

Health Technology Assessment in Health-Care Decisions in the United States

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Introduction

Health technology assessment (HTA) is a form of policy research that examines short- and long-term consequences of the application of a health-care technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real-world effectiveness, cost, and cost-effectiveness as well as social, legal, ethical, and political impacts [1].

At least five distinct activities define a formal health technology assessment process: 1) horizon scanning; 2) topic determination and queuing; 3) collection and assessment of evidence; 4) appraisal; and 5) funding and policy implementation. Horizon scanning involves the early examination and active monitoring of emerging technology to determine, in part, potential evidence requirements, and budgetary implications. Topic determination and queuing activities focus on setting priorities and sequencing of emerging and previously considered technologies for assessment or reassessment. The assessment function entails the process of collecting, evaluating, and systematically reviewing all available evidence for the technology under consideration. Appraisal is the decision-making function and is often distinguished by an external body (e.g., a pharmacy and therapeutics committee in the United States) that considers and weighs the summarized evidence in order to render a recommendation to the payer. Funding and policy implementation are the final steps in the HTA process.

The explicit objective of organizations that operate formal HTA programs is to carefully consider a full range of clinical and economic evidence in order to render decisions as to the acceptance, modification, or rejection of technologies on a rational basis [2]. The UK National Health Service National Coordinating Center for HTA suggests that HTA programs directly consider the following attributes of health technology as they undertake their mission: When compared with existing alternatives, does the technology work, in whom does the technology work, and what is the cost impact? [3].

The funding for and use of health technology assessment programs in the United States has a long and storied history, is fragmented and uncoordinated, and includes both public and private sector initiatives. Some readers will be surprised to learn that a number of US HTA programs predate the development of well-known international efforts in Australia (Pharmaceutical Benefits Advisory Committee), Canada (Canadian Agency for Drugs and Technologies in Health), Sweden (Swedish Council on

Technology Assessment in Health Care) and the United Kingdom (National Institute for Health and Clinical Excellence [NICE]). Regrettably, a number of these early US initiatives have been discontinued or have been substantially altered in large part because of political, financial and commercial pressures.

In this article, we consider the changing landscape for systematic health technology assessment in the United States and what it means for health-care payers. In Section I, we start with a description of the many public and private agencies supplying and using health technology assessment reports to make coverage and reimbursement decisions. In Section II, against a backdrop of escalating costs and few restrictions on the pricing and use of health-care technology, we discuss the factors that are shaping and challenging private and public sector HTA programs. Finally, in Section III, we offer commentary on the potential role that a more formal approach to HTA can play in health care in the United States.

SECTION I: PUBLIC AND PRIVATE AGENCIES PRODUCING OR USING HTA REPORTS IN THE UNITED STATES

Federal Health Technology Assessment Initiatives

The federal government has provided substantial financial support for health technology assessments since the early 1970s. The mechanisms by which the US government has funded HTA have changed over this time period, largely because of the policy decisions in the legislative and executive branches.

The Office of Technology Assessment. The nonpartisan Congressional Office of Technology Assessment (OTA) was established in 1972 with funding by the US Congress to undertake technology assessments to inform federal funding decisions about emerging health and nonhealth technology. The OTA was commissioned to evaluate technologies as requested by Congressional members and committees on matters related to legislative policies that were either undergoing development or review. At its peak, the OTA staff produced upwards of 50 reports annually. The publicly available HTA reports were comprehensive and often described multiple policy options as well as the costs and consequences of each option. Congress withdrew funding for the OTA in 1995, in part because of controversy over the content of several of its reports and political pressure from the commercial health technology industries [4].

Medicare and Medicaid. The Medicare and Medicaid programs are the largest government-sponsored purchasers of health care in the United States. Together, these programs provide medical

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care coverage for more than 60 million individuals. In 2006, Medicaid and Medicare spending totaled \$288 billion and \$374 billion, respectively [5]. The majority of services for beneficiaries of these programs are provided by hospitals and health-care institutions, physicians, and pharmacies. The Medicare program provides a comprehensive benefits package for US citizens age 65 years and above. Beginning in 2007 with the implementation of the Part D program, Medicare became the largest purchaser of outpatient pharmaceuticals. The Medicaid programs for the indigent and disabled are jointly financed by states and the federal government. The Center for Medicare and Medicaid Services (CMS) is the federal agency responsible for program oversight, financing and implementation.

