



Future Strategies for U.S. Technology Assessment Conference Report April 4, 2006

New medical advances save lives, improve health and enhance quality of life, but, the rapid development and adoption of new technology is a major factor driving growth of U.S. healthcare spending. This creates a dilemma for public and private policymakers who must balance affordability with the need to ensure appropriate access to beneficial services, as rising health costs stress government budgets and erode employer-sponsored health insurance coverage.

Americans strongly support access to new medical innovations, yet the value of new technologies relative to existing treatments is often uncertain. Health technology assessment (HTA) -- the systematic evaluation of impacts of health care technology to inform policymaking conducted by interdisciplinary groups using explicit analytical frameworks¹ -- would seem to be a useful concept for U.S. policy makers. Yet, the federal government has been conservative in funding HTA research programs and in using HTA for Medicare coverage decisions.

Of concern to some is that the scientific knowledge base to make many important technology coverage decisions is limited. The United States has never engaged in a serious national debate on how much we should spend to extend life or improve patients' quality of life. US policy contrasts sharply with that of other developed nations that operate under fixed healthcare budgets and have established formal processes for technology review.

On April 4, 2006, Brandeis University and the Health Industry Forum convened a meeting to discuss whether U.S. policy makers should consider establishing or funding a more extensive HTA capability. There is growing interest in expanding the availability of clinical research to help patients and providers make informed treatment decisions. How private and government third-party payers use this information to make coverage and reimbursement decisions is more controversial. The conference began with an overview of HTA in the U.S. and Europe. It then examined opportunities and practical challenges for developing an expanded HTA capacity in the US.

¹ Definition adapted from *Etext on Health Technology Assessment (HTA) Information Resources*. National Information Center on Health Services Research and Health Care Technology (NICHSR).

I. Technology Assessment in the U.S.

Steven Pearson, Special Advisor to the Center for Medicare and Medicaid Services began the conference with a discussion of HTA's history in the U.S. and current trends. The federal government's first major HTA effort began with Congressional passage of the Food Drug and Cosmetics Act in 1938 which established many of the powers that define the modern Food and Drug Administration (FDA). The FDA's original mandate to review drug safety was expanded to include clinical effectiveness in 1962. In 1976, Congress further expanded the FDA's authority to regulate medical devices. Today all new prescription drugs and medical devices must be approved by the FDA prior to marketing to physicians or the general public. A variety of other federal technology evaluation efforts were initiated in the 1970s and 1980s including the Congressional Office of Technology Assessment (OTA), National Center for Health Care Technology (NCHCT), Office of Health Care Technology Assessment (OHCTA), and Agency for Healthcare Policy and Research (now AHRQ). Of these organizations, only AHRQ remains. The discontinued initiatives lacked a strong constituency and encountered intense opposition from groups like the American Medical Association and Health Industry Manufacturers Association. The OTA's observation that only 15 – 20 percent of medical practice is based on good clinical trials is emblematic of the controversies raised by "evidence-based medicine" and was one of the factors leading to its demise in 1995.

Many U.S.-based organizations conduct, sponsor or utilize HTA. More than 5,000 hospitals use HTA to help make technology investment decisions. The Centers for Medicare and Medicaid Services (CMS), state Medicaid programs, and private health plans use HTA to inform coverage and reimbursement decisions. HTA studies are mandated or sponsored by federal agencies like the Food and Drug Administration (FDA), Centers for Disease Control (CDC), Veterans Administration, and AHRQ; non-profit consortia like the Blue Cross and Blue Shield Technology Evaluation Center (BCBS-TEC), Oregon's Drug Effectiveness Review Project (DERP); drug and device companies, private HTA firms, and academic organizations. Payers and providers establish their own processes for reviewing evidence and making medical policy decisions. Some organizations have highly sophisticated technology review processes but many do not. The pluralism that characterizes the U.S. health care system extends into technology assessment with multiple users and suppliers of information.

