We conducted in-depth interviews with eight medical device manufacturers and nine managed care organizations about the processes of technology assessment and technology adoption by MCOs. Combining information from these interviews, the discussion at the October 7 meeting, and the literature provides an incomplete, yet in many ways revealing, view of these processes. This view, in turn, suggests several issues that might be confronted in hopes of improving the system.

**BALANCING COSTS AND BENEFITS OF TECHNOLOGY ADOPTION**

No matter how much society values medical care and medical innovation, it must also accept the relevance of costs of delivering health care under private insurance arrangements.\(^1\) While medical innovation is believed to be a leading cause of increasing costs of medical care, the consequent improvements in health are highly valued by consumers.\(^2\) Undoubtedly, some medical innovations that are

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\(^1\)Organizations insuring and delivering health care cannot long survive in the marketplace without covering their costs. Payers and consumers care very much about how much they pay for care, both directly and indirectly, through insurance premiums. Premium levels are an important cause of lack of health insurance by many Americans.

\(^2\)Newhouse (1993, p. 163) argues that the most plausible explanation for the bulk of increases in medical care costs over time has been technological advance in medicine. He emphasizes, however, that the key questions are whether the well-being of con-
adopted improve consumer well-being and others do not. In principle, comparing the social benefits and costs of medical care for individual technologies is the best way of promoting consumer well-being through medical-technology adoption.

Stated generally, we as a society should want medical technologies—new or old—to be used in particular circumstances if and only if the social benefits of use exceed the social costs. Moreover, it seems safe to presume that doing a better job of implementing this criterion would also provide socially appropriate incentives for inventors, innovators, and investors.

Striking an appropriate balance between benefits and costs is very difficult, and the stakes are high. Use of unproven technologies involves risks of injuries to patients, lost patient benefits from failing to use a different technology, and wasted resources. But, of course, all successful technologies were initially unproven, and limiting or delaying use of new technologies also involves risks: lost benefits to patients who could have been treated more effectively, and taking the profit out of innovation, thus reducing incentives to innovate, among others.

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3 Social benefits of medical care include all of the consequences that improve the well-being of patients over their lifetimes—including increased length of life, reduced morbidity, improved functioning, lessened pain, any other beneficial effects—and benefits to any members of society in the form of social costs avoided (e.g., lost productivity, future treatment or rehabilitation costs) because the care is provided. Social costs of medical care include the value of all resources required to make decisions about and deliver the care, no matter who bears these costs (e.g., payers, insurers, providers, patients).

4 If inventors and innovators believe that demand for their products will be higher the greater the social benefits their products can deliver, this will provide strong incentives to focus their efforts on research and development aimed at technologies satisfying the benefit-cost criterion.

5 Ramsey et al. (1998, p. SP192) discuss the trade-off between adopting technologies more and less rapidly. Sheingold (1998, p. SP123) emphasizes risks of adopting too quickly. Eisenberg (1999, p. 1867) writes: “The worst-case scenario could be a restriction on coverage to those services for which there is evidence of effectiveness, but no resources being spent on obtaining the evidence... Policymakers need to remember that the absence of evidence of effectiveness is not the same as evidence of the absence of effectiveness.”
The enormous complexity of the processes determining such consequences and the substantial uncertainty about most elements of the calculus mean that coming close to perfection in winnowing technologies is not possible. The social goal should be identifying and implementing means of getting closer to the ideal.

**MCOs AND THE TECHNOLOGY-ADOPTION PROCESS**

Amid all this complexity and uncertainty, managed care organizations make decisions that can have crucial effects on medical-technology adoption and innovation. MCOs influence technology adoption by performing two broad functions: (1) determining, along with payers, the contractual contexts in which care will be organized, delivered, and financed; and (2) undertaking various activities, including contracting with providers, developing coverage policies, determining how much to pay providers or reimburse patients when care is delivered, and instituting procedures for managing care, such as practice guidelines and pre-authorization and other forms of utilization review.

However, it is essential to recognize that technology adoption is also greatly affected by factors beyond the control of MCOs. As a practical matter, for example, MCOs cannot completely control behavior of their providers and enrollees that can have profound effects on technology adoption. Technology adoption also depends on coverage and payment policies of public insurance programs (e.g., Medicare, Medicaid), preferences of private payers (expressed in contract negotiations), government mandates that constrain MCO behavior, litigation exposure, government support for medical research and technology assessment, and the behavior of manufacturers.

