
THE LEGISLATIVE BATTLE OVER HEALTH SERVICES RESEARCH

by Bradford H. Gray

*Prologue: The large geographic variations that characterize medical practice trouble health policymakers because of implications that a rational basis is lacking for much medical care and that money is being wasted. In 1989 these concerns took legislative form in the law that created the Agency for Health Care Policy and Research (AHCPR) and gave it a mandate that focused heavily on research on the outcomes and effectiveness of medical care and on the development and dissemination of practice guidelines. As Brad Gray notes in this paper, this legislation almost did not pass, not because of its controversial nature but because of political complexities like those that face any legislative proposal. Both the improbability of this legislation and its implications regarding accountability in health care led Gray to seek to understand how it came into being. The results of his inquiry should interest both health services researchers and students of the policy process. Gray's history is followed by the brief comments of John Wennberg, whose ideas and research on practice variations are central in Gray's account. Gray, a respected researcher and scholar of ethical and policy issues in health care, is a professor in the Department of Epidemiology and Public Health at the Yale School of Medicine and director of Yale's Program on Non-Profit Organizations. He received his doctorate in sociology/medical sociology from Yale. For ten years he was a senior staff officer and study director at the National Academy of Sciences' Institute of Medicine. His book, *The Profit Motive and Patient Care: The Changing Accountability of Doctors and Hospitals*, was published by Harvard University Press in 1991.*

Abstract: Budget reconciliation legislation in 1989 created the new Agency for Health Care Policy and Research (AHCPR), which folded in the National Center for Health Services Research and Health Care Technology Assessment, among the law's other provisions. The creation of the new agency represented a shift in priorities toward outcomes and effectiveness research in medical practice and made explicit the federal government's role in developing practice guidelines. The new agency was born in the midst of an extraordinary bipartisan budget negotiation process in late 1989; its becoming linked to the contentious issue of physician payment reform nearly killed the new agency before it appeared. The narrative of political wrangling that resulted in the creation of AHCPR spans Capitol Hill, the White House, the agencies of the Department of Health and Human Services, and renowned health services researchers on either coast and in Washington, D.C.

The governmental face of American health policy changed significantly in 1989. Buried deep within the 385-page Omnibus Budget Reconciliation Act (OBRA) of 1989 were twenty pages that created the Agency for Health Care Policy and Research (AHCPR) and gave it an important set of responsibilities. The new agency, which replaced the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), was assigned a high bureaucratic location, parallel in the Public Health Service to the Centers for Disease Control, the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

Much about this legislation was improbable. Although 1989 was a year of enormous budgetary turmoil and stringency, the law contained provisions for significant new funding for health services research, a field that was not known to have many friends on Capitol Hill. Much of the new funding, however, was for a particular type of research: on the outcomes of medical care. The new agency was also charged with the development and dissemination of guidelines and standards for medical practice. Many observers would have thought that such a federal role would have been anathema to the medical profession, but these provisions had strong support from such professional groups as the American Medical Association, the American College of Physicians, and the American Society of Internal Medicine.

The close examination of how a particular law came into being sheds light on the policy process and provides clues about the law's broader implications. The legislative process can be harrowing to those involved and fascinating to the observer. Any proposal of consequence attracts opposition. Although some issues can only be decided by votes, compromise and modification are commonly used to reduce opposition and build coalitions long before any final vote is taken. The strategies and compromises that brought this particular piece of legislation into being have implications for health services research and for U.S. health policy.

Products of the legislative process are affected by ideas, political

ideologies, and the power of interest groups. These factors interplay with the process itself—the divisions of power across levels and branches of government and within Congress, the ways in which budgetary constraints are imposed, and the rules and procedures that frame the tortuous and sometimes quirky path along which a bill must move to become law. The result also depends on the power and influence of members of Congress who favor and oppose a proposal. A bill's chances are enormously enhanced if it is supported by key committee chairs, and a strategically located opponent can spell doom. The history of the legislation that created AHCPR amply illustrates all of these points.

