

The History of Technology Assessment and Comparative Effectiveness Research for Drugs and Medical Devices and the Role of the Federal Government

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I. INTRODUCTION

ONE OF THE MAIN CRITICISMS of the health care system in the United States is that it spends too much while achieving too little. Reports consistently indicate that the U.S. spends a greater percentage of its gross domestic product (GDP) on health care and has higher health expenditures per capita than any other industrialized country.¹ However, these high levels of spending have not necessarily produced better health outcomes or improved access to care. Evidence indicates that the U.S. achieves health outcomes similar to those of other industrialized countries that spend far less on health care.² Furthermore, for certain outcome indicators, such as the infant mortality rate, the U.S. performs particularly poorly.³

One of the contributors to increases in health care expenditures in the U.S. is new technology in the form of new drugs and medical devices.⁴ These generally are more costly than previously approved technologies.⁵ However, under the current framework of regulation, it is difficult to evaluate whether these new technologies are actually superior to existing treatments.⁶ Inability to make these comparisons may lead to unjustified increases in health care expenditures in a technological climate where a “few products will be breakthroughs that improve health outcomes; [and] most will offer little, if any, advantages over existing treatments.”⁷

In recent years, researchers, patient groups, government officials, professional associations, and other stakeholders in the healthcare system have focused on the concepts of health technology as-

essment (HTA) and comparative effectiveness research (CER) as means of decreasing health care expenditures in the United States. Health technology assessment has been defined as “a form of policy research that examines the short- and long-term consequences of the application of a health-care technology.”⁸ Comparative effectiveness research

¹See WORLD HEALTH ORGANIZATION, WORLD HEALTH STATISTICS 2013 131–9 (2013); *OECD Health Data 2013: How Does the United States Compare*; available at www.oecd.org/unitedstates/Briefing-Note-USA-2013.pdf (last visited Apr. 5, 2014). According to the Organisation for Economic Co-operation and Development (OECD), the U.S. spent US\$8,508 per capita on health in 2011, whereas the next highest spending per capita in the OECD was in Norway, which spent the equivalent of US\$5,669. *Id.*

²See DAVID A. SQUIRES, THE COMMONWEALTH FUND, THE U.S. HEALTH SYSTEM IN PERSPECTIVE: A COMPARISON OF TWELVE INDUSTRIALIZED NATIONS 2 (2011); *c.f.* David M. Cutler, *Equality, Efficiency, and Market Fundamentals: The Dynamics of International Medical-Care Reform*, 40 J. ECON. LIT. 881, 894 (2002).

³See, *e.g.*, Starfield B. Is US health really the best in the world? *JAMA* 2000;284:483; Murray CJL *et al.* Ranking 37th: measuring the performance of the U.S. health care system. *N Engl J Med* 2010;362:98 (noting that in 2006, the United States was “number 1 in terms of health care spending per capita but ranked 39th for infant mortality”).

⁴Stafford RS, *et al.* New, but not improved? Incorporating comparative-effectiveness information into FDA labeling. *N Engl J Med* 2009;361:1230.

⁵*Id.* at 1231.

⁶*Id.* at 1230.

⁷*Id.* at 1232.

⁸Sean D. Sullivan *et al.*, *Health Technology Assessment in Health-Care Decisions in the United States*, 12 VALUE HEALTH S39, S39 (2009); see also OFFICE OF TECHNOLOGY ASSESSMENT, DEVELOPMENT OF MEDICAL TECHNOLOGY: OPPORTUNITIES 4 (1976).

is an activity closely related to HTA, which the Institute of Medicine defined as:

the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist customers, clinicians, purchasers, and policy-makers to make informed decisions that will improve health care at both the individual and population levels.⁹

Health technology assessment and CER have been portrayed as potential avenues by which to obtain information to make informed, evidence-based decisions with the aim of improving health outcomes and containing healthcare costs.¹⁰ The use of such information seems particularly beneficial given that currently, “less than half of medical care in the United States is based on or supported by evidence about its effectiveness, resulting in care that is inappropriate and unnecessary.”¹¹ In recent years, many stakeholders in the health care system have called on the federal government to establish a sustainable national program of HTA or CER.¹² These efforts culminated in the establishment of the Patient-Centered Outcomes Research Institute (PCORI) in 2010. Its purpose is to fund and oversee CER at the national level.¹³

Although there has been an increased drive for federal support of HTA and CER in the past several years, HTA, in fact, has a long (though fragmented) history of federal funding in the U.S. dating back to the 1970s.¹⁴ Federal agencies that have played a major role in HTA in the past include the Office of Technology Assessment, the National Institutes of Health, and the Agency for Health Care Policy and Research.¹⁵ The Food and Drug Administration (FDA), in contrast, has traditionally played a more limited role in HTA and CER activities.¹⁶ Some commentators, noting that the FDA is the primary federal regulator of drugs and medical devices, have called on the agency to play a more active role in promoting HTA and CER.¹⁷

This paper explores the history of HTA and CER in the U.S. with a particular emphasis on the role of federal agencies within the executive and legislative branches. Part II gives a brief history and overview of the concepts of HTA and CER. Part III examines the roles that various federal agencies and initiatives have played in generating HTA or CER and applying their results to health care decisions. To illustrate the historical development of HTA and CER, agencies are discussed chronologically, with refer-

ence to their involvement with HTA or CER activities. Part IV discusses past challenges that the federal HTA and CER funding faced, as well as the implications of such challenges for current federal CER efforts. Part V highlights potential HTA or CER strategies that the federal government could pursue in the future. Particular focus is given to the potential role of using HTA or CER in the regulation of therapeutic drugs and medical devices.

II. DEVELOPMENT OF THE TERMINOLOGY

The terms “HTA” and “CER” are often used to describe activities that generate or use evidence to make healthcare decisions. Although HTA and CER are closely related conceptually, the terms describe arguably distinct, although often overlapping, activities.¹⁸ The inconsistent and imprecise use of these terms has sometimes led to confusion among stakeholders.¹⁹ What follows, then, is an overview of the origin and development of the terms “HTA” and “CER,” as well as an attempt to understand more precisely the similarities and differences between them.

⁹COMMITTEE ON COMPARATIVE EFFECTIVENESS RESEARCH PRIORITIZATION, INSTITUTE OF MEDICINE, INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 41 (2009).

¹⁰See, e.g., Lucien Wulsin, Jr. and Adam Dougherty, CALIFORNIA RESEARCH BUREAU, A BRIEFING ON HEALTH TECHNOLOGY ASSESSMENT 1 (2008).

¹¹Corinna Sorenson et al., *The Politics of Comparative Effectiveness Research: Lessons from Recent History*, 39 J. HEALTH POL. POL’Y & L 140, 141 (2013); see also Elizabeth A. McGlynn and Robert H. Brook, *Keeping Quality on the Policy Agenda*, 20 HEALTH AFFAIRS 82, 83 (2002).

¹²See, e.g., COMMITTEE ON COMPARATIVE EFFECTIVENESS RESEARCH PRIORITIZATION, *supra* n. 9, at 142.

¹³Sorenson et al., *supra* n. 11, at 140.

¹⁴Sullivan et al., *supra* n. 8, at S39.

¹⁵David Banta, *The Development of Health Technology Assessment*, 63 HEALTH POL’Y 121, 125 (2003).

¹⁶Sullivan et al., *supra* n. 8, at S41.

¹⁷See, e.g., Stafford et al., *supra* n. 4, at 1230; Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WISC LAW REV 2011.

¹⁸Sorenson et al., *supra* n. 11, at 143–144.

¹⁹See Bryan R. Luce et al., *EBM, HTA, and CER: Clearing the Confusion*, 88 MILBANK Q. 256, 257 (2010); see also Erwin R. Blackstone et al., *Will Comparative Effectiveness Research Finally Succeed*, BIOTECHNOLOGY HEALTHCARE, Fall 2012, at 22 (suggesting that HTA, outcomes research, EBM, and CER describe the same activity, with use varying over different time periods).

Health technology assessment was the first of these terms to be developed. Use of the more general term “technology assessment” (TA) began in the mid-1960s.²⁰ At that time, when technology was beginning to play an increasingly important role in society, there was a growing recognition that new technologies could have undesirable consequences.²¹ Furthermore, stakeholders appreciated that decision-makers did not have adequate means to evaluate the broad social effects of new technologies, which could result in the overutilization of some technologies and the underutilization of others.²² The term “TA” was coined by Representative Emilio Q. Daddario, then Chairman of the Subcommittee on Science, Research, and Development of the Committee on Science and Astronautics of the U.S. House of Representatives, to describe the “sociotechnical research that discloses the benefits and risks to society emanating from alternative courses in the development of scientific and technological opportunities.”²³

Around the same time, there was an increasing push for healthcare to be based on scientific evidence. In the early 1970s, two prominent members of the healthcare community, Archie Cochrane and Jack Wennberg, published influential articles identifying the problems of unjustified variations in healthcare and the lack of evidence verifying the effectiveness of many standard medical practices.²⁴ This type of research led to the emergence of the evidence-based medicine (EBM) movement, which seeks to ground medical practice in scientific evidence, with the goal of improving individual patient health outcomes.²⁵

It was against this backdrop that the notion of using empirical evidence to formulate health policy first took root. Healthcare technologies were the subject of early TAs, and the term “HTA” came to be used to describe TAs that were specifically focused on healthcare technologies ranging from drugs and devices to procedures and systems of organization.²⁶ The term “HTA” soon spread to other industrialized countries, many of which established offices or agencies dedicated to HTA that continue to play a major role in domestic healthcare policy-making.²⁷ In the U.S., however, many HTA efforts have been discontinued, and the concept does not appear to have ever been effectively established within the national government.²⁸ At present, the term appears to have fallen into disfavor in the U.S., as it has been replaced with other terms such as “CER,” “outcomes research,” and “effectiveness research.”²⁹

Comparative effectiveness research is a newer term that has been the subject of much attention in recent years as a result of care reform efforts. The term was coined around the early 1990s.³⁰ Many of the early CER efforts were private endeavors undertaken

by entities such as insurance providers.³¹ Since then, CER has come into focus out of a desire to contain the ever-increasing costs of medical care and redoubled efforts to improve medical decision-making.³² Recently, several attempts have been made to persuade the federal government to establish a national center for CER resulting in the establishment of PCORI in 2010.³³

²⁰Clifford S. Goodman, THE LEWIN GROUP, HTA 101: INTRODUCTION TO HEALTH TECHNOLOGY ASSESSMENT 10 (2004); available at www.nlm.nih.gov/nichsr/hta101/hta101.pdf

²¹See Harvey Brooks and Raymond Bowers, *The Assessment of Technology*, SCI. AM., Feb. 1970, at 13, 13; Emilio Q. Daddario, *Technology Assessment—A Legislative View*, 36 GEO. WASH. L. REV. 1044, 1046–1047 (1967–1968).

²²*Id.* at 14.

²³COMMITTEE ON PUBLIC ENGINEERING POLICY, NATIONAL ACADEMY OF ENGINEERING, A STUDY OF TECHNOLOGY ASSESSMENT 2 (1969); see Norman J. Vig and Herbert Paschen, PARLIAMENTS & TECHNOLOGY: THE DEVELOPMENT OF TECHNOLOGY ASSESSMENT IN EUROPE 3 (2000); Goodman, *supra* n. 20 at 10.

²⁴Berger ML, Grainger D. Comparative effectiveness research: the view from a pharmaceutical company. *Pharmacoeconomics* 2010;28:915–916; see Cochrane AL. Effectiveness & efficiency: random reflections on health services. Nuffield Provincial Hospitals Trust, 1972, p 86; Wennberg J, Gittelsohn A. Small variations in health care delivery. *Science* 1973;182:1102, 1107.

²⁵See Banta, *supra* n. 15, at 124; Berger and Granger, *supra* n. 24 at 916.

²⁶See Goodman, *supra* n. 20, at 11; Luce *et al.*, *supra* n. 19 at 258.

²⁷See Banta, *supra* n.15, at 124 (noting that during the 1990s, almost all member states of the European Union had national and regional HTA agencies or programs); Luce *et al.*, *supra* n. 19 at 258; Sullivan *et al.*, *supra* n. 8 at S39 (indicating that 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] all have national HTA programs).

²⁸See Banta, *supra* n. 15, at 124; Sullivan *et al.*, *supra* n. 8 at S39.

²⁹Luce *et al.*, *supra* n. 19, at 258.

³⁰American Society of Clinical Oncology. Comparative effectiveness: its origin, evolution, and influence on health care. *J Oncol Pract* 2009;5:80.

³¹Marko NF, Weil RJ. An introduction to comparative effectiveness research. *Neurosurgery* 2012;70:425, 427.

³²*Id.* at 426.

³³Kalipso Chalkidou, *et al.*, *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience from Four Countries*, 87 MILBANK Q. 339, 342 (2009)(noting that legislation to “establish an entity that would deliver CER information to decision makers” was introduced several times in 2007 and 2008 before President Obama signed the American Recovery and Reinvestment Act, which provided funds for CER, in 2009).

Although HTA and CER address similar questions, they are nevertheless thought to be distinct terms.³⁴ The framework offered by Luce *et al.* elucidates the primary differences between them.³⁵ Under that framework, HTA is a method of evidence synthesis that is concerned with evaluating the overall worth of a given intervention.³⁶ Health technology assessment considers evidence concerning cost-effectiveness, safety, and clinical effectiveness and can also include the social, ethical, and legal aspect of using health technologies.³⁷ Comparative effectiveness research, by contrast, includes evidence generation as well as evidence synthesis, and focuses on comparing two or more medical interventions in routine practice settings.³⁸ The outputs can be valuable in developing clinical guidelines, EBM, and HTA.³⁹ Thus, a significant difference between the two terms is that HTA generally includes economic cost-effectiveness inputs, while CER generally does not.⁴⁰

In the following discussion of HTA and CER efforts by federal agencies, this paper will reference the terms that were used at the time a particular initiative was implemented.

III. HTA AND CER AND ROLE OF FEDERAL AGENCIES

A. The Food and Drug Administration

Although the FDA is the primary federal regulator of drugs and medical devices, it plays a minimal role in funding and regulating formal HTA or CER activities.⁴¹ The Food, Drug, and Cosmetic Act (FDCA) of 1938 established the foundations of the FDA's current approach to the regulation of drugs and medical devices.⁴² The FDCA initially required pre-market safety notification to the FDA for all new drugs.⁴³ In addition to prohibiting deceptive or false labeling, the Act had affirmative labeling requirements for drugs and devices.⁴⁴ The Act did not require pre-market testing of medical devices. Congress has amended the FDCA many times since its passage, with the effect of expanding and strengthening the FDA's regulatory authority.⁴⁵

Under the current regulatory framework, manufacturers of drugs and medical devices must demonstrate that the products are safe and effective for their intended use in order to receive approval for market entry.⁴⁶ The FDA does not require drug or device developers to perform HTA or CER as a precondition of gaining market approval for their technologies. For approval of new drugs,

the FDA reviews pre-market studies of safety and efficacy submitted by manufacturers in connection with their applications for approval.⁴⁷ Within the FDA, the Center for Drug Evaluation and Research (CDER) is the specific division that evaluates new drug applications.⁴⁸ The focus of the FDA's review process for new drugs is on the results of Phase III human trials, which are aimed at determining the dose at which a drug is effective for its intended use.⁴⁹ The "gold standard" for such trials is the randomized, double-blind, placebo-controlled trial.⁵⁰ Thus, drugs are typically approved on the basis of their statistical superiority over an inactive

³⁴See, e.g., Berger and Grainger, *supra* n. 24 at 917; Prasan Subedi *et al.*, *Something Old, Something New, Something Borrowed...Comparative Effectiveness Research: A Policy Perspective*, 17 J. MANAGED CARE S5, S5 (2011).

³⁵See Luce *et al.*, *supra* n. 19, at 267–71.

³⁶See *id.* at 271.

³⁷*Id.* (noting that the precise inputs that go into an individual HTA depend on its purpose).

³⁸*Id.*

³⁹*Id.*

⁴⁰Sorenson *et al.*, *supra* n. 11, at 144.

⁴¹The FDA does help to fund and support the Centers for Education and Research on Therapeutics, which is discussed in Part H of this Section. However, the program is administered by the Agency for Health Care Quality and Research. Judith M. Kramer *et al.*, *Centers for Education and Research on Therapeutics (CERTs)*, 36 THERAPEUTIC INNOVATION & REG. SCI. 717, 717 (2002).

