Prologue: The pace of health system reform has intensified since the election of President Bill Clinton in 1992. This has been a mixed blessing for those interested in health care innovation, however; some analysts fear that increasingly strict cost controls do not bode well for the future of technological innovation. Indeed, as Leighton Read and Kenneth Lee report in their DataWatch on medical innovation in this volume, “It is widely believed in the industry that health care reform has slowed investment in biotechnology, because of the uncertainty that President Clinton’s early proposals cast over the entire health care economy.” In this paper June Sisk and Sherry Glied evaluate the three leading approaches to reform—managed competition (including the Health Security Act), single payer, and insurance market reform—regarding their implications for technological innovation. Sisk and Glied emphasize the heterogeneity of innovation and the effects of reform proposals. Expanding the people and services covered could spur innovation in prevention and other primary care. At the same time, spending constraints and uncertainty could deter development of expensive procedures and innovations with longer lead times. June Sisk is a professor in the Division of Health Policy and Management, Columbia University School of Public Health. She received her doctorate in economics from McGill University in Montreal. She previously served as senior associate and project director at the congressional Office of Technology Assessment. Sherry Glied, an assistant professor of public health and economics at Columbia’s School of Public Health and Department of Economics, received her doctorate in economics from Harvard. She was senior economist for health care at the President’s Council of Economic Advisers and participated in the task force that produced the Clinton administration’s Health Security Act in 1992-1993.
Abstract: Health care reform, which seeks to expand coverage and control spending, contains mixed messages for innovators. Policies that advance reform goals are likely to shift resources away from hospitals, specialists, and expensive procedures and toward areas such as prevention and primary care where innovation may yield greater health improvements per dollar spent. The size of these effects depends critically on the extent of cost containment achieved. Constraining spending will be politically difficult because it requires that consumers forgo some possible health benefits in return for lower costs. In a climate of cost containment, systematic evaluation of new technology is vital to identify and expand coverage to worthwhile innovations and to assure a fair hearing for innovators.

The twin pillars of health care reform—ensuring health insurance coverage for the entire populace and controlling health care spending—contain mixed messages for future innovators. On the one hand, developers of new products and processes will face expanded markets, as universal coverage brings more people into the health care system and increases their use of medical services. On the other hand, potential developers may cut back their innovative activities because they fear that measures to constrain rapidly rising expenditures will also constrain profits.

The implications of reform proposals for innovation merit high priority for policymakers. Our society values technological progress—the introduction of new products and processes—and progress serves as one criterion for evaluating the U.S. economy. New products and processes ipso facto are not necessarily desirable, however. Innovations are valuable only if they ultimately improve the quality of care or the efficiency of providing care.

The U.S. health care system has spawned myriad medical and administrative breakthroughs and has supported the commercialization of many breakthroughs developed elsewhere. Despite, or perhaps because of, these successes, there is much room for better incentives for future innovative activity. The historical structure of entitlements, payment policies, subsidies, and regulations has channeled innovation into directions that have culminated in today’s costly health care patterns. Coverage, payment, and training policies concentrated expenditures, and hence innovative activity, in hospitals rather than in ambulatory sites. These policies promoted acute, curative care delivered by specialists and slighted preventive and rehabilitative care delivered by primary care clinicians. Procedures, specialties, and settings that relied on expensive, sophisticated medical devices received a particular stimulus. Innovation in surgical procedures has been most favored: Compared with drugs and devices, surgical procedures have been less subject to regulation and have commanded higher payment rates.

Health care reform proposals seek to change these incentives and exact greater value for expenditures on health care. Indeed, many of the changes promoted by health care reform are already under way. Payers have increasingly constrained spending for inpatient treatment and have encouraged shifting care to ambulatory and home settings. Insurers have expanded
coverage of preventive services, pharmaceuticals, and dentistry and have raised relative payment rates for primary care. Patients must pay a greater share of costs when they use services. Providers and consumers have joined integrated delivery systems in growing numbers. Strategies abound to train more generalist and fewer specialist physicians. Governments and employers are assessing the cost and quality of care and making the information available to the public. Although these developments predate the current health care reform debate, they are responses to the same underlying pressures. No matter what shape health reform takes, pressure to control spending will certainly continue to change the market for innovations.

