed in-house or acquired from the outside.³²⁶ More open attitudes have led to links between large pharmaceutical companies and smaller outside firms, particularly biotech and diagnostic companies, as well as a greater willingness on the part of large pharmaceutical companies to collaborate with each other, and with academic and government researchers such as in the SNP Consortium.³²⁷ It is telling that InnoCentive, one of the premier examples of bringing outsiders into the R&D process, began as a subsidiary of Eli Lilly.³²⁸

Not Sold Here

The other syndrome, “Not Sold Here,” also is becoming less useful in defining and predicting organizational behavior. “Not sold here” is when an organization doesn’t attempt to pursue a direction or capture the value of an idea that it has generated because it is outside the core activities of the organization—what the organization “sells.” One example would be a company’s refusal to sell or lease research results that have not led to the company’s development of a product.³²⁹ Again, it is not hard to understand the reasoning. A company’s employees might fear that its rivals will benefit from their ideas—even if their own company will not. Maybe the other company will take the idea and make it into a brilliant success. Who would want to acknowledge responsibility for letting that now successful idea get away?³³⁰ There is also value for competitors in learning about what doesn’t work so they can avoid research “rabbit holes”—why make life easier for rivals?

Yet here, too, changes are in the wind. Novartis is making the raw data from its genomic research on Type 2 diabetes broadly available. Perhaps this is due, in part, to altruism, but observers point to the benefits for Novartis, including the building of stronger relationships with leading academic researchers and

the stimulation of other work in the area.³³¹ Merck, for example, has invested millions in a public genome database to stimulate research it hopes will help to develop its core “end products.”³³²

Other pharmaceutical companies are collaborating with companies (often smaller and more focused) by making available, from their large libraries of small molecules, certain molecules that they are not pursuing, with the prospect of sharing in any profits that the other company might obtain.³³³ (One can even imagine an Internet-enabled auction where companies with such molecular libraries might progressively “open” them, providing more and more information about specific molecules they are not pursuing in return for increased payments or larger shares of any downstream profits.)

We have not addressed in any detail possible public-policy initiatives to encourage more open business models—companies will make their choices about the appropriate degree of openness based on their own situations. But others have made proposals, for example, to provide tax incentives for greater collaboration.³³⁴ In some cases, public policies have been adopted that may discourage greater openness. P&G, for example, had a policy in the past of making research results available after three years if the company decided not to pursue them. P&G provided these results to colleges and universities to be developed and commercialized but ceased doing so when the tax code was changed. Perhaps the tax code should not favor openness, but it should not discourage it either.

Companies seeking a profit understand the importance of innovation and are increasingly building global strategies to locate and benefit from innovations around the world. The beliefs underlying the move toward greater openness—that more people can benefit from more information and that more people can make unique contributions based on their interests, experiences, and insights—may be captured in the maxim: All other things being equal, the team with the most smart people wins.* There are obviously many different kinds of “smartness.” Different kinds are needed in different circumstances—just as the optimal degree of openness will depend on the specifics of a situation. But greater openness offers an opportunity to benefit from the contributions of more people, whether to create public or private value.

* Coined by DCC project director Elliot Maxwell.



Conclusion

Openness is not binary; information or processes are not open or closed. They sit on a broad continuum stretching from closed to open, based on their accessibility and responsiveness. And the most open result is not always the best result, depending on the particular goals to be accomplished and the specific circumstances. But greater openness can be of great benefit, from the academic world to the business world, from the research endeavor to the delivery of treatment, from the development of medical devices to the fostering of a more-responsive global public-health system. Greater openness enhances, and is in turn fostered by, increased collaboration.

This report is a first attempt to identify some of the areas that are being changed by greater openness. It is not exhaustive and, as information and communications technologies suffuse the healthcare arena, the list is likely to grow over time. We hope that others will be encouraged to develop this theme and spotlight other areas where openness can help us transform today's pre-industrial and wasteful healthcare system toward one that is more responsive, more efficient, more personalized, more evidence-based, and more oriented toward fostering life-long good health.

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- 17 Google Technology, "The technology behind Google's great results," available at <<http://www.google.com/technology/pigeonrank.html>>.
- 18 Collins and Guttmacher, "Realizing the Promise of Genomics in Biomedical Research," p. 1399.
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