Health technology assessment within the Medicare and Medicaid programs is complicated and fluid. Coverage determinations for Medicare-financed medical technology can be made at the local or national level (national coverage decisions supersede local decisions). Here we discuss only the national coverage determination process.

The Medicare Coverage Division within CMS is responsible for undertaking or commissioning HTA reports to support considerations for a national coverage determination [6]. The Medicare Evidence Development and Coverage Advisory Committee, an appointed body of national experts on medical technology, is tasked with weighing the evidence from the HTA in an open, public meeting. The evidence dossiers, public submissions of evidence from technology manufacturers, and the final coverage policies are placed on the CMS web site (<http://www.cms.hhs.gov/mcd>) for transparency. Coverage determinations are issued by staff within the Coverage Division through a National Coverage Decision memorandum. Notably, the Coverage Division is explicitly prohibited by law from considering evidence relating to the cost or cost-effectiveness of technologies when making coverage determinations [7].

Operating separately from the CMS Coverage Division, the Medicare Part D outpatient drug program was established as a publicly funded yet privately administered benefit. The consequence of such a public-private program is that all pharmaceutical coverage and reimbursement decisions are made by Part D contractors. Medicare regulations regarding coverage for particular drugs and drug classes, however, limit the flexibility of Part D contractors' drug benefit designs. Some have questioned the rigor and transparency of private-sector HTA efforts to support formulary listing in the Medicare Part D program. We discuss in depth the private-sector HTA activities later in this article.

Many state Medicaid programs support HTA activities for pharmaceuticals and other medical technologies. Typically, these HTA programs are administered by local program staff with support from clinical experts. Rarely are state Medicaid employees trained in technology assessment or resource allocation decision-making methods. To support these local efforts, state programs often purchase HTA's from private organizations that specialize in this area. In general, the operating budgets for state-sponsored HTA activities—which largely come from the state rather than the federal government—are insufficient for the workload. On the one hand, observers may see multiple state HTA programs as redundant and inefficient, often creating inconsistencies in coverage policies between states. On the other hand, variable state coverage policies may reflect local health-care needs, state-specific resource constraints, and policy agendas of elected officials.

Drug Effectiveness Review Project. In 2001, the Oregon Health and Sciences University created the Drug Effectiveness Review

Project (DERP) to produce evidence syntheses of pharmaceutical products to support decision-making for the Oregon Medicaid Preferred Drug List (<http://www.ohsu.edu/drugeffectiveness/>). Oregon Health and Science University scientists envisaged DERP as a program that could serve multiple state Medicaid drug programs in an effort to reduce redundancy and support consistency in the evaluation of evidence to support formulary listing [8].

Currently, DERP has contracts with 14 Medicaid programs to supply evidence reports on pharmaceuticals. These publicly available reports contain a description of the HTA questions, a listing and synthesis of the supporting literature and a recommendation on the quality of available evidence. Evidence concerning the cost and cost-effectiveness of drugs is not included in the evidence summaries. Importantly, the reports do not contain a coverage or funding recommendation to the state Medicaid program and thus, states may reach different conclusions using the same evidence reports regarding specific pharmaceuticals or therapeutic classes. In addition to informing their drug coverage policies, states sometimes use evidence from the DERP reports to negotiate prices with manufacturers.

There is no shortage of controversy surrounding the DERP program [9]. The pharmaceutical industry has criticized DERP reports as providing "political cover" for cost-containment decisions taken by state Medicaid programs. Others have expressed concern that DERP's selection of evidence is too strict and effectively eliminates available research that would inform coverage policies [10]. In particular, this strict standard of evidence limits the usefulness of agencies such as DERP in providing rapid initial assessments of newly emerging technologies; as such technologies rarely arrive with sufficient published evidence meeting the standard to support a conclusion as to the technology's appropriate role in medical practice.