⁴²See Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 USC §§301–399 (2000)).

⁴³See *id.* at 1052–53.

⁴⁴See *id.* at 1050–51.

⁴⁵See Peter B. Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 435 (2008) (describing Congress's expansion of the FDA's statutory mandate since the passage of the FDCA); Efthimios Parasidis, *supra* n. 17 (discussing the evolution of the FDA's statutory authority).

⁴⁶21 USC §355 (b)(2011); see 21 USC §360c (2011); Hutt, *supra* n. 45, at 435.

⁴⁷Sullivan, *supra* n. 8, at S41.

⁴⁸See *About the Center for Drug Evaluation and Research*, FDA; available at www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/default.htm (last visited Apr. 14, 2014).

⁴⁹JAMES T. O'REILLY, FOOD AND DRUG ADMIN. §13:80 (3d ed. 2013).

⁵⁰Jonathan J. Darrow, *Pharmaceutical Efficacy: The Illusory Legal Standard*, 70 WASH. & LEE L. REV. 2073, 2090 (2013).

placebo or, in occasional cases, an established drug for the same indication.⁵¹ Generally speaking, then, there usually is no requirement for a manufacturer to demonstrate that a new drug is superior to existing treatments in order to be approved.⁵² In addition to the premarket requirements for new drugs, the FDA requires post-market activities for approved drugs.⁵³ For most drugs, these requirements take the form of passive monitoring of adverse drug events.⁵⁴ Post-market activities required by the FDA generally are not aimed at gathering data for comparative purposes but instead at identifying safety risks.

The majority of new medical devices are subject to fewer pre-market requirements than new drugs. Under the current framework of medical device regulation, the FDA divides new devices into one of three regulatory classes (I, II, and III), each class level reflecting the device's expected risk.⁵⁵ New devices enter the market either through a showing of "substantial equivalence" to a previously approved, legally marketed device (510(k) pathway) or through a Premarket Approval Application (PMA), which requires demonstration of the safety and effectiveness of a device through clinical data.⁵⁶ Most new medical devices receive approval for market entry via the 510(k) pathway, which generally does not require the submission of safety or efficacy data.⁵⁷ Within the FDA, the Center for Devices and Radiological Health (CDRH) has primary responsibility for overseeing the pre-market approval process for medical devices.⁵⁸ This center also is tasked with monitoring approved devices through a post-market surveillance system.⁵⁹ However, like its approach to the post-market surveillance of drugs, the FDA's approach to the post-market surveillance of medical devices is largely passive. For example, device manufacturers, academics, and clinical investors are much more likely to identify safety problems and initiate potential device recall than is the FDA itself.⁶⁰

B. Office of Technology Assessment

In 1967, Representative Daddario introduced a bill to establish a Technology Assessment Board that would serve as a congressional information agency to "provide a method for identifying, assessing, publicizing, and dealing with the implications and effects of applied research and technology."⁶¹ When Daddario introduced the bill, his purpose was to stimulate discussion rather than to enact a perfected piece of legislation.⁶² Previously, there had been other efforts to establish an entity that would advise Congress on scientific and technical

matters, but none of these efforts was framed in the language of TA.⁶³ Daddario's bill and the earlier efforts seem to have been introduced in response not only to a recognition of the potential negative consequences of newly emerging technologies, but also to the Executive's perceived superior access to technical and scientific advice *vis-à-vis* that of Congress.⁶⁴ Members of Congress were concerned that the Executive's privileged position was interfering with their ability to evaluate and potentially

⁵¹Stafford *et al.*, *supra* n. 4 at 1231. Commentators have criticized the FDA for relying mainly on placebo-controlled trials in the drug approval process. *See, e.g.*, Stafford *et al.*, *supra* n. 4. Some commentators have suggested that such trials are generally unethical when there is an effective therapy available for use in an active-comparator trial; hence, the occasional use of another drug rather than a placebo, especially when the condition being treated is likely to be fatal in the absence of active treatment. *See, e.g.*, Rothman KJ, Michels KB. The continuing unethical use of placebo controls. *N Engl J Med* 1994;331:394–5. Others have suggested that allowing drug manufacturers to submit only results from placebo-controlled trials when an active-comparator trial would have been possible favors creation of drugs that are only minimally different from existing therapies and dampens clinical innovation. *See* Stafford *et al.*, *supra* n. 4, at 1231.

⁵²Sullivan, *supra* n. 8, at S41.

⁵³*See* Continuation of long-term studies, records, and reports on certain drugs for which new drug applications have been approved, 21 CFR §310.303 (1999).

⁵⁴*See* Parasidis, *supra* n.17, at 950–3 (giving a detailed description of the FDA's post-market requirements and initiatives).

⁵⁵21 USC §360c (2011).

⁵⁶Maisel WH. Medical device regulation: an introduction for the practicing physician. *Ann Intern Med* 2004;140:296–8. For detailed discussion of current medical device regulation, *see* Jordan Bauman, *The "Déjà Vu Effect": Evaluation of United States Medical Device Regulation*, 67 *FOOD & DRUG L. J.* 337 (2012).

⁵⁷Feldman MD *et al.* Who is responsible for evaluating the safety and effectiveness of medical devices? The role of independent technology assessment. *J Gen Intern Med* 2007; 23(Suppl 1):57, 58.

⁵⁸*See* *About the Center for Devices and Radiological Health, FDA*; available at www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ (last visited Apr. 14, 2014).

⁵⁹*See id.*

⁶⁰*See* Feldman *et al.*, *supra* n. 57, at 58.

⁶¹Daddario, *supra* n. 21, at 1045–7.

⁶²*Id.* at 1046.

⁶³*See* Gregory C. Kunkle, *New Challenge of the Past Revisited? The Office of Technology Assessment in Historical Context*, 17 *TECH. SOC'Y* 175, 177 (1995).

⁶⁴*See* Daddario, *supra* n. 21, at 1047; Kunkle, *supra* n. 63, at 177–8.

push back on executive actions concerning technological matters.⁶⁵

After Daddario's introduction of the bill, the Subcommittee on Science, Research, and Development requested that the National Academy of Sciences, the National Academy of Engineering, the National Academy of Public Administration, and the Science Policy Research Division of the Legislative Reference Service of the Library of Congress (now the Congressional Research Service [CRS]) convened panels to evaluate how to approach TA.⁶⁶ The reports of these panels, in conjunction with other Congressional hearings convened by the Subcommittee, subsequently led to the introduction by Daddario and Representative Charles A. Mosher of H.R. 17046. This bill, which was passed in 1972, would later authorize the establishment of the Office of Technology Assessment (OTA).⁶⁷ The establishment of OTA was not without opposition: various members of Congress objected to the creation of such an entity on the grounds that it would lead to too much interference by the government with innovation, be duplicative of the work of other agencies, waste money, and infringe on congressional power.⁶⁸

While its authorizing legislation was passed in 1972, OTA did not become operational until 1974.⁶⁹ It was overseen by a bipartisan Technology Assessment Board (TAB) comprised of a director, six Senators, and six Representatives.⁷⁰ Daddario was appointed OTA's first director.⁷¹ Within OTA resided the Technology Assessment Advisory Council (TAAC), an advisory body whose membership comprised primarily scientific and technological experts, and whose purpose was to counsel the TAB on activities undertaken by the Office.⁷² In practice, the TAB sharply limited the role of the TAAC.⁷³

The OTA, generally at the request of Congressional committees, compiled TAs and technology-related policy reports relating to legislative policies that were in development or under review.⁷⁴ During its existence from 1972 to 1975, OTA produced more than 750 reports.⁷⁵ The OTA staff compiled these documents with the assistance of advisory panels and input from industry, consumer, academic, private sector, and public sector stakeholders.⁷⁶ These reports were extensively peer-reviewed.⁷⁷ The reports did not make recommendations; instead, they presented the views of various stakeholders, described a range of policy options for Congressional consideration, and surveyed the costs and consequences of each option.⁷⁸ These reports considered many factors including, *inter alia*, cost-effectiveness, clinical trial results, ethical implications, legal implications, consensus methods, and systems analysis.⁷⁹

At its peak, OTA produced upwards of 50 reports annually, had a budget of around \$20 million, and employed a staff of about 200.⁸⁰

The OTA played a large role in defining the concept of HTA, and its reports often focused on health technology.⁸¹ In fact, OTA's very first report was health technology-related, focusing on bioequivalence and the viability of generic drugs.⁸² The OTA comprised nine programs, of which two related to health technology: the Health and the Biological Applications programs.⁸³ The agency defined medical technology broadly as "the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the systems within which such care is delivered."⁸⁴ Over time, OTA produced

⁶⁵Kunkle, *supra* n. 63, at 177–8.

⁶⁶See Brooks and Bowers, *supra* n. 21, at 13; Goodman, *supra* n. 20, at 10; Roger C. Herdman and James E. Jensen, *The OTA Story: The Agency Perspective*, 54 TECHNOLOGICAL FORECASTING & SOC. CHANGE 131, 133 (1997).

⁶⁷See The Technology Assessment Act of 1972, Pub. L. No. 92-484, 86 Stat. 797; *A Bill to Establish an Office of Technology Assessment for the Congress as an Aid in the Identification and Consideration of Existing and Probable Impacts of Technological: Hearing on H. R. 17046 Before the Subcomm. on Sci. Research, & Dev. of the Comm on Sci. & Astronautics*, 91st Cong. 3 (1970)(statement of Elmer B. Staats, Comptroller Gen. of the United States); Kunkle, *supra* n. 63 at 180.

⁶⁸Kunkle, *supra* n. 6,3 at 180–2.

⁶⁹*Id.* at 184.

⁷⁰The Technology Assessment Act, 86 Stat. at 798.

⁷¹Kunkle, *supra* n. 63, at 186.

⁷²Technology Assessment Act, 86 Stat. at 801–2.

⁷³Kunkle, *supra* n. 63, at 186–7.

⁷⁴See Roger Herdman, *The Living History of Technology Assessment Organizations*, ECRI INSTITUTE 15TH ANNUAL CONFERENCE SESSIONS 8 (2007); available at https://www.ecri.org/comparativeeffectiveness/Pages/Comparative_Effectiveness_Presentations.aspx; Sullivan, *supra* n. 8, at S39.

⁷⁵Herdman and Jensen, *supra* n. 66, at 138–9; see *OTA Publications*, PRINCETON UNIV.; available at https://www.princeton.edu/~ota/ns20/pubs_f.html (last visited Apr. 15, 2014).

⁷⁶*Id.*

⁷⁷Herdman and Jensen, *supra* note 66, at 138.

⁷⁸*Id.* at 136.

⁷⁹See Goodman, *supra* n. 20, at 11.

⁸⁰Herdman, *supra* n. 74, at 8; Sullivan, *supra* n. 8, at S39.

⁸¹See Banta, *supra* n. 15, at 123.

⁸²DRUG BIOEQUIVALENCE STUDY PANEL, OFFICE OF TECH. ASSESSMENT, DRUG BIOEQUIVALENCE (1974).

⁸³Herdman, *supra* n. 74, at 8.

⁸⁴OFFICE OF TECH. ASSESSMENT, DEVELOPMENT OF MEDICAL TECHNOLOGY: OPPORTUNITIES FOR ASSESSMENT 4 (1976).

numerous reports dealing with various health technology matters, including cholesterol screening,⁸⁵ HIV vaccines,⁸⁶ special care units for patients with Alzheimer's disease,⁸⁷ screening and treatments for osteoporosis,⁸⁸ and genetic testing.⁸⁹

An early example of an HTA by OTA was its 1978 report on computed tomography (CT) scanning.⁹⁰ In the report, OTA provided an overview of CT scanning and its principles, as well as an assessment of the safety and efficacy of the technology.⁹¹ The report also examined the distribution of CT scanners and their patterns of use⁹² and reviewed data on the expenses, charges, and profits of CT scanning.⁹³ The report then presented policy alternatives for Congress to consider.⁹⁴ In this section, OTA identified problems concerning the use of CT scanners and diagnostic medical technologies. The Office pointed out that many of the decisions concerning medical technologies were not based on evidence, but rather were informal *ad hoc* judgments that could contribute to excessive or inappropriate use.⁹⁵ Furthermore, the report indicated that existing incentives often encouraged the inappropriate use of technology.⁹⁶

The report also provided various policy alternatives to ensure the proper and economically judicious use of technologies such as CT scanning. The policy recommendations fell into three main categories. First, OTA suggested that the federal government could strengthen its information provision capabilities in the area of medical technologies.⁹⁷ For example, OTA proposed creating of an official government agency that would perform research on the safety and efficacy of medical technologies and collect more extensive data than required by the FDA for market approval.⁹⁸ The proposed agency would take into account the effects of the populations being treated, the particular medical problem, and the conditions of use and then disseminate the results of its research to the medical community.⁹⁹ In addition, such an agency could make formal judgments about the value of medical technologies, although compliance by medical professionals would be voluntary.¹⁰⁰ Second, OTA suggested stricter government regulation as a possible means to moderate the use of technologies such as CT scanning.¹⁰¹ For example, the FDA (or another federal agency) could be authorized to restrict the use of medical technologies to the intended uses specified on any FDA-approved labeling.¹⁰² Third, OTA suggested that reimbursement mechanisms could be used to discourage inappropriate use of CT scanning and other technologies.¹⁰³ For example, a potential option would be to establish rates of payment for Medicare and Medicaid based on ef-

ficient use of medical technology.¹⁰⁴ The report identified many issues with the practice of medicine and highlighted how medical devices frequently entered widespread use without consensus understanding or complete information regarding the benefits of the drugs and medical devices.¹⁰⁵

The CT scanning report, which critically depicted the largely uninformed use of medical technology, and as well as subsequent reports that made similar observations, soon made OTA unpopular with both the medical profession and drug and device manufacturers.¹⁰⁶

⁸⁵OFFICE OF TECH. ASSESSMENT, COSTS AND EFFECTIVENESS OF CHOLESTEROL SCREENING IN THE ELDERLY (1989).

⁸⁶OFFICE OF TECH. ASSESSMENT, ADVERSE REACTIONS TO HIV VACCINES: MEDICAL ETHICAL AND LEGAL ISSUES (1995).

⁸⁷OFFICE OF TECH. ASSESSMENT, SPECIAL CARE UNITS FOR PEOPLE WITH ALZHEIMER'S AND OTHER DEMENTIAS: CONSUMER EDUCATION, RESEARCH, REGULATORY AND REIMBURSEMENT ISSUES (1992).

⁸⁸OFFICE OF TECH. ASSESSMENT, EFFECTIVENESS AND COSTS OF OSTEOPOROSIS SCREENING AND HORMONE REPLACEMENT THERAPY, VOL. I: COST-EFFECTIVENESS ANALYSIS (1995).

⁸⁹OFFICE OF TECH. ASSESSMENT, GENETIC TESTS AND HEALTH INSURANCE: RESULTS OF A SURVEY (1992). For a listing of OTA's publications see Princeton University's website *The OTA Legacy*, which includes a complete collection of OTA publications along with additional materials about the Office and its work. See *The OTA Legacy*, PRINCETON UNIV.; available at <https://www.princeton.edu/~ota/> (last visited Apr. 15, 2014).

⁹⁰OFFICE OF TECH. ASSESSMENT, POLICY IMPLICATIONS OF THE COMPUTED TOMOGRAPHY (CT) SCANNER (1978). With the profound advances in CT technology that have taken place in recent years, the conclusions of this report may presently be of little value. However, the report is a good example of the analysis and factors considered by OTA in making recommendations concerning emerging health technologies.

⁹¹See *id.* at 15–43.

⁹²See *id.* at 47–78.

⁹³See *id.* at 81–101.

⁹⁴See *id.* at 105–19.

⁹⁵*Id.* at 106.

⁹⁶*Id.* at 117.

⁹⁷*Id.* at 107.

⁹⁸*Id.* at 109.

⁹⁹*Id.*

¹⁰⁰*Id.* at 109–10.

¹⁰¹*Id.* at 111.

¹⁰²*Id.*

¹⁰³*Id.* at 117.

¹⁰⁴*Id.* at 117–8.

¹⁰⁵*Id.* at 6.