U.S. health policy makers have been more ambivalent about using HTA, and in particular cost-effectiveness analysis, to inform coverage decisions than their counterparts in Europe. Many in the U.S. view HTA as more of a "pure science" than as a decision tool. Those who oppose expanded use of technology review for coverage decisions in the U.S. often focus on deficiencies in HTA methods rather than challenging its role in a broader social context.

Although politicians talk freely about the need to measure the effectiveness of health care interventions, Congress has provided very little funding for doing so. The 2003 Medicare Modernization Act (MMA) authorized the Agency for Health Care Research and Quality (AHRQ) to study "the outcomes, comparative clinical effectiveness, and appropriateness

of health are items and services (including prescription drugs).” Annual funding for this initiative is \$15 million, a modest investment compared to the expected \$500 billion cost of the new Medicare drug benefit over the next 10 years. Politicians have also set limits on how this new research can be used, specifying in law that “the Administrator of the CMS may not use data obtained in accordance with this section to withhold coverage of a prescription drug.”

HTA conducted in the U.S. has focused primarily on measuring clinical effectiveness. Despite the potential benefit of trying to evaluate the incremental value of spending on new technologies, policy makers have been reluctant to sponsor cost effectiveness analysis (CEA) or to use it explicitly to guide coverage decisions. On a number of occasions, federal officials have proposed cost effectiveness as a criterion for Medicare coverage of new technologies, but these recommendations have never been adopted.

Limited enthusiasm for health technology assessment and cost effectiveness analysis in the U.S. can be attributed to a variety of factors. Patient advocates fear that HTA and CEA could be used as a rationale for cost containment that could deny patients’ access to beneficial services. Physicians feel they are best positioned to make decisions about the risks and benefits of technologies for individual patients and do not want their discretion limited by third-party reviewers. Manufacturers argue that HTA slows down the rate at which they can bring new products to market, reducing the incentive for investments in innovation through increased costs and reduced revenue potential. Other stakeholders argue that methodologies other than randomized controlled trials (RCTs) are “not ready for prime time.”

National culture may be the most important factor behind America’s reluctance to embrace HTA. Americans place great value on individual choice and are distrustful of limits placed upon them by government or corporate bureaucrats. In other countries, finding the best way to use scarce resources (efficiency) or allocating resources towards those with the greatest unmet needs (equity) are more accepted aspects of health policy making.

Although federal investment in HTA remains modest, state and private initiatives are growing, particularly those evaluating prescription drugs. The most prominent effort is the Drug Effectiveness Review Project (DERP), a consortium that includes fifteen states and two non-profit organizations. DERP commissions systematic reviews for high priority drug classes through an evidence-based practice center (EPC). Reviews are published on a website maintained by the Center for Evidence-Based Policy at Oregon Health and Sciences University. Many of DERP’s members use the reviews to help structure Medicaid preferred drug lists or public employee drug benefit programs.

Many health plans are placing more emphasis on HTA as part of new “value-based” benefit initiatives. A number of plans have adopted the Academy of Managed Care Pharmacy (AMCP) formulary submission guidelines which require that pharmaceutical companies submit a standard dossier with information on a drug’s economic value, safety, and effectiveness relative to alternative therapies. The guidelines also ask for

information about unpublished studies and data on off-label indications. By 2002, more than 50 health plans, a variety of pharmacy benefit management (PBM) firms, and several public agencies had adopted the AMCP guidelines or some similar process. It is presently unknown how aggressively health plans are using these guidelines or the quality of dossiers submitted by pharmaceutical firms. Nevertheless, it is likely that health plans' will continue to demand more detailed information from pharmaceutical companies as a condition of formulary placement.

II. Technology Assessment in the UK and Europe

Sir Michael Rawlins, Chairman of Britain's National Institute for Health and Clinical Excellence (NICE) provided a perspective on technology assessment in Europe. All European countries have national health care systems and make explicit decisions about the type and level of publicly financed health care resources. In 2002, median per capita health spending in Organization for Economic Cooperation and Development (OECD) countries was \$2,193 compared with \$5,267 in the US. Median OECD health spending was 8.5 percent of GDP in 2002 compared with 14.6 percent of GDP in the US. Despite lower health spending, European countries are extremely concerned about the rate of cost growth. Most European policy makers view health technology assessment as an essential tool for evaluating societal health care resource allocation trade-offs.

