Rationalizing The Drug Patent System

To the Editor:

Over the past twenty years the pharmaceutical industry has brought us some terrific new drugs that ease pain and suffering and make our lives better and more productive (Sep/Oct 01). Just because the industry is producing useful products doesn’t mean it should be immune from scrutiny, however. A growing number of physician, business, and consumer organizations have begun to question the industry’s business strategies and whether the regulatory environment in which it operates best serves consumer interests.

The pharmaceutical marketplace is increasingly torn asunder by litigation. Because of complex federal rules and because they have deep pockets, companies that make brand-name patented drugs routinely submit numerous new patent filings on drugs with imminently expiring patents and file lawsuits to block generic companies from marketing competing products when a drug’s patent is set to expire. No other industry litigates its patents with such regularity or ferocity. The brand companies lose a fair share of these battles. But that doesn’t matter, because the litigation triggers automatic statutory delays (of thirty months) in the marketing of competing generics. Consumers are the losers, as access to less expensive generic drugs gets delayed. In addition, the price of this litigation is built into every new drug. Relevant to this issue, Rebecca Eisenberg makes the point that FDA regulation protects and sometimes lengthens the industry’s patent monopolies every bit as much as patent law. This is a critical point to consider as lawmakers wrestle with ways to make the system work better.

The pharmaceutical industry argues that it needs every day of added patent protection and market exclusivity so that it can plow revenue back into research and development (R&D). A careful look at the flow of drugs to market in the past five to ten years reveals a growing number that are not all that innovative or better than older drugs. Companies have begun to spend small fortunes aggressively marketing their drugs to convince doctors (and, more recently, consumers) that they are true breakthroughs; some are, most aren’t. Ditto the practice of “evergreening” existing blockbusters by reformulating and repackaging drugs. In all too many cases, the drugs appear to be improved only marginally if at all.

I agree with Uwe Reinhardt that we need more consumer cost sharing and far better information on the cost-benefit ratios of individual drugs. But a strategy to steer payers and consumers to appropriate, cost-effective medicines must be accompanied by efforts to rationalize the system under which drugs are patent-protected, gain periods of special market exclusivity, and ultimately go off patent.

Steven Findlay
National Institute for Health Care Management Foundation
Washington, D.C.

Useful Lessons For Policymakers

To the Editor:

David Cutler and Mark McClellan, Frank Lichtenberg, and F.M. Scherer (Sep/Oct 01) present important empirical findings on pharmaceutical innovation that are consistent with the results of broader economic studies of industrial R&D. The authors’ results provide useful lessons for policymakers as they begin structuring a Medicare prescription drug benefit and other possible public policy
changes affecting the drug and biotechnology industries.

Both the Cutler-McClellan and the Lichtenberg papers indicate typically large positive spillovers from drug innovation and find that the social benefits from new drug introductions far exceed their social costs. Scherer’s paper is consistent with the hypothesis that pharmaceutical R&D investment is driven by future expected returns and that pharmaceutical firms use the profits from past commercial successes to finance most of this effort. These results accord with my own research with John Vernon. Our work also shows that the distribution of returns from pharmaceutical R&D is highly skewed. Specifically, a significant therapeutic advance for a given medical condition is typically followed by significant R&D investments by competitors, resulting in additional advances in the same chemical or biopharmaceutical class, a process that Scherer characterizes as a “virtuous rent-seeking model.”

These findings reinforce the basic thesis of Reinhardt’s paper, that policymakers should avoid imposing supply-side constraints or price controls on the industry. Reinhardt makes the further point that all of the industry’s profits in 1999 amount to only about 1 percent of national health care spending. Hence, greatly constraining, or even eliminating, industry profits would do little to further cost containment. As the other papers in this issue indicate, such constraints would have adverse consequences for R&D outlays and the large potential societal benefits from future new drug introductions.

Industry data indicate that there are now more drugs in the R&D pipeline than at any time in recent decades. Furthermore, the human genome project and other biomedical advances have resulted in a huge increase in new drug targets and promising leads on future drug candidates. As policymakers begin work on structuring an outpatient drug benefit for Medicare, it is imperative that they do so in a way that preserves strong incentives for innovation. The Clinton health care reform act provides an apt model of how not to proceed.