¹⁰⁶See John M. Eisenberg and Deborah Zarin, *Health Technology Assessment in the United States*, 18 INT'L J. OF TECH. ASSESSMENT IN HEALTH CARE 192, 194 (2002).

Political pressure from the health technology industry, as well as controversy over OTA's inclusion of cost and cost-effectiveness data, helped lead to the Office's closure in 1995.¹⁰⁷ However, there were other factors that contributed to its demise. One factor was budgetary and domestic political concerns. After the general election of 1994, new Republican majorities in the House and Senate were determined to enforce budgetary discipline and reduce the size of the federal government.¹⁰⁸ The 104th Congress demonstrated its commitment to these goals by cutting its own budget.¹⁰⁹ Among Congressional units, OTA seemed like an easy target for defunding because it was more obscure than other units, and its functions were elective.¹¹⁰ The General Accounting Office and the Government Printing Office, for example, served much more necessary functions than OTA.¹¹¹ And while the CRS also served arguably elective functions, many more members of Congress routinely used CRS than OTA.¹¹² A second major factor contributing to OTA's demise was its fundamental concept. As two former OTA officials noted: "[t]o tolerate an internal independent voice that might, even diplomatically, contradict party policies or critique favored programs has always been asking a lot from the political leadership of Congress."¹¹³ Republicans may also have viewed OTA as having been captured by the Democrats, as it had served under a long and virtually uninterrupted period of Democratic control.¹¹⁴ There also were concerns over the Office being duplicative of other public and private sector entities undertaking similar work.¹¹⁵ As a result of these factors, OTA's budget was eliminated and the agency shuttered on September 30, 1995.¹¹⁶

C. National Institutes of Health Consensus Development Program

By the mid-1970s, many stakeholders felt that the National Institutes of Health (NIH), the agency within the Department of Health, Education, and Welfare (now the Department of Health and Human Service [DHHS]) that serves as the federal government's research agency for biomedical and health-related research, should play a more prominent role in HTA activities.¹¹⁷ In 1975, Donald S. Fredrickson was appointed the Director of NIH, and in his first policy statement, he expressed the opinion that NIH had a responsibility to evaluate and assess both existing and newly developed health care technologies.¹¹⁸ A year later, in 1976, the President's Biomedical Research Panel, which was charged with reviewing and assessing biomedical and behavioral research conducted by NIH, released its report recommending that NIH play

a more prominent role in HTA.¹¹⁹ At the same time, members of Congress, specifically Senators Edward M. Kennedy and Jacob J. Javits, echoed the conclusions of the Research Panel's report and recommended that NIH be more proactive in leading HTA activities.¹²⁰ In 1976, OTA issued a report titled *Development of Medical Technology: Opportunities for Assessment*, which outlined several options through which the federal government could support HTA.¹²¹ Options included a proposal to establish HTA programs within NIH.¹²²

Director Fredrickson subsequently sought to establish a formal HTA program within NIH. In May 1977, Fredrickson requested that DHHS establish the Office for Medical Application of Research (OMAR).¹²³ On October 13, 1978, OMAR was formally established within the Office of the Director of NIH.¹²⁴ Its purpose was to facilitate the translation of the results of biomedical research into knowledge that could be used to better inform the

¹⁰⁷See Wulsin and Dougherty, *supra* n. 10, at 12; Eisenberg and Zarin, *supra* n. 106, at 194; Sullivan, *supra* n. 8, at S39.

¹⁰⁸Herdman and Jensen, *supra* n. 66, at 139.

¹⁰⁹Herdman, *supra* n. 74, at 8.

¹¹⁰Herdman and Jensen, *supra* n. 66, at 139.

¹¹¹*Id.*

¹¹²*Id.*

¹¹³*Id.* at 140.

¹¹⁴*Id.*

¹¹⁵Sorenson *et al.*, *supra* n. 11, at 145.

¹¹⁶Herdman, *supra* n. 74, at 9.

¹¹⁷See Perry S, Kalberer JT. The NIH Consensus Development Program and the assessment of health care technologies: the first two years. *N Engl J Med* 1980;303:169.

¹¹⁸*Id.*

¹¹⁹Perry S. The NIH Consensus Development Program: a decade later. *N Engl J Med* 1987;317:485.

¹²⁰*Id.* at 485-86; see Edward M. Kennedy, *Where Should the Money Go?* SCIENCES, Nov.-Dec. 1976, at 10.

¹²¹See OFFICE OF TECH. ASSESSMENT, *supra* n. 84, at 57-63.

¹²²*Id.* at 58-60. Options included establishing an HTA program conducted and administered by the Office of the Director of NIH; forming a new NIH unit dedicated to HTA; conducting HTA assessments through the offices of the directors of NIH's categorical institutes; conducting HTA as part of the programs, divisions, or task forces already existing within the categorical institutes; constituting groups of representatives from among the relevant programs or divisions within NIH to conduct HTAs; or requiring grant and contract recipients to submit HTAs or similar analyses as part of their completion report. *Id.*

¹²³Ferguson JH. NIH Consensus Conference: dissemination and impact. *Ann NY Acad Sci* 1993;703:180-2.

¹²⁴National Institutes of Health: Statement of Organization, Functions, and Delegations of Authority, 43 FR 47285 (October 13, 1978).

medical decision-making of practicing physicians and other health care professionals.¹²⁵ Its specific responsibilities were to: advise the NIH Director on applications of medical research; coordinate certain HTA activities within NIH; promote effective transfer of information generated by these activities to the health care community; provide a link between the various HTA activities undertaken by the constituent parts of NIH; and monitor the effectiveness and progress of the assessment and transfer activities of NIH.¹²⁶

The principal activity overseen by OMAR was known as the Consensus Development Program (CDP).¹²⁷ These activities actually began in 1977, before OMAR was formally established.¹²⁸ The NIH chose to approach HTA through “consensus development,” which consisted of activities that brought together various stakeholders in order to seek general agreement on the issues raised by a given medical drug, device, or procedure.¹²⁹ The main activity that the CDP facilitated was the consensus development conference, which consisted of large, directed meetings that were open to the public and which solicited the participation of all concerned parties.¹³⁰ The NIH divided consensus development into two categories: technical and interface.¹³¹

Technical consensus was used to describe the assessment of the scientific and medical aspects of a given health technology.¹³² According to NIH, technical consensus activities involved the assessment of “the clinical significance of new findings; whether validation for safety and efficacy has been adequate, and if not what more needs to be done; and what cost, ethical or other social impacts need to be identified for caution when formal recommendations are made.”¹³³ Under such a framework, technical consensus development could involve identifying potential cost, ethical, and social issues that a technology might raise but would take into account only safety and efficacy considerations when reaching conclusions.¹³⁴

Interface consensus development, by contrast, involves taking into account not only the scientific and medical issues, but also the economic, social, legal, and ethical implications of a given technology.¹³⁵ Both OMAR and the CDP were conceived as involving only technical consensus development.¹³⁶ Interface consensus development activities were to be addressed by another agency within DHHS, the National Center for Health Care Technology, which is discussed in Part D of this Section.

The OMAR did not actually perform HTA activities; rather, its function within the CDP was advisory.¹³⁷ Its role was to provide logistical sup-

port and relevant information (that it had gained from previous consensus development conferences) to NIH’s constituent institutes and centers.¹³⁸ Conducting the actual consensus development activities would be performed by NIH’s various subunits.¹³⁹

In the initial phase of the consensus development process, an institute or center within NIH would identify a topic that would ultimately become the focus of a consensus development conference.¹⁴⁰ The primary considerations for topic selection included: the importance of the technology to public health; the presence or absence of controversial or unresolved issues; and the availability of data that would be useful in the consensus development process.¹⁴¹ Other considerations included: the existence of a perception of inappropriate or widespread use prior to sufficient testing; wide variations in clinical practice; the absence of a safe and effective alternative measure; and political concerns.¹⁴² Although it was envisioned that the CDP would focus on emerging technologies, consensus activities soon centered on technologies already used in medical practice.¹⁴³ The reasons for this shift included the realization that many older technologies had not been fully assessed for safety and efficacy, as well as the recognition that inadequate data existed to perform HTAs for many emerging technologies.¹⁴⁴ During the lifetime of the CDP, more

¹²⁵Perry and Kalberer, *supra* n. 117, at 169.

¹²⁶National Institutes of Health Statement, *supra* n., at 124.

¹²⁷Paul W. Wortman *et al.*, *Do Consensus Conferences Work? A Process Evaluation of the NIH Consensus Development Program*, 13 J. HEALTH POL. POL’Y & L. 469, 460 (1988).

¹²⁸See *id.* at 470.

¹²⁹Perry and Kalberer, *supra* n. 117, at 169.

¹³⁰*Id.* at 170.

¹³¹Perry, *supra* n. 119, at 486.

¹³²Perry and Kalberer, *supra* n. 117, at 169.

¹³³Perry, *supra* n. 119, at 486 (quoting OFF. OF DIRECTOR, NATIONAL INSTITUTES OF HEALTH, THE RESPONSIBILITIES OF THE NIH AT THE HEALTH RESEARCH/HEALTH CARE INTERFACE (1977)).

¹³⁴*Id.*

¹³⁵Perry and Kalberer, *supra* n. 117, at 169.

¹³⁶*Id.*

¹³⁷*Id.* at 170.

¹³⁸*Id.*

¹³⁹*Id.*

¹⁴⁰Wortman *et al.*, *supra* n. 127, at 472.

¹⁴¹Ferguson, *supra* n. 123, at 184.

¹⁴²*Id.*

¹⁴³Perry and Kalberer, *supra* n. 117, at 170.

¹⁴⁴*Id.*

than 160 consensus conference statements were produced.¹⁴⁵ Topics were wide-ranging, covering issues as diverse as breast cancer screening,¹⁴⁶ hydroxyurea treatment for sickle-cell anemia,¹⁴⁷ inhaled nitric oxide therapy for premature infants,¹⁴⁸ surgical treatment of morbid obesity,¹⁴⁹ use of microprocessor-based “intelligent” machines in patient care,¹⁵⁰ and clinical use of botulinum toxin.¹⁵¹

After the selection of a topic, the relevant NIH institute or center would prepare for the consensus conference. This process consisted of meeting with OMAR staff in planning meetings and consulting with experts, not only to identify and outline the key issues raised by a topic, but also to brainstorm potential approaches to be used to reach consensus.¹⁵² The NIH program staff, with input from OMAR, would draft consensus questions that were to be addressed.¹⁵³ These questions would control the types of input going into the assessment.¹⁵⁴ Although NIH’s approach to HTA was intended to focus on the scientific and medical aspects of a given technology, research indicates that consensus questions sometimes raised economic, legal, or ethical issues.¹⁵⁵ Furthermore, data indicate that such issues, particularly those related to cost, were often raised during conference discussion.¹⁵⁶ As part of conference preparation, NIH staff would prepare background reports, often commissioning outside experts to compile summaries on the scientific issues involved.¹⁵⁷

Another major pre-conference activity was the selection of participants, namely the speakers, panel, and panel chair. *Conference speakers* were scientific experts who would present research findings that would help to address consensus questions.¹⁵⁸ The *conference panel* was the body chosen to assess the evidence presented and to compile recommendations that would go into the “consensus statement,” a written report to be disseminated after the conclusion of the conference.¹⁵⁹ Panels were generally composed of people with a wide variety of health technology backgrounds. They included not only medical experts, but also consumers, lawyers, economists, and other informed laypeople.¹⁶⁰ The NIH staff generally tried to choose “neutral” panelists who did not have a publicly stated position on the topic under discussion.¹⁶¹ However, for some conferences, staff would select an “adversarial” panel that would try to balance opposing viewpoints.¹⁶² The role of the *panel chair* was to lead the panel in coming to agreement.¹⁶³ Although there appears to have been some general guidelines for the selection of conference participants, actual participant selection procedures appear to have been opaque, non-systematic, and largely based on personal or professional relationships.¹⁶⁴

Consensus development conferences were the cornerstone of the CDP’s HTA activities. These conferences were usually two-and-a-half day events held at NIH headquarters in Bethesda, Maryland.¹⁶⁵ Conferences were free and open to the public, and conference announcements were widely circulated.¹⁶⁶ In the first two days of a conference, speakers made presentations regarding the state of the science relevant to the consensus questions.¹⁶⁷ These presentations were followed by comments from the panel and questions and answers from conference attendees.¹⁶⁸ The conference panel subsequently met in an attempt to

¹⁴⁵*Retirement of the National Institutes of Health Consensus Development Program*, NIH CONSENSUS PROGRAM ARCHIVE, U.S. DEP’T OF HEALTH & HUM. SERVS.; available at <http://consensus.nih.gov/> (last visited Apr. 16, 2014).

¹⁴⁶NATIONAL INSTITUTES OF HEALTH, BREAST CANCER SCREENING NIH CONSENSUS CONFERENCE STATEMENT (1977).

¹⁴⁷NATIONAL INSTITUTES OF HEALTH, NIH STATE OF THE SCIENCE CONFERENCE STATEMENT ON HYDROXYUREA TREATMENT FOR SICKLE CELL DISEASE (2008).

¹⁴⁸NATIONAL INSTITUTES OF HEALTH, NIH CONSENSUS DEVELOPMENT CONFERENCE: INHALED NITRIC OXIDE THERAPY FOR PREMATURE INFANTS (2010).

¹⁴⁹NATIONAL INSTITUTES OF HEALTH, SURGICAL TREATMENT OF MORBID OBESITY NIH CONSENSUS CONFERENCE STATEMENT (1978).

¹⁵⁰NATIONAL INSTITUTES OF HEALTH, MICROPROCESSOR-BASED “INTELLIGENT” MACHINES NIH CONSENSUS CONFERENCE STATEMENT (1979).

¹⁵¹NATIONAL INSTITUTES OF HEALTH, CLINICAL USE OF BOTULINUM TOXIN NIH CONSENSUS CONFERENCE STATEMENT (1990). For a listing of the CDP’s conference topics, see NIH’s website *NIH Consensus Development Program Archive*, which includes a complete collection of the CDP’s consensus conference statement. See *Previous Conference Statements*, NIH CONSENSUS DEVELOPMENT PROGRAM ARCHIVE, U.S. DEP’T OF HEALTH & HUM. SERVS.; available at <http://consensus.nih.gov/previous.htm> (last visited Apr. 15, 2014).

¹⁵²Perry and Kalberer, *supra* n. 117, at 171.

¹⁵³Wortman *et al.*, *supra* n. 127, at 476–7.

¹⁵⁴*Id.*

¹⁵⁵Wortman *et al.*, *supra* n. 127, at 477.

¹⁵⁶Ferguson, *supra* n. 123, at 184–5.

¹⁵⁷Perry and Kalberer, *supra* n. 117, at 171.

¹⁵⁸Wortman *et al.*, *supra* n. 127, at 478.

¹⁵⁹Perry and Kalberer, *supra* n. 117, at 171.

¹⁶⁰Wortman *et al.*, *supra* n. 127, at 478.

¹⁶¹*Id.*

¹⁶²Perry and Kalberer, *supra* n. 117, at 171.

¹⁶³*Id.*

¹⁶⁴See Ferguson, *supra* n. 123, at 183; Wortman *et al.*, *supra* n. 127, at 478–9.

¹⁶⁵Wortman *et al.*, *supra* n. 127, at 478.

¹⁶⁶Perry and Kalberer, *supra* n. 117, at 171.

¹⁶⁷Wortman *et al.*, *supra* n. 127, at 478.