Agency for Healthcare Research and Quality. The Agency for Healthcare Research and Quality (AHRQ) historically has been the largest federal funder of publicly available health technology assessments in the United States. The AHRQ supports HTA research primarily through three external research networks coordinated within the Agency's Effective Healthcare Program: 1) The Evidence-Based Practice Centers (EPCs); 2) the Centers for Education and Research on Therapeutics (CERT); and 3) the Developing Evidence to Inform Decisions about Effectiveness (DECIDE) Program. These three programs conduct systematic evidence reviews to assess the effectiveness, comparative effectiveness, safety, and, in rare instances, the cost-effectiveness of medical technologies and interventions. HTA topics are nominated by a mix of federal and nonfederal partners, may or may not include comparative effectiveness or cost-effectiveness questions, and generally take between 15 and 18 months to complete. Once finished, the HTA reports are published on the agency's web site (<http://www.ahrq.gov>) and disseminated in print. The hope is that AHRQ technology assessment reports would be widely used to inform coverage decisions. However, timing and relevance to private sector payers have limited their usefulness.

The AHRQ's technology assessment activities are continuously challenged by political pressures that translate directly into funding decisions [11]. To illustrate how political forces have influenced resources allocated to the agency for these programs, one only has to look to recent federal legislation. The DECIDE program was established to support Section 1013 of the Medicare Modernization Act—the legislation that gave rise to the outpatient prescription drug program for Medicare beneficiaries (Medicare Part D). Section 1013 authorized AHRQ to conduct and support research on the outcomes, comparative clinical

effectiveness, and appropriateness of pharmaceuticals, devices, and health-care services. Whereas the MMA authorized an annual budget of \$50 million, AHRQ was ultimately appropriated \$15 million per year for these activities. Furthermore, Section 1013 prohibits the CMS—the federal agency responsible for the Medicare Part D program—from using information produced by the DEcIDE program to withhold or restrict access to pharmaceuticals.

Of the agency's approximately \$350 million annual budget, only a small fraction goes to the production of health technology assessments. The future of AHRQ and federally-sponsored HTA would change dramatically if the US Congress approves funding for a proposed comparative effectiveness center [12].

Other federal programs. The Department of Veterans Affairs (VA) Pharmacy Benefits Management Strategic Healthcare Group (PBMSHG) undertakes pharmaceutical technology assessments to support the appropriate use of medications within the VA health-care system. The HTAs are developed by internal experts and are used to inform national drug formulary placement, treatment guidelines, and contracting decisions. In an effort to promote transparency, the HTAs for a number of therapeutic class reviews are published on the PBMSHG Web site although in some cases confidential information is unavailable and in no case are prices revealed (<http://www.pbm.va.gov>).

The Military Health System is supported in its mission to improve the clinical and economic outcomes of drug therapy through the Department of Defense Pharmacoeconomic Center (PEC). PEC internal staff undertakes comprehensive cost-effectiveness studies of existing and new pharmaceuticals to support the decision-making processes of the DOD Pharmacy and Therapeutics Committee, the National Mail Order Pharmacy formulary list, and in some instances, the VA. Public access to PEC reports is limited (<http://www.pec.ha.osd.mil>), but what is available for evaluation suggests that the HTA reports are strictly limited to comparative economic analyses [13].

National Institutes of Health. The National Institutes of Health does not have a program for conducting health technology assessments of medical interventions, but often will conduct evidence reviews in the process of developing clinical practice policies for particular medical conditions. For example, the National Heart, Lung, and Blood Institute support the National Cholesterol Education Program (NCEP). The NCEP panel of experts reviews evidence regarding cholesterol and coronary artery disease, and produces treatment guidelines in the process of making its recommendations for the evaluation and management of hypercholesterolemia. Similar evidence reviews have been produced for asthma, emphysema, and many other diseases.

Food and Drug Administration (FDA). Although the FDA has been the primary federal agency of drug safety and efficacy for decades, this agency does not conduct formal technology assessments. Instead, FDA staff evaluates prelicensing studies of safety and efficacy submitted by manufacturers in support of their new drug applications. Cost-effectiveness analysis lies outside the defined scope of these reviews, and in general, the FDA has focused on Phase 3 placebo-controlled trials as the gold standard of evidence, as opposed to head-to-head trials against the most appropriate active comparator.