This paper addresses the likely implications of health care reform for innovation, with particular reference to three leading approaches to health care reform. Many proposals discuss innovation only tangentially. Their influence on innovation would come mainly through their effects on expected future returns to innovation, which in turn drive the decision to undertake innovative activity. We focus on factors that determine the size and profitability of the market for innovation: the basis of competition, the scope of benefits covered, spending constraints, the training of medical specialists, regionalization and supply controls, the organization of health care delivery, and the process to evaluate new technologies.

Health Care Reform And Innovation

Health care reform proposals fall into three general categories: single payer; managed competition, including the Clinton administration’s Health Security Act; and insurance market reform (Exhibit 1). As the legislative process unfolds, reform proposals will continue to multiply and evolve, and any specific proposal may be a hybrid of these three types.

**Single payer.** Single-payer proposals would consolidate the provision of health insurance into a public system administered by the federal government or by the states under federal standards. Such proposals would eliminate Medicare, Medicaid, and certain other federal programs and incorporate their beneficiaries into the national system. As exemplified by H.R. 1200, introduced by Rep. Jim McDermott (D-WA), and S. 491, introduced by Sen. Paul Wellstone (D-MN), the government under a single-payer system would ensure universal coverage for a comprehensive package of standard benefits. Financing would come from increases in broad-based taxes, with little or no premiums or patient cost sharing.

Single-payer proposals typically assign a federal agency or national board responsibility for overall policy, such as managing the benefit package and setting a national health care budget. The national health care budget provides a mechanism for controlling expenditures, through direct pay
### Exhibit 1

**Comparison Of Leading Health Care Reform Proposals**

<table>
<thead>
<tr>
<th>Managed competition</th>
<th>Managed competition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coverage</strong></td>
<td><strong>In general</strong></td>
</tr>
<tr>
<td>Universal</td>
<td>Partial</td>
</tr>
<tr>
<td><strong>Services covered in program</strong></td>
<td><strong>Health Security Act</strong></td>
</tr>
<tr>
<td>Prevention, hospital, medical, pharmaceutical, long-term care</td>
<td>Prevention, hospital, medical, pharmaceutical</td>
</tr>
<tr>
<td><strong>Cost sharing</strong></td>
<td><strong>Insurance reform</strong></td>
</tr>
<tr>
<td>No copayments or deductibles</td>
<td>Limited options specified in standardized benefit package</td>
</tr>
<tr>
<td><strong>Management of benefit package</strong></td>
<td><strong>Prevention, hospital, medical, pharmaceutical</strong></td>
</tr>
<tr>
<td>Federal agency or commission</td>
<td>National health board</td>
</tr>
<tr>
<td><strong>Outcomes research</strong></td>
<td><strong>State or federal agency for standard benefit package only</strong></td>
</tr>
<tr>
<td>Expanded</td>
<td>Expanded</td>
</tr>
<tr>
<td><strong>Structure of plan</strong></td>
<td><strong>Medicare and firms with more than 5,000 employees</strong></td>
</tr>
<tr>
<td>Single payer</td>
<td>Purchasing cooperatives, mandated for firms below some stated size limit</td>
</tr>
<tr>
<td><strong>Expenditure control</strong></td>
<td><strong>Small firms and individual insurance purchasers may join insurance purchasing pools</strong></td>
</tr>
<tr>
<td>Budget enforced by federal government, to grow at GDP</td>
<td>No budget; cap on tax deductibility</td>
</tr>
<tr>
<td><strong>Payment mechanisms</strong></td>
<td><strong>No budget; some plans cap tax deductibility</strong></td>
</tr>
<tr>
<td>Global budgets for hospitals; fee schedules for physicians; capitated payments to HMOs</td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Primary care physicians</strong></td>
<td><strong>No regulatory intervention</strong></td>
</tr>
<tr>
<td>Increase primary care residencies; adjust fee schedules to favor primary care</td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Integrated delivery systems</strong></td>
<td><strong>Some plans have tax cap to encourage choice of lower-cost plans</strong></td>
</tr>
<tr>
<td>May exist; no financial incentive to join</td>
<td>Flat contribution rule; individual purchase to provide consumer incentives; tax cap</td>
</tr>
<tr>
<td></td>
<td>Flat contribution rule; individual purchase to provide consumer incentives</td>
</tr>
</tbody>
</table>
ments to providers or allocations to each state. H.R. 1200, for example, would limit annual increases to the percentage rise in gross domestic product (GDP). The federal government or state governments would pay for care according to prospectively set rates: fee schedules for individual practitioners, global budgets or Medicare’s current diagnosis-related group (DRG) method for hospitals, and capitation payments to comprehensive care organizations similar to health maintenance organizations (HMOs). Single-payer proposals would promote primary care through higher payment rates and expanded training and would usually manage capital supply through explicit restrictions on equipment purchases.