Sources of information. This essay comes from a larger study of the history of this legislation and the issues with which it dealt. The legislative process creates an extensive documentary record of budgetary actions, bills, hearings, committee reports, floor debate, and completed legislation. I have reviewed such materials going back to 1984 and reauthorization and appropriations hearings going back further. To understand better how and why different developments took place, I also interviewed most of the individuals who played a role in Congress, in the Department of Health and Human Services, in the Office of Management and Budget, and in lobbying on the issues.¹

Elements Of The Legislation

AHCPR was created as Title IX of the Public Health Service Act by Section 6103 of OBRA 1989. (Section 6103 also amended the Social Security Act's Title XVIII—the Medicare program.) In replacing NCHSR and ending that center's long struggle for funding and respect, AHCPR was assigned its personnel, assets, liabilities, and functions (such as technology assessment)—in some cases with substantial modifications, as with the research program on the outcomes of care. It was also given some important new functions, most notably in the Forum for Quality and Effectiveness in Health Care, which is to develop and disseminate “practice guidelines, quality standards, performance measures, and medical review criteria.”

The new agency was given general authority to carry out research, demonstrations, guideline development, training, and dissemination activities with respect to health care services and systems of information regarding the following areas: the effectiveness, efficiency, quality, and outcomes of health services; clinical practice, including primary care; health care technologies, facilities, and equipment; health care costs, productivity, and market forces; health promotion and disease prevention; health statistics and epidemiology; and medical liability.

The law contained detailed specifications about such matters as the nature of various research and dissemination activities, database development and standards, reporting requirements, how priorities would be set, and how funding decisions for proposed research would be made. A seventeen-member National Advisory Council for Health Care Policy, Research, and Evaluation was established and assigned duties regarding agenda setting and priorities. This panel was to include researchers in health care; practicing physicians and other health professionals; individuals from “business, law, ethics, economics, and public policy;” and individuals representing the interests of consumers. All except the latter were required to be “distinguished.”

The law’s funding provisions involved appropriated funds under both the Public Health Service Act and the Social Security Act, transfers from the two Medicare trust funds, and 40 percent of the 1 percent evaluation monies attached to the Public Health Service (PHS).² Authorizations for appropriations under the two acts began at \$85 million in fiscal year 1990 and increased to \$185 million in 1994; the evaluation funds were estimated to produce an additional \$30–\$40 million. (NCHSR’s funding for 1989 was \$53 million, and the 1990 appropriation, which was being considered simultaneously with the outcomes research bill, was \$78 million.)

Legislation As A Problem-Solving Activity

Legislative proposals frequently emerge in response to something that an individual, a group, or the public has defined as a problem. Advocates commonly seek to convince legislators that there is a public interest in addressing the advocate’s concerns. The outcomes research legislation involved stitching together solutions to three related problems: the poor scientific basis for much medical care; congressional reluctance to fund health services research; and Medicare costs.

Lack of scientific basis for medical practice. The first “problem” grew out of research: studies by John Wennberg of Dartmouth University and his colleagues of geographic variations in patterns of medical practice, and studies by Robert Brook and his colleagues at RAND of the appropriateness of certain procedures. (Other research existed on these topics, but the work by Wennberg and Brook had the highest profiles on Capitol Hill.) The problem these studies revealed was the lack of scientific basis for much of medical practice. Services that patients received depended in part on random factors, such as what Wennberg termed the “practice style” of the physician. Thus third-party payers were uncertain about what services they should pay for and under what circumstances.

Beginning in the mid-1980s Wennberg set out to convince key legislators (and their staffs) that the problem revealed by his research was both significant and solvable, if only the federal government would provide substantial funding for research on the outcomes of services.

Difficulty in obtaining research funds. Wennberg soon picked up some allies who were concerned with a second, related “problem:” the difficulty in getting Congress to appropriate funds for health services research. This was a problem for NCHSR, the lead federal agency for support of such research, and for individual health services researchers. It was the main reason that researchers had formed the Association for Health Services Research (AHSR) in the early 1980s. At Appropriations Committee hearings through the 1980s, AHSR was the only voice in favor of increased funding for NCHSR. This testimony had little measurable effect, however. The funds appropriated to NCHSR for general health services research changed little from year to year and never exceeded \$20 million, even while Congress was appropriating more than \$6 billion for biomedical research at the National Institutes of Health (NIH) and while outlays from the two Medicare trust funds were approaching \$100 billion.³

By the late 1980s AHSR’s leaders were convinced that NCHSR itself was part of the problem. Its bureaucratic location within the office of the Health and Human Services (HHS) assistant secretary for health lacked prestige and visibility, and its leadership had been ineffective in budgetary battles within the executive branch and on Capitol Hill.