The reference pricing scheme in that proposed legislation, which used the regulated drug prices in other countries as key benchmarks, would have had devastating consequences for new drug innovation. Policymakers should be able to construct a Medicare drug benefit that ensures that the government is a prudent purchaser of pharmaceuticals, while at the same time maintaining strong innovative incentives. Ample public- and private-sector models exist in this regard, including the Federal Employees Health Benefits Program and various competitive pharmacy benefit management plans.

Henry Grabowski
Duke University
Durham, North Carolina

Paying For Medical Breakthroughs

To the Editor:

The papers by Cutler and McClellan, J.D. Kleinke, and Reinhardt (Sep/Oct 01) represent an important beginning to a much needed debate. Most purchasers rank determining how to pay for the explosion of new technologies alongside health system quality and the uninsured as the three biggest challenges facing the U.S. health care system. Framing the issues appropriately is crucial, however.

First, we should acknowledge and accept as a national value that U.S. society is passionately in favor of new technologies that cure disease and improve well-being. Next, we need to integrate economic theory with the practical realities of the health care market. The authors’ failure to discuss the relationship between quality and technological breakthroughs is baffling. The potential misuse and overuse of new technologies, and the challenge of educating consumers about their value, need to be key parts of the national discussion. Finally, we need to factor in the unintended consequences inherent in applying policy recommendations to reality. Faulty projections that underestimate costs by millions may be trivial in proportion to our multi-trillion-dollar economy but are significant for those who have to make payroll.
Encouraging innovation is the right way to drive value. But the quality of the delivery system into which new technologies should diffuse is as important as the macro-economic analyses that help us to quantify their return. Purchasers and plans need to get active in this area and apply their business acumen to move the right innovations quickly to the right patients, with quality as the compass.

Robert Galvin
General Electric
Fairfield, Connecticut

Assessing The Relative Value Of Drug Therapies

To the Editor:

When Kleinke described six ways that new, expensive prescription drugs add value to the health care system (Sep/Oct 01), he failed to note that sometimes these drugs increase health care costs without improving health care quality. Many newer drugs offer significant therapeutic improvements to a broad population; some are beneficial to only a small share of patients but are nevertheless widely advertised. Other new drugs provide little therapeutic improvement over alternative, less costly medications.

Newer, higher-price drugs are a major contributor to double-digit growth in prescription drug spending. Consumers ultimately bear the cost of increased drug spending. Therefore, it is important that consumers and their physicians have information to determine whether their health care dollars are spent on the most effective therapy.

This need clearly influenced Reinhardt’s call for a more systematic approach to assess the value of prescription drugs relative to other therapies. His proposal for independent, federally funded pharmacoeconomic research institutes whose purpose would be to provide an objective source of information that will enable consumers and providers to compare the value of therapeutically similar drugs has substantial merit. Leveling the playing field so that the public can assess both the pharmaceutical industry’s claims of drug value and third party payers’ efforts to restrain drug costs will help to achieve more appropriate and more efficient drug pricing and delivery.

John Rother
AARP
Washington, D.C.

Balancing Access And Innovation

To the Editor:

Kleinke’s categorization of drug categories (Sep/Oct 01) is a helpful analytic construct to understand institutional interests but is less helpful as a policy guide. Defining these categories for insurance contracts or legislative purposes is practically impossible. His proposal to mandate coverage of “pay-me-laters” (costly drugs that increase future costs) and “narrow-pays” (costly drugs to treat a wide population with a narrow benefit) is based on the questionable premise that payers are racing to target these drugs for exclusion. Many of these drugs are covered by health plans. However, as drug costs continue to increase, payers who have to finance the increased costs in the short term must contend with the limited resources available for health care.

Missing from Kleinke’s list of drug categories is one that might be called “pay-for-nothings.” These drugs provide little if any therapeutic advantage over existing drugs but cost many times more. For example, when a Cox-2 inhibitor provides a decrease in gastrointestinal side effects over the standard therapy, how many multiples in increased cost should a consumer or employer pay for the newer drug? What if a generic low-risk drug provides the same benefit? Also in this category are drugs that would be generically available (and therefore less expensive) but for manufacturers’ interest in protecting their...
monopolies. Many products, such as food and clothing, provide thousands of dollars’ worth of improved quality of life every year. Yet grocers and tailors are expected to offer their products and services in a competitive marketplace, rather than to price to the abstract “value” that food and clothing ultimately provide. Drug manufacturers justify monopoly rents on the grounds that the profit motive stimulates useful innovation. Innovation is critical to therapeutic progress, but Congress must assure that access today and innovation tomorrow are balanced in a way that benefits society as a whole.