NICE was established in 1999 as part of the British National Health Service (NHS) to provide guidance on the use of new medical technologies and management of specific conditions. NICE provides four general areas of guidance: appraisals of individual or classes of medical technologies (pharmaceuticals, devices, procedures, diagnostic tests); clinical guidelines for management of specific conditions; guidance on the safety and efficacy of interventional procedures including diagnostic procedures; and public health interventions such as needle exchange programs. NICE is explicitly required to consider both clinical and cost effectiveness as part of its technology appraisals.

NICE economic evaluations focus on the value of a particular service rather than its affordability. NICE does not explicitly consider the budgetary impact of new technologies, only whether they are cost effective. The NHS is responsible for the overall budget and could decide not to fund technologies that NICE has recommended as cost effective, however, it has not yet done so. Once NICE recommends a technology to the NHS, local health care bodies are required to provide funding for that technology within three months for patients that meet approved indications for treatment.

NICE appraisals examine the incremental cost effectiveness of new technologies – commonly based on the cost per quality-adjusted life year (QALY). As an operational rule of thumb, NICE uses a band ranging from about \$30,600 to \$45,900 per QALY as a general threshold for considering when a technology may be cost-ineffective². But decisions are made on a case-by-case basis. In general, as technologies become more

² Pearson SD Rawlins MD. Quality, innovation, and value for money: NICE and the British National Health Service. JAMA. 2005 Nov 23;294(20):2618-22.

expensive they must demonstrate a higher efficacy standard. NICE also considers such factors as the innovative nature of the technology, special features of the condition (e.g., prognosis, equity issues) and wider societal interests. NICE convenes a “citizen’s council” made up of 30 residents from around the UK to ensure that “preferences of people,” not just scientists are considered during the decision making process.

III. Considerations in Evaluating Clinical Effectiveness

Organizations like NICE that establish a clearly defined and reasonably transparent process for technology review can make difficult decisions more acceptable to the general public. Nevertheless, the science underlying technology review is frequently challenging. Professor Barbara McNeil from Harvard Medical School discussed sources of uncertainty facing decision-makers when using scientific evidence to make treatment and coverage decisions.

In an ideal world, coverage decisions would be supported by multiple large randomized controlled trials (RCTs) with consistent findings. This level of evidence is rarely available to decision makers in the real world. For example, decision makers may have data from only a single RCT. Although RCTs are considered the “gold standard” for clinical research, they are costly and time consuming. RCTs are often conducted with relatively small homogeneous patient populations that may differ from treatment populations in actual practice. RCTs may track patients for a relatively short time period and measure intermediate outcomes (e.g., lipid or blood pressure control) rather than longer term outcomes (e.g., heart attack or stroke). Because of this, results from RCTs may differ from effects observed in larger patient populations under normal practice conditions. To emphasize this point, Dr. McNeil cited an analysis of 49 highly cited clinical studies in the medical literature that found nearly one-third of the studies were later contradicted or shown to have stronger effects than shown subsequently.³ A single study, even if it is a RCT, may not be considered sufficient to support treatment or coverage decisions.

A second source of uncertainty comes when decision makers need to rely on studies other than randomized controlled trials. Some have suggested expanding the use of practical trials and observational studies to support decision making. However, observational data have a much larger possibility for bias when used to measure clinical efficacy. In the above-cited analysis of contradicted studies – conclusions based on observational data were more likely to be later contradicted than those from RCTs. Scientists disagree about the usefulness of observational data as part of an information “portfolio” for decision making. Policy makers lack a framework that can help them evaluate what types of decisions can be made with observational data at what level of accuracy. Nevertheless, there is growing pressure to incorporate a wider range of information into medical policy decisions. The new CMS policy of coverage with evidence development (CED) that will

³ Ioannidis JP. Contradicted and initially stronger effects in highly cited clinical research. JAMA. 2005 Jul 13;294(2):218-28.

collect registry data as a way to expedite coverage decisions is an important test of this approach.