Our interviews with both MCOs and manufacturers and review of the existing literature indicate that, in many cases, careful and critical consideration of clinical evidence may play little or no role in technology adoption. In particular, technologies are often adopted by individual physicians and paid for by MCOs without any conscious decisions or oversight by MCOs. Technologies adopted through this route are unlikely to have been evaluated in cost-benefit terms: As a rule, physicians are not in a position to carefully and capably con-
sider, evaluate, and weigh the relevant clinical evidence before making adoption decisions.\textsuperscript{6,7} Our interviews and the literature also suggest that some technologies, including especially costly or novel technologies, are subjected to substantial scrutiny by MCOs. Our interviews with MCOs suggest—and participants in the October 7 meeting generally agreed—that the available clinical evidence about an emerging technology is often equivocal, and that coverage and medical-necessity decisions often require considerable guesswork and judgment. It is unclear how well the tension between adopting too quickly or too slowly is currently being resolved. Even assuming for the sake of argument that MCOs have strong incentives to adopt new technologies slowly in order to limit costs,\textsuperscript{8} government mandates and threats of litigation can push in the opposite direction.

**IMPROVING CLINICAL INFORMATION**

A major difficulty in making appropriate decisions about adopting emerging technologies is limited information about the performance of these technologies, both absolutely and in comparison with alternative technologies. This issue seems to get the most attention in the literature and in practice. We consider it at some length presently, followed by brief discussions of several other seemingly important challenges in improving the processes of technology adoption by MCOs.

What are the prospects for improving the clinical information available to MCOs for making technology-adoption decisions? It is helpful to distinguish four elements of information availability.

\textsuperscript{6}See, for example, Grimes (1993).

\textsuperscript{7}Little solace is provided by recognizing that many technologies that are adopted without much awareness or concern by MCOs are sufficiently similar to established technologies to be reimbursed under existing codes, and thus are likely in many cases to be similar to technologies already in use, because many of these earlier technologies were themselves not adopted on the basis of careful weighing of evidence.

\textsuperscript{8}According to our interviews with MCO medical directors, costs play a role primarily in the negotiation of contracts with payers.
• **Developing better information before market introduction.** Some of our interview respondents, participants in the October 7 meeting, and some commentators apparently believe that many device trials could have been designed, implemented, and reported to deliver more useful information with little or no increase in cost. In contrast, increasing the sizes of clinical trials (numbers of patients) would typically involve higher costs. Increasing costs of clinical trials or delaying market introduction of promising technologies can threaten the financial viability of socially worthwhile innovation efforts.

• **Learning more from experience in the marketplace.** Often, there is much to be learned about the safety, effectiveness, and costs of new technologies after they enter the marketplace. Even the highest-quality and most extensive clinical trials leave much unknown. Our interviews, the October 7 meeting, and the literature suggest that there is marked interest in finding ways for MCOs and manufacturers to work together to introduce technologies into the marketplace using approaches that would allow more to be learned from experience. This process might involve, for example, collecting systematic information on outcomes, creating mechanisms to pool such information, and, in some cases, initially restricting use of new technologies to physicians or facilities that are expected to have the best results.

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9 Ramsey et al. (1998, pp. SP198–SP199) suggest guidelines—developed by the Task Force on Technology Assessment of Medical Devices—for technology assessment of therapeutic medical devices. Rettig (1997, p. 106) discusses the view that clinical trials are often not well designed to provide useful information to those making decisions about whether and how technologies will be used in routine clinical practice.

10 Clinical trials illuminate efficacy or performance of the technology when applied by experts. How well a technology will perform under routine clinical (i.e., less favorable) conditions can be established only from broader use. Moreover, unlike drugs, devices are often modified after market introduction, in attempts to improve performance (Ramsey et al., 1998, p. SP191).

11 Buto (1994) and Adler (1996) discuss such possibilities in the context of Medicare and private insurance, respectively. See also Eisenberg (1999, pp. 1867–1868) and NIHCM Foundation (1999, p. 32). Along these lines, in December 1999 health insurers in New Jersey agreed to cover the costs of routine care for their enrollees who participate in clinical trials for cancer therapies. The research sponsors would still be responsible for covering the administrative costs of the trials and the drugs under study (Kolata and Eichenwald, 1999).
Evaluating and synthesizing clinical information. Technology-assessment functions are performed by many public and private organizations. Government agencies perform technology assessments and sponsor others; these assessments are generally available to the public. Many larger private insurers and MCOs perform in-house evaluations to support internal decision making, and other private organizations perform technology assessments for insurers, MCOs, and government agencies. Many privately produced technology assessments are proprietary. Little is known about the general quality of these assessments, which undoubtedly varies over organizations and particular cases.\(^\text{12}\)

While it can be difficult for manufacturers to be objective about their own technologies, they are knowledgeable about them and the existence of evidence. The feasibility, advantages, and disadvantages of allowing manufacturers to comment on proprietary assessments—as part of the MCO technology assessment or coverage-decisionmaking process—is worth exploring. The extent to which purchasers of assessments detect and the market rewards higher-quality assessment will affect the general state of technology adoption.

