design and development, it is not clear that a regulatory regime designed to control the production of medical device hardware is necessarily optimal for the regulation of software development.

In the face of these difficulties, the FDA has made a concerted effort to promulgate guidance for software manufacturers regarding the use of “software development life-cycle models,” which, if effectively employed, offers manufacturers some hope that their efforts will be deemed to be compliant. The FDA acknowledges, however, that the results produced by many potential software systems—such as diagnostic models developed via application of artificial neural networks—may be impossible to evaluate using available industrial engineering approaches. Given the risks of rapid product obsolescence that software developers face, even in the absence of elaborate regulatory process requirements, the status quo is likely to prove unsustainable.

Given these facts, it is increasingly likely that at some point we will face a significant controversy about the appropriate regulation of freestanding software applications. Yet Congress’s most recent work on device regulation (in Title II of the FDA Modernization Act of 1997) made no explicit policy regarding software regulation.

Should we ask the parties to this debate to soldier on under the 510(k) framework, or begin work on a de novo regulatory model that bears greater relevance to the design and development of software applications? In the policy debate to date, this question has rarely been asked and has never been answered.

**Implications Of Telemedicine**

In comparison with other issues affecting the ultimate potential of health information technology, telemedicine is somewhat higher up the policy radar screen. Most observers of health policy—particularly those attuned to concerns about the delivery of medical care in rural and geographically remote areas—have at least a basic grounding in the issues. The promise of these technologies is significant. Their diffusion into widespread clinical practice, however, faces a number of policy barriers, ranging from border disputes among professionals about licensure issues to concerns about the fiscal implications of more liberal insurance coverage policy.

In the 1997 Balanced Budget Act (BBA) Congress made some initial steps in the direction of more liberal coverage for Medicare and Medicaid. Subsequently, the Clinton administration submitted a report required under Subtitle C, Section 192 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, which, while praising the promise of telemedicine, leaned strongly against further expansions of coverage. The report cited the lack of evidence on safety, quality, and cost advantages to justify publishing the rules that would, in effect, create a health information technology industry to deliver the promise of telemedicine.

It should be said that the HIPAA regulations will probably not come close to realizing the potential of the technology. The federal government does not have the regulatory capacity to foster the necessary innovations in these areas. The time required to develop these technologies, and the cost of regulatory and reimbursement policies, could well outstrip the technical potential of the information systems.

In particular, the constraints on telemedicine in the California medical community are likely to extend to similar constraints in the national effort. The policy debate, however, is far from over.

**Do We Need More Private Information?**

The proliferation of automated systems in the collection, storage, and dissemination of public health data in Europe has raised some concerns about the privacy of individuals. So far, these systems have not been adopted in the United States, at least in part because of a lack of data security and confidentiality controls. However, a comparison of the experiences with these systems in Europe and the United States suggests that legislative enhancements are not necessary to address these concerns.

The key to the success of any systems depends on a careful implementation that minimizes the risk of revealing personal information. The potential benefits of these systems justify the need for a careful and measured approach to their implementation.
on safety and effectiveness, the absence (outside teleradiology) of published standards, and a variety of other concerns that add up to a healthy respect for telemedicine's capacity to break the bank were it to diffuse widely under a regime of unmanaged fee-for-service financing.9

It seems likely in this sort of environment that the effort to promote reimbursement of telemedicine will be a game of inches for the foreseeable future. If this potential impasse comes to dominate the public policy debate over telemedicine, however, it probably will prove unfortunate, since in the longer term the issues regarding licensure and liability are likely to prove far more important than short-term concerns about reimbursement.

The great promise of telemedicine, in the long run, is that it has the capacity to powerfully enhance productivity, leading to marked improvements in the cost-effectiveness of medicine. Limiting the scope of medical practice to problems physicians can physically confront often results in a profound misallocation of resources. The potential productivity of highly focused and experienced specialists is particularly tightly constrained under such a regime.10 Absent regulatory and legal barriers to remote practice, it would be rational for multisite managed care organizations to build their physician networks based on the assumption that pediatric oncologists, say, California could advise and coordinate care for children in Oregon. The current regime, inadvertently or inadvertently, requires redundant capacity in all sites for many or most narrow subspecialties.

In a world in which we can in seconds log onto a Web site in Tibet, is it rational to restrict the range of application of medical practice to the confines of narrow geographic areas? The health policy debate has been largely silent on this question.

Do We Have A 'Health Information Policy'?

The policy status quo in these various debates suggests that despite the conversations that are taking place regarding the appropriate public policy posture toward health information technology, we have yet to find a way to discuss these issues as a coherent whole. In my view, this state of affairs is suboptimal, because although all of these conversations are occurring in different languages, they all address a single subject: whether public policy should promote, retard, or remain neutral toward private innovation in health information technology development.