¹⁶⁸*Id.*

reach general agreement on resolution of the consensus questions, after which, it prepared a draft consensus statement.¹⁶⁹ On the last day of the conference, the panel chair presented the draft consensus statement to the conference audience for comment.¹⁷⁰

The post-conference period involved preparing and disseminating a final consensus statement. With the assistance of OMAR, panelists made revisions to the consensus statement.¹⁷¹ Post-conference changes to consensus statements were generally cosmetic rather than substantive.¹⁷² Once the final consensus statement was complete, it was disseminated along with supporting materials to members of the health care and biomedical research communities through means such as mailings, NIH channels, and publication in medical and other journals.¹⁷³ Consensus conferences were often the subject of media coverage.¹⁷⁴

The CDP's goal was to have a substantial impact on the practice of medicine; however, despite its status as one of the most visible HTA activities established by the federal government, the CDP's activities do not appear to have had a significant influence on the delivery of health care.¹⁷⁵ Evidence suggests that, in general, recommendations in consensus statements did not result in meaningful changes in physician practices—even when physicians were aware that the conferences had occurred and viewed the product as scientifically credible.¹⁷⁶ For example, in a study published 10 years after the CDP was established, researchers found that for six of the eleven recommendations studied, physician compliance remained below 50% post-conference.¹⁷⁷ Furthermore, the study found that although compliance with practices promoted in conference recommendations increased during the 2 years immediately preceding the conference, compliance actually decelerated post-conference.¹⁷⁸ Such results suggest that the conferences did not substantially affect physician practice.¹⁷⁹ Studies by OMAR and other organizations confirm that the CDP's impact on the behavior of health care professionals was limited.¹⁸⁰ Nonetheless, there were a few individual conferences that did appear to effect major changes in patient care.¹⁸¹

Perhaps the most apparent impact that the CDP had was seen in other countries. After the CDP was developed, several other countries initiated HTA activities based on NIH's consensus development model, including Canada, Sweden, Switzerland, France, the United Kingdom, Denmark, the Netherlands, Israel, Finland, and Norway.¹⁸² In at least one instance, the recommendations of an NIH CDP conference were adopted by a foreign government, which led to major changes in reimbursement policy and, consequently, physician practices.¹⁸³

The lack of impact that the CDP had on health care delivery in the U.S. is likely attributable to the conference process and the nature of the Program. Although the CDP's aim was to have an impact on health care professionals, conferences were designed and attended mainly by members of the academic community rather than practitioners.¹⁸⁴ Communication difficulties between the two groups likely contributed to the limited effects of the CDP's recommendations.¹⁸⁵ Furthermore, the Program was intentionally designed not to be (and not to be perceived as being) regulatory.¹⁸⁶ This careful design was likely in response to opposition from politically powerful groups within the health care profession, such as the American Medical Association (AMA).¹⁸⁷ As a result, implementation of the recommendations of consensus statements relied entirely on voluntary adoption by physicians and other health care professionals. In addition, OMAR and the CDP did not have any formal relationship with Medicare and generally tried to avoid any involvement, real or perceived, with reimbursement policy.¹⁸⁸ Although this approach appears to have insulated the CDP from political backlash,¹⁸⁹ it probably also contributed to its attenuated impact on health care practices.

¹⁶⁹Perry and Kalberer, *supra* n. 117, at 171; Wortman *et al.*, *supra* note 127, at 479.

¹⁷⁰*Id.*

¹⁷¹Wortman *et al.*, *supra* n. 127, at 479.

¹⁷²*Id.*

¹⁷³Perry and Kalberer, *supra* n. 117, at 171–2.

¹⁷⁴*Id.*

¹⁷⁵See Ferguson, *supra* n. 123, at 188–91; Kosecoff *et al.* Effects of the National Institutes of Health Consensus Development Program on physician practice. *JAMA* 1987;258:2708; Perry, *supra* n. 119, at 487.

¹⁷⁶See Kosecoff *et al.*, *supra* n. 175, at 2712.

¹⁷⁷*Id.*

¹⁷⁸*Id.*

¹⁷⁹*Id.*

¹⁸⁰See Ferguson, *supra* n. 123, at 188–91.

¹⁸¹Perry, *supra* n. 119, at 487.

¹⁸²See Ferguson, *supra* n. 123, at 191.

¹⁸³*Id.* at 190.

¹⁸⁴*Id.* at 189.

¹⁸⁵*Id.*

¹⁸⁶*Id.* at 183.

¹⁸⁷See Perry, *supra* n. 119, at 487.

¹⁸⁸See Ferguson, *supra* n. 123, at 190; Perry, *supra* n. 119, at 487.

¹⁸⁹See David Blumenthal, *Federal Policy toward Health Care Technology, The Case of the National Center*, 61 MILBANK MEMORIAL FUND Q. 584, 589–90 (1983).

By the late 1990s, OMAR and the CDP were significantly less active, releasing only around three or four consensus statements per year.¹⁹⁰ In 2012, OMAR ceased to be an independent office within NIH. Its resources, staff, and activities were merged with the Office of Disease Prevention.¹⁹¹ The CDP was formally dissolved in 2013.¹⁹²

D. National Center for Health Care Technology

The National Center for Health Care Technology (NCHCT) was a short-lived initiative dedicated solely to broad HTA activities. Like the CDP, the Center was housed within DHHS, and the creation of the Center was stimulated in part by OTA's work on HTA. In November 1978, Congress passed Public Law 95-623 creating NCHCT.¹⁹³ The Center was authorized for 3 years, with a budget of \$73 million over those years.¹⁹⁴ The Center's mission was to undertake and support assessment of health care technology, taking into account "the safety, effectiveness, and cost effectiveness of, and the social, ethical, and economic impact of health care technologies."¹⁹⁵ The NCHCT was to perform the "interface consensus" work that NIH had identified but did not pursue.¹⁹⁶ Under the Center's mandate, health care technologies were given a broad definition that encompassed "any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient well-being or facilitate the provision of health care services."¹⁹⁷ The Center was also tasked with establishing assessment priorities and making recommendations to the Secretary of DHHS regarding laws under his or her jurisdiction, including advice with respect to reimbursement.¹⁹⁸ Furthermore, NCHCT was required to compile an annual list of emerging health care technologies.¹⁹⁹

Public Law 95-623 also established the National Council of Health Care Technology, which would serve as an advisory body to NCHCT.²⁰⁰ The Council was to be comprised of 18 members appointed by the Secretary of HHS as well as *ex officio* members representing almost all of the federal agencies with a stake in health care.²⁰¹ Of the 18 appointed members, six were to be distinguished persons in the fields of medicine, engineering, or science, including two members who would represent the health care technology industry. The remaining 12 appointed members were to consist of two physicians, two hospital administrators, two economists, two lawyers, one ethicist, and three individuals from the general public.²⁰² In addition to advising NCHCT and the Secretary of DHHS, another purpose of the Council was to develop "exemplary

standards, norms, and criteria concerning the use of particular health care technologies" and publish these developed standards, norms and criteria through the National Library of Medicine."²⁰³

The NCHCT also ran an extramural grant program. This program supported research related to assessments of specific technologies, as well as research into methods for performing HTA, methods of disseminating HTA information, and factors affecting the use of health technologies.²⁰⁴ To prevent NCHCT-funded activities from duplicating work done by NIH, the Center was not authorized to fund traditional clinical trials; however, funding of comparative clinical studies was allowed.²⁰⁵

Like OMAR and the CDP, NCHCT was not intended to be a regulatory agency for health care technologies. Rather, its statutorily authorized

¹⁹⁰See Manchikanti L *et al.* The evolution of the Patient-Centered Outcomes Research Institute. *J Neurointerventional Surg* 2012;4:157, 160; *Historical Consensus Development Program Statements*, NIH CONSENSUS PROGRAM ARCHIVE, U.S. DEP'T OF HEALTH & HUM. SERVS.; available at <http://consensus.nih.gov/historical.htm> (last visited Apr. 16, 2014).

¹⁹¹*Important Update Regarding the Office of Medical Applications of Research (OMAR)*, NIH CONSENSUS PROGRAM ARCHIVE, U.S. DEP'T OF HEALTH & HUM. SERVS.; available at <http://consensus.nih.gov/CDPNews.htm> (last visited Apr. 16, 2014).

¹⁹²*Retirement of the National Institutes of Health Consensus Development Program*, *supra* n. 145.

¹⁹³Health Services Research, Health Statistics, and Health Care Technology Act of 1978, Pub. L. No. 95-623, 92 Stat. 3443 (1978).

¹⁹⁴*Id.* at 3450-1.

¹⁹⁵*Id.* at 3447.

¹⁹⁶Perry, *supra* n. 119, at 487.

¹⁹⁷Health Services Research, Health Statistics, and Health Care Technology Act of 1978, 92 Stat. at 3450.

¹⁹⁸*Id.* at 3448.

¹⁹⁹*Id.* at 3450.

²⁰⁰*Id.* at 3449.

²⁰¹*Id.* Federal agencies with representation on the Council were the National Institutes of Health, the Veterans' Administration, the Department of Defense, the National Council on Health Planning and Development, the Office of Science and Technology Policy, the FDA, the Centers for Disease Control (as it was then), and the Health Care Financing Administration. *Id.*

²⁰²*Id.* at 3449-50.

²⁰³*Id.* at 3449.

²⁰⁴See *id.* at 3448; Perry S. Special report: The brief life of the National Center for Health Care Technology. *N Engl J Med* 1982;307:1095, 1096; Perry S, Eliastam M. The National Center for Health Care Technology. *JAMA* 1981;245:2510-1.

²⁰⁵Perry, *supra* n. 204, at 1096.

activities were aimed at knowledge development and processing.²⁰⁶ However, the Center was perceived by some as having a regulatory or quasi-regulatory role because of its authority to advise the Secretary of DHHS on reimbursement policy.²⁰⁷ Through this authority, NCHCT influenced coverage decisions for publicly funded health programs.²⁰⁸ Even though the Center's recommendations were advisory, they could influence the potential marketability of new health technologies and potentially limit the range of options available to health care professionals in treating a significant group of patients.²⁰⁹ Such an influential role contributed to the Center's demise.

The NCHCT engaged itself primarily in two types of assessment activities. The first of these involved broad HTAs of high-priority technologies.²¹⁰ Using the advice of the National Council of Health Care Technology, NCHCT identified technologies that were regarded as requiring special attention because they were widely used, produced large expenditures, or raised particular safety, efficacy, ethical, or legal issues.²¹¹ The Council identified numerous technologies for high-priority assessment, including coronary bypass grafting (CABG), dental radiology, caesarean section, treatment of end-stage renal disease, and hip and knee replacement.²¹² Once selected for a broad HTA, NCHCT would commission an overview paper regarding the technology.²¹³ Concurrently, the Center would work with DHHS to create a list of key issues raised by the technology and name a committee to plan the assessment.²¹⁴ These broad HTAs would usually result in a technology assessment forum, which was an open meeting where the issues regarding the technology would be discussed with various stakeholders with the goal of reaching a consensus.²¹⁵ Prior to the Center's closure in 1981, it sponsored or co-sponsored broad HTAs on CABG, dental radiology, and cesarean sections, disseminating its findings in various publications.²¹⁶ In these assessments, NCHCT also highlighted areas requiring further research or analysis.²¹⁷ These highlighted areas often became subjects for NCHCT's extramural grant program.²¹⁸

The second major HTA activity that NCHCT performed was assessments for the Health Care Financing Administration (HCFA), the agency within DHHS responsible for, *inter alia*, administering Medicare and the predecessor to the Centers for Medicare and Medicaid Services (CMS).²¹⁹ For this second type of report, HCFA would request an assessment of a health care technology for use in making a Medicare reimbursement decision, and NCHCT would perform the HTA, focusing on safety and effectiveness.²²⁰ In these assessments,

NCHCT did not look at the cost or cost-effectiveness of the technology under review. These factors were not considered because the Medicare statute requires taking into account only whether a given technology is "reasonable and necessary," which therefore precludes cost considerations.²²¹ After the receipt of a request for an assessment by HCFA, NCHCT would publish announcements in the *Federal Register* and other publications soliciting opinions and evidence concerning the technology at issue.²²² The Center would also directly contact professional societies such as the AMA, members of industry, and other federal agencies to gather relevant information.²²³ If issues were particularly complicated, NCHCT might also convene panels or conferences addressing the technology in question.²²⁴ The NCHCT would then use the responses received, along with insight gathered from reviewing the relevant literature, to synthesize a single report for the HCFA recommending coverage or non-coverage.²²⁵ During the Center's 3 years of existence, it produced evaluations for 75 health care technologies.²²⁶ The HCFA adopted NCHCT's recommendations in all of these evaluations with only minor administrative changes.²²⁷ Forty percent of the Center's evaluations for the HCFA were for non-coverage.²²⁸ The

²⁰⁶Blumenthal, *supra* n. 189, at 592.

²⁰⁷*Id.* at 591–2.

²⁰⁸*Id.* at 591; *see infra* discussion of second major HTA activity.

²⁰⁹*Id.* at 592.

²¹⁰Perry, *supra* n. 204, at 1097.

²¹¹*Id.*

²¹²*Id.*

²¹³Perry and Eliastam, *supra* n. 204, at 2511.

²¹⁴*Id.*

²¹⁵*Id.*

²¹⁶Perry, *supra* n. 204, at 1097; *see, e.g.*, NCHCT Technology Assessment Forum. Coronary artery bypass surgery. JAMA 1981;246:1646.

²¹⁷*See, e.g.*, NCHCT Technology Assessment Forum, *supra* n. 216, at 1648–1649.

²¹⁸Perry, *supra* n. 204, at 1097.

²¹⁹Perry and Eliastam, *supra* n. 204, at 2511.

²²⁰Perry, *supra* n. 204, at 1097.

²²¹42 USC §1395y (2011); Perry, *supra* n. 204, at 1097; *see* Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577 (2005).

²²²Perry, *supra* n. 204, at 1097.

²²³*Id.*

²²⁴*Id.*

²²⁵*Id.* at 1097–8; Perry and Eliastam, *supra* n. 204, at 2511.

²²⁶Perry, *supra* n. 204, at 1098.

²²⁷*Id.*

²²⁸*Id.*

NCHCT would recommend non-coverage where it determined that a technology was obsolete, experimental, unproved, or ineffective.²²⁹ In seven of these recommendations for non-coverage, NCHCT commissioned additional studies to evaluate the cost impact of adopting its recommendations.²³⁰ Studies by the schools of public health at the University of California at Los Angeles and Harvard University indicated that savings to Medicare resulting in non-coverage for each of these technologies ranged from \$100 million to \$10 billion annually.²³¹ In the final year of the Center's operation, the results of NCHCT's assessments were not only conveyed to HCFA, but also sent to various organizations for distribution to private health insurers.²³²

Although the Center served arguably important functions, it was ultimately a limited and short-lived operation. Even though NCHCT's authorized budget was for \$73 million over 3 years, Congress appropriated only \$7.8 million for it during that time.²³³ Furthermore, the Center's congressional allocation of staff never exceeded 20.²³⁴ The NCHCT's authorization expired at the end of the fiscal year 1981.²³⁵ Despite opposition from the Reagan administration, Congress did reauthorize the Center for another 3 years, but at a significantly reduced budget of \$12 million for that time.²³⁶ However, the administration's position ultimately prevailed, as no money was allocated to NCHCT during the appropriations process for the 1982 fiscal year. The Center closed in December 1981.²³⁷

The NCHCT's demise can be attributed to numerous factors, including budgetary concerns, institutional friction, and opposition from industry and professional groups.²³⁸ Under the Reagan administration, there was extreme pressure to slash federal government spending and to lower the budget deficit, both of which contributed substantially to NCHCT's defunding.²³⁹ However, budgetary pressures on NCHCT were felt even before the Reagan administration took office in 1981.²⁴⁰ Under the Carter administration, the Office of Management and Budget had repeatedly reduced requests from DHHS to fund the Center, and Congressional appropriations committees cut these requests further.²⁴¹ Furthermore, the Center never had strong backing from leaders within DHHS.²⁴² This lack of vigorous support was especially problematic given DHHS' limited budgetary resources, which resulted in agencies housed within the Department competing for funds and personnel.²⁴³ Three other DHHS agencies—NIH, HCFA, and the National Center for Health Services Research (NCHSR)—regarded NCHCT as encroaching on their spheres of influence.²⁴⁴ These agencies tended to be more

established and could better fend off budgetary reductions, sometimes at the expense of the Center.²⁴⁵ Furthermore, NIH and OMAR were openly hostile to NCHCT.²⁴⁶ The OMAR officials felt that the Center added little to what could be achieved through the CDP, which may have reflected NIH's skepticism toward inclusion of social and economic issues in HTA.²⁴⁷ This hostility manifested itself in statements made during departmental deliberations and private communications with legislative staff, who articulated the view that NCHCT was "an unnecessary bureaucratic appendage."²⁴⁸ This idea that NCHCT was superfluous and could be spared in a time of budgetary crisis would be repeated by Congressmen opposed to the reauthorization of the Center.²⁴⁹

One of the most significant contributing factors to NCHCT's downfall was opposition by powerful interest groups. In particular, the AMA and the Health Industry Manufacturers' Association (HIMA), the trade association representing medical device manufacturers, were staunchly opposed to the Center.²⁵⁰ Both of these groups voiced their opposition to the reauthorization of the Center in the Congressional hearings on the reauthorization of the NCHCT.²⁵¹ The AMA expressed concerns regarding the comparative institutional competence of the Center.²⁵² In its statements, the AMA took the position that judgments about risks, costs, and benefits were better left to the medical profession.²⁵³ The AMA's opposition appears to have

²²⁹*Id.*

²³⁰*Id.*

²³¹*Id.*

²³²*Id.*

²³³Blumenthal, *supra* n. 189, at 592.