An opportunity to do something about NCHSR arose early in 1989, when it became apparent that Congress might establish a significant new program of outcomes research. Two senior House staffers, Peter Budetti and Peter Bouxsein, who worked for the House Energy and Commerce Subcommittee on Health and the Environment and its chair, Rep. Henry A. Waxman (D-CA), began sketching out ideas on a piece of paper in the cafeteria of the Longworth House Office Building about how the momentum that was developing for outcomes research might be used for matters of great concern to them. Their work was to lead to the introduction of legislation by Waxman several months later.

Bouxsein had a long-standing interest in improving the rationality with which patient care and payment decisions were made. If large sums were to be spent on outcomes research, careful thought would need to be given to how the research could be translated into practice. Bouxsein’s ideas would develop into the Forum for Quality and Effectiveness in Health Care. Budetti’s concern was with the poor treatment of health services research in the federal budget. He realized that if a major outcomes research program were to move forward, it would open up the

question of where this new initiative belonged. Was outcomes research similar to clinical research and thus the province of NIH? Or was its purpose to support Medicare and Medicaid coverage and payment decisions and thus the province of the Health Care Financing Administration (HCFA)? Perhaps it belonged someplace in between—NCHSR or a new agency, as AHSR (with Budetti's encouragement) began arguing.⁴

Medicare costs. Through much of the 1980s Wennberg and AHSR sought to link their concerns to a third problem that already worried policymakers: the rapidly rising costs (and threatened bankruptcy) of the Medicare program. Key administration officials and legislators had to be convinced that solutions to the problems that concerned Wennberg and AHSR (the "health services research entrepreneurs," in the words of one House staffer) would also address the Medicare cost problem and that researchers had common interests with these officials. The federal deficit and the House Appropriations Committee's disdain for health services research made it clear that Medicare was the most likely source of new funding for research. OBRA 1989 thus linked solutions to the problems of the inadequate scientific basis of medical practice, congressional reluctance to fund health services research, and runaway health care costs, with outcomes research as the driving force.

The Role Of The Policy Entrepreneur

The legislation that passed late in 1989 grew out of three bills introduced earlier that year by Sen. George J. Mitchell (D-ME) and Reps. Willis D. Gradison, Jr. (R-OH) and Waxman. (A fourth bill was introduced near the end of the budget reconciliation process by Sen. Edward M. Kennedy [D-MA]. It was based substantially on the Waxman bill and had little impact on the final legislation.) The events that led to the legislation began several years before. Much of the impetus can be traced to one individual—John Wennberg. He was motivated in part by the funding needs for his own research, but he also had a larger vision regarding the creation of a field of "evaluative clinical sciences" that would fill the gap between clinical research and medical practice.

Of course, no legislation can be attributed to one individual. Other people—most notably RAND's Brook; William Roper, then HCFA administrator; and members and staff of the Physician Payment Review Commission (PPRC)—helped to educate Congress about the potential value of research on outcomes and effectiveness of medical care, and a handful of individuals on Capitol Hill played key roles in moving legislation forward. The 1989 push to frame the new research and guidelines development initiative in a new agency came from AHSR in conjunc-

tion with Budetti. Nevertheless, Wennberg was responsible for so many of the ideas and so much of the work that provided the momentum for the legislation that it can fairly be cited as example of public policy initiated by an individual.⁵

Wennberg was there at the beginning and the end and was the common denominator of everything that happened in between. He testified at almost every relevant congressional hearing, and his name was invoked by almost every witness. Through many speeches in many forums and through countless conversations with members of Congress and their staffs, Wennberg sought to create awareness of the implications of his research that showed large practice variations within states and between cities, to advocate his approach to the issue (his model was the Maine Medical Assessment Project in Senator Mitchell's home state, where physicians' practice patterns changed after physicians were provided with data showing practice variations within the state), and to show why the federal government as the nation's largest purchaser should be concerned. He drafted concept papers and legislative ideas that showed up in several different bills between 1985 and 1989.