Gerry Shea
RxHealth Value Project
Washington, D.C.

Drug Price Moderation Still Needed
To the Editor:

Reinhardt (Sep/Oct 01) proposes the use of demand-based approaches to promote more appropriate drug spending. Using tiered coinsurance to increase insured consumers’ price-sensitivity may be appropriate, but any such approach must incorporate consumer protections, including low-income subsidies and limitations on consumers’ financial exposure. Tightening regulation of direct-to-consumer (DTC) advertising is another demand-focused strategy that would help to moderate costs.

Reinhardt suggests that savings on the supply side (prices and profits) might reduce R&D and reduce the availability of drugs. Perhaps, but that’s debatable—especially since virtually all of the large drug companies spend two to three times as much on marketing, advertising, and administration, and receive considerably more in net profits than they spend on R&D.

This is an industry that benefits from significant public support, including taxpayer-funded research, extensive patent protection, special tax breaks, and prohibitions on reimportation of drugs. Further, the industry’s behavior sometimes runs counter to the public good. Seeking to extend brand-name monopolies by initiating frivolous lawsuits, paying manufacturers to withhold generics, and trying to patent metabolites that the body produces when a pill is ingested all cry out for public policy intervention that will, as a corollary, affect profits.

Reinhardt correctly notes that the proper social response to individuals burdened by prescription drug costs is adequate insurance coverage. This is also the response that will best address drug prices by consolidating purchaser power and eliminating opportunities for regressive price discrimination. However, as the debate on a Medicare drug benefit shows, achieving that objective is not easy. The government—like other payers—looks at both price and demand when considering the cost of coverage. The lack of price moderation makes it harder politically to reach the goal of adequate coverage. A complete response to the issue of drug costs, therefore, must include initiatives aimed at the industry’s supply and demand sides.

Ron Pollack
Families USA
Washington, D.C.

Increased Transparency For Drug Research
To the Editor:

Reinhardt’s assessment of the “ineffective flailing at the supply side” of the pharmaceutical marketplace (Sep/Oct 01) is correct. Drug firms, like all publicly traded companies, have an overarching legal and ethical obligation to maximize return to shareholders within the legal limits that regulation places on the industry. They do that by charging the maximum prices that the market will bear and by opposing regulation that imposes costs on them.

However, Reinhardt’s remedies presume that buyers—insurers, consumer groups, provider groups, employers, and pharmacy benefit managers—will be able to organize their mutual interests and pursue them in Congress and the marketplace. The current conflict among buyers over medical necessity criteria and notions of benefit design in the patient’s bill of rights legislation is one indica-
tion of how difficult alignment of interests will be.

Reinhardt’s solution is to redesign benefits along a model similar to reference pricing and to develop a transparent information market based on pharmacoeconomic research. He has the order in reverse. We need first to develop an objective, well-funded research effort, similar to a public-private utility that can provide information to physicians and patients to support clinical and economic decisions. Objectivity and transparency of research methods are necessary if such research is to be credible to physicians and consumers. Reference pricing could correct cost-insensitive utilization, assuming that criteria such as medical necessity could be agreed upon to determine what health plans define as clinically appropriate. That dilemma, as reflected in the patients’ rights debate, only seems to be splitting groups on the same side. Buyers should consider Reinhardt’s proposal as a good starting point for reconsidering their joint interests.

Mark Cloutier
Health Priorities Group
Berkeley, California

Faulty Links Between Profits And R&D Spending

To the Editor:

Scherer’s analysis (Sep/Oct 01) is faulty. First, merely showing correlation between industrywide levels of profit and R&D does not prove that more profits lead to more R&D; association is not causation. Moreover, Scherer ascribes great importance to relatively trivial differences in the data. (At most, there are 20 percent deviations from the raw outlay and trend lines.) Second, the author relies on aggregate industry data when, in fact, decisions that determine the relationship between profits and R&D, such as what to do with profits, are made at the company level. The analysis would be more relevant if it showed that as one company’s profits went up, its R&D increased at a corresponding rate. Finally, there are many reasons why aggregate profits and R&D might have increased concomitantly—growth in exports, rising prices, more companies, and increased advertising.