²³⁴*Id.*

²³⁵*Id.*

²³⁶*Id.* at 593.

²³⁷*Id.*; Perry, *supra* n. 204, at 1096.

²³⁸Blumenthal, *supra* n. 189, at 609.

²³⁹*Id.* at 592.

²⁴⁰*Id.*

²⁴¹*Id.*

²⁴²*Id.* at 594.

²⁴³*Id.* at 596.

²⁴⁴*Id.*

²⁴⁵*Id.*

²⁴⁶*Id.* at 602.

²⁴⁷*Id.*

²⁴⁸*Id.*

²⁴⁹*Id.*

²⁵⁰Perry, *supra* n. 204, at 1098.

²⁵¹*Id.*

²⁵²*Id.*

²⁵³*Id.*

been motivated by concern that NCHCT would interfere with the practice of medicine. In particular, it was concerned about the Center's ability to develop "exemplary standards, norms, and criteria" concerning the use of particular health care technologies.²⁵⁴ The HIMA's position was similar to the AMA's, but HIMA also voiced concerns that the efforts of the Center were duplicative of the work of other federal agencies.²⁵⁵ In support of this position, HIMA produced a list of 20 federal agencies that it maintained had statutory authority that permitted them to perform all of the Center's functions.²⁵⁶ However, as Seymour Perry, Director of the NCHCT, later highlighted, "none of the organizations cited by [HIMA had] the mandate to fulfill the responsibilities that had been assigned to the Center" and none was "recognizable as having meaningful assessment activities with respect to health care technologies."²⁵⁷ The HIMA's overall concern was that NCHCT's evaluations could stifle innovation, damage emerging companies, and generally constrain the industry's marketplace freedom.²⁵⁸ In particular, HIMA was concerned about the Center's authority to compile lists of emerging technologies and the potential that the NCHCT would prioritize these technologies for HTAs.²⁵⁹ Both the AMA and HIMA were politically powerful organizations, and ultimately, their positions prevailed.

E. Office of Health Technology Assessment

The Office of Health Technology Assessment (OHTA) was established in 1981, largely to replace NCHCT's role in advising HCFA.²⁶⁰ Although some regarded OHTA as NCHCT's successor, OHTA did not assume the broader HTA work that NCHCT had conducted on high-priority technologies. Instead, OHTA's work was focused on performing smaller-scale HTAs that aided in determining Medicare reimbursement policy.²⁶¹ The agency was housed in NCHSR, the center within DHHS that had been formed in 1968 to study the organization, financing, and outcomes of health services.²⁶² The OHTA was a small office with an annual budget of around \$1 million and a staff of approximately 6.²⁶³

The mandate of OHTA was to make recommendations to HCFA regarding whether specific health technologies should be reimbursable under federally financed health programs.²⁶⁴ The OHTA was to consider the safety, efficacy, and effectiveness of technologies, as well as their cost-effectiveness and appropriate uses.²⁶⁵ In evaluating a specific technology, OHTA was also required to consult

with NIH, the FDA, and other federal agencies where appropriate.²⁶⁶ Other federal agencies with which OHTA would consult included the Centers for Disease Control and the Alcohol, Drug Abuse, and Mental Health Administration.²⁶⁷ If the technology in question had already been assessed in an NIH consensus conference, OHTA generally adopted the consensus statement's findings.²⁶⁸ The OHTA did not have any role in setting HTA priorities, which was a controversial feature of NCHCT.²⁶⁹ The assessment activities generally were dictated by HCFA requests.

The OHTA engaged in two types of HTA activities for HCFA: simple, informal inquiries and full assessments.²⁷⁰ For *informal inquiries*, HCFA would ask OHTA questions about the regulatory and research standing of a particular technology.²⁷¹ The OHTA staff would respond by providing information obtained by agencies and medical professional groups.²⁷² According to one commentator, OHTA was somewhat uncomfortable with the informal inquiry process, as it would not know how

²⁵⁴Blumenthal, *supra* n. 189, at 601; see Health Services Research, Health Statistics, and Health Care Technology Act of 1978, Pub. L. No. 95-623, 92 Stat. 3443, 1449 (1978).

²⁵⁵Perry, *supra* n. 204, at 1098.

²⁵⁶*Id.* at 1099.

²⁵⁷*Id.*

²⁵⁸Blumenthal, *supra* n. 189, at 601; Perry, *supra* n. 204, at 1099.

²⁵⁹See Blumenthal, *supra* n. 189, at 601.

²⁶⁰See Eisenberg and Zarin, *supra* n. 106, at 194; NAT'L CTR. FOR HEALTH SERVS. RES. & HEALTH CARE TECH. ASSESSMENT, U.S. DEP'T HEALTH & HUM. SERVS., OFFICE OF HEALTH TECHNOLOGY ASSESSMENT REPORTS, 1981—1985: TITLES AND ORDERING INFORMATION 1 (1986).

²⁶¹See OFFICE OF TECH. ASSESSMENT, MEDICAL TECHNOLOGY AND THE COSTS OF THE MEDICARE PROGRAM 177 (1984).

²⁶²Susan B. Foote, *Assessing Medical Technology Assessment: Past, Present, and Future*, 65 MILBANK Q. 59, 71-72 (1987).

²⁶³Sean R. Tunis and Hellen Gelband, *Health Care Technology in the United States*, 30 HEALTH POL'Y 335, 360 (1994).

²⁶⁴42 USC §242c (1988)(repealed 1989).

²⁶⁵*Id.*

²⁶⁶*Op. cit.*, n. 264.

²⁶⁷See OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁶⁸Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869, 881 (1988).

²⁶⁹See Foote, *supra* n. 262, at 72.

²⁷⁰*Id.*

²⁷¹See OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁷²*Id.*; Kinney, *supra* n. 268, at 881.

HCFA would use the information it provided in making reimbursement policy decisions.²⁷³

Full assessments were a much more elaborate process that required 12 to 18 months.²⁷⁴ The first step involved meeting with HCFA in order to clarify its request and to identify issues to be addressed.²⁷⁵ The OHTA would subsequently review the medical and scientific literature concerning the technology and consult other organizations to obtain additional information.²⁷⁶ The agency would reach out to a wide spectrum of sources in an effort to hear from all interested parties.²⁷⁷ It would consult with medical specialty groups and professional organizations, commercial and industry groups, specific manufacturers, private organizations conducting HTAs, and consumer groups.²⁷⁸ It also would send formal letters of inquiry to NIH, FDA, and other relevant federal agencies regarding the technology.²⁷⁹ In addition, OHTA would publish a notice in the *Federal Register* soliciting comments from all interested parties.²⁸⁰ These notices and the responses they elicited represented OHTA's primary contact with the general public during the assessment process.²⁸¹ The Office would publish notices and advertisements in professional and trade publications requesting information about particular coverage issues.²⁸² Proponents of new medical technologies were expected to submit information to OHTA in the form of scientific and clinical studies.²⁸³

Once OHTA completed its information-gathering process, staff would analyze and synthesize the information collected to produce a report and recommendation for HCFA.²⁸⁴ In drafting its reports and recommendations, OHTA did not engage in any primary data collection activities, and thus, it relied solely on data from extramural sources.²⁸⁵ In accordance with its statutory mandate, the primary considerations in OHTA assessments were safety, efficacy, and clinical effectiveness.²⁸⁶ Because HCFA could not consider costs in making reimbursement decisions, OHTA did not perform formal cost-effectiveness analyses; however, it could and sometimes did include cost information in its reports.²⁸⁷ Once an assessment was completed, it would be peer-reviewed within OHTA and then sent to the FDA, NIH, and any other appropriate federal agencies.²⁸⁸ The OHTA would also prepare and send to HCFA a memorandum recommending for or against coverage of the technology at issue.²⁸⁹ Furthermore, OHTA would publish and disseminate its assessments to make them available to the general public, but only after HCFA had taken action on a recommendation.²⁹⁰ Ultimately, HCFA made final decisions on coverage and could choose to accept or disregard OHTA's recommendation.²⁹¹

Because OHTA's recommendations were not published, disseminated, or otherwise made available to the public, it is unclear how often HCFA went against OHTA's recommendations.²⁹²

In addition to the influence it had on Medicare coverage decisions, OHTA's work appears to have had some influence on the coverage decisions of private insurers. Published OHTA assessments were often used by private insurers when developing their own coverage policies.²⁹³ Furthermore, private insurers often followed HCFA and Medicare's lead in coverage decisions, excluding technologies from private coverage until Medicare had decided to include them as part of its coverage.²⁹⁴

In contrast to NCHCT, OHTA was not a short-lived operation. It remained a part of NCHSR when it was renamed the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) in 1984, following reorganization efforts within DHHS.²⁹⁵ The 1984 reorganization also created the National Council on Health Care Technology Assessment (NCHCTA), which helped advise the OHTA and the NCHSR/HCTA with

²⁷³Kinney, *supra* n. 268, at 881.

²⁷⁴OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁷⁵*Id.*

²⁷⁶Kinney, *supra* n. 268, at 882.

²⁷⁷OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁷⁸Kinney, *supra* n. 268, at 882.

²⁷⁹COMMITTEE ON PRIORITIES FOR ASSESSMENT AND REASSESSMENT OF HEALTH CARE TECHNOLOGIES, INSTITUTE OF MEDICINE, SETTING PRIORITIES FOR HEALTH TECHNOLOGY ASSESSMENT 29 (Molla S. Donaldson and Harold C. Sox, Jr., eds., 1992).

²⁸⁰OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁸¹*Id.*

²⁸²*Id.*

²⁸³COMMITTEE ON PRIORITIES FOR ASSESSMENT AND REASSESSMENT OF HEALTH CARE TECHNOLOGIES, *supra* n. 279, at 29.

²⁸⁴Kinney, *supra* n. 268, at 882-3.

²⁸⁵*Id.* at 883.

²⁸⁶OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁸⁷Tunis and Gelband, *supra* n. 263, at 360.

²⁸⁸COMMITTEE ON PRIORITIES FOR ASSESSMENT AND REASSESSMENT OF HEALTH CARE TECHNOLOGIES, *supra* n. 279, at 29-30.

²⁸⁹*Id.* at 30.

²⁹⁰OFFICE OF TECH. ASSESSMENT, *supra* n. 261, at 178.

²⁹¹Kinney, *supra* n. 268, at 883.

²⁹²*See* COMMITTEE ON PRIORITIES FOR ASSESSMENT AND REASSESSMENT OF HEALTH CARE TECHNOLOGIES, *supra* n. 279, at 30.

²⁹³Tunis and Gelband, *supra* n. 263, at 361.

²⁹⁴Eisenberg and Zarin, *supra* n. 106, at 194.

²⁹⁵*See* Foote, *supra* n. 262, at 72.

respect to performing HTA for Medicare coverage decisions.²⁹⁶ The NCHCTA's recommendations were largely organizational and procedural.²⁹⁷ When the Agency for Health Care Policy and Research (discussed in Part G of this section) was created in 1989 as the successor agency to the NCHSR/HCTA, it inherited the functions of OHTA.²⁹⁸ The OHTA exists today in the form of the Technology Assessment Program of the Agency for Healthcare Research and Quality (discussed in Part H of this section).²⁹⁹

F. Council on Health Care Technology

Even though some public sector HTA (for the purpose of advising HCFA) continued to be performed after the closure of NCHCT, many stakeholders felt that there should be continued federal funding of broader HTA work.³⁰⁰ In response, Congress created the Council on Health Care Technology (CHCT), which was a private–public partnership initiated with the Institute of Medicine (IOM), which is an independent, non-profit organization within the National Academy of Sciences dedicated to providing advice to decisionmakers and the public on issues relating to biomedical science, health, and medicine.³⁰¹ The CHCT was established by the passage of Public Law 98-551 in 1984.³⁰²

Prior to the CHCT's creation by Congress, the IOM had convened a panel in 1982 to study the possibility of a private–public partnership to support HTA work.³⁰³ The panel's report, published in 1983, envisioned an organization that would be based in the private sector but receive funding from both governmental and private sources.³⁰⁴ The report recommended that such an entity be created with the responsibilities of establishing and maintaining a clearinghouse for HTA, collecting and analyzing the work of other HTA organizations, conducting or commissioning original HTAs, identifying needs in HTA, developing criteria and methods for HTA, and educating, training, and providing assistance to others involved in HTA activities.³⁰⁵ Congress adopted all of these recommendations by establishing the activities of the Council.³⁰⁶ As provided by Public Law 98-551, the CHCT was to be comprised of ten members appointed by the IOM representing the private sector, three members appointed by DHHS, and the Directors of the OTA as *ex officio* members.³⁰⁷ The federal government was to fund the CHCT in part by a grant of as much as \$500,000.³⁰⁸ However, as a condition of receiving the grant, the CHCT had to raise funds from private sources equal to at least twice the amount of the federal grant.³⁰⁹

Although the Council was intended to be a public–private partnership, legal constraints resulted in a much more limited public role than that embodied in Public Law 98-551.³¹⁰ In signing the law, President Reagan expressed concerns about the constitutionality of the provision detailing the Council's composition.³¹¹ In particular, he was concerned that the provision violated the Appointments Clause of Article II of the U.S. Constitution.³¹² Citing the Supreme Court's decision in *Buckley v. Valeo*, the President expressed the view that because the Council would perform significant governmental duties pursuant to a public law, its members would need to be appointed in a manner consistent with the Appointments Clause, which would not allow for appointment by a Congressional panel or a body that is not an agency of the United States.³¹³ Problematically, the IOM was a body that was not an agency of the United States. Thus, the President recommended that the law be amended to reconstitute the Council as either a governmental agency with members appointed in conformance with the Appointments Clause, or as a private, nongovernmental organization whose members would not

²⁹⁶Health Promotion and Disease Amendments of 1984, Pub. L. No. 98-551, 98 Stat. 2815, 2818.

²⁹⁷Rettig RA. Health policy in radiology: technology assessment—an update. *Invest Radiol* 1991;26:165, 166.

²⁹⁸Eisenberg and Zarin, *supra* n. 106, at 195.

²⁹⁹See Bryan Luce and Rebecca S. Cohen, *Health Technology Assessment in the United States*, 1 INT'L J. TECH. ASSESSMENT HEALTH CARE S33, S35 (2009).

³⁰⁰See, e.g., Tunis and Gelband, *supra* n. 263, at 354; Abrams HL, Hessel S. Health technology assessment: problems and challenges. *AJR* 1987;149:1127.

³⁰¹*Id.*

³⁰²See Health Promotion and Disease Amendments of 1984, 98 Stat. at 2820.

³⁰³INSTITUTE OF MEDICINE, COUNCIL ON HEALTH CARE TECHNOLOGY: 1986 AND 1987 1 (1987).

³⁰⁴See DIVISION OF HEALTH SCIENCES POLICY, INSTITUTE OF MEDICINE, A CONSORTIUM FOR ASSESSING MEDICAL TECHNOLOGY: PLANNING STUDY REPORT xii (1983).

³⁰⁵*Id.* at xii–xiii.

³⁰⁶See Health Promotion and Disease Amendments of 1984, 98 Stat. at 2821.

³⁰⁷*Id.*

³⁰⁸*Id.*

³⁰⁹*Id.*

³¹⁰*Id.*

³¹¹Presidential Statement on Signing of S. 771 into Law 1984, 20 WEEKLY COMP. PRES. DOC. 1690 (Nov. 5 1984).

³¹²*Id.*; see U.S. CONST. ART. II, §2, cl. 2.