Decision makers also face uncertainty when different sources of research have had conflicting conclusions about such expensive technologies as positron emission tomography (PET) scans and bariatric surgery. Even a single study may show that a treatment has both beneficial and negative outcomes. For example, a 5-year randomized trial found that transmyocardial revascularization (TMR) with coronary artery bypass graft (CABG) surgery resulted in less chest pain relief but greater long-term survival than CABG surgery alone.⁴ Individuals may weigh these outcomes differently, complicating policy determinations.

Decision makers face substantial pressures from patient groups, manufacturers, and politicians to cover new technologies and must consider trade-offs between making positive coverage decisions under uncertainty and requiring additional studies. Decision makers also grapple with “indication creep” as many technologies are used for populations or clinical indications beyond what they were originally approved for. It is extremely challenging for the current research enterprise to keep up with the rapid rate of biomedical advances. Even with new funding to accelerate clinical research, medical decision makers will continue to operate in an environment of incomplete information.

IV. Evidence Development and Evidence-Based Decision Making

Marc Berger, Vice President of Merck, began his remarks by commenting that before U.S. policymakers consider a national HTA capacity, progress is need to define what we mean by “evidence” and to clarify how this evidence will be used for decision making. Policy makers often frame questions that they would like to answer without establishing the level of evidence required to answer specific questions. Policy makers would be well served by identifying study designs and research methodologies appropriate to the questions they are trying to answer.⁵ For example, a higher standard of evidence (i.e., RCTs that permit attribution of causality with greater certainty) may be required when assessing the relative efficacy and safety of a treatment designed to treat large populations of asymptomatic patients and for which good treatment alternatives exist. Lower standards of evidence may be acceptable when assessing the efficacy and safety of treatments for fatal conditions for which there are no good existing therapies.

Scientific evidence is only one input into any decision making process. While scientific evidence is considered context-free, other kinds of evidence may project beyond the scientific data or rely on other relevant considerations including the values and preferences of stakeholders, equity issues, and budget constraints.⁶ Whereas there has

⁴ Allen KB et al. Adjunctive transmyocardial revascularization: five-year follow-up of a prospective, randomized trial. *Ann Thorac Surg.* 2004 Aug;78(2):458-65.

⁵ Teutch SM Berger ML Weinstein MC. Comparative effectiveness: asking the right questions, choosing the right method. *Health Aff (Millwood).* 2005 Jan-Feb;24(1):128-32.

⁶ Lomas J et al. Conceptualizing and Combining Evidence for Health System Guidance. Canadian Health Services Research Foundation. May 2005.

been much discussion of the appropriate use and limitations of scientific evidence, far less attention has focused on these other “types of evidence.” Organizations like the Cochran Collaboration have developed best practice guidelines for evidence reviews of RCTs. Similar guidance about best practices for evidence-based decision making have not emerged in the US. It can be argued that evidence-based decision making is a distinct process from that of evidence-based reviews or health technology assessments.⁷

Dr. Berger emphasized that ensuring accountability for reasonableness in decision making requires a process that clearly identifies the types of evidence reviewed and how key elements of evidence were applied in coming to a decision. This includes establishing appeals processes that permit stakeholders to challenge decision makers’ conclusions. Only through transparency and fair deliberations can decisions be viewed as legitimate in a pluralistic society.

The approaches of policymakers in the UK and the U.S. offer sharp contrasts. NICE and the National Health Service have established a process where technologies are reviewed through a well-defined and reasonably transparent process with broad stakeholder participation. Coverage decisions are subject to a flexible “value” standard where the NHS will generally not cover technologies that fall below the standard. Approved technologies are covered across the entire NHS. Although many aspects of the NICE review process are viewed favorably, most manufacturers are uncomfortable having the fate of their product determined by a single entity. In the U.S., manufacturers must seek coverage from multiple payers according to a standard of “reasonable and necessary” that may vary substantially across plans. Private payers are under no obligation to be transparent in their coverage determination process. However, neither public nor private payers in the U.S. have been willing to establish explicit “value” standards to guide coverage decisions.