**Managed competition.** Managed competition proposals seek to have government create a more competitive environment that would raise the cost-consciousness of decisionmakers, including consumers, employers, insurers, and providers. Health plan purchasing cooperatives would certify insurance plans and run the enrollment process. To encourage choices based on price, enrollees would pay less for plans with lower premiums, and employers would face limits on tax deductions for coverage they sponsor. Plans would have to offer a standardized benefit package, report specified indicators of quality, and accept anyone who wishes to enroll, regardless of health status. Managed competition proponents expect that competition based on price and quality would drive plans and providers to form integrated delivery systems that provide care more efficiently.

Built on work by Alain Enthoven and the Jackson Hole Group, the managed competition approach is embodied in the Clinton administration’s Health Security Act (H.R. 3600, S. 1757) and in legislation introduced by Rep. Jim Cooper (D-TN) (H.R. 3222) and Sen. John B. Breaux (D-LA) (S. 1579). Unlike other proposals in this category, the Health Security Act provides universal coverage, by mandating that employers cover their workers and by subsidizing others, and requires a national budget to control spending. To achieve the annual budget limit, the Health Security Act would constrain Medicare and Medicaid spending and, when fully implemented in 1999, would restrict private insurance plan premiums to annual increases in the Consumer Price Index (Section 6001). Both the Clinton and the Cooper-Breaux bills go beyond changes in financing to require structural reforms related to the provision of care: initiatives to increase the number of residencies for primary care physicians, greater funding for outcomes research, and changes in malpractice law.

**Insurance market reform.** A number of less interventionist proposals focus on reform of the health insurance market to improve access to insurance without overly disrupting the existing system. A typical mechanism is to create small voluntary purchasing pools that offer a standardized benefit package to small businesses and individuals. The proposals also limit
insurance plans’ ability to exclude coverage for preexisting conditions and subsidize insurance coverage for low-income people.

The Senate Republican Health Equity and Access Reform Today proposal and the Bush administration’s Comprehensive Health Reform Program exemplify this approach. These proposals do not cap private health spending, but some would restrict the growth of federal health programs. To encourage greater cost-consciousness, some proposals would allow consumers to use medical savings accounts only to purchase catastrophic coverage with higher deductibles, and others would limit the tax-deductibility of employer-provided insurance.

**Basis Of Competition**

Much of the competition in the U.S. health care system has historically centered on expensive, sophisticated medical technologies. Reflecting the high value that U.S. society places on technology, hospitals have wooed physician specialists and patients with the newest medical equipment and procedures. The result has been a proliferation of expensive equipment and facilities that are often used far below capacity. The spread of per case inpatient payment, such as DRGs, during the past decade has rewarded organizational innovations that shorten lengths-of-stay. These payment methods appear to have had less impact, however, on the inclination of providers to use new technologies with insufficient regard to cost. Financial constraints in the inpatient arena have encouraged spending and use to flow to the relatively unfettered ambulatory setting, as illustrated by the almost complete turnabout of cataract surgery from an inpatient to an ambulatory procedure.

All three types of health reform proposals will change health markets in ways that affect the nature of competition. Although insurance reforms would make the smallest structural changes in the market, even they would heighten cost awareness. Features such as the formation of health plan purchasing groups for small employers, increases in cost sharing through the encouragement of catastrophic coverage, and reductions in the tax subsidy for health insurance purchases would each increase price-consciousness.

The more extensive purchasing groups created in managed competition reform proposals would move the choice of plans for many people from the employer to the individual. Cost-consciousness for consumers would increase, because employer contributions for health care could not vary with plan choice and because the tax-deductibility of employer-provided health insurance would be reduced. These reforms would give those in purchasing cooperatives the opportunity to choose the level and style of technology use through their choices among plans. For example, women could opt for a
more expensive plan that offered more technology-intensive care during pregnancy and delivery, or opt for a less expensive plan that minimized technology use and relied on birthing centers rather than on hospital admission for low-risk pregnancies.