³¹³Presidential Statement on Signing of S. 771 into Law 1984, 20 WEEKLY COMP. PRES. DOC. AT 1690–1691; see *Buckley v. Valeo*, 424 U.S. 1, 126–7 (1976).

have significant duties under a public law.³¹⁴ Thus, Congress amended the statutory authority for the Council in 1985 so that all members of the council would be chosen from the private sector.³¹⁵ The only public involvement with the partnership was that the federal government provided “matching” grant funding, and the CHCT was required to submit an annual report to DHHS that would be forwarded to committees in the Senate and House of Representatives.³¹⁶ The council that was eventually chosen consisted of 16 members, and the first meeting was held in early 1986.³¹⁷ Members included representatives from a wide spectrum of health care constituencies, including health care providers, consumer groups, insurers, health technology manufacturers, hospital groups, health maintenance organizations, bioethicists, and scientific and medical researchers.³¹⁸

The CHCT’s HTA activities in practice were severely limited by funding constraints. In making federal funding contingent on obtaining private funds, it appears that Congress overestimated the willingness of the private sector to finance HTA. As a result, the CHCT’s staff was of a very limited size, which made it difficult to engage in HTA activities.³¹⁹ According to one commentator, the Council’s main role was acting as a clearinghouse for information on HTA activities.³²⁰ Most of the assessment-related work in which the Council engaged was focused on conceptual and methodological issues of HTA.³²¹ Such issues included procedures for priority setting, the relation of HTA to quality assurance, approaches to assessing diagnostic technologies, and other methods to rationalize HTA.³²² In the Council’s three years of existence, it produced HTAs on only two technologies: end-stage renal dialysis and the artificial heart.³²³

Ultimately, the inability of the CHCT to attract private funding led to its demise.³²⁴ In 1989, the IOM did not request further public funding for the Council, and the statutory authorization for the public funding was allowed to expire.³²⁵ The CHCT’s lack of clear priorities for HTA work,³²⁶ as well as opposition from the medical profession and the pharmaceutical and medical device industries, were also significant to the Center’s downfall.³²⁷

G. Prospective Payment Assessment Commission

The Social Security Amendments of 1983 brought a fundamental shift in part of Medicare reimbursement policy.³²⁸ The Amendments began the transformation of the program from a cost-based reimbursement system to a Prospective Payment System (PPS), which meant that health care providers

would be paid on the basis of a specified fixed amount, where the amount paid for a given service would depend on the classification system for that service.³²⁹ For example, for hospital in-patient services, the Amendments created the diagnosis-related group (DRG) system, which divides possible diagnoses into groups called DRGs that serve as the basis for reimbursement. A particular DRG payment generally takes into account the average resources required to treat the underlying condition and adjusts these payments for variables such as hospital location, proportion of low-income patients served by the hospital, and teaching status of hospital.³³⁰

The Social Security Amendments also created the Prospective Payment Assessment Commission (ProPAC) to advise HCFA on setting DRG rates and to analyze the impact of PPS on health care.³³¹ The Commission was to be composed of 15 members from a range of health care constituencies who were appointed by the Director of the OTA.³³² ProPAC’s responsibilities included compiling an annual report for HCFA regarding appropriate payment rates and submitting an annual report to Congress on the functioning and progress of the Commission as well as any HTA activities performed.³³³

³¹⁴Presidential Statement, n. 313.

³¹⁵Health Services Amendments of 1985, Pub. L. No. 99-117, 99 Stat. 491, 494.

³¹⁶*Id.*

³¹⁷See INSTITUTE OF MEDICINE, *supra* n. 303, at 1.

³¹⁸*Id.*

³¹⁹See Rettig, *supra* n. 297, at 167.

³²⁰Seymour Perry, *Technology Assessment in Health Care: the U.S. Perspective*, 9 HEALTH POL’Y, 317, 321 (1988).

³²¹Tunis and Gelband, *supra* n. 263, at 354.

³²²See Banta HD, Thacker SB. The case for reassessment of health care technology: once is not enough. JAMA 1990; 264: 235, 237.

³²³Tunis and Gelband, *supra* n. 263, at 354.

³²⁴See Rettig, *supra* n. 297, at 167–8.

³²⁵*Id.* at 168.

³²⁶Tunis and Gelband, *supra* n. 263, at 354.

³²⁷See Eisenberg and Zarin, *supra* n. 106, at 195.

³²⁸Social Security Amendments of 1983, Pub. Law No. 98-21, 97 Stat. 65.

³²⁹*Id.* at 149.

³³⁰*Acute Inpatient PPS*, CTRS. FOR MEDICARE & MEDICAID SERVS.; available at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteinpatientPPS/index.html (last visited Apr. 24, 2014).

³³¹Social Security Amendments of 1983, 97 Stat. at 157–9.

³³²*Id.* at 160.

³³³*Id.* at 159–61.

Although only a portion of its mandated activities involved assessments, ProPAC was given the statutory authority to perform a wide range of HTA activities such as evaluating for safety, efficacy, and cost-effectiveness health technologies that could have an impact on DRG rates.³³⁴ ProPAC could collect and assess information regarding new and existing technologies by utilizing existing information, carrying out or commissioning original research and experimentation, and adopting procedures to allow interested parties to submit information.³³⁵

ProPAC began its operations in 1986.³³⁶ However, despite its statutory authority to engage in HTA activities, it does not appear to have ever undertaken a significant HTA program.³³⁷ ProPAC was later merged into the Medicare Payment Advisory Commission (MedPAC), which currently advises Congress on issues related to Medicare, with the passage of the Balanced Budget Act of 1997.³³⁸

H. Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research (AHCPR) was created by the Omnibus Budget Reconciliation Act of 1989.³³⁹ Established as part of DHHS, the stated purpose of the agency was to “enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.”³⁴⁰

The AHCPR both assumed and expanded the responsibilities of the NCHSR.³⁴¹ As discussed above, AHCPR was regarded as the successor to the NCHSR and was assigned the Center’s personnel, assets, liabilities, and general functions.³⁴² However, in addition to continuing many of the NCHSR’s programs, AHCPR was given some important new responsibilities, including HTA activities. Importantly, the Agency was given the general authority to conduct and support research, demonstrations, evaluations, training, guidelines developments, and the dissemination of information on health care services and their delivery systems in the following areas: the effectiveness, efficiency, and quality of health services; the outcomes of health care services and procedures; clinical practice; health care technologies, facilities and equipment; health care costs, productivity and markets; health promotion and disease prevention; health statistics and epidemiology; and medical liability.³⁴³ Its budget for 1989 was \$99 million, of which \$38 million was designated for medical effectiveness research and guideline development.³⁴⁴

The AHCPR conducted three programs involving HTA. First, as discussed above in Part E, the AHCPR housed the OHTA, which performed HTAs requested by HCFA to aid in Medicare reimbursement policy.³⁴⁵ Second, within the agency, the newly created Center for Medical Treatment Effectiveness research had responsibility for administering research under the Medical Treatment Effectiveness Program (MEDTEP), which performed HTA work focusing on the treatment of particular clinical conditions. (However, at the time, MEDTEP’s work was referred to as “outcomes and effectiveness research.”)³⁴⁶ Third, the Office of the Forum for Quality and Effectiveness in Health Care was established within the AHCPR. The purpose of this office was to develop and update clinical guidelines to be used by health care professionals to prevent, diagnose, treat and clinically manage health conditions effectively and appropriately; as well as to develop these guidelines into standards of quality, performance measures, and medical review criteria.³⁴⁷

³³⁴*Id.* at 161.

³³⁵*Id.*

³³⁶See *Prospective Payment Commission*; available at <https://www.federalregister.gov/agencies/prospective-payment-assessment-commission> (last visited Apr. 24, 2014).

³³⁷See, e.g., Anne K. Burns, *Technology Assessment for Public Payment Policy: the Prospective Payment Commission (ProPAC)*, 1 INT’L J. TECH. ASSESSMENT 756, 759 (1985)(noting the limited nature of ProPAC’s HTA activities aimed mostly at examining structural issues in the DRG system); Perry, *supra* n. 320, at 321; see generally Young DA. The Prospective Payment Assessment Commission: responsibilities and recent findings. *Acad. Med.* 1991;66:400 discussing the responsibilities and activities of ProPAC without any mention of HTA-related activities).

³³⁸*Prospective Payment Commission, supra* n. 336.

³³⁹Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106, 2189.

³⁴⁰*Id.*

³⁴¹Tunis and Gelband, *supra* n. 263, at 355.

³⁴²See Bradford H. Gray, *The Legislative Battle Over Health Services Research*, 11 HEALTH AFFAIRS 38, 40 (1992).

³⁴³Omnibus Budget Reconciliation Act of 1989, 103 Stat. at 2189.

³⁴⁴Eisenberg and Zarin, *supra* n. 106, at 195.

³⁴⁵Tunis and Gelband, *supra* n. 263, at 355.

³⁴⁶See Omnibus Budget Reconciliation Act of 1989, 103 Stat. at 2195; J. Jarett Clinton, *Agency for Health Care Policy and Research: Overview of Purpose and Programs*, 49 FOOD & DRUG L.J. 449 (1994); Luce and Cohen, *supra* n. 299, at 34.

³⁴⁷See Omnibus Budget Reconciliation Act of 1989, 103 Stat. at 2192.

The goal of MEDTEP was to conduct and support research with respect to the “outcomes, effectiveness, and appropriateness of health care services,” and in doing so was expected to evaluate the “comparative effects on health,” as well as the “functional capacity of alternative” therapies.³⁴⁸

A major component of MEDTEP’s activities consisted of various research projects called Patient Outcomes Research Teams (PORTs).³⁴⁹ Each PORT focused on a specific clinical condition that was common and costly to treat and for which there was evidence of both regional variation in treatment and available data for analysis.³⁵⁰ The PORTs included projects dedicated to, *inter alia*, back pain, acute myocardial infarction, benign prostatic hyperplasia (BPH) and localized prostate cancer, knee replacements, and diabetes management.³⁵¹ Each PORT was funded for five years at \$5 million to \$6 million dollars and was aimed at determining what treatments worked for which populations, and at what cost.³⁵² The work of PORTs involved comparisons of available treatments that today would be considered under the rubric of CER. The PORT documents were the culmination of substantial research efforts. The PORTs would conduct systematic and formal literature reviews of the medical conditions at issue; analyze administrative databases, such as Medicare and Medicaid claims, to gather information on clinical patterns of care and regional variations; survey patients to gather data on the probability of certain post-treatment outcomes; and synthesize the data gathered.³⁵³ Primary research on clinical or comparative effectiveness was not part of the PORT process.³⁵⁴ The PORT findings would be disseminated to the health care community and consumers through the AHCPR’s Center for Research Dissemination Liaison.³⁵⁵

The results of PORT studies often offered significant insight into choosing treatment options; however, the utility of these findings was sometimes limited by a PORT’s inability to engage in primary clinical research. For example, the PORT concerning BPH discovered that prostate surgery resulted in rates of complication that were higher than previously believed.³⁵⁶ Given these findings and results indicating that patients were not as irritated by symptoms of BPH as might have been indicated by objective measures, the BPH PORT concluded that patient preferences should be a significant factor in treatment decisions.³⁵⁷ The BPH PORT also found that transurethral resection of the prostate (TURP) counter-intuitively resulted in higher delayed mortality rates than open surgery, even though TURP is a less-invasive procedure.³⁵⁸ The PORT indicated that it was possible that this result could be explained

by unmeasured comorbidity differences between treatment groups.³⁵⁹ However, in order to determine the true difference in delayed death between TURP and open surgery, a clinical trial would be required.³⁶⁰ Perhaps not surprisingly, proposals for such a trial were rejected by AHCPR and NIH.³⁶¹

Development and dissemination of clinical practice was another major HTA-related activity of AHCPR. It was hoped that health care professionals would adhere closely to these guidelines, resulting in the delivery only of appropriate care as well as a reduction in unnecessary care, both of which would reduce health care costs.³⁶² However, guidelines were not meant to be regulatory, and adherence to them in health care treatment was completely voluntary. The enabling legislation for AHCPR provided some criteria for choosing guideline topics, namely that the condition account for a significant portion of public health care expenditures, have a significant variation in the frequency or type of treatment provided, or otherwise meet the needs of Medicare.³⁶³ However, selection of

³⁴⁸*Id.* at 2195.

³⁴⁹D’Arcy LP, Rich E. From comparative effectiveness research to patient outcomes research: policy history and future directions. *Neurosurg Focus* 2012;33:1, 2.

³⁵⁰Freund *et al.* Patient Outcomes Research Teams: contributions to outcomes and effectiveness research. *Annu Rev Pub Health* 1999;20:337–8.

³⁵¹Tunis and Gelband, *supra* n. 263, at 358. The original PORTs focused on the following conditions: acute myocardial infarction, back pain, biliary tract disease, caesarean section, cataracts, childbirth, diabetes, osteoarthritis and hip fracture repair, ischemic heart disease, low birth weight, community-acquired pneumonia, prostate disease, stroke, schizophrenia, and total knee replacement. Freund *et al.*, *supra* n. 250, at 338.

³⁵²*Id.* at 357.

³⁵³See Freund *et al.*, *supra* n. 350, at 340–51.

³⁵⁴Luce and Cohen, *supra* n. 299, at 35.

³⁵⁵See Tunis and Gelband, *supra* n. 263, at 357.

³⁵⁶See AGENCY FOR HEALTH CARE & POL’Y RES., U.S. DEP’T HEALTH & HUM. SERVS., PUB. NO. 94-0582, BENIGN PROSTATIC HYPERPLASIA: DIAGNOSIS & TREATMENT, AHCPR CLINICAL PRACTICE GUIDELINES NO. 8 5 (1994); Tunis and Gelband, *supra* n. 263, at 357.

³⁵⁷See AGENCY FOR HEALTH CARE & POL’Y RES., *supra* n. 356, at 140; Tunis and Gelband, *supra* n. 263, at 358.

³⁵⁸See AGENCY FOR HEALTH CARE & POL’Y RES., *supra* n. 356, at 125.

³⁵⁹*Id.*

³⁶⁰Tunis and Gelband, *supra* n. 263, at 358.

³⁶¹*Id.*

³⁶²Tunis and Gelband, *supra* n. 263, at 355.

³⁶³See Omnibus Budget Reconciliation Act of 1989, 103 Stat. at 2196.

guideline topics for at least the first few years of the Agency's operation was not formalized.³⁶⁴ Although the AHCPR did contract with the IOM for assistance in developing a priority-setting mechanism, it is unclear whether such a mechanism went into effect before the demise of the guideline development program in 1996.³⁶⁵ Guidelines were developed by panels of experts selected from a wide group of health care stakeholders.³⁶⁶ The AHCPR would facilitate the work of these panels and provide financial and logistical support as appropriate.³⁶⁷ In producing clinical guidelines, panels were expected to engage in comprehensive literature review, multidisciplinary expert panel discussion, and broad external review.³⁶⁸ Guidelines were sometimes directly linked to PORT activities.³⁶⁹ It is unclear whether guidelines had any real impact on patterns of health care delivery.³⁷⁰ In total, 19 clinical practice guidelines were developed by the AHCPR.³⁷¹

The AHCPR's PORTs and clinical guideline development work generated controversy and was often the subject of criticism by medical professional groups.³⁷² Perhaps the most significant episode of opposition to AHCPR occurred in 1994 and 1995, when the North American Spine Society (NASS) and other back surgeons voiced strong disapproval of the PORT on back pain, which had questioned the value of back surgery in various clinical situations.³⁷³ The NASS publicly denounced the methods used in the PORT's literature review and suggested that it had been a waste of taxpayer money.³⁷⁴ Subsequently, the Center for Patient Advocacy was formed to lobby on the issue and opposed AHCPR's funding on the grounds that it was supporting unsound and wasteful research.³⁷⁵ Opposition to the agency came at a time when it was particularly vulnerable because of concerns over government spending and calls from the Republican Party to reduce the size of the federal government.³⁷⁶ Those arguing in favor of defunding the AHCPR out of budgetary concerns criticized the agency for being duplicative of other federal agencies and private organizations, as well as for failing to meet its original statutory goals.³⁷⁷ Although it seemed possible for a time that opposition groups might prevail in their push to defund the AHCPR, the agency was able to survive these attacks. However, such attacks did substantially impact the operations of the AHCPR. In 1996, the agency's budget was decreased by 21%, and the AHCPR ceased its guideline development program in favor of supporting "evidence-based practice centers," which were responsible for collecting and organizing data to be used primarily by private organizations to develop practice guidelines.³⁷⁸

The AHCPR was reauthorized and renamed the Agency for Health Research and Quality (AHRQ) under the Health Care Quality and Research Act of 1999.³⁷⁹ The Act also effected a substantial reorganization of the agency, which in some respects reflected some of the concerns of those who had worked to defund the AHCPR.³⁸⁰

I. Agency for Health Research and Quality

The reauthorization statute gave AHRQ the same general purposes as the AHCPR.³⁸¹ However, under its new name, the former AHCPR distanced itself from some of the activities that had previously generated negative political attention. One prominent indication of this shift was the removal of the word "policy" from the agency's name. The leadership of the agency and DHHS felt that use of the word invited misconceptions about the agency's activities and risked associating it with the then-unpopular health policies of the Clinton administration.³⁸² Furthermore, the Healthcare Research and Quality Act removed any reference to "clinical

³⁶⁴Tunis and Gelband, *supra* n. 263, at 355.