V. Practical Considerations for Third Party Payers

Alan Rosenberg, Vice President of Wellpoint Inc. provided a payer perspective on technology assessment and medical policy development. According to Rosenberg, WellPoint’s mission is to “improve the lives of the people we serve and the health of our communities” and included as an important component of this benefit “support for appropriate technologies and procedures while maintaining affordability.”

Availability of high quality clinical evidence is important for the medical policy formation process. However, from a payer perspective other factors that influence this process are the health plan contract and benefit documents, the regulatory environment, and the way technologies are and are not able to be identified in the claim adjudication and utilization management processes.

⁷ Teutch SM Berger ML (b). Evidence synthesis and evidence-based decision making: related but distinct processes. *Med Decis Making*. 2005 Sep-Oct;25(5):487-9.

At Wellpoint, the technology review process begins by determining whether the plan can identify a specific technology or procedure through its claims system or one of its clinical review programs. In many cases, new technologies, particularly those without explicit billing codes such as medical equipment used in the hospital setting cannot be identified on health care claims. A significant portion of the cost of many new technologies is built into the rates negotiated by hospitals and other providers but which are not identifiable in the adjudication process. Given the limited information submitted through the claims process, payers may also have difficulty identifying when approved technologies are used for non-approved indications. A practical reality for payers is that if they can't readily identify a new technology in the claim adjudication or utilization management process, they can't readily review it.

Once payers identify a new technology, they must determine whether a review is an appropriate use of resources within the benefit plan. An important aspect of this is the cost of reviewing the claims submissions including the costs of clinical review, and the cost of the appeals process when it determines that a service is investigational or not medically necessary. These costs are compared with the potential savings from a determination that services are not medically necessary. Part of what increases the cost of review is the regulatory environment. For example, some states require mandatory use of specific external organizations for independent physician review of certain claims before they can be denied. In many states there are mandatory appeals requirements. These regulatory reviews may require as many as three external reviewers through the state mandated process, for which costs are borne by the plans. These requirements reduce the economic practicality for plans to manage certain types of high volume and low cost technologies.

A health plan's decision to develop a new medical policy also is dependent on the legal contract that defines the benefit plan for customer accounts. Benefit plan language generally covers "medically necessary" services and excludes investigational or experimental treatments. Benefit contracts frequently have specific exclusions (e.g., bariatric surgery) precluding the need for a medical policy. Provider contracts may also specify how the plan will reimburse and cover specific classes of technologies, limiting the need for a technology review.

WellPoint's Office of Medical Policy & Technology Assessment evaluates a wide array of information sources in its reviews including peer reviewed literature, national specialty society recommendations and information from independent technology assessment organizations including BCBS-TEC, Hayes, and NICE. At present, its reviews focus on evidence that a technology, device or procedure produces a net improvement in health outcome; in general it does not include cost-benefit analysis as part of coverage decisions. Wellpoint has established 250 to 300 consistent medical policies across its affiliated plans which it publishes on the plans' websites.

Rosenberg also stated that health plans are challenged keeping up with the rapid proliferation of new technologies. Consider the annual volume of medical devices

determinations made by from the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration.

- Approved 38 new medical devices (2005).
- Received 51 original applications for new devices (2004).
- Received 226 applications for investigational device exemptions (IDEs) to allow unapproved devices to be made available to patient s with life threatening conditions (2004).
- Recalled 437 devices (2004).
- Cleared 2,617 510(k) submissions for changes to an existing device that was previously approved.

The information generated by the regulatory approval process is frequently far more limited than what payers need for making coverage decisions. Drug manufacturers must demonstrate both safety and clinical efficacy relative to a placebo for FDA approval. Many medical devices come to market without even this requirement and simply are required to show that the device is safe and does what it claims to do, which may not prove clinical effectiveness. Through the 510(k) submission process devices may be approved without outcomes data - manufacturers only need to provide evidence to the FDA that the device is “substantially equivalent” to one that is already marketed. With the “incremental evolution” of medical devices, manufacturers regularly release newer and more costly versions of existing devices with little supplemental data payers can use to evaluate incremental value.

