INTRODUCTION

Chapter One

PROJECT BACKGROUND AND OBJECTIVES

Health policy analysts and policymakers often struggle with conflicting views about the development and adoption of new pharmaceuticals, medical devices, and procedures. Society looks to technological advances to improve the quality and outcomes of medical care. Although new technologies sometimes enable improved quality with lower costs, new technology is often viewed as a major cause of increasing costs of health care in the United States.¹

Knowledgeable, reasonable participants and observers disagree about the extent to which new medical technology affects health and health care costs. But most agree in principle that the well-being of society as a whole is improved when health-care providers adopt those new technologies whose contributions to health warrant any additional costs and reject technologies—old and new—that do not satisfy this criterion. A collection of processes that effectively winnows technologies in this fashion would also send a socially valuable message to aspiring inventors and innovators: Technologies that serve the social good are likely to be rewarded in the marketplace; other technologies are not. Making socially desirable technology-adoption decisions and sending clear signals to inventors, innovators, and investors are, of course, much easier said than done. However, the enormous health and economic stakes suggest that even minor improvements over current practices of technology de-

¹See, for example, Weisbrod (1991) and Newhouse (1993).
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Development, marketing, and adoption could be well worth the costs of achieving them.

The project on which we report here had two primary objectives: (1) to understand current processes of managed care organizations (MCOs) for making coverage, medical-necessity, and payment decisions involving emerging medical technologies, and how device developers and manufacturers prepare for and participate in these processes; and (2) to identify ways that private, voluntary action by the managed-care and device industries, individually or jointly, might improve—for the benefit of society—the processes by which new medical technologies are developed, evaluated, and adopted or rejected for coverage. We focus on decisions and actions by medical device manufacturers and managed care organizations regarding coverage of and payment for innovative medical devices and related medical procedures. We refer to such devices and procedures as “emerging medical technologies” to connote that these technologies have as yet been neither widely adopted nor widely rejected in the marketplace. We define managed care organizations broadly to include both health plans (such as health maintenance organizations) and medical groups that contract with health plans to provide care to patients on a capitated basis or through other arrangements that place the groups at financial risk.

Managed care uses various organizational forms and management techniques to try to control costs while preserving or enhancing the quality of care. These efforts affect the processes and outcomes of technology adoption. Management of care per se is not problematic; the earlier approach of generally paying for whatever physicians and patients requested when someone else was bearing the costs left much to be desired. The critical questions are how well managed care currently handles technology adoption and how improvements that benefit society at large might be achieved. In light of the ongo-

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2 Goddeeris (1984a,b), Baumgardner (1991), and Ramsey and Pauly (1997) present formal theoretical analyses of how health insurance arrangements can affect technology adoption. Goddeeris (1984a,b) and Baumgardner (1991) conclude that insurance can lead to technology adoption that makes society as a whole worse off. Baumgardner shows how different approaches to cost control (i.e., traditional fee-for-service with coinsurance, and a prepaid health plan without coinsurance but with institutional restrictions on treatment levels) are vulnerable to inefficiencies from different types of technological change. Ramsey and Pauly (1997) incorporate the ability of...
ing and intense public debate over managed care, proposals for expanded federal and state regulation, and the widespread public interest in medical innovation, investigating how managed care affects medical-technology adoption is particularly timely.

OVERVIEW OF THE STUDY

Our work contributes to—and begins to fill some significant gaps in—a growing literature on technology adoption in the U.S. health care marketplace. Previous studies include econometric analyses of adoption of specific medical technologies\(^3\) and of decisionmaking by health plans based on interviews or mail surveys designed to probe determinants of adoption of specific medical technologies or medical technology broadly construed. Our study focuses on innovative medical devices and related procedures. We gathered empirical information from in-depth, semi-structured interviews with eight manufacturers of innovative devices and nine managed care organizations. We also collected information from representatives of manufacturers, MCOs, and the sponsors of this study—the California Goldstrike Partnership,\(^4\) the Economic Development Administration of the U.S. Department of Commerce, and the Health Industry Manufacturers Association (HIMA)\(^5\)—at a half-day, invitation-only meeting held at RAND headquarters on October 7, 1999.\(^6\) At this meeting, we presented the preliminary findings from our interviews, and participants were encouraged to critique and elaborate. The study is especially novel in collecting extensive information from manufacturers and in juxtaposing their reported experiences and perspectives with those of MCOs.

fee-for-service plans to control use of new technologies and conclude that Health Maintenance Organizations (HMOs) may adopt some costly technologies that are not adopted under fee-for-service arrangements and vice versa.