Since managed competition-based plans have not been attempted on a large scale, the likely effects on technology and innovation remain speculative. There is evidence that persons sharing premium costs are more likely to choose low-cost plans, but persons who have established relationships with providers are less likely to base their choices on premium cost if they would have to switch providers. Even if price does motivate consumer choice, it is not clear in advance what trade-offs between technology use and price will be acceptable and whether the incentives created will mute the apparent preference of consumers and providers for new technology.

It is also possible that private insurance plans competing on price will simply intensify their efforts to attract low-risk beneficiaries and to avoid those at high risk of incurring substantial medical expenditures. In the past, insurers have refused to accept people with certain preexisting conditions or have made their plans less appealing to those with high expected expenditures, for example, by lowering maximum coverage amounts. Although these particular practices would not be permitted under either insurance reform or managed competition proposals, less obvious forms of risk selection may persist. Some managed competition-based proposals, including the Health Security Act, and some insurance reform proposals would adjust payments to insurance plans for the risk of enrollees in each plan. The government would undertake research to improve initial categories, such as age and sex, that account for only a small portion of the variance in health care spending. Developing methods to better adjust payments to plans is a critical feature of any proposal that relies on insurance plans as intermediaries. Without better adjusters, plans will continue to have a financial incentive to seek out the low risks and to avoid the high risks.

It is unclear whether proposals that retain competition among private insurers will successfully channel competition away from acquiring sophisticated technology and enrolling low-risk people and toward lowering premium rates while maintaining or improving quality of care. There is little experience at the state, national, or international levels on which to base predictions.

Under single-payer proposals, the government would set payment rates for providers. Individual physicians and hospitals, as price-takers, would continue to compete for patients by offering better service, whether that entailed more amenities, better access, or improved technical or interpersonal aspects of quality. Direct regulation of capital investment by hospitals, limitations on ownership of technology by physicians, and fee limita-
tions may restrict the ability of providers to compete through investing in more costly medical technology. External budget limitations in plans with competing private providers, such as the Health Security Act, could similarly intensify pressure on providers and plans to limit use and cost.

**Benefits Covered**

Health insurance generally increases the use of and hence the market for covered services. This applies to broad areas of health care and to specific technologies. Adding services to a basic benefit package can be expected to increase their use for two reasons. First, insured people are more likely to obtain covered than uncovered services because even with cost sharing the net price to patients is lower. Second, clinicians who are sensitive to patients’ finances are more likely to order covered services. Through its effect on expected future returns, the scope of services included as basic benefits will thus influence where innovative activity takes place.

Preventive services (especially primary prevention), mental health services, dental care, and long-term care have had less coverage under indemnity insurance than other types of services. Most reform proposals call for expanding coverage for preventive services, especially for vaccinations and other primary preventive care. The Health Security Act and single-payer plans also would add pharmaceutical coverage for current Medicare beneficiaries. Having a larger, more secure market will likely increase research and development on prevention-related and pharmaceutical products.

Extending coverage to those currently uninsured is likely to further expand the markets for prevention-related and pharmaceutical products and services. The uninsured now use about two-thirds as many hospital services as the insured use, but only 45 percent as many pharmaceuticals and only half as much outpatient care. In pharmaceuticals, the boost to innovation from expansion of the market could be tempered by price limits on breakthrough drugs. The Health Security Act would require a report on the reasonableness of such prices, and the McDermott-Wellstone bill would set maximum prices for prescription drugs. Public policy in this realm faces a dilemma between rewarding innovation with a patent that confers monopoly power and obtaining health benefits from innovations at an affordable cost.

**Spending Constraints**

Although many potential reforms of the health care system could lead to savings in the short run—for example, through reduced administrative costs, increased regionalization, or reform of the malpractice system—it is
less clear that they could reduce expenditure growth. Although controlling spending growth is one of the primary goals of all federal health care reform proposals, the degree of control that will be realized, especially in the longer term, will depend critically on the political will to limit payments for and alter existing incentives to use costly services. The Congressional Budget Office (CBO) has argued that increased centralization of payment would make spending easier to control.

Plans with explicit limits on health spending usually propose to hold total spending to approximately the level of growth of GDP. This implies reducing annual growth in health spending from a recent average of 11 percent to about 4 percent. Even with the proposed limitations, national health spending would still consume a large and growing share of GDP; by 2000 spending under the Health Security Act would reach 16.9 percent of GDP, compared with an estimated 18.2 percent without reform. Recent reports suggest that increases may have slowed somewhat over the past year. This slowdown may stem from self-restraint by providers and plans to forestall federal restrictions, factors associated with a sluggish economy, or even underlying changes in organization and financing.

