

products for their potential to cause significant problems.

The FDA should facilitate the development of safety standards where none exist and then, working with our international partners, build a system with multiple levels of oversight. Safety must be the shared responsibility of not only the producer but also the country of origin, the importer, the importing country, and the final company in the supply chain. Some elements of this system, such as international outreach and coordination, can be implemented quickly; others will take years to develop. Along the way, new challenges are likely to arise. As they do, the FDA must respond forcefully and provide timely and credible information to the public.

Indeed, one of the greatest challenges facing any public health agency is that of risk communication. We all accept small risks in our daily lives, from the risk of falling in the shower and sustaining a head injury to the risk of having a car accident on the way to the grocery store. One reason we are rarely fearful of these risks is our perception that we have control over them. When it comes to food and drugs, even small risks can cause considerable fear and anxiety, especially when they seem to be out of our control. Yet all pharmaceuticals have some potential adverse effects, and many raw foods may harbor natural pathogens.

The FDA's job is to minimize risks through education, regulation, and enforcement. To be credible in all these tasks, the agency must communicate frequently and clearly about risks and benefits — and about what organizations and individuals can do to minimize risk. When, like the FDA, Americans must make choices about medication, devices, foods, or nutrition in the absence of perfect information, the FDA cannot delay in providing reasonable guidance — guidance that informs rather than causes unnecessary anxiety.

For these communications to have credibility, the public must trust the agency to base its decisions on science. We recognize the importance of a management approach that respects the expertise and dedication of the FDA's career scientists. In recent years, the agency has struggled to handle controversies involving the safety of regulated products, opening the door to legitimate questions from the media, the public, and Congress about whether the public interest is being served. Establishing the FDA as a public health agency requires a culture that encourages scientific exchange and respects alternative viewpoints along the path of decision making. It also requires that the agency define and protect integrity in its basic processes.

Transparency is a potent element of a successful strategy to

enhance the work of the FDA and its credibility with the public. Whenever possible, the FDA should provide the data on which it bases its regulatory decisions and other guidance and explain its decision-making process to the public.

We are honored to be chosen by President Obama and inspired by his commitment to the FDA and his proposed historic increase to its budget. More than a century ago, his predecessor President Roosevelt could not have foreseen the introduction of modern antibiotics, chemotherapy, and genomic medicine or the potential regulation of tobacco products — let alone the challenges of the 21st century. The FDA has always been a work in progress. Updating this work means modernizing scientific and legal regulatory approaches to a host of complex matters. Succeeding will require respecting the tradition of the FDA and its mission of public health.

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Dr. Hamburg is the commissioner, and Dr. Sharfstein the principal deputy commissioner, of the Food and Drug Administration, Silver Spring, MD.

1. United States v. Bacto-Unidisk, 394 U.S. 784 (1969). (Accessed May 21, 2009, at <http://supreme.justia.com/us/394/784/case.html>.)

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Achieving Health Care Reform — How Physicians Can Help

Elliott S. Fisher, M.D., M.P.H., Donald M. Berwick, M.D., M.P.P., and Karen Davis, Ph.D.

This year, we have the best chance in a generation of enacting legislation worthy of being called health care reform and

of setting the United States on the path to high-quality, affordable health care for all Americans. The recent commitment by

several major stakeholders — including the American Medical Association — to slowing the growth of health care spending

is a promising development. But the controversy about whether the organizations actually agreed to a 1.5-percentage-point reduction in annual spending growth is just one indication that success is still far from assured.

Two threats in particular put reform at risk: conflicting doctrines (regarding the creation of a new public insurance option and government support for comparative-effectiveness studies) and opposition to change among some current stakeholders. In the face of this uncertainty, physicians have a choice: to wait and see what happens or to lead the change our country needs. We'd prefer the latter.

Physicians should first help to create a shared vision that could overcome doctrinal divides — and bring providers together to create a system better aligned both with public needs and with providers' fundamental interests and values. The starting point is to recognize, as most physicians do, that improving a complex health care system requires action on multiple fronts. In its landmark report *Crossing the Quality Chasm*, the Institute of Medicine (IOM) described a "chain of effect" that links systems at four different levels as the interrelated determinants of health care quality that must be aligned for reform to yield the desired results.

The first level is aims. For health care reform, we propose that physicians, through their advocacy, help lead the country to embrace the so-called triple aim: better experience of care (safe, effective, patient-centered, timely, efficient, and equitable), better health for the population, and lower total per capita costs.¹

The second level is the design of the care processes that affect

the patient — clinical "microsystems." Health care microsystems are famously unreliable, variable in costs, and often unsafe. Physicians, through their participation in quality-improvement initiatives in their practices and hospitals, can and should lead the needed changes in the systems of care in which they work, to make them safer, more reliable, more patient-centered, and more affordable.

However, neither physicians nor anyone else on the front lines can improve care much on their own. Their most important source of support for improvement is the third level described by the IOM — the health care organizations that house almost all clinical microsystems and can ensure coordination among them. We need organizations large enough to be accountable for the full continuum of patients' care as well as for achieving the triple aim. We will create a high-performing health care system only if integrated delivery systems become the mainstay of organizational design. Organizations could be virtually integrated, such as networks of independent physicians sharing electronic health records and administrative and clinical support for care management and quality improvement, or structurally integrated, such as multispecialty group practices or staff-model health maintenance organizations.² Fostering the development of such accountable care organizations need not be disruptive to patients or providers: almost all physicians already work within natural referral networks that provide the vast majority of care to patients seen by the primary care physicians within the network.³

The IOM's fourth level is the

environment, which includes the payment, regulatory, legal, and educational systems. On this front, too, we need physician advocacy. The United States cannot achieve the triple aim without health insurance for everyone. Integrated delivery systems that are accountable for populations won't thrive unless payment systems encourage their development and unless we change the laws and regulations — including proscriptions of gainsharing and anti-kickback rules — that prevent cooperation among health care professionals and organizations.