Rosenberg also pointed out that many new health care interventions are procedural. Examples include a variety of bariatric surgical approaches and bone marrow transplantation. There is no government approval process for new medical procedures in the absence of a device. Therefore much of our national health spending – medical treatments and surgical procedures are not subject to any formal governmental review and approval process. Medical and surgical procedures may be in use for many years before any systematic outcomes information is collected or published. This creates an important gap in health plans’ ability to establish evidence-based medical policies for both new and evolving procedures.

VI. Improving the Value of Health Technology Assessment for Decision Makers

Carolyn Clancy, Director of the Agency for Health Care Research and Quality (AHRQ) began her remarks by pointing out that just because technologies and services are covered doesn’t mean that they are used effectively. This is documented by the 2003 Rand study showing that U.S. adults only receive recommended care slightly more than half of the time. While improving the availability and quality of HTA is important, making sure the research is accessible to an audience of informed users who can help translate evidence into improvement is equally critical. This work takes place in an environment of constrained funding. While Congressional support for biomedical research has been strong, funding for health services research has been limited According to one estimate, 6 percent of U.S. health care resources are devoted to biomedical research while less than

one-tenth of one percent is spent on evaluating the effectiveness of new and existing treatments.⁸ Other challenges for technology assessment in the U.S. include:

- Focusing research on the most important user needs (i.e., asking the right questions).
- Ensuring that users are equipped to make best use of available information and translating research for multiple audiences.
- Accelerating practical studies to generate improved information for decision makers

Key elements of a clinical research strategy to promote effective health care includes priority setting, user education, methodology enhancements, and targeted funding for critical new studies.

Focusing clinical research on the top priorities of end users – particularly patients and physicians – is critical for promoting effective health care. Section 1013 of the MMA of 2003 authorized AHRQ to develop evidence on the comparative effectiveness of different approaches to treating high priority health problems. The Secretary of Health and Human Services conducted a priority setting process to identify the top 10 conditions affecting Medicare beneficiaries and research on these 10 priority areas is now underway at AHRQ’s Evidence-based Practice Centers (EPCs) and DEcIDE Network. Continuing to align the priorities of researchers, medical professionals, patients, and health policy makers will require more effective involvement of these stakeholders in all aspects of clinical research including priority setting, study design, and funding.

A second strategy to improve the value of HTA is ensuring that studies have an audience of informed decision makers. Scientific studies are often accompanied by substantial uncertainty. Even experts have difficulty deciding how research results apply to practical decisions. As consumers are enrolled in high-deductible products and other “consumer-directed” health plans the demand for comprehensible clinical information will grow. To begin addressing this need, AHRQ has established a new Clinical Decisions & Communications Science Center that will focus on translating scientific evidence for patients, providers and policy makers and to inform development of new health care information products and decision aids.

A third component of an effective health care strategy is developing simpler, less expensive methods for evaluating clinical effectiveness such as practical clinical trials and observational studies (i.e., registries). These methods are not considered reliable by some in the medical and scientific communities. A methods improvement strategy could include several components: clarifying the appropriate uses of different research methodologies (i.e., which methods can be used to answer which questions); improving the reliability of different methods; and establishing standards to increase the consistency and reliability of different types of non-RCT approaches.

⁸ Moses H et al. Financial anatomy of biomedical research. JAMA. 2005 Sep 21;294(11):1333-42.

AHRQ has established a new program to focus on practical studies called the DEcIDE Research Network. The network is made up of academic, clinic, and practice-based centers with access to electronic health information databases and capacity to conduct accelerated research. Using health information technology (HIT) to create detailed longitudinal patient data bases has great potential to increase the value of clinical research by reducing its cost. Doing so will require not only HIT infrastructure, but also standards for drawing consistent clinical data from these systems. As one step in this process, AHRQ has funded development of a new “how-to” reference manual to help organizations create patient registries including guidelines for how registry data can be used for valid scientific research.