Congressional Activity

Capitol Hill action began in late 1984 when Sen. William Proxmire (D-WI) held a hearing on variations in medical practice.⁶ Two of Proxmire's staffers, Tom van der Voort and Larry Patton, had become interested in the topic after attending a session of the National Health Policy Forum at which Wennberg and Brook had presented results of their respective research on practice variations and inappropriate medical care. This forum was initiated and cosponsored by *Health Affairs*, which had devoted its Summer 1984 issue to medical practice variations, with Wennberg as the lead author. The forum was an opportunity for a handful of the volume's authors to present their published work to Capitol Hill staff. The journal also held a press seminar on the morning of the forum, which garnered broad publicity for Wennberg in *The Washington Post*, *The New York Times*, *The Boston Globe*, the *Los Angeles Times*, and other major newspapers.

Proxmire set the context for the hearing by noting that Medicare was "on the verge of bankruptcy," that research had documented large variations in the use of procedures, and that no one knew "if more is better." HCFA, NCHSR, and NIH were invited to explain how their agencies were addressing the problems that Wennberg identified in his testimony, which was the focus of the hearing. Wennberg presented data showing large geographic variations in the use of common surgical procedures, in

hospital admissions for various medical conditions, and in numbers of hospital beds and admissions. He showed that per capita hospital costs were more than twice as high in Boston as in New Haven and attributed the difference to the greater number of hospital beds in Boston. He offered some estimates of the savings that could be achieved if the low utilization rates of certain areas were to become “the norm.”

Wennberg offered this explanation for the practice variations: “The necessary scientific studies that allow physicians to define the optimum treatment have not been done.” He then offered a plan, which he had published in the Summer 1984 *Health Affairs*, for dealing with the variations phenomenon.⁷ The plan included a major program of research into the outcomes of common diagnostic and therapeutic interventions. Wennberg suggested that one-half of 1 percent of the Medicare trust fund should be allocated to such research. Both in the remainder of the hearing and in congressional activity over the next five years, the ideas that Wennberg laid out were the core of discussion and legislative proposals for outcomes research.

The first legislation to authorize funds for outcomes research was introduced in 1985 by Proxmire. The senator’s bill failed, in part because he was not a member of the key committees but also because he actually proposed funding on the scale that Wennberg had suggested. Proxmire was greatly embarrassed when the director of NCHSR was then quoted in a newspaper in the senator’s home state as saying that his agency might not know how to spend so much money.⁸ Proxmire quickly introduced another bill with much more modest funding, and no more was heard about it.

The outcomes research idea was picked up in 1986 by Sen. Dave Durenberger (R-MN), who chaired the Senate Finance Subcommittee on Health. His bill authorized modest funding (increasing from \$6 million to \$8 million between fiscal years 1987 and 1989) for a “patient outcome assessment research program” and passed in the 1986 budget reconciliation act. Difficult appropriations struggles followed, producing nothing in 1987, \$1.9 million in 1988, and \$5.9 million in 1989. The first research that NCHSR funded with the money authorized by Durenberger’s bill was Wennberg’s work on prostate surgery.

Roots Of Other Provisions

As with the outcomes research provisions, the other important elements of the 1989 law creating AHCPR had earlier origins. The guideline development provisions had antecedents in NCHSR’s technology assessment work, NIH’s consensus development panels, the work of

medical review organizations (Professional Standards Review Organizations [PSROs] and their successors, Peer Review Organizations [PROs]), and Medicare coverage decisions made by HCFA with advice from PHS agencies. Much practice guidelines development activity was being done outside of government by 1989, and practice guidelines had been touted by the PPRC in its 1988 report to Congress.⁹ In its 1989 report, issued in April, the PPRC explicitly recommended that the “federal government should support effectiveness research and practice guidelines through funding, coordination, and evaluation.”¹⁰ There were also precedents for the law’s more unusual funding provisions. Medicare trust fund monies were already being used for some PHS research, and a small portion (7.5 percent) of the 1 percent PHS evaluation funds were already being allocated to NCHSR for the National Medical Expenditure Survey.