³⁶⁵*See id.*

³⁶⁶J. Jarett Clinton, *supra* n. 346, at 455.

³⁶⁷*Id.*

³⁶⁸Tunis and Gelband, *supra* n. 263, at 356.

³⁶⁹Luce and Cohen, *supra* n. 299, at 35.

³⁷⁰*See, e.g.,* Tunis and Gelband, *supra* n. 263, at 355.

³⁷¹*See Clinical Practice Guidelines Archive*, AGENCY FOR HEALTH CARE RES. & QUALITY; available at www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/archive.html (last visited Apr. 26, 2014).

³⁷²Bradford H. Gray *et al.*, *AHCPR and the Changing Politics of Health Services Research*, W3 HEALTH AFFAIRS 283, 297 (2003).

³⁷³*See* D'Arcy and Rich, *supra* n. 349, at 2; Gray *et al.*, *supra* n. 372, at 297; Acute Low Back Pain in Adults, AGENCY FOR HEALTH CARE & POL'Y RES., U.S. DEP'T HEALTH & HUM. SERVS., PUB. NO. 95-0642, ACUTE LOW BACK PAIN IN ADULTS: AHCPR CLINICAL PRACTICE GUIDELINES NO. 14 (1994); available at www.ncbi.nlm.nih.gov/books/NBK52408/?report=reader

³⁷⁴*Id.*

³⁷⁵*Id.*

³⁷⁶Sorenson *et al.*, *supra* n. 11, at 148.

³⁷⁷*Id.*

³⁷⁸Gray *et al.*, *supra* n. 372, at 301-03.

³⁷⁹Healthcare Research and Quality Act of 1999, Pub. Law 106-129, 113 Stat. 1653, 1653.

³⁸⁰*See* Sorenson *et al.*, *supra* n. 11, at 148.

³⁸¹Healthcare Research and Quality Act of 1999, 113 Stat. 1653 at 1653.

³⁸²Gray *et al.*, *supra* n. 372, at 302.

practice guidelines” from the agency’s reauthorization.³⁸³ To ensure that any connection with the AHCPR’s clinical practice guideline work would be severed, the Act clearly stated that the agency “shall not mandate national standards of clinical practice or quality health care standards,” and provided that any “[r]ecommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.”³⁸⁴

The AHRQ is arguably the most prominent agency to have supported HTA and CER in the past two decades and historically has been the largest funder of such research.³⁸⁵ Furthermore, since the agency’s reauthorization, the AHRQ’s role in HTA and CER has been expanded by Congress in acts such as the Medicare Prescription Drug Improvement, the Modernization Act of 2003,³⁸⁶ the American Recovery and Reinvestment Act of 2009,³⁸⁷ and the Patient Protection and Affordable Care Act of 2010.³⁸⁸

The agency currently supports HTA and CER primarily through five initiatives within its Effective Health Care Program (EHCP). First, the agency funds the Healthcare Horizon Scanning System (HHSS). Established in 2010, the purpose of HHSS is to identify and monitor emerging medical technologies and to assess which target technologies have the highest potential impact on clinical care, the health care system, patient outcomes, and cost.³⁸⁹ The goal of HHSS’s work is to help AHRQ and others to plan and prioritize CER resource expenditures and to ensure that CER performed by the agency remains relevant.³⁹⁰ The HHSS’s research involves conducting comprehensive analyses of both published and unpublished sources to identify putative target technologies.³⁹¹ In analyzing the literature, HHSS uses specified criteria to sort and prioritize topics and consults with expert informants to assess the potential impacts of target technologies.³⁹² The process ends with dissemination of findings.³⁹³ Currently, HHSS produces several types of reports, including status update reports, individual topic profiles, potential high-impact reports, and systematic reviews.³⁹⁴ *Status update reports* are revised every 2 months; they identify and track potential target technologies.³⁹⁵ *Individual topic profiles* discuss particular interventions about to enter practice.³⁹⁶ *Potential high-impact reports* present information on target technologies that are predicted to have the greatest impact on the health care system and health care outcomes.³⁹⁷ *Systematic reviews* analyze the most recent methods for horizon scanning.³⁹⁸ Because HHSS is a new program, it is still unclear how important its reports and findings will be.

Second, the AHRQ funds Evidence-based Practice Centers (EPCs). At present, there are 11 EPCs housed primarily in academic institutions.³⁹⁹ The purpose of EPCs is to prepare effectiveness and comparative effectiveness reviews for use by health care professionals, consumers, policymakers, and other stakeholders.⁴⁰⁰ The EPC reports are sometimes prepared at the request of CMS or other federal agencies like the U.S. Preventive Services Task Force.⁴⁰¹ Some reports are commissioned at the request of MedPAC, the successor to ProPAC.⁴⁰² Other reports are nominated by the AHRQ’s outside partners.⁴⁰³ If an issue is nominated rather than requested by a federal agency, AHRQ prioritizes the issue based on criteria such as the prevalence of the medical condition, the cost of treating the

³⁸³*Id.* at 303; see Healthcare Research and Quality Act of 1999, 113 Stat. at 1653.

³⁸⁴Healthcare Research and Quality Act of 1999, 113 Stat. at 1655.

³⁸⁵Sullivan *et al.*, *supra* n. 8, at S40; Wulsin and Dougherty, *supra* n. 10, at 12.

³⁸⁶Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

³⁸⁷American Recovery and Reinvestment Act of 2009, Pub. Law. No. 111-5, 123 Stat. 115.

³⁸⁸Patient Protection and Affordable Care Act of 2010, Pub. Law. No. 111-148, 124 Stat. 119.

³⁸⁹AGENCY FOR HEALTH CARE & POL’Y RES., U.S. DEP’T HEALTH & HUM. SERVS., PUB. NO. 13-EHC104-EF, A SYSTEMIC REVIEW OF METHODS FOR HEALTH CARE TECHNOLOGY HORIZON SCANNING 1 (2013).

³⁹⁰*Id.* at 42.

³⁹¹*Id.* at 42, 43.

³⁹²*Id.* at 43.

³⁹³*Id.*

³⁹⁴AHRQ Healthcare Horizon Scanning System, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/ahrq-horizon-scanning-system/> (last visited Apr. 26, 2014).

³⁹⁵*Id.*

³⁹⁶*Id.*

³⁹⁷*Id.*

³⁹⁸*Id.*

³⁹⁹About Evidence-based Practice Centers, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-evidence-based-practice-centers-eps/> (last visited Apr. 26, 2014).

⁴⁰⁰*Id.*

⁴⁰¹See Atkins D *et al.* Better information for better health care: the Evidence-Based Practice Center Program and the Agency for Healthcare Research and Quality. *Ann Intern Med* 2005;142:1035, 1036.

⁴⁰²See Eisenberg and Zarin, *supra* n. 106, at 195.

⁴⁰³Atkins *et al.*, *supra* n. 401, at 1036.

condition, and the potential for a review to have an impact on health care practices.⁴⁰⁴ Once a topic is chosen for review, a preliminary appraisal of the available literature is performed to ensure that enough evidence exists for a full review, as well as to formulate questions to be addressed in a full review.⁴⁰⁵ An EPC convenes a panel of experts to refine and prioritize questions and suggest how to tackle a full review.⁴⁰⁶ The Center then performs a systematic review of the scientific and medical literature of the topic and synthesizes a report.⁴⁰⁷ Reports generally take about a year to compile and are reviewed extensively prior to dissemination.⁴⁰⁸ The EPC reports have been used to inform health care coverage decisions, generate clinical guidelines, and educate health care professionals.⁴⁰⁹ Reports have used cost-effectiveness as a factor in making recommendations.⁴¹⁰

Third, the AHRQ coordinates the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network. The DEcIDE program is a network of research institutions created specifically to conduct research on the outcomes, effectiveness, safety, and usefulness of specific medical treatments.⁴¹¹ Unlike many of the other HTA/CER programs of the Agency, the DEcIDE program does not take cost-effectiveness into account as a factor in its activities.⁴¹²

Fourth, the Agency funds and operates, in conjunction with the FDA, the Centers for Education and Research on Therapeutics (CERTs). This is an initiative aimed at optimizing the use of drugs, medical devices, and biological products through research and education.⁴¹³ The ultimate goal of the CERTs is to change the prescribing behaviors of health care professionals.⁴¹⁴ The CERTs prepares HTA/CER reports on specific therapeutics or conditions that take into account clinical risks and benefits, interactions with other therapies, and economic implications.⁴¹⁵ Currently, six CERTs are part of the program and focus on health information technology, therapies for health and blood vessel disorders, mental health therapeutics, musculoskeletal disorders, pediatric therapeutics, and tools for optimizing prescribing.⁴¹⁶

Fifth, the AHRQ operates the Scientific Resource Center (SRC). The SRC supports the activities of the EHCP.⁴¹⁷ SRC's responsibilities are largely technical and logistic.

J. Patient-Centered Outcomes Research Institute

Starting in late 2006, policymakers began to show increasing interest in CER.⁴¹⁸ A shift from a Republican to a Democratic majority in Congress stimulated a renewed interest in health care reform.⁴¹⁹ CER, like HTA before it, began to be

seen as a means of addressing quality and cost-containment problems in the United States health care system.⁴²⁰ Congressional leaders and other stakeholders began to call for a new federal entity with greater focus on CER.⁴²¹ However, the idea of such an entity was not without its opponents. In particular, conservative groups and industry representatives expressed concern that a new CER entity would restrict physician choice and patient access to care, as well as stifle innovation.⁴²² Despite this opposition, provisions for a CER entity in the form of the Patient Centered Outcomes Research Institute (PCORI) were included in the Patient Protection and Affordable Care Act of 2010 (PPACA) and its subsequent amendments in the Health Care and Education Reconciliation Act of 2010 (HCERA).⁴²³

The creation of the PCORI by the PPACA and HCERA was the culmination of the efforts of many CER proponents.⁴²⁴ The PCORI is an independent, non-profit, tax exempt corporation whose purpose is to

⁴⁰⁴*Id.*

⁴⁰⁵*Id.*

⁴⁰⁶*Id.* at 1037.

⁴⁰⁷Eisenberg and Zarin, *supra* n. 106, at 194.

⁴⁰⁸See Atkins *et al.*, *supra* n. 401, at 1037.

⁴⁰⁹Wulsin and Dougherty, *supra* n. 10, at 12–3.

⁴¹⁰*Id.* at 13.

⁴¹¹*About the DECIDE Network*, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-decide-network/> (last visited Apr. 26, 2014).

⁴¹²Wulsin and Dougherty, *supra* n. 10, at 12.

⁴¹³*About CERTs*, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-certs/> (last visited Apr. 26, 2014).

⁴¹⁴See Nash DB. CERTainly a great idea! *Pharmacol Ther* 2001;26:285.

⁴¹⁵Wulsin and Dougherty, *supra* n. 10, at 12.

⁴¹⁶*About CERTs*, *supra* n. 413.

⁴¹⁷*About the Scientific Resource Center*, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-scientific-resource-center1/> (last visited Apr. 26, 2014).

⁴¹⁸Sorenson *et al.*, *supra* n. 11, at 141.

⁴¹⁹*Id.*

⁴²⁰*Id.*

⁴²¹*Id.*

⁴²²*Id.*

⁴²³*Id.*; Health Care and Education Reconciliation Act of 2010, Pub. Law 111–152, 124 Stat. 1029.

⁴²⁴Patient Protection and Affordable Care Act of 2010, 124 Stat. at 728.

assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis...and the dissemination of research findings.⁴²⁵

The ultimate goal of PCORI's work is to improve health care delivery and outcomes by helping people to make informed health care decisions.⁴²⁶ The PCORI is governed by a board consisting of the directors of AHRQ and NIH as well as 17 members appointed by the Comptroller General who represent various health care stakeholder groups.⁴²⁷

In conducting and supporting CER, PCORI is limited by its statutory authorization. In order to ensure PCORI's establishment, proponents of CER had to make various concessions. Thus, PCORI is prohibited from using certain cost-effectiveness methodologies and cannot frame its research findings as mandates, guidelines, or recommendations for payments, coverage, or treatments.⁴²⁸ Furthermore, in making coverage decisions, the Secretary of DHHS is prohibited from relying solely on PCORI-sponsored CER. In order to use PCORI-sponsored CER findings in coverage decisions, the Secretary must go through "an iterative and transparent process that includes public comment and considers the effect [of the findings] on subpopulations."⁴²⁹ Moreover, in using these findings, the Secretary is prohibited from differentiating the value of life for an elderly, disabled, or terminally ill patient from that of a healthy patient.⁴³⁰

The PCORI is charged with identifying national research priorities, creating a research agenda based on these priorities, funding CER in furtherance of this agenda, and disseminating research findings to patients and health care professionals.⁴³¹ In May 2012, PCORI's Board of Governors adopted five national priorities for research: assessment of prevention, diagnosis, and treatment options; improving health care systems; communication and dissemination research; addressing disparities; and accelerating patient-centered outcomes research and methodological research.⁴³²

To select particular topics for CER in furtherance of these priorities, PCORI has adopted two complementary approaches.⁴³³ Under the first approach, known as the "investigator-initiated approach," PCORI solicits research proposals in the five national priority areas using what are known as PCORI Funding Announcements (PFAs).⁴³⁴ Under

the second approach, known as the "patient- and other stakeholder-initiated approach," PCORI solicits potential research questions from patients and other stakeholders through a variety of means.⁴³⁵ The PCORI then engages in a systematic topic selection and prioritization process that involves reviewing a potential topic against a set of defined criteria.⁴³⁶ Topics then undergo preliminary literature review before they are selected by a PCORI Advisory Panel for a final assessment.⁴³⁷ Selected topics are submitted to the PCORI Board of Governors, which then approves a final list of topics to be developed into targeted PFAs.⁴³⁸ Thus far, PCORI has identified five topics for targeted PFAs using this process: treatment options for uterine fibroids; treatment options for severe asthma in African Americans and Hispanics/Latinos; preventing injuries from falls in the elderly; treatment options for back pain; and obesity treatment options in diverse populations.⁴³⁹

⁴²⁵*Id.*

⁴²⁶*About the Scientific Resource Center*, AGENCY FOR HEALTH CARE RES. & QUALITY; available at <http://effectivehealthcare.aahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-scientific-resource-center1/> (last visited Apr. 26, 2014).

⁴²⁷Patient Protection and Affordable Care Act of 2010, 124 Stat. at 735.

⁴²⁸*Id.* 739–41.

⁴²⁹*Id.* at 740.

⁴³⁰*Id.* at 740–1.

⁴³¹PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE, NATIONAL PRIORITIES FOR RESEARCH AND RESEARCH AGENDA 1 (2012); see Patient Protection and Affordable Care Act of 2010, 124 Stat. at 728–35.

⁴³²*Id.* at 8.

⁴³³*How We Select Research Topics*, PATIENT-CENTERED OUTCOMES RES. INST., <http://www.pcori.org/funding-opportunities/funding-announcements/how-we-select-research-topics/> (last visited Apr. 26, 2014).

⁴³⁴*Id.*

⁴³⁵*Id.*

⁴³⁶*From Questions to Funding: About Our Topic Generation and Research Prioritization Process*, PATIENT-CENTERED OUTCOMES RES. INST.; available at www.pcori.org/funding-opportunities/funding-announcements/from-research-questions-to-research-funding-about-our-topic-generation-and-research-prioritization-process/ (last visited Apr. 26, 2014).