Private Sector Health Technology Assessment Initiatives

The commercial health insurance market finances medical care services for more than 200 million individuals through diverse

employer-sponsored and self-insured health benefits programs. The five largest health insurers (Aetna, Cigna, Kaiser Permanente, United Healthcare, and WellPoint) cover or are responsible for >50% of all employer-sponsored members in the United States. The Pharmacy Benefits Management (PBM) industry is even more concentrated. Roughly 95 percent of all persons with drug coverage receive pharmaceutical benefits through a PBM. The four largest PBMs (Caremark, Medco, Express Scripts, and WellPoint NextRx) process nearly 70% of the 3 billion prescriptions dispensed annually. Many private insurers and PBMs have sizeable HTA programs staffed by qualified clinical experts and financial analysts and supported by sophisticated data systems.

The level of HTA work performed by other US private health plans is variable in terms of HTA processes such as formal evidence synthesis, evaluation of pharmacoeconomic analyses when such are available, and a pharmacy and therapeutics committee or other expert decision-making panel whose members are not employed by the health plan and are screened for financial conflicts of interest. Smaller health plans have much more limited staffing and often depend on technology assessments produced by outside private or public agencies. Plan size is not necessarily correlated with the quality of its processes, as has been described [14].

Very little information is available regarding the scope, internal processes and conduct of HTA's by private insurers and PBMs. WellPoint does make its HTA Guidelines publicly available on its websites. However, most other private organizations generally view their HTA programs as proprietary, offering a competitive advantage over each other in a marketplace that demands effective cost control. Recently and in response to consumers, private payers have provided information on the extent of medical and pharmaceutical product reimbursement on their websites, allowing consumers to compare and contrast coverage policies between competing plans; however, the process by which these decisions are taken is usually not transparent.

SECTION II: FACTORS SHAPING PRIVATE AND PUBLIC SECTOR HTA PROGRAMS IN THE UNITED STATES

The Academy of Managed Care Pharmacy Format

Historically, the relationship between technology manufacturers and health-care purchasers has been strained. Manufacturers complain that insurers coverage and reimbursement policies are arbitrary or opaque, whereas insurers often charge that manufacturers charge exorbitant prices and are not forthcoming with all available evidence on products. In response, the Academy of Managed Care Pharmacy (AMCP) produced its first guidance document on evidence requirements to support formulary listing in 2000. The intent of the AMCP Format was to provide a framework and evidence tool for private and public payers to request appropriate clinical and economic data to support coverage and reimbursement deliberations.

Additionally, the AMCP Format solved a failure of the market to provide information that would improve decision-making and contracting. Federal regulations enforced by the FDA restrict the promotion, and therefore dissemination of drug evidence to that contained within the approved product label [15,16]. Historically, this meant that when evidence was available on product safety, benefit, or cost-effectiveness but was not contained within the approved label, it could not be shared with the payer without an explicit request. Health insurers may find such information to be valuable for decision-making, but would not necessarily identify it, either because of resource constraints

or because the data would not be found through systematic review of the literature. To solve this problem, if a health professional or payer specifically requests clinical evidence, data or economic studies not contained within the approved label, the pharmaceutical company can supply the information so long as the request was unprompted—an unsolicited request. The AMCP Format in effect created a safe harbor for the transmission of a much larger body of evidence regarding pharmaceuticals from manufacturers to payers.

By lowering the transaction cost of acquiring a more complete evidence picture on pharmaceutical products, it was anticipated that the AMCP Format would “jumpstart” more formalized assessments of pharmaceuticals within the private payer organizations. The AMCP Format is not compulsory, but voluntary. Adopting payers number more than 50 and include many of the largest private insurers and PBMs. The evidence and reporting requirements of the AMCP Format have been revised twice since adoption and the most recent version (v2.1) can be found on the AMCP web site (<http://www.amcp.org>).

Introduction of the AMCP Format initially was met with resistance by the pharmaceutical industry and a small number of payers. Industry was concerned over possible legal issues stemming from the unsolicited request process as well as the cost of producing evidence dossiers. Some manufacturers questioned the expertise of smaller payers with limited staffing to perform rigorous reviews. Payers expressed unease regarding availability of implementation resources, specifically resources to support appropriate staffing to review the information provided in the dossiers. Others were concerned about the quality and completeness of clinical and economic evidence received directly from industry. Recent research supports continuing concern about evidence quality in industry submissions to US payers [17].