The creation of a new agency was the law’s major innovation. It followed years of debate in the Office of Management and Budget (OMB) at the White House, HHS, and AHSR and on Capitol Hill regarding the role and bureaucratic location of health services research. The issue arose in Congress each time reauthorization legislation was needed for NCHSR. There had been proposals at various times to move NCHSR from the office of the HHS assistant secretary for health to the office of the assistant secretary for planning and evaluation, the Health Resources and Services Administration (HRSA), and NIH. Until 1989, however, there had been no serious proposal to move health services research into a new high-level agency.

Events Of 1989

The path to legislative action in 1989 began with the inclusion of \$52 million for “medical effectiveness research” in the president’s fiscal year 1990 budget, which was released in January. This provision followed struggles in HHS and OMB over the amount of money and the bureaucratic jurisdiction for the research.

Roper, who was then HCFA administrator, was the most important and effective advocate for outcomes research within HHS, and he also had great credibility on Capitol Hill. He claimed a role for his agency not only in the department’s internal processes but also in a very public way—in a 1988 article in *The New England Journal of Medicine* about HCFA’s “effectiveness initiative.”¹¹

Roper’s enthusiasm was an important asset for such research, and the Medicare trust funds were a tempting source of funding, but other parts of HHS also had claims on this research arena. NCHSR already had a Patient Outcome Assessment Research Program (POARP) in place

under the 1986 Durenberger legislation (and had supported Wennberg's research for many years), and HRSA had gained inclusion of \$15 million for itself in the president's 1989 budget for "medical technology and medical practice assessment research." In some quarters in HHS (such as NCHSR), Roper's article was viewed as a preemptive strike, aimed at claiming this territory for HCFA and made very dangerous by Roper's close ties to the White House, his previous place of employment.

In HHS's internal budgetary process, Roper initially proposed that more than \$100 million be set aside for the effectiveness initiative. This amount had been scaled back to \$52 million—25 percent of the department's discretionary funds, according to HHS Chief of Staff Thomas Burke—when Secretary Otis Bowen's initial budget request for the department went to OMB. Although OMB supported the initiative—in fact, OMB officials cite an internal staff paper written in 1987 as the original source for it—no funding was included in the first OMB pass-back to the department. The reason was the internal disarray stemming from the multiple claims being made in HHS for the program. HCFA, HRSA, and NCHSR all wanted it, and some at OMB believed that the effort belonged at NIH.

HHS eventually secured OMB's agreement on the plan whereby the \$52 million effectiveness initiative would be located in the office of the HHS assistant secretary for health (the bureaucratic home of NCHSR) and would be funded by \$24 million in PHS funds and \$28 million from the Medicare trust funds. The battles that resulted in this provision of the president's budget occurred over much of the year prior to the introduction of outcomes research legislation. Many of the same arguments were to be repeated in congressional struggles over how to fund the research and where it should be located.

Legislative Action

The president's budget gave a push to an issue that was already rapidly ripening. After touting "practice guidelines" in its 1988 report, the PPRC had held a conference on this topic in October 1988, less than a month after a hearing on the topic before Waxman's health subcommittee. Management methods that used criteria of appropriate utilization had become ubiquitous in employment-based health benefit plans.¹² Roper and his colleagues had published their article about the HHS effectiveness initiative at about the same time that Secretary Bowen and Burke were publishing an article suggesting that research on effectiveness of medical treatment could contribute to the reduction of the 25 percent of health care dollars that were wasted and help the nation

“avoid rationing health care.”¹³

Without waiting to see how the president’s budgetary request would fare in the appropriations process, Mitchell and Gradison introduced legislation to authorize more funding for research into the outcomes of medical care. Mitchell was the new Senate majority leader, having previously chaired the health subcommittee of the Senate Finance Committee, and Gradison was the ranking Republican on the House Ways and Means Subcommittee on Health. The chair of that subcommittee, Rep. Fortney H. (Pete) Stark (D-CA), was the sole cosponsor of Gradison’s bill. With such powerful sponsors in both the House and Senate, the proposed legislation had instant plausibility.