Up until very recently, medical informatics has had only a limited impact on the day-to-day practice of medicine. Given the combination of generic technological advances, advances in health-specific applications, and the tidal wave of capital poised to wash into this
area if the promise proves real, however, we can now say confidently that we can have a profoundly different tomorrow—if we want one. There are a number of reasons to doubt that the ultimate policy consensus will center around a laissez-faire attitude toward these questions once the debate is fully joined. But if it turns out that we want to promote intensive investment in the promise of these technologies, we are going to need to know pretty soon, since many of the decisions policymakers will have to confront over the next few years will have a profound effect on whether much of this ever gets off the ground.

Should We Even Want A Health Information Policy?

Beyond considerations of sheer tidiness, is there any convincing policy reason why the central questions posed by health information technology developments should be considered en bloc, rather than continuing to be handled in their present niches? I submit that there is, because the factors that affect the generation and management of health care information lie at the heart of every question bearing on the quality of health care services delivered to the American people.

In an important sense, information is the only resource we have to bring to bear in attempting to assess, and influence, the efficacy and appropriateness of medical practice. Our ability to obtain and evaluate health care information constrains the extent of our knowledge regarding the efficacy of clinical practices (old or new). Also, our ability to generate and disseminate new information about clinical practices governs the rate at which "state-of-the-art" knowledge diffuses to clinical practitioners. If we as a nation face problems that derive from suboptimal knowledge about the effectiveness of medical practice, and confront evidence of inexplicable variations in clinical practice, we need substantially new and better sources of information if we want to even begin addressing these problems.

From this perspective, the central question facing policymakers is whether the health information infrastructure that is likely to develop in the presence or absence of different sets of constraints will add up to the information sources we need to address present and emerging issues in clinical assessment. Quite clearly, we can look at this question only by examining the potential effects of various sorts of constraints in combination. This perspective argues for some form of national health information policy, and it makes the implicit case for a government-promoted national health information policy.
form of "health information policy" viewpoint that permits policymakers contending with disparate legal and regulatory policies to take the opportunity, at least from time to time, to ponder the implications of what it all adds up to as an environment in which to promote the desired degree of technological innovation.

**How Much Is Enough?**

As we contemplate this landscape, it is important to distinguish the notion of a centralized policy viewpoint from the notion that the evolution of the private health information technology marketplace could in any meaningful sense be centrally planned. Given the complex and ever-evolving character of the state of both information technology and clinical knowledge, it is impossible to render prospective judgments about which technologies ultimately will advance the cause of clinical improvement, and which represent blind alleys. We should expect the evolving health information technology marketplace to be chaotic, with clear progress measurable only through the rear-view mirror.

Having said that, I believe that we should proceed from the assumption, with respect to the information tools that will be required to support rigorous clinical assessment and knowledge dissemination, that "more is better." The case for erring on the side of relatively robust capabilities is that, from the perspective of quality assessment, our problems are certain to get a whole lot worse without a major leap forward in our health information infrastructure.

The reason is that the rate of technological innovation in medicine itself is rapidly accelerating and is poised to explode as practical applications from human genomics hit the system over the next ten to twenty years. Much or most of this new product throughput will be aimed directly at community-based practitioners—if not marketed directly to the consumer—rather than being filtered through the academic medical setting. In fact, a whole host of efforts are under way under the broader banner of "telehealth" to use information technology to directly engage patients in the management of their own health care. In this environment, comparative efficacy assessment will become progressively more difficult, rather than easier, absent profound improvements in our ability to assess new diagnostic and therapeutic technologies "on the fly."

An important corollary of this is that, without major improvements in the technologies by which clinical information diffuses to practitioners "on the ground," natural limits on the ability of a stable or declining supply of physicians to absorb all of this information will sharply exacerbate the degree of variation in practice patterns that is observable in the day-to-day workings of the health care system.
In this emerging scenario there are only two meaningful points of traction: the rate of new product innovation, and the diffusion rate. Assuming, for the sake of argument, that aging baby boomers are likely to be hostile to policies that seek to slow the rate of biomedical innovation solely for the sake of imposing order on the system, then the only way out is to use markedly improved information technologies to (1) enhance our ability to screen out clinical techniques that, while promising, can be demonstrated to be comparatively inefficacious; and (2) rapidly accelerate the diffusion of the "real-time" state of clinical knowledge to the physician's office and the patient's bedside.

This analysis suggests that we should err on the side of caution in the face of policy options that would have the effect of materially retarding the development and dissemination of major improvements in the nation's health information infrastructure.