\(^3\)Baker and Wheeler (1998) and Spetz and Baker (1999) and studies cited in them.

\(^4\)The Goldstrike Partnership is a program of the California Trade and Commerce Agency’s Office of Strategic Technology.

\(^5\)HIMA is a trade association based in Washington, D.C. It represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems.

\(^6\)Some of the manufacturers and MCOs that participated in interviews also sent representatives to the meeting, and others did not. Many of the manufacturers and MCOs represented at the meeting had not participated as interview subjects.
In conducting this research and reporting our findings, we had four primary audiences in mind:

- Medical device developers and manufacturers
- Managed care organizations
- Public-policy makers
- Researchers and analysts.

Members of all four audiences are likely to find something of interest here. Experienced device manufacturers—i.e., companies that have already marketed devices in the United States—may, for example, be spurred to think about marketing to MCOs in new ways. Aspiring device manufacturers—i.e., organizations that are attempting to develop innovative devices but have no experience in marketing such products—and their investors may learn the most. In particular, many observers believe that such organizations often fail to look past Food and Drug Administration (FDA) approval of their products to the challenges they will face in the marketplace, and then find themselves poorly prepared for the commercialization effort. As a consequence, they may perform less well for themselves and their employees, investors, communities, and potential consumers than if they had been more forward-looking.7

Likewise, as MCOs attempt to make numerous difficult decisions regarding emerging technologies, they are likely to benefit from considering the perspectives of manufacturers and the processes and perspectives of other MCOs. Public policies8 can influence MCO technology-adoption decisions for privately insured consumers. It would be beneficial, then, for policymakers to consider how their

7 In fact, concerns of this sort motivated the Goldstrike Partnership and the Economic Development Administration to provide financial support for this project. More specifically: “The changing dynamics in the healthcare delivery system and increasing penetration of managed care organizations has changed the way business is done in this arena. Most new technology companies are unprepared to address the new dynamics in this industry and need assistance in dealing with these critical commercialization issues” (Johnston and Company, 1998).

8 Such as coverage and reimbursement policies of the Health Care Financing Administration (HCFA) and technology assessments supported and disseminated by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research, or AHCPR).
decisions may affect medical innovation indirectly through their effects on technology adoption and incentives to innovate, along with the more obvious direct effects of their decisions about coverage and payment under public health insurance programs. In addition, government agencies concerned with job creation and economic development should be interested in our findings concerning determinants of commercial success for medical-technology developers and manufacturers. Finally, researchers and analysts may be interested in various issues discussed below, such as decisionmaking by MCOs, device manufacturers' commercialization strategies and tactics, how the interaction of the two determines demand for emerging medical technologies, and the nature of incentives for medical innovation.

The remainder of this report comprises five chapters. For the convenience of our diverse audiences, the main text is written to be accessible to nonresearchers; details and technical material—including guides to related literature—are presented in footnotes. In Chapter Two, we briefly describe steps that can be involved in determining MCO coverage for a particular technology. In Chapters Three and Four, we summarize and interpret what we were told in our interviews with manufacturers and managed care organizations, respectively. In Chapter Five, we present advice offered by the two sets of interview respondents for consideration by device manufacturers as they decide how to invest in medical technology development and plan commercialization efforts. In the concluding chapter, Chapter Six, we step back to consider implications of the interviews, the discussion at the October 7 meeting, and the literature and discuss key challenges for improving the processes of evaluating and adopting or rejecting medical devices and the medical procedures employing them.

Much of the value of the information we present requires recognition of the variety of clinical and economic contexts of emerging medical technologies and the wide range of factors that determine the outcomes of commercialization efforts. We hope that the information offered here enables readers to develop an enhanced understanding of our highly complex and varied technology-adoption system. If so, it may aid readers as they pursue their distinct objectives, and contribute to the social goals of balancing health care costs and quality and providing socially appropriate signals to guide investments in medical innovation.