The AMCP Format provided for a uniform listing of evidence requirements for drug formulary considerations of private payers in the United States. The drafters of the Format expected that payers would customize the evidence requirements tool within the Format to meet specific HTA program needs. Although the AMCP Format does not necessarily encourage insurers to develop their own HTA programs, it can result in an assessment process that is closer to the spirit and substance of a formal HTA. Organizations with robust HTA departments also benefit from the manufacturer dossiers. DERP, the VA, and the Department of Defense PEC are notable examples of HTA programs that tailored the Format for their own unique requirements. However the Format is included in the HTA process, its effective use depends on a mutual understanding on the part of the manufacturer and the health plan that the Format is a tool to facilitate communication between the two parties. As such, it will not be optimally effective unless both participate actively in the process. When properly understood, it serves as a vehicle through which the plan can request specific types of information for the review and the manufacturer can respond by providing information and analysis to support the drug’s value proposition in ways that will be meaningful to the plan’s reviewers.

WellPoint Health Technology Assessment Guidelines

WellPoint is one of the largest private health plans in the United States, providing health benefits to more than 35 million commercial, Medicare, and Medicaid clients, and is widely viewed as a leader in innovative pharmacy benefit programs. On October 9, 2008, WellPoint released its revised set of evidence requirements for pharmaceutical technology assessments to improve transparency to the pharmaceutical and biotechnology industries regarding the type of data the company is looking for in order to make

value-based, health-care decisions on drug therapy for its members. The WellPoint Outcomes-Based Formulary process will include specific requirements for: 1) new products, new indications, and new formulations; and 2) reevaluation of products, indications and formulations. The revised guidelines emphasize budgetary impact projections and potential medical cost offsets based on the drug company claims regarding the product, employee productivity effects, usefulness, and validity assessment of clinical trials, a recommendation that the drug company product claims allow for monitoring and validation over short and medium time frames (3 years recommended), and effects on patient-reported outcomes and quality of life).

SECTION III: THE FUTURE OF HEALTH TECHNOLOGY ASSESSMENT IN THE UNITED STATES: LESSONS LEARNED

Health insurers in the United States will continue to be challenged by the need to balance access to effective new medical technologies against the impact that these technologies are having on the cost of medical care. On one side is the steady proliferation of high cost new technologies, combined with pressures by patients, clinicians, and advocacy groups to adopt these technologies. On the other are health-care purchasers, who are finding it increasingly difficult to bear the cost of providing health insurance for their employees and members. The principles of HTA will be the foundation on which payers will balance the competing objectives of access and affordability, so that coverage of older technologies that are supported by solid evidence is not jeopardized. HTA has evolved over time, and will continue to change in response to the changing needs of decision-makers. After briefly summarizing lessons learned from early attempts at using HTA, we will discuss issues that we feel will shape the future of HTA in the United States.

HTA and Clinical Practice Guidelines

Decision-makers have learned much from their early experiences with HTA. Initial applications of HTA frequently involved incorporation of evidence reviews into relatively inflexible clinical practice guidelines. The evidence appraisal systems that were used to create these guidelines were often ad hoc and based on the guideline creators’ interpretation of what constituted higher and lower quality evidence. Many were not transparent as to their methods. As a result, there was rapid proliferation of hundreds of “evidence-based guidelines” that often contained conflicting recommendations. This proliferation of numerous guidelines of highly variable quality created a backlash among clinicians, patient advocacy groups, and even some payer groups.

In response, thought leaders in the evidence-based medicine movement responded by describing the core principles of evidence appraisal, at the same time emphasizing that decision-makers needed flexibility in using many types of evidence for patient care and practice policy. In particular, David Sackett, Brian Haynes, and colleagues clearly articulated both the need to have clear standards for evidence appraisal and the means to synthesize evidence from a number of sources [18]. As a result, highly directive clinical practice guidelines were replaced with evidence summaries that were more uniform in their evaluation of available information. Many publicly and privately funded organizations—including several based in Europe, Canada, and Australia—now use more uniform evidence appraisal methods. The evidence summary reports by organizations such as the Cochrane Collaboration, UK-NICE, DERP, and the CADTH now are more similar than they are distinct. As a result, decision-

makers in the United States have begun to rely on these sources in their HTA processes, and are thus less prone to develop ad hoc or nontransparent approaches to evidence appraisal.