Disseminating information. Two methods for improving dissemination of information\(^\text{13}\) are standardizing forms for reporting and improving communication between insurers and manufacturers.\(^\text{14}\) The activities of the private technology-assessment industry, which seems to be growing in importance, expand the scope of technology assessment, and reduce—relative to complete decentralization—social costs from duplicative efforts. However, private organizations must cover their costs and, therefore, cannot be economically viable without restricting access to their reports. How this industry evolves will

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\(^{12}\)Sheingold (1998, pp. SP122–SP123) comments on duplication of effort across technology assessors and the uneven quality of assessments. Some manufacturers reported in interviews that proprietary assessments can be of poor quality or out of date.

\(^{13}\)Ramsey et al. (1998, p. SP192) point to some factors limiting availability of existing information.

\(^{14}\)For example, Ramsey et al. (1998, pp. SP196-SP197) propose guidelines for information exchange between manufacturers and insurers.
determine the extent to which it promotes socially beneficial technology adoption in the future.\textsuperscript{15}

**OTHER ISSUES THAT WARRANT CONSIDERATION**

Our interviews, discussion at the October 7 meeting, and literature suggest other important issues that affect the quality of technology adoption.

**Aligning Private Incentives of MCOs and Payers with Social Values**

MCO decisions about technology adoption are made within a context determined by contract negotiations with payers. The cost-conscious, competitive environments in which MCOs market their products limit greatly the extent to which they can factor into their decisions social costs they do not bear or social benefits for which they cannot capture revenues. Our interviews suggest examples: (1) reduced treatment costs years down the road when these savings are unlikely to accrue to the MCO bearing the current treatment costs; and (2) treatment benefits that are of significant value to consumers but that might reasonably be characterized as “nonmedical.”

Expecting or imploring MCOs or payers to act substantially in conflict with their self-interest\textsuperscript{16} is not realistic, especially given the state of competition among health plans and pressures from payers to limit premium increases. Better information for employees and consumers about the quality of care delivered by different MCOs could help, but developing and implementing quality reporting systems that could effectively discipline the market to make socially appropriate adoption decisions about individual technologies is not plausible any time soon. Perhaps the best hope is more government tar-

\textsuperscript{15}For example, a consolidation of the TA industry or expanding demand for TA industry services might lead to lower prices for proprietary technology assessments (since almost all costs of assessment are fixed), wider dissemination of particular assessments, assessment of more technologies, and reduced duplication of effort.

\textsuperscript{16}For example, the Guidelines for Technology Assessment of Therapeutic Medical Devices include: “Conducting the analysis from a societal viewpoint or perspective is strongly encouraged” (Ramsey et al., 1998, p. SP199).
geting of funding for basic and clinical research related to medical technologies that provide delayed health benefits or other social benefits to which the market may fail to give adequate weight.

Enhancing MCO Capabilities to Evaluate Technologies and Make Decisions

The most obvious possible steps in this direction, such as devoting more resources to technology assessment and coverage decision-making, are appropriately left to individual MCOs to consider. However, there may be a role for collective action in providing training in technology-assessment methods or general information to MCOs. Regarding the latter, it may be helpful to provide MCOs with information about, for example, what FDA approval of devices and Medicare coverage of technologies do and do not imply about safety, effectiveness, and costs of emerging technologies. 17

Improving Decisions by Physicians

Our interviews, the discussion at the October 7 meeting, and the literature provide an ample basis to conclude that, in many cases, technology adoption for managed care enrollees is being driven by decisions of individual physicians, not of MCOs. This is unlikely to change any time soon. Improving physician decisions—e.g., by wider development, dissemination, and use of practice guidelines or information systems—might greatly improve the technology-adoption process. Providing physicians with information about FDA regulation of devices and development of Medicare-coverage policies might also be beneficial.