In any case, Scherer fails to address the more important public health question: To what degree can profits that he describes as “supranormal” be reduced without a substantial impact on important R&D? (In 2000 the eleven drug companies in the Fortune 500 enjoyed a median profit margin that was nearly four times that for all other Fortune 500 companies.) Much R&D is not vital to public health because it supports me-too drugs. It is therefore likely that some profits, as well as some R&D, could be reduced without harm to consumers.

Bob Young
Public Citizen’s Congress Watch
Washington, D.C.

Imperfect Data

To the Editor:

Scherer (Sep/Oct 01) uses a creative approach, necessitated by the paucity of detailed data for a more precise analysis. It is interesting and provocative how R&D spending and gross margins vary from fitted trend lines with quite high correlations. Given that the data for R&D and margins came from different sources, with a less than perfect coverage match, the consistent patterns and correlations indeed may suggest that something is occurring. But three caveats come to mind.

First, the analyses not only explain “what firms do with their (gross) profits,” they also may suggest fine-tuned pricing and demand (and thus revenue) forecasting capabilities that effectively translate into expense budgeting for R&D (plus promotional and other operating expenses). Scherer’s analyses of margin and expense correlations relative to trend lines effectively are pricing analyses, since prices drive profit margins. The notion that margins and expenses have a high correspondence comes as no surprise to managers in large organizations like drug firms, where budgets are key planning and management tools; a correspondence between what is budgeted and spent is a normal phenomenon.

Second, the paper suggests that policy in-
Interventions aimed at reducing prices and profits have self-evident implications for firms that compete to exploit expanded profit opportunities by increasing R&D investment. However, the analysis shows that R&D spending grows at a faster rate than prices and has done so consistently for more than thirty years. If this long-term, “self-inflicted” lower rate of expanding gross profits has yielded a higher R&D growth rate, would policy interventions bring a different response? If better data were to show lower (or higher) growth rates for margins than profits, then what? Finally, although the analyses explain potentially how gross profits are used, how well the spending converts into new, useful advances and whether that process is efficient may be thornier issues that are more difficult to assess.

David H. Kreling
University of Wisconsin
Madison, Wisconsin

The author responds:
I am amused but not surprised that my paper elicits such conflicting comments. In the paper I observed that the analysis was simple and the results surprising. I presented several alternative causal hypotheses. I found only the “R&D leads to profit” hypothesis unsupported by the analysis, but we know it is true with different lag structures and considerable skewness. I would very much like to have “clean” company data with which to carry out the analysis. Alas, as I stated, existing company data are seriously contaminated by non-pharmaceutical activity. Had the Federal Trade Commission’s Line of Business reporting program, which I helped to develop a quarter-century ago, survived attacks from industry, we would now have the data needed for an ideal test. Several other points raised in the letters are addressed by me elsewhere at too great a complexity to be discussed here. I would be happy to supply references by e-mail, <fscherer@princeton.edu>.

F.M. Scherer
Princeton University
Princeton, New Jersey

Leaders Need Followers To Improve Quality Of Care

To the Editor:
Elise Becher and Mark Chassin’s analysis (Sep/Oct 01) is persuasive, chilling, and depressing. Concluding that any widespread societal movement to promote quality is almost inconceivable, they turn to the one source of hope they have not totally demolished: leadership. They then dismiss virtually every potential source of leadership—consumers, purchasers, government, academic medicine, organized medicine—until only “health care providers” are left standing. It is easy to eliminate providers as well, since they, too, are mired in a system that, by the authors’ description, seems as conducive to progress as the Russian mud was to Napoleon’s divisions.

The authors are correct in asserting that leadership is an essential element in creating quality improvement in our health care system. But leadership is powerless without followership—a broad constituency that is ready and willing to be led. It is not by chance that memorable leaders such as Washington, Lincoln, Roosevelt, and Churchill were wartime heads of state who assumed power at times of national crisis. When followers are ready, the emergence of leadership becomes more likely. During the past decade of debate over quality, many individuals and organizations have tried to exert leadership in quality and have been defeated by toxic systemic conditions.

Persistence in research, policy development, advocacy, and local efforts at changing the behavior of groups and organizations is likely to be the critical element in creating an environment that is conducive to quality improvement. Decades may pass before any success is evident, if then. But without these con-
Continuing efforts to improve quality, leadership will prove unavailing.