⁴³⁷*Id.*

⁴³⁸*Id.*

⁴³⁹*Accelerated Process to Targeted Funding*, PATIENT-CENTERED OUTCOMES RES. INST.; available at www.pcori.org/funding-opportunities/funding-announcements/accelerated-process-to-targeted-funding/ (last visited Apr. 26, 2014).

The PPACA also established the Patient-Centered Outcomes Research Trust Fund (PCORTF) to support the operations of PCORI.⁴⁴⁰ The PCORTF received \$10 million in 2010, \$50 million in 2011, and \$150 million for 2012.⁴⁴¹ For 2013 to 2019, PCORTF is to receive \$150 million from the general fund of the U.S. Treasury, as well additional funds from small fees assessed on Medicare, private health insurance, and self-insured plans.⁴⁴²

K. Other Federal Programs

In addition to the major HTA and CER efforts of the federal government discussed above, other federal entities have engaged in HTA and CER. This paper will briefly discuss three of these federal agencies: Centers for Medicare and Medicaid Services (CMS); the Department of Veterans Affairs (VA); and the Department of Defense (DoD). While conducting HTA or CER is not a primary purpose of these agencies, they do perform a significant amount of these activities, and therefore warrant analysis.

1. Centers for Medicare and Medicaid Services. Although CMS (previously HCFA) has a long history of engaging in formal agreements with other federal entities to perform HTA and CER to aid in reimbursement policy decisions, CMS itself makes final determinations of whether a procedure is “reasonable and necessary.”⁴⁴³ This process has generally involved analysis of outside reports along with activities within CMS. The Coverage and Analysis Group (CAG) of the Office of Clinical Standards and Quality of CMS currently has responsibility for undertaking or requesting HTAs or CER reports to support reimbursement policy.⁴⁴⁴

Starting in the 1980s, HCFA developed an internal process for making national coverage decisions involving an informal committee of physicians for controversial treatments.⁴⁴⁵ The committee met privately with no outside participation.⁴⁴⁶ For more complex coverage determinations, HCFA would request an HTA from an outside agency, such as the NCHCT. In response to a lawsuit challenging coverage policy, HCFA published a notice explaining its procedures for making its coverage decisions in 1987.⁴⁴⁷

Throughout the 1980s and the 1990s, HCFA struggled to design a coverage process that adequately addressed the concerns of the spectrum of health care stakeholders.⁴⁴⁸ In 1998, HCFA established the Medicare Coverage Advisory Commission (MCAC), which comprised outside health care experts.⁴⁴⁹ The MCAC was renamed the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) in 2008 and is currently the main body advising CMS on national coverage decisions.⁴⁵⁰

The MedCAC’s role is to compile evidence and conduct open public meetings concerning coverage of particular technologies where evidence, including any requested HTA or CER reports, is weighed.⁴⁵¹ If it is determined that there is sufficient evidence to make a decision, MedCAC members vote on whether they think the particular technology is effective.⁴⁵² The MedCAC’s input is not binding, and final decisions on reimbursement are made by the CAG and issued through a National Coverage Determination memorandum.⁴⁵³ The CAG is prohibited from considering costs or cost-effectiveness in making these determinations.⁴⁵⁴ The evidence considered at the meeting, other publicly submitted evidence, and final coverage determinations are all posted on the CMS website.⁴⁵⁵

2. The Department of Veterans Affairs and the Department of Defense. Federal initiatives in HTA and CER have also included the efforts of the VA and the DoD. Both of these entities are significant providers of health care and engage in various HTA activities.

⁴⁴⁰Patient Protection and Affordable Care Act of 2010, 124 Stat. at 728.

⁴⁴¹See D’Arcy and Rich, *supra* n. 349, at 3.

⁴⁴²*How We’re Funded*, PATIENT-CENTERED OUTCOMES RES. INST.; available at www.pcori.org/about-us/how-were-funded/ (last visited Apr. 26, 2014).

⁴⁴³While Medicare makes both local and national coverage determinations, this paper focuses its discussion of Medicare’s HTA/CER activities on CMS’s national coverage policies. Furthermore, this paper will not discuss HTA/CER activities for the Medicaid Program, as its focus is the role of the federal government, and these activities are generally handled by states. See Sullivan *et al.*, *supra* n. 8, at S40.

⁴⁴⁴UNITED STATES GENERAL ACCOUNTING OFFICE, MEDICARE: DIVIDED AUTHORITY FOR POLICIES ON COVERAGE OF PROCEDURES AND DEVICES RESULTS IN INEQUALITIES 8 (2003).

⁴⁴⁵Eleanor D. Kinney, *Comparative Effectiveness Research Under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J.L. & MED. 522, 534 (2011).

⁴⁴⁶*Id.*

⁴⁴⁷*Id.*

⁴⁴⁸*Id.* at 534–5.

⁴⁴⁹*Id.* at 535.

⁴⁵⁰Centers for Medicare & Medicaid Services. CMS creates MedCAC from MCAC. *J Nuclear Med* 2008;48:43N.

⁴⁵¹Sullivan *et al.*, *supra* n. 8, at S40.

⁴⁵²See Centers for Medicare & Medicaid Services, *supra* n. 450, at 43N.

⁴⁵³Sullivan *et al.*, *supra* n. 8, at S40.

⁴⁵⁴*Id.*

⁴⁵⁵*Id.*

The VA runs its own health care system under the purview of the Veterans Health Administration (VHA), which is the country's largest integrated health care system.⁴⁵⁶ The DoD runs the Military Health System (MHS), which provides care to active-duty personnel, military retirees, and the eligible dependents of both of these groups.⁴⁵⁷ Both the VA and the DoD have significant experience performing HTA and CER and have a number of programs dedicated to these activities.⁴⁵⁸ An example of a CER activity involving both of these departments is a collaboration in which VA and DoD together review evidence of treatment efficacy through comprehensive analysis of patient records.⁴⁵⁹ The CER methods are then used to generate clinical guidelines and establish a drug formulary.⁴⁶⁰

IV. CHALLENGES IN THE FEDERAL FUNDING OF HTA AND CER EFFORTS

Although efforts to create a national, publicly funded HTA or CER entity have existed for almost half a century, these efforts have been fragmented and have faced significant obstacles. Both HTA and CER have long represented a means to achieve better health outcomes while controlling costs, but in practice, the results of federally funded HTA and CER efforts do not seem to have had much effect on patterns of care or health care spending. Drawing on the history of previous HTA and CER entities and their demise, there are recurrent themes that may help to inform current and future efforts. Three recurring challenges to the establishment of a permanent and effective federal entity that substantially performs HTA or CER are budgetary concerns, opposition from health care interest groups, and the lack of a mechanism to effect meaningful change.

The first challenge has been budgetary problems. Both HTA and CER efforts have been particularly vulnerable to calls for defunding in times of budgetary instability despite the promise of potential cost savings that HTA and CER programs represent. Because of the fragmented and uncoordinated nature of these programs, there generally has not been a single repository of HTA or CER work in the federal government. Rather, at any given time, multiple federal agencies have been engaged in HTA, CER, or related activities. Thus, in times of budgetary crisis, federally funded agencies primarily engaged in HTA or CER efforts have often been portrayed as duplicative of other agencies. In particular, these criticisms were leveled against both the OTA and the NCHCT, which likely contributed to their demise. Furthermore, these programs

have generally been short-lived and, perhaps as a result, have not had a major measurable impact on reducing health care spending. Thus, they have often been attacked for wasting tax dollars. Moreover, HTA and CER efforts often lack a strong advocate in the legislature to counter these attacks.⁴⁶¹ Such attacks have been especially successful in tough fiscal times when Republican Congressional majorities have focused on scaling down the size of the federal government and eliminating agencies seen as unnecessary or wasteful as a means of enforcing budgetary discipline. Even when there has not been complete defunding, the Congressional appropriations process has often led to limited budgets for HTA and CER efforts.

The second challenge has been interest group opposition. In particular, the medical profession and industry groups have voiced staunch opposition to such programs. The health care profession seems to have two primary problems with HTA and CER efforts. First, groups such as the AMA take issue with what they view as an intrusion into medical practice by persons who often are not physicians. Both HTA and CER programs often make recommendations or guidelines for how to use health care technologies and how to treat particular conditions. Although these recommendations and guidelines have been voluntary, they often have a quasi-regulatory effect. For example, both the NCHCT and OHTA performed HTAs that influenced reimbursement policy. Lack of reimbursement may effectively cut off a treatment option. The medical profession generally views treatment choice as a judgment better made by individual physicians rather than committees. Second, groups within the medical profession have been threatened by HTA and CER efforts when individual reports recommend against a particular treatment they endorse or highlight evidence of its ineffectiveness. For

⁴⁵⁶See *Veterans Health Administration: About VHA*, U.S. DEP'T OF VETERANS AFFAIRS; available at www.va.gov/health/aboutVHA.asp (last visited Apr. 23, 2014).

⁴⁵⁷Don J. Jansen, CONG. RESEARCH SERV., RL33537, MILITARY MEDICAL CARE: QUESTIONS AND ANSWERS (2012).

⁴⁵⁸See, e.g., John Concato *et al.* Comparative effectiveness research: what kind of studies do we need? *J Invest Med* 2010;58:764, 765; Sullivan *et al.*, *supra* n. 8, at S41.

⁴⁵⁹Wulsin and Dougherty, *supra* n. 10, at 13.

⁴⁶⁰*Id.*; see, e.g., MANAGEMENT OF POST-TRAUMATIC STRESS WORKING GROUP, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF DEFENSE, VA/DoD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF POST-TRAUMATIC STRESS (2010).

⁴⁶¹See Sorenson *et al.*, *supra* n. 11, at 159.

example, the NASS took swift action against the AHCPR when it published reports indicating that the utility of a particular spine operation for acute back pain was not supported by evidence.⁴⁶² This type of backlash may be attributable not only to concern about governmental intrusion into the field of medical decision-making, but also the potential negative financial effects of such recommendations. Industry groups also have been opposed to HTA and CER programs. These groups generally are concerned that recommendations will hurt the profitability of the industry and that they may stifle innovation and the growth of emerging companies.

The third challenge to a lasting and effective federal HTA or CER agency has been reliance by policy makers on voluntary mechanisms to effect change. Generally, care has been taken to ensure that federal HTA and CER efforts are not perceived as being regulatory, and compliance with published recommendations and guidelines by health care providers has been voluntary. In the past, such guidelines have not been followed.⁴⁶³ There are perhaps not enough incentives for the medical profession to use these recommendations and guidelines voluntarily. Although there is a general professional and ethical duty to deliver high-quality care to patients, clinical decisions are rarely subject to formal quality review or required to adhere to the latest standards of care,⁴⁶⁴ although this is changing to some extent with the recent emphasis on “standard of care” treatment. Furthermore, when recommendations and guidelines are not connected with reimbursement policy, financial incentives may not exist to follow them. In fact, health care financing structures in the United States that reward volume of care may provide an incentive for health care professionals to ignore HTA and CER reports.⁴⁶⁵ Moreover, it seems untenable to have patients play a significant a role in their own health care decisions, even when HTA and CER reports are available to them, as the nature of the physician–patient relationship generally results in complete deference to the physician’s decisions. Furthermore, laws generally do not require policy-makers to consider HTA and CER findings when making decisions about health care policies. Restriction on the use of cost and cost-effectiveness in HTA and CER efforts may also limit the impact that such programs can have on cost containment.

Whether the federal government’s current CER efforts, like PCORI, will face the same obstacles and succumb to the same fate as previous programs is still yet unclear. However, unlike some of the federal government’s earlier HTA and CER initiatives, PCORI has features that make it less politically vulnerable. Both its status as an independent, non-

profit corporation and its receipt of funding through PCORTF shelters PCORI from the volatility of the Congressional appropriations process.⁴⁶⁶ However, restrictions on methodologies available to PCORI and on the use of its findings in policy decisions may limit its ability to effect meaningful change in health care practices.

V. POTENTIAL APPROACHES FOR THE FUTURE

It may be that in order to have a meaningful effect on patterns of health care delivery, the recommendations of CER will have to be given more regulatory force or be incorporated into market approval schemes for drugs and devices. Some observers have suggested that the FDA should have a greater role in mandating CER and disseminating its results.⁴⁶⁷ Two areas where this may be possible under FDA authority are in the approval process and labeling requirements.

First, several commentators have suggested that the FDA should require pre-market CER and use this information in making approval decisions for drugs and devices.⁴⁶⁸ Such a requirement would likely mean that drug and device developers would be required to have active-comparator trials instead of or in addition to placebo-controlled trials.⁴⁶⁹ Approval decisions would not necessarily require that a new therapy be more efficacious than a prior drug or device, but that CER information would be incorporated into the approval process.⁴⁷⁰ For example, a treatment with only disadvantages compared with an existing drug or device might not be approved unless developers were able to demonstrate that the treatment fell within a niche, such as use as a booster therapy for patients with refractory conditions.⁴⁷¹

Second, Stafford *et al.* have suggested that comparative effectiveness information should be

⁴⁶²Gray *et al.*, *supra* n. 372, at 301–3.

⁴⁶³See Kosecoff *et al.*, *supra* n. 175, at 2713.

⁴⁶⁴See Sorenson *et al.*, *supra* n. 11, at 160.

⁴⁶⁵*Id.*

⁴⁶⁶D’Arcy and Rich, *supra* n. 349, at 3.

⁴⁶⁷See, e.g., Alexander GC, Stafford RS. Does comparative have a comparative edge? JAMA 2009;301:2488.

⁴⁶⁸See, e.g., *id.*; O’Connor AB. Building comparative efficacy and tolerability into the FDA approval process. JAMA 2010;303:979.

⁴⁶⁹*Id.* at 980.

⁴⁷⁰*Id.*

⁴⁷¹*Id.*

incorporated into FDA labeling of drugs and devices.⁴⁷² In such a scheme, in the absence of CER, drug and device labels would be required to indicate that there is no evidence that a product is superior to others.⁴⁷³ Under the proposal, payers would have readily available comparative information on products that could be used to negotiate prices, and drug and device developers would be given an incentive to design trials to differentiate their products with respect to clinically important features.⁴⁷⁴

Although such approaches may generate useful information and decrease the likelihood that new, but less effective, treatments would replace established treatments, it is unclear whether they would be politically or practically viable. Industry in particular likely would be vehemently opposed to such changes—particularly to a requirement for active-comparator trials, which would increase both costs and the risk that a treatment would be discovered to be inferior only in the late stages of development.⁴⁷⁵ It is arguable that these financial risks would stifle innovation and the growth of emerging companies. Any such proposals would thus likely face staunch political opposition from industry groups. Furthermore, more regulatory approaches to HTA and CER generally have been disfavored in the past. Moreover, it is unclear to what extent such proposals would require additional resources from the FDA. For example, use of CER in the approval process might require greater FDA oversight of active-comparator trials and more consultation with experts to evaluate the evidence generated. It is unclear whether such a shift would be viable, given the FDA's already strained resources and chronic underfunding.⁴⁷⁶

VI. CONCLUSION

Containing health care expenditures while ensuring quality of health care delivery has been and continues to be a major concern for the federal government. However, HTA and CER are two activities by which many think these goals can be furthered. Federal programs dedicated to HTA and CER in the United States have a long, but fragmented, history, dating back to the establishment of the OTA in the early 1970s. Efforts at establishing a national repository of HTA or CER activities have been impeded by factors such as budgetary concerns, lack of clear goals, and resistance from health care professionals, industry groups, and others. In recent years, there has been renewed focus on HTA and CER, which has resulted in increased CER activities by the AHRQ and the establishment of PCORI. Whether this renewed focus will affect cost-containment and patterns of health care delivery remains to be seen. CER activities may have a greater impact if their findings are used in a more regulatory manner. In particular, the FDA could play a larger role in requiring CER activities. However, it is unclear that such a move would be politically viable, given the history of opposition to more regulatory approaches.

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⁴⁷²See Stafford *et al.*, *supra* n. 4, at 1232.

⁴⁷³*Id.*

⁴⁷⁴*Id.*

⁴⁷⁵O'Connor, *supra* n. 468, at 980.

⁴⁷⁶INSTITUTE OF MEDICINE, CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 15 (2007).