Should We Fasten Our Seat Belts?

Having striven to make the case that "health information policy" is somewhat more than a theme park for academics and theologians, I acknowledge that, once engaged, the "health information policy" debate may prove to be a very rough ride. Once the full implications become clear, it is by no means certain that we be able to achieve a meaningful consensus in any open, public debate about workable solutions to the potentially intractable problems involved.

First, for all of the reasons noted above, there is an inherent tension between our traditional view of health care policy and the radically different view that may be required to cope successfully with the coming irruption of new technologies into health care. Our historical view could be characterized as highly conservative of medical privacy, cautious about the introduction of new technologies on safety grounds, and incremental in the approach taken by payers and regulators to material changes in the economic organization of the health care system. It is more than remotely possible that when confronted with the challenge posed by the emerging flood of new issues, our political institutions may be structurally unable to move fast enough to cope.

Second, many of the implications of the intersection between information technology and biomedical innovation point directly at the heart of the notion of medicine as an individual profession, as distinct from a collective enterprise involving multidisciplinary care teams that are interlinked with—and increasingly dependent on—a host of umbilical technology supports. Physicians are, at their core, scientists and will ultimately go where the flow of objective evidence takes them, yet the psyche of the profession can reasonably be

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Expected benefits of this approach...

Final thoughts on health information policy and implications of the ongoing medical and technological developments in medical education are necessary...
expected to experience wrenching changes as the implications of all of this unfold.

Finally, unless we are very careful, the emerging capabilities of health information systems could engender the thermonuclear escalation of the ongoing war between cost and quality considerations in medicine. The same technology that provides the infrastructure necessary to optimize clinical practice from the perspective of clinical efficacy also could easily support efforts to optimize the cost-effectiveness of the system. The restriction of available automated data sources to claims data now provides clinicians with powerful defenses against meddling by nonclinicians, since the clinical value of these data is extremely limited. As detailed medical records information on broad populations becomes increasingly available in automated form, however, these defenses will be stretched ever thinner, to the point at which the clinicians and the "bean counters" will eventually have to duke it out.

What Constitutes A "Health Information Policy"?

For all of these reasons, the road to the "brave new world" of the paperless clinical enterprise is likely to be a rocky one. If the potential value of these technologies is to be realized, policymakers will need to furnish active leadership toward answers to several important questions. First, how far down the road to the "paperless clinical enterprise" do we really need to go to address the nation's emerging clinical information management problems? Is the "Buck Rogers" version of the vision a technical necessity? Or can we make reasonable progress with a less robust infrastructure? If so, how will we know it when we see it? Next, we need to understand how far the private market will in fact get us toward this objective absent material intervention (pro or contra) by government. Can we reasonably expect commercial market developments to produce an infrastructure that will support all expected requirements? Or should we expect gaps and anticipate their character well enough to promote the development of timely solutions? Once we have a clearer picture of what we may or may not achieve through the normal operations of the private marketplace, can we define a consensus agenda for public-sector action? Should government promote action in such areas as technology standards to speed development? Are there areas of regulation where government should forbear?

Acknowledging that the process of seeking consensus answers to these questions is likely to be a mess, I believe that now is the time to get on with it.
The author acknowledges the contributions to his thinking of the attendees at a meeting at the Health Affairs office, 13 April 1998. The participants were Robert Berenson, Levin Group; Philip Caper, Codman Research Group; Mary Jo Deering, U.S. Department of Health and Human Services; John Kelly, HBO and Company; David Kendall, Progressive Policy Institute; J.D. Kleinke, health policy consultant; Lawrence Lewin, Levin Group; Clement McDonald, Regenstrief Institute; Stephen Parente, Project HOPE Center for Health Affairs; and Gail Wilensky, Medicare Payment Advisory Commission and Project HOPE Center for Health Affairs.

NOTES
2. Ibid.
3. See, for example, the testimony of Janlori Goldman, director of the Health Privacy Project at Georgetown University's Institute for Health Care Research and Policy, before the Senate Committee on Labor and Human Resources, 24 February 1998.
5. The FDA also regulates software devices that are offered as "accessories" to the use of regulated medical devices.
8. Section 4206 covers teleconsultations-effective 1 January 1999 in Health Professions Shortage Areas, while Section 4207 authorizes a demonstration of telemedicine applications in the home management of diabetes mellitus.
10. In a number of quaternary subspecialties, the population base required to support one clinical full-time-equivalent subspecialist is much greater than the population of most metropolitan areas of the country.
11. As several reviewers of an earlier draft of this paper pointed out, however, information is necessary but hardly sufficient to solve the problem of practice pattern variations.