David Blumenthal
Massachusetts General Hospital
Boston, Massachusetts

Building on Quality-of-Care Improvements

To the Editor:

Becher and Chassin’s analysis of the causes of poor quality (Sep/Oct 01) is accurate and comprehensive. They rightfully point out the failure of various stakeholder sectors—consumers, purchasers, government, organized medicine—to create adequate pressure or resources for improvement. I take exception, however, with the paper’s tendency to diminish limited successes rather than to propose building on them. Stories like Intermountain Health Care’s relentless focus on medication errors and New York’s Cardiac Reporting System are dismissed as too narrow or too unique to be replicated. Other examples are not mentioned at all. If we look at the history of successful management outside of health care, we see that clear-eyed determination, multiple strategies, and a relentless focus on results pay off.

One major set of achievements we can look to is the little-heralded success story of managed care plans’ performance against a set of important determinants of clinical quality. In September 2001 the National Committee for Quality Assurance released its fifth annual State of Managed Care Quality report. In the past five years health plans have achieved solid improvements in preventive medicine; on newer Health Plan Employer Data and Information Set (HEDIS) measures related to the effectiveness of care for the sick, results are even more impressive. Use of beta-blockers rose from 62.2 percent in 1996 to 89.5 percent in 2000. Control of hypertension, first reported in 1999, rose from 39 percent to 51.5 percent in 2000. The political, regulatory, and economic environment for HMOs could hardly have been more hostile. Improvements were obtained through expensive, grinding work—direct outreach to patients and feedback and reminders to harried physicians. Even so, not only has average performance greatly improved, but the gap between the lowest- and highest-achieving plans has narrowed, reflecting higher quality performance overall.

I agree that more active leadership on quality from providers would be welcomed by employers, consumers, health plans, and others. But it can’t be their job alone. What is truly needed is collective leadership. Leaders from all sectors need to get about the business of crafting a national strategy. The work will be complex—it took us years to get here. But with a careful process of setting priorities and holding to them, we can certainly make major change.

Margaret O’Kane
National Committee for Quality Assurance
Washington, D.C.

The Head, The Heart, And Neonatology

To the Editor:

In the Sep/Oct 01 issue, once fledgling pediatrician John Lantos swoons in the confines of a neonatal intensive care unit (NICU). Does this visceral reaction provide morally relevant information or guidance? The answer is neither simple nor static. Clearly, harnessing emotional responses constructively is tricky business. “Flying into a passion is easy,” Aristotle asserted in his Ethics. “Anybody can do that—but to be angry with the right person and to the right extent and at the right time and with the right object and in the right way—that is not easy, and it is not everyone who can do it.”

Lantos provides us with an uncommon view of how a pediatrician has conducted his own emotional tutelage. We should consider carefully his views on using high technology to tackle health problems that have social and behavioral causes, on the interdependency of tertiary pediatric hospitals and their tiniest patients, and on the unseemly influence that economic considerations play in the way our society cares for its children. Even more, we should heed the implicit lessons of Lantos’s
moral modus vivendi, an ongoing dialogue between head and heart.

Chris Feudtner
University of Washington
Seattle, Washington

Doing Right For Children

To the Editor:

Some will undoubtedly think that Lantos (Sep/Oct 01) is overreacting when he says the preemies are “working for us.” I don’t think so. The NICU is only one example of our country’s preoccupation with income-producing health care rather than health. We spend the most by far on health care and have little to show for it, particularly in children’s health. Investment in health care brings a substantial return to those who work in the trillion-dollar industry. The return on investment that would produce better outcomes is harder to measure, and the beneficiaries are not primarily those who invest in the private health care system.

Prevention of injuries is another example referred to by Lantos. We have known for thirty years how to predict child abuse before a newborn leaves the nursery, and we know that home visitors can prevent physical abuse in many of these families. Virtually every industrialized country invests in home visitors; we invest in magnetic resonance imaging (MRI) scanners and intracranial pressure monitors so we can take very good care of the intracranial bleeding after it occurs.

Winston Churchill said that you could always trust the American people to do the right thing, after they had exhausted all of the other possibilities. Lantos highlights one example of our expanding exploration of the other possibilities.

Norman Fost
University of Wisconsin
Madison, Wisconsin

Debate Needed About Neonatal Intensive Care

To the Editor:

As an “ancient” neonatologist who entered the field in 1951, like Lantos (Sep/Oct 01) I found a strange, fascinating little world. The “premature nurseries” of fifty years ago were quiet places isolated from visitors and parents to prevent infections. The death rates were high, the challenges great.