Timeliness and Efficacy versus Effectiveness

Although the HTA process has become more uniform and flexible over time, several challenges remain. The producers of HTA's have been criticized for being too slow in producing reviews for the needs of decision-makers, for relying too heavily on evidence from randomized controlled trials, and for ignoring interventions that are supported by less rigorous forms of evidence. One important issue is the difference between evidence that is needed for regulatory approval to market a product and the needs of end users. For example, a major limiting factor in the HTA process is the fact that most drugs come to market with evidence of efficacy based on placebo controlled trials. Differences between trials—including the patient populations, management of conditions, and end points chosen for study—limit the comparability of drugs within classes used to treat the same condition. When is a new agent—with its attendant claims of superiority in one or more clinical domains—truly incrementally better than current therapies? Furthermore, are the additional costs of the new agent justifiable given these purported benefits? Questions such as these have spurred the current health policy debate towards the development programs that would conduct prospective “head-to-head” clinical trials comparing the effectiveness of new and existing treatments. This movement, now dubbed “comparative effectiveness,” is often envisioned as both entirely government financed and run or as public-private configurations (e.g., private centers funded by federal, state, and private sources).

Comparative Effectiveness Programs

Comparative effectiveness programs would move HTA into a new realm; specifically, toward the creation of evidence that is designed to be directly applicable to clinical decision-making rather than the synthesis and appraisal of existing evidence. A primary motivation for insisting on comparative effectiveness is the recognition that this information will otherwise never be generated by either manufacturers or the public sector. Although comparative effectiveness studies would address many important HTA issues, these studies still have important limitations. High quality comparative effectiveness studies would be costly and potentially of long duration, thus limiting the number that would be available to inform decisions over time. In addition, the clinical questions most comparative effectiveness studies would pose would focus on improving care and patient outcomes rather than reducing cost. In addition, selective enrollment may limit the generalizability of these studies.

Coverage with Evidence Development

Another movement within the health insurance community with implications for the HTA field is commonly termed coverage with evidence development (CED). At its core, coverage with evidence posits that the evidence generated to support regulatory approval of a product is sometimes insufficient to support coverage and reimbursement in general or selected clinical settings. This “evidence gap” arises because the design of the trial(s) supporting the product are considered to be of poor quality (e.g., nonrandomized designs) or because the patient population and clinical experimental setting does not represent the way the technology appears to be used in practice. In either case, coverage with evidence development is an attempt by the insurance community to permit reimbursement of the technology with the condition

that additional evidence is gathered systematically—typically either in the form of prospective registries or prospective, controlled clinical trials—to better understand its risks and benefits relative to alternatives. The CMS' Coverage with Evidence Development (CED) program is at the forefront of this movement in the United States [19]. Under CED, a new technology is granted provisional reimbursement while evidence is generated through a clinical research protocol. The protocol may take the form of an observational study, or at the opposite extreme, a prospective randomized clinical trial. A final coverage decision on the new technology would be issued only after the evidence has been reported. The National Emphysema Treatment Trial was an early application of coverage with evidence. Here, an experimental technology known as lung volume reduction surgery was covered by CMS only for patients who agreed to participate in a trial where they were randomized to either the surgery or usual medical care. The trial was completed in 2005, and CMS modified its coverage to fit the findings of the study [20].

Cost-Effectiveness Thresholds

Some HTA procedures that have been implemented overseas are unlikely to be replicated in the United States. First, explicit use of cost-effectiveness thresholds is unlikely because of the complexity of health-care delivery, with multiple competing private health insurers and political resistance among public health insurers to explicitly incorporate treatment costs into their decision-making policies. Second, simulation modeling—which is used in the United Kingdom, Canada, and other countries to address problems where evidence is unavailable—continues to meet resistance among clinicians and policymakers in the United States. Third, the centralization of HTA that has occurred in much of the world is unlikely to be replicated in the United States, also because of the fact that health-care financing is not centralized.

Conclusions

Health technology assessment will continue to evolve to accommodate the needs of health insurers. It will always be shaped in part by the political landscape that will in turn be influenced by public perceptions of HTA as either a system that improves patient care or simply restricts access to promising medical technologies. Such perceptions will influence the level of public financing of HTA, but they will not change the real need that payers have for controlling health spending at the same time ensuring access to effective medical technologies. The medical technology industries will need to grapple with the seeming paradox of meeting regulatory and licensing requirements while building an evidence-base necessary to satisfy health-care payers.

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