If policymakers slow the growth of spending, providers are likely to respond by reducing their adoption of new technologies that increase costs without corresponding gains in efficiency. There is some evidence that similar revenue constraints from prospective hospital payment stimulated the adoption of equipment to streamline the provision of medical care.

In the short term, the health reform debate may have immediate effects on innovation. Uncertainty about the likelihood and effectiveness of spending constraints makes it difficult to predict future markets for innovation. In this climate, firms and individuals who have counted on continuous growth in the health care sector may delay planned research and development until future payment arrangements are clarified. Such uncertainty could retard innovation, especially in areas with longer lead times.

Medical Specialization

Innovation in U.S. medical care has been closely linked with the trend toward medical specialization. Specialists conducting research in academic medical centers have played a key role in the development and early adoption of innovations. Specialties and subspecialties, such as nuclear medicine and gastroenterology, have formed around new medical technologies. Moreover, studies have repeatedly documented that medical specialists use diagnostic tests and therapeutic procedures more intensively.

The Health Security Act and single-payer proposals would emphasize primary care, both through limitations on practice choice and through
payment incentives. Implementation of such a policy would reverse a thirty-year trend toward greater specialization: Specialists rose from half of U.S. physicians in 1961 to two-thirds of all allopathic physicians in 1990.\(^{17}\) Although 41 percent of U.S. medical students graduating in 1993 accepted residencies in family medicine, internal medicine, or pediatrics, 60 percent of internal medicine residents and 40 percent of pediatric residents subsequently entered subspecialties.\(^{18}\) Redirecting clinical training to primary care is supported by a congressionally mandated report from the Council on Graduate Medical Education and the Physician Payment Review Commission (PPRC).\(^{19}\)

Within fee-for-service arrangements, relative payment rates may contain incentives for differential use of technologies and hence for innovative activity. Payment rates have generally rewarded physicians for procedural services, which are associated with medical devices, much more generously than for nonprocedural services, such as taking a medical history or counseling a patient.\(^{20}\) Medicare’s recently implemented fee schedule attempts to rectify that imbalance. Single-payer systems, especially those using the Medicare fee schedule, would extend rate scales that favor primary care throughout the system. The experience of Medicare with changes in relative payment rates will provide empirical evidence of the effect of payment rates on physician behavior. On conceptual grounds, one would expect a greater flow of revenue into office visits as relative payment rates for office visits increase. On its face, it seems unlikely that revenue and hence innovative activity will flow out of surgical and other technology-intensive areas. More consistent with past experience would be additional office visits for these services, with little diminution in revenue.\(^{21}\)

If successful, increasing the share of practitioners who provide primary care would eventually imply reductions in physicians’ rates of performing tests and procedures, with derived slowdowns in the markets for certain medical products. Even the changes envisaged, however, would alter the generalist/specialist mix only over a long period of time. Contraction in the growth of markets for innovations in the affected areas also would occur over a long period and would have a steady and predictable effect on innovation.

### Regionalization And Supply Controls

Empty hospital beds and underused technological capacity seem to be natural targets for cost reduction efforts under health system reform. Proposals with explicit limits on health spending, such as single-payer proposals and the Health Security Act, usually include new measures aimed at increasing regionalization of costly facilities.
Under some single-payer proposals, hospitals would be paid under global budgets, with separate allocations for capital spending. Global budgets would reduce the incentives for and ability of hospitals to compete by purchasing new technology. Separate capital budgets would force regulators to make the difficult decisions needed to allocate equipment and thus would reduce the market for costly new equipment. Global hospital budgets may also limit process innovation in hospitals, reducing hospitals’ incentives to shorten lengths-of-stay and to move services to outpatient departments. Hospitals with global budgets may instead have an incentive to keep beds occupied by patients who are less sick to reduce overall costs.

Proposals based on private insurance, including managed competition and insurance reform, could lead to increased regionalization of expensive specialized equipment and procedures if competition intensifies the pressure to lower costs or improve quality. Regionalization would enable integrated delivery systems to realize economies of scale for technologies with high fixed costs and to improve quality for procedures whose outcomes are better when providers perform them more frequently.