The early neonatologists were research-oriented problem solvers who, unlike Lantos, didn’t pay much attention to the big picture. They have been successful; some would say too successful. They have faced constant criticism as more and more tiny infants survive. Lantos has raised some important questions about the long-term outcomes and costs attached to the success of neonatal intensive care.

More than 5,000 “fetal infants” weighing 400 to 500 grams are born each year in this country. Twelve percent survive; in some units the survival rate is higher: 20–40 percent. The world has never seen so many of these infants. What are their long-term prospects? Sadly, we do not know. Everyone is worried about these so-called miracle babies. It’s time for a major public debate on this subject. Should we follow other countries by setting a birthweight and gestational age below which no intensive care is offered?

Jerold F. Lucey
Pediatrics
Burlington, Vermont

Treating The Mentally Ill

To the Editor:

In the July/Aug 01 issue, Daniel Gitterman and colleagues state: “Following the lead of the American Psychiatric Association, the American Medical Association (AMA) has defined managed behavioral health care through carve-outs as discriminatory in principle. The AMA suggests that behavioral health care should be managed and administered as other health care services are. This suggests not a next sequential step, but either returning to a prior equilibrium of limited mental health benefits (as it destroys the policy bargain) or shifting managed care into a new positive direction with greater integration of mental health with primary care.”

As the original authors of this American
Psychiatric Association action, we were surprised and disappointed to see the authors misstate our intentions. We are unaware that they made any effort to reach us before this was printed. Our intention was neither to return to the past discriminations nor to achieve greater integration with primary care. The value expressed in this initiative was to attain real integration within the general medical care system. Simply stated, persons with psychiatric illness should be treated equally to those with cardiac, neurological, or ophthalmologic illnesses, not segregated into a system that promotes and reinforces the stigmatization of mental illness, isolation of mental health professionals from the body of general medical care delivery, and fragmentation of care. We believe that it would be a huge error to continue on the path toward the Balkanization of health care delivery into numerous carve-outs.

Roger Peele
George Washington University
Washington, D.C.

Larry Kline
Suburban Hospital
Bethesda, Maryland

Barry Herman
National Coalition of Mental Health Professionals and Consumers, Inc.
Commack, New York

The authors respond:

We never attempted to question the intentions of Roger Peele and his colleagues. Our comments are about real-world implications, not intentions, because even the best intentions do not automatically make good policy. Perhaps we simply disagree on the diagnosis of the problem and the likely impact of the reform proposed.

What would happen if mental health and chemical dependency carve-outs were eliminated and benefits were managed and administered like other health care services are? Access to these “other health care services” is generally constrained by primary care gatekeeping. Removing the alternative entry path to specialty care offered by carve-outs may achieve equality and fairness in the procedural management of medical and mental health services. Whether it improves quality of care, given detection and diagnosis rates of mental health problems (and, consequently, referral to specialists) in primary care, or how much primary care physicians would like that idea, is a different issue. Some proposals go further and call for insurance to provide direct access to psychiatrists and for coverage of providers outside the plan panel. These proposals either imply preferential treatment of psychiatrists or more broadly negate managed care when extended to all types of providers. It is not clear that either of these steps would further “real integration within the medical care system.” Instead, they appear to recreate a mental health care arrangement that failed.

Roland Sturm
RAND
Santa Monica, California

Daniel Gitterman
University of North Carolina
Chapel Hill, North Carolina

Richard Scheffler
University of California
Berkeley, California

Grim Prognosis For M+C

To the Editor:

I agree with the low grade given by Marsha Gold to the Medicare+Choice (M+C) program (July/Aug 01). However, I believe that the key provisions of the Balanced Budget Act (BBA) and the Health Insurance Portability and Accountability Act (HIPAA) are to blame for the program’s not measuring up to the growth promised at its inception.

The BBA of 1997 included a revised formula for paying managed care companies to participate in M+C. Unfortunately, it also capped the rate of increase for participation at an unreasonably low rate. The previous formula, which worked, created incentives for both managed care companies and beneficiaries to...
participate. But the BBA changed the formula and the incentives. With a cap on the rate of increase that managed care companies would receive, the long-term prospects of the program dimmed. Managed care companies have to invest capital to establish a product in a market and make a return on their investment. Without formula changes, they will continue to be unwilling to participate in M+C.