The US has not established a coordinated capacity for health technology assessment because of concern that such a capacity would serve as a “gatekeeper” that could limit patients’ access to effective services. Some also fear that a national HTA strategy would limit regional variations based on patient needs or preferences, limit the decision making authority of state and local governments, or become a barrier to free enterprise. Because of this, regional HTA systems may be more acceptable. A decentralized HTA structure, however, has limitations. Rules and processes used to determine whether certain products and services are covered could vary across regions. Local, regional, or private HTA entities may be far less transparent than what would be required under a national model. Finally, it is likely that standards of evidence could be different across entities – creating inequities for both patients and manufacturers.

VII. Should the U.S. Establish a Coordinated National Technology Assessment Capacity?

Technology evaluation, adoption, and reimbursement decisions in the U.S. take place in a decentralized environment. Hundreds of health plans, thousands of hospitals, and millions of physicians and patients must assemble the available evidence, evaluate it according to their preferences and values, and make decisions. The current system provides less than the socially optimal level of information for decision makers while resulting in excessive costs and duplication as multiple organizations evaluate the same technologies at the same time.

There was no consensus among conference participants about whether the U.S. should establish a more coordinated HTA capacity. Proponents argued that doing so would lead to more efficient distribution of information across the U.S. healthcare system. A national or series of regional HTA organizations could become clearinghouses for technology reviews – assembling all of the relevant information in a format that would be easily accessible for a wide range of users. Such organizations could establish guidelines to ensure that technology reviews are conducted with high scientific standards and help users interpret study findings.

Critics of this concept fear that a nation HTA capacity could evolve into an entity that issues “all or nothing” coverage decisions. Any U.S.-based HTA entity would necessarily

differ from European organizations because it would serve a pluralistic multi-payer system rather than a unitary national health system. Coverage and reimbursement decisions would remain in the context of a free market and U.S.-based HTA organizations would primarily act as information resources. Nevertheless, skeptics worry that any prominent new HTA organization could lead to de-facto standards that would be widely adopted in the marketplace.

Few supporters of a formal HTA capacity believe that such a function could be effectively carried out by a federal agency. History has shown that federal HTA organizations willing to make unpopular decisions quickly find their funding at risk. Despite potential benefits, there appears to be little consensus in the U.S. for moving forward with an expanded HTA capacity. The success of NICE in the U.K. is predicated on a general consensus in British society about the need to obtain good value within a limited national health care budget. In the U.S., however, there is little desire for budget constraints. The national constituencies for access and choice continue to be stronger than the constituencies for value.

The voices for moving cautiously on HTA point to a need for advances in health services research before the country makes large new investments in HTA. From this perspective the federal government should continue to build on the types of activities underway at AHRQ – setting research priorities, educating users, improving methodologies, developing data collection standards, and funding selected research in areas of national interest. Nevertheless, as health spending rises, pressure will build for greater federal investment in technology assessment and practical clinical research. HTA is not a silver bullet for controlling health care costs. Nevertheless, demand for better information about the value of America's health care investment will continue to rise along with escalating concern over the economic impact of U.S. health care spending growth.

The Health Industry Forum

The Health Industry Forum is based at Brandeis University and is devoted to developing practical, actionable, market-oriented strategies to improve the quality and value of the U.S. healthcare system. The Forum's charter members include Aetna Inc., Johnson & Johnson, HIP Healthplan of New York, Lifemasters Supported Selfcare Inc., Merck & Company, Novartis Pharmaceuticals Corporation, and Wellpoint Inc. The Forum also receives generous support from Blue Cross & Blue Shield of Massachusetts, Cigna Healthcare, Kaiser Health Plans, Partners Healthcare, Pfizer, Inc., Schering-Plough Corporation, and Wyeth. This synopsis was prepared by Robert Mechanic based on the Forum's April 4, 2006 meeting on the Future of U.S. Health Technology Assessment and subsequent discussions with conference speakers.