The Health Security Act also includes measures to directly promote regionalization, with the stated objective of ensuring that all patients have access to specialized services at academic health centers (AHCs). All insurance plans will be required to contract with AHCs for certain specialized procedures and therapies. Furthermore, government grants would help AHCs to develop an information and referral system with rural health networks and to support health care networks within inner cities. These provisions recognize the special role of AHCs and directly address concerns about the effect of spending limits on innovations in specialized clinical care. These measures may offset the financial incentives in the proposal for insurance plans to skimp on expensive, specialized care and will ensure continuing funding for centers at which technology is developed.

Containing health care spending in the longer term requires that providers, plans, and consumers forgo some possible health benefits in return for lower costs. Previous regulatory interventions in the US. health care system intended to reorganize and rationalize the allocation of health resources have been notable failures. The politically charged debates that have plagued these attempts illustrate the likely difficulties of making these decisions in the future.

**Organization Of Health Care Delivery**

The diversity of organizational arrangements to insure and deliver health care in the United States far exceeds that of any other country. In 1991 plans that paid separate providers fees for their services covered 71 percent...
of those insured, but HMOs and preferred provider organizations (PPOs) also covered a sizable share—15 percent and 14 percent, respectively.\(^{26}\)

Of the three types of reform proposals considered here, managed competition places the most emphasis on integrated delivery systems, in the belief that insurance plans with integrated delivery systems paid on a capitation basis can and will deliver care more efficiently. Such systems are epitomized by large prepaid group practices that own their own hospitals, such as Group Health Cooperative of Puget Sound and the Kaiser Permanente Medical Care Program, but medium-size and small prepaid groups with their own ancillary facilities are much more numerous. There is evidence that HMOs, including prepaid group practices, can deliver care at lower cost than separate fee-for-service practices can, chiefly because of lower hospitalization rates.\(^{27}\) Too few studies have looked at other “managed care” arrangements, including PPOs, to support conclusions.

To the extent that consumers gravitate in greater numbers to prepaid group practices, rates of hospitalization and the use of technologies associated with it will be lower.\(^{28}\) Differential technology use may also stem from staffing patterns, since these groups tend to have a higher percentage of primary care physicians.

Insurance reform and single-payer proposals provide less incentive for the use of managed care. Increased cost-consciousness under some insurance reform plans may increase incentives for consumers to choose integrated plans. Single-payer plans would allow capitated plans to exist, but in a system without cost sharing or premium payments, consumers would have little reason to select these plans. Canada’s experience has illustrated this situation, where a single-payer arrangement may even have undercut nascent prepaid group practices in Ontario.

Movement to larger networks of providers, as in managed competition proposals, would increase price competition for medical products. Large networks are likely to standardize products, such as operating room supplies and hospital beds, and to exert sufficient buying power to negotiate volume discounts from suppliers. Regulation of providers that limits their ability to pass on price increases, as in single-payer proposals, might also encourage providers to be more sensitive to price in their purchasing decisions. Although medical product suppliers have been facing growing cost pressure in the hospital market, greater cost-consciousness among purchasers would intensify activities to streamline health care products and systems.

### Evaluating New Health Care Technologies

Health care innovations, especially surgical procedures, often diffuse into general use without evaluation of their efficacy, safety, or cost implications.
The problem is less intense for pharmaceuticals and medical devices, which require premarketing approval by the Food and Drug Administration (FDA), but different uses and combinations of approved products are not well evaluated. Funding from the National Institutes of Health (NIH) for clinical trials has been limited and concentrated on select patients and settings. As cost pressures have grown, public and private insurers have stepped up rejection of claims for procedures considered to be experimental. Ironically, this development occurred as policymakers recognized the dearth of evidence on the effectiveness of even routine medical practices and were calling for more and better clinical studies.

Health reform proposals commonly mandate increased funding for clinical and health services research, including evaluation of new technologies. Taken together, the legislative proposals contain the ingredients for comprehensive technology evaluation, although no single bill incorporates all aspects. Reform plans with explicit budgets and standardized benefits require that covered services be “medically necessary and appropriate” and that costs be considered in expanding benefits. Although the Cooper-Breaux managed competition bill leaves the details of the benefit package to be determined later, it specifies research priorities and an administrative structure and explicitly links the findings of technology assessments to benefit coverage. The Health Security Act ties quality measurement to the findings of technology assessments and stresses the dissemination of information to consumers and providers. Under insurance reform proposals, the government would inform consumers about the efficacy of new innovations, provide guidance to private insurers about the inclusion of new technologies, and revise basic benefit packages for individual coverage.