In 1996 HIPAA added numerous fraud-and-abuse provisions to crack down on Medicare wrongdoers; these provisions were needed. But the zeal to root out bad actors also heightened the awareness of insurance company executives to the dangers of working with the federal government. The M+C regulations included requirements for these executives to frequently attest to the accuracy of data submitted to the government, even when they did not have control over those data. In addition, investigatory organizations and prosecutors announced new initiatives to seek out managed care wrongs. Thus, a much more adversarial relationship was created between the federal government and the managed care industry. Little wonder that managed care counsels advise executives of the liabilities involved in contracting with the federal government.

The health insurance industry is by and large a commercial enterprise regulated by the states. From a business perspective, Washington cannot expect insurers to become involved with a new set of regulatory and legal headaches for a limited return on investment. Also, managed care companies cannot be expected to create and market a product in the presence of potential liability that could destroy the company. The prognosis for M+C, as currently structured, is not good.

Douglas R. Guerdat
Health Policy Consultant
Annandale, Virginia

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The AMA And Tax Credits

To the Editor:

Elisabeth Simantov and colleagues (July/Aug 01) remind us that tax credit proposals must consider a wide array of complex issues. The question is not simply whether tax credits can work in the current market. Such a question fails to appreciate the impact of infusing the market with many billions of new health care dollars to which the market will respond and change.

The AMA’s tax credit proposal acknowledges that today’s health market is more costly to individual than to group purchasers. However, the AMA is encouraged by the expansion of patient options found in various new forms of health insurance, particularly Internet-based enterprises.

Members of both sides of Congress have extolled the benefits of tax credits, and the discussion has become increasingly sophisticated, as noted in the letter from David Kendall and colleagues (May/June 01). The AMA supports the use of refundable tax credits, inversely related to income, to expand coverage and patient choice, as part of a comprehensive proposal for health system reform. As such, the AMA developed principles to guide the development of tax credits in a manner that expands coverage, empowers patients, liberates employers, and focuses the health care subsidy on those who need it most—persons with low incomes—while encouraging market responsiveness to individuals.

Richard F. Corlin
American Medical Association
Chicago, Illinois

Primary Care In Canada

To the Editor:

Brian Hutchison and colleagues (May/June 01) provide a concrete explanation of why Canadian primary care renewal has met with mixed results. The authors’ conclusion to sub-
stitute incremental change for the “big-bang” approach is sensible. However, we take issue with their argument that a major policy impediment is the comprehensiveness principle in the Canada Health Act (CHA). The CHA simply sets out program criteria that must be satisfied for a province to receive federal funding. The range of health programs that provinces elect to deliver and the ways in which they are delivered remain very broad. If the CHA has influenced a province’s primary care path, policymakers have misinterpreted it.

We agree that physicians’ openness to change in primary care is shaped by how they think those changes will affect their professional autonomy, income, and working conditions. But physicians are also concerned with how reforms will affect the quality of patient care. Too often in Canada, practicing physicians, as well as the public, are largely excluded from the reform process. Canadians are very concerned with how alternative primary care models will affect their choice of physicians and the privacy and security of their personal health information.

Canadian government-driven reform attempts need to be reassessed. With limited public acceptance and an acknowledged lack of evidence to support reform efforts, lasting change must be provider- and public-driven. Shifting focus from dictating rigid practice models to a cooperative change management strategy will expedite the evolution of primary care delivery. The authors’ advice should be heeded.

**The authors respond:**

We agree that the CHA is not a direct impediment to primary care reform; meaningful reform can happen, albeit incrementally, with it in place. We believe, however, that two elements—its privileging of hospital-based and physician-provided care as the types of services that qualify for universal, first-dollar coverage, and its enshrinement of “private practice, public payment” as the principle that underpins how physicians are treated within the system—have conditioned the behaviors of decision makers. For example, with the increasing cost of hospital-based and physician-provided care, provincial governments may be hesitant to provide new funding to support the expanded use of nonphysician primary care providers. And with physicians operating private practices, few provincial governments are likely to support any new agreement that establishes standards and funding entitlements for primary care infrastructure such as information technology.

**Brian Hutchison, John Lavis, and Julia Abelson**
McMaster University
Hamilton, Ontario

**Darrell Thomson and Michael Epp**
British Columbia Medical Association
Vancouver, British Columbia

**Darrel Weinkauf**
Ontario Medical Association
Toronto, Ontario

**Michael Gormley**
Alberta Medical Association
Edmonton, Alberta