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17In the case of the FDA, our respondents and the literature suggest that many MCO decisionmakers are not familiar with the varying degrees to which devices are scrutinized before they are approved for marketing. For example, “many purchasers and providers are unaware that clinical testing and regulation of medical devices is vastly different from that for pharmaceutical products” (Ramsey, 1998, p. SP188). In the case of Medicare, many MCO decisionmakers may not be aware of how infrequently the HCFA makes national coverage decisions, how long these decisions generally take, and the extent to which technologies are reviewed by Medicare contractors before they are accepted or rejected for coverage.
Reducing Use of Inappropriate or Obsolete Technologies

The substantial attention to technology adoption tends to deflect attention from another important social objective: reducing use of technologies that are dangerous, do not work in many or all of the circumstances in which they are used, or for which superior alternatives are available.\textsuperscript{18}

Reducing Costs of Decisionmaking for Manufacturers and MCOs

Manufacturer interview respondents pointed to the high costs of attempting to make their cases to numerous insurers. Mainly because of time and money costs, MCOs review and make formal coverage decisions about a small fraction of new technologies. Some standardizing of procedures for developing and exchanging information could be helpful.\textsuperscript{19}

Improving Manufacturer Understanding of the Market Environment

Our interviews with manufacturers and MCOs and the discussion at the October 7 meeting suggest that some device developers and manufacturers, especially inexperienced ones, have very limited understanding of the managed care market environment. Such misunderstandings can lead innovators and manufacturers to fail financially. When their efforts are misguided, society loses as well: resources are wasted, and opportunities may be lost to develop commercially successful and medically beneficial technologies. In our interviews we have collected—and reported above—advice from both manufacturers and MCOs that could help medical innovators better anticipate the market environments they will face. However, this advice pertains to the environment as it exists today. U.S. health care organization and financing are in a state of flux; major changes are

\textsuperscript{18}For example, Rettig (1997, p. 104) reports that technology assessors pay almost no attention to obsolete technologies.

\textsuperscript{19}For example, along the lines of the guidelines proposed by the Task Force on Technology Assessment of Medical Devices (Ramsey et al., 1998).
likely because of market forces and changes in regulatory and public reimbursement policies. It is very difficult to predict what the coverage and payment system will look like five or ten years from now, when products under development today might be ready for market.20

Helping MCOs and Employers Anticipate What Is in the Pipeline

Our MCO interviews suggest that managed care organizations could make more appropriate technology decisions if they and the payers were better able to anticipate market introduction of major new technologies. Our interviews suggest—and one participant in the October 7 meeting emphasized—that new technologies can confront MCOs with enormous financial uncertainty. How might systematic information about emerging technologies be developed and disseminated to aid planning by MCOs—for example, in negotiating benefit provisions and premium levels with employers? What organizations or consortia might be well placed to play a leadership role?

MOVING FORWARD

As the preceding discussion suggests, the processes of medical-technology adoption by MCOs raise numerous, complex issues. Even when promising ideas for improvement are identified, major hurdles can stand in the way of agreement and implementation. Revolutionary changes or magic bullets are not likely. In view of the size of the U.S. health care system and the potential contributions of new technology to health and to costs, even incremental improvements could have large payoffs.

For the foreseeable future, such efforts to improve the system will take place within an environment in which mistrust of MCOs and medical-product manufacturers is widespread and health care deliv-

20For example: Will market forces and public responses to the current unpopularity of managed care reduce emphasis on cost containment? Will these forces greatly change how health plans attempt to control costs? As consumer-driven demands for treatment continue to grow—e.g., due to manufacturer marketing to consumers and expanding use of the Internet—how will systems respond?
Technology adoption has been politicized. Neither our interview respondents nor the participants at the October 7 meeting expressed confidence that increasing the scope or intensity of government activities such as FDA regulation, coverage mandates, or technology assessment offers substantial hope for improving technology adoption by MCOs. As a participant in the October 7 meeting suggested: “Healthcare has become very political, but the solutions aren’t.” It is hard to dismiss this view.

The discussion at the October 7 meeting also provided reason to hope that representatives of the managed-care and medical-technology industries could engage in constructive, joint exploration of what might be accomplished by private, voluntary action. It was also agreed that it would be very helpful to include payers (e.g., consortia of employers) in such a process. The issues raised above provide potential agenda items for such discussions.

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21 For some contrasting views, see Perry and Thamer (1999) and sources cited there for calls for the establishment of a federal government agency or other national entity to assess health technologies of national importance.

22 Consistent with this view, despite painting a sobering picture of the quantity and quality of information about the performance of many medical devices and about the processes of technology adoption, Ramsey et al. (1998) offer recommendations that rely on private—but not public—action. Rettig (1997) discusses political forces limiting an expanded role of government in technology assessment.

23 Sheingold (1998) reviews sources of conflict between the two industries over technology adoption and argues that attenuating or controlling conflicts can be critical to meeting social objectives for health-care quality and cost.