The process for evaluating and adding technologies to basic benefit packages has short- and long-term implications for innovation. In the short term, a systematic process that weighs the benefits and risks of alternative strategies for managing a medical condition can better inform the decisions of health professionals, consumers, and administrators. In the long run, the evaluation process sends strong signals to potential innovators about what kinds of products, and hence what kinds of research and development, will be rewarded with coverage and use. Depending on the health reform approach, the assessment process can also convey the stringency of spending controls. In fact, the stricter the spending constraints, the more essential is a systematic process to preserve continued improvement in the quality of care and to assure potential innovators and other interested parties that their technologies will get a fair hearing. Innovators otherwise would have justifiable concern that policymakers would place such a high priority on containing costs that they would retard coverage of even worthwhile innovations. To minimize the likelihood that evaluations would be
driven by cost considerations, rather than by a balance of cost and effectiveness, the analyses should be as independent as possible of coverage and cost containment decisions, preferably performed by a separate agency.

Some proposals would pay for routine patient care delivered under an approved research protocol, although insurance plans would retain discretion over whether or not to pay for the investigational technology itself (H.R. 3600, H.R. 3222). Some private insurers are already cooperating on randomized controlled trials, such as the ongoing trial of autologous bone marrow transplants for breast cancer. This policy would channel revenue from insurance premiums to address gaps in information on the efficacy, effectiveness, safety, and cost of new and existing technologies. To further reduce financial barriers to evaluation and innovation, payment could include investigational technologies, especially surgical procedures not sponsored by medical products companies seeking FDA approval.

All payers, including health plans, the government, and patients, as well as providers and innovators, could benefit from this policy. Instead of continuing to pay for innovations of dubious efficacy and effectiveness, payers would obtain information about their worth before they spread into general use. Physicians and other providers could draw on this knowledge to reduce uncertainty and improve their clinical decisions. By fostering the evaluation of innovations, this policy would encourage worthwhile innovations and hinder others.

Conclusions

Traditional health insurance has financed medical innovations and their dissemination, especially in areas with the most coverage and most lucrative payment rates. Incentives inherent in health insurance have thereby favored developments in hospital-based care, surgical procedures, and diagnostic tests. Innovations in these areas have been adopted with little evaluation of whether the benefits to be gained justified their costs.

Health care reform proposals will affect innovation primarily indirectly, by containing costs and altering the composition and extent of health insurance coverage. Proposals that incorporate regulatory cost containment, including the Health Security Act and single-payer proposals, almost certainly will reduce the extent of the market for costly new technologies. Proposals that emphasize competition, such as insurance reform and managed competition, will provide incentives to shift away from cost-increasing technologies, but the extent of consumer and provider responsiveness to these incentives is harder to gauge. Proposals that expand the scope and extent of insurance coverage, through comprehensive standard benefit packages and universal coverage, are likely to expand the market for pre-
ventive and pharmaceutical innovations, even under cost containment.

The effect of cost containment and coverage expansion on the composition of innovation is easier to predict than their net effect on the level of innovation. In general, cost containment is likely to mean forgoing medical care and innovation in areas that have been the most heavily funded in the recent past. Redirecting innovative activity into areas that have been slighted, such as prevention and other primary care, may produce greater health benefits. Rather than being a cause for alarm, this rebalancing may allow our society to reap greater health improvements per dollar spent.

Under any cost-cutting reform, however, regulators or providers may exert pressure to limit even valuable innovations to keep budgets under control. Health reform should build in measures to check and balance these incentives. For example, the federal government should develop a system to evaluate innovations, and the responsibility for evaluation should be separated from the agency responsible for the health care budget.

Many of the changes anticipated as a result of health care reform are already under way—greater coverage of preventive services in insurance plans, encouragement of primary care through higher payment rates, growing market share for integrated delivery systems so that historical incentives for innovation are already changing. The major additional effect of health care reform on innovation could come from marketwide cost containment, whether regulatory or competition-based. Such cost containment, however, depends critically on the political will to restrain payments and alter incentives. In its absence, we may have greater coverage without added discipline on innovation and its applications.

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