If stakeholders can agree on such a vision of health care reform, perhaps we could shift our focus from the conflict over whether a new public plan should be created to a more constructive insistence that all health plans, whether public or private, focus on the development of professionally led, integrated systems.

The second and largest threat to reform, which looms ever larger in a weakened economy, is the possibility that Congress will conclude that expanding coverage to all the uninsured is unaffordable. Without some guaranteed savings, skeptical watchdogs, such as the Congressional Budget Office, are unlikely to accept the vague promise that integration will save enough money to offset the cost of coverage expansion.

So how might physicians help us all "get to yes"? The first step is to acknowledge that delivery-system reform offers a potential win-win situation for providers. Physicians should support and help to develop integrated systems of care. Integration pioneers that have arranged new, population-based payment models — such as the Geisinger Health System in Pennsylvania — have

achieved substantial savings while preserving generous net incomes for physicians and hospitals.^{3,4} Such integrated systems also have strong incentives to invest in primary care.

The second step is for physicians to recognize that achieving savings sufficient to cover the cost of expanded coverage need not impose a hardship on patients or providers. A 1.5-percentage-point reduction would still allow spending — and thus the total incomes of providers — to rise from \$2.6 trillion in 2010 (17.7% of the gross domestic product [GDP]) to \$4.3 trillion in 2020 (18.5% of the GDP). But because of the miracle of compounding, a “1½-percent solution” that reduced the growth in annual spending from 6.7% to 5.2% could save the health care system \$3.1 trillion of the \$40 trillion we are currently projected to spend between 2010 and 2020, according to the Lewin Group.

If health care providers and suppliers could actually achieve this reduction in growth rates, the federal government would harvest about \$1.1 trillion in savings over the 11-year period — enough, perhaps, to close the deal on affordable health insurance for all. Others would also see savings: \$497 billion for employers, \$529 billion for state and local governments, and \$671 billion for households. One simple way for physicians to start contributing to this goal is by reassessing and scaling back, where appropriate, their use of clinical practices now listed as “overused” by the National Quality Forum’s National Priorities Partnership.⁵ Ideally, providers would also agree to slow fee increases for private payers further, allowing Medicare to catch up.

The Congressional Budget Office, however, is unlikely to score as savings purely voluntary restraints on price increases. It may therefore be necessary to set a legislative target for the growth of spending at 1.5 percentage points below currently projected increases and to grant the federal government the authority to reduce updates in Medicare fees if the target is exceeded. These moves would guarantee near-term budget savings while building a foundation for fundamental payment reform.

The final step is to craft a deal that all stakeholders can support. We suggest linking the proposed savings of 1.5 percentage points both to health insurance for all (which will result in revenue gains for providers who deliver care to the newly insured) and to comprehensive reform of the delivery and payment systems. The reforms should encourage providers to establish accountable care organizations through an array of incentives, including the adoption of innovative payment models, such as shared savings, bundled payments, or global fees for care; a shift toward performance measures that reinforce providers’ shared accountability for health outcomes and care coordination; and a requirement that subsidies for electronic health records be available only to providers demonstrably on the path toward integrated care. With new global payment methods and strong organizational support for clinical improvement, providers, patients, and payers would all gain from the elimination of wasteful care and avoidable complications.

Ultimately, we believe that the United States can reduce its per capita health care costs — with-

out harming patients — by much more than the proposed 1.5-percentage-point reductions in growth would shrink them. But let’s make that deal stick. Physicians can become our most credible and effective leaders of progress toward a new world of coordinated, sensible, outcome-oriented care in which they and their communities will be far better off. Defending the status quo is a bankrupt plan, and physicians have an opportunity to help us all see beyond it.

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Dr. Fisher is a professor of medicine and of community and family medicine and associate director for Population Health and Policy at the Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School, Lebanon, NH. Dr. Berwick is a professor in the Department of Health Policy and Management, Harvard School of Public Health, Boston, and president and chief executive officer of the Institute for Healthcare Improvement, Cambridge, MA. Dr. Davis is the president of the Commonwealth Fund, New York.

1. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)* 2008;27:759-69.
2. Shih A, Davis K, Schoenbaum SC, Gauthier A, Nuzum R, McCarthy D. Organizing the U.S. health care delivery system for high performance. New York: Commonwealth Fund, August 2008.
3. Fisher ES, McClellan MB, Bertko J, et al. Fostering accountable health care: moving forward in Medicare. *Health Aff (Millwood)* 2009;28:w219-w231.
4. Steele GD. Reforming the healthcare delivery system, invited testimony before the U.S. Senate, Committee on Finance. April 21, 2009. (Accessed May 21, 2009, at <http://finance.senate.gov/hearings/testimony/2009test/042109gstest.pdf>.)
5. National Priorities Partnership. National priorities and goals: aligning our efforts to transform America’s healthcare. Washington, DC: National Quality Forum, November 2008. Copyright © 2009 Massachusetts Medical Society.