Wennberg had had extensive contacts for several years with both Mitchell and Gradison and their staffs. His entrée to Mitchell had come through colleagues in the Maine Medical Assessment Project; he had met Gradison several years before at a health policy retreat for Ways and Means Committee members and staffers. Wennberg had actively cultivated these and other contacts. Both legislators were impressed with the importance of the problem identified by Wennberg and the value of his approach to it. Mitchell had introduced a bill to increase the authorization for such research in 1988 and had given speeches on the topic. The key minority health staffer on Gradison’s subcommittee, Charles (Chip) Kahn, had worked for Durenberger when his outcomes research bill was introduced and passed in 1986.

The Gradison and Mitchell bills had similar purposes and inspiration and were introduced on the same day. Identical bills might have been introduced except for the timing of a staff change in Mitchell’s office. Had the bills that were eventually passed by the Senate Finance and House Ways and Means committees been identical, it might have been more difficult for a third bill, which came from the House Energy and Commerce Committee, to become dominant. This third bill, introduced later by Waxman, was the bill that Budetti and Bouxsein had begun preparing months earlier. It put the outcomes research program proposed by Mitchell and Gradison into a new, broader framework, by making it one of the duties of a new agency to be created within HHS.

A fourth bill was the Senate version of Waxman’s bill and was introduced by Kennedy in time to be included in the budget reconciliation bill (S. 1750) that was reported out by the Senate Budget Committee on 12 October 1989. The provisions that were signed into law by President Bush in December 1989 grew out of these bills.

The Gradison bill. Gradison introduced the Medical Care Quality Research and Improvement Act of 1989 (H.R. 1692) on 5 April 1989. It would amend the Social Security Act to require the HHS secretary to

provide for “outcome, effectiveness, and appropriateness research with respect to specific medical treatments or specific medical conditions under the Medicare and other programs.” Authorized funding began at \$72 million in fiscal year 1990 and increased to \$270 million in fiscal year 1994. Two-thirds of the funding was to come from the Medicare trust funds, which gave the House Ways and Means Committee a jurisdictional claim that otherwise would have been lacking.

Most of the brief (nine-page) Gradison bill was devoted to such matters as defining what this research would consist of, providing for dissemination of results, and creating an advisory council and coordinating group. The research would be done through grants and contracts. There was an emphasis on increasing the usefulness of medical claims data and information on clinical and functional status of patients. The bill also required that the secretary of HHS develop “treatment-specific or condition-specific practice guidelines” to be used in the education of providers and in reviews of the quality and appropriateness of medical care. The secretary was directed to initiate a project by 1 January 1991 to apply such guidelines to at least three clinical treatments or conditions that would be selected on the basis of two criteria: their cost implications for Medicare and their having “significant variation in the frequency or the type of treatment provided.” The bill was silent regarding the bureaucratic location of these activities within HHS.

The Mitchell bill. The Patient Outcomes Research Act of 1989 (S. 702) was introduced that same day by Senate Majority Leader Mitchell and a bipartisan group of nine cosponsors from the Senate Finance Committee. Like the Gradison bill, it was structured as an amendment to the Social Security Act and made use of Medicare trust fund monies. Other similarities were the provision of funding to enhance the scientific underpinnings of medical care, the location of this work in HHS (with no further specification of where), an emphasis on dissemination activities, and the requirement that practice guidelines be developed for the education of providers. At twenty-six pages, the Mitchell bill was much more detailed about many matters—such as the definition of the research, how it was to be conducted and disseminated, and various advisory and coordination mechanisms—but these differences were relatively minor in comparison to the shared elements. The harmony of the Gradison and Mitchell efforts was emphasized when the two legislators had a joint press conference to announce the introduction of their bills.

The Waxman bill. Waxman’s Health Care Research and Policy Act of 1989 (H.R. 2601) was introduced 13 June 1989. It contained all of the important ideas from the Mitchell and Gradison bills, including a program of research on patient outcomes and the development of practice

guidelines. However, Waxman's bill was designed to use the momentum that had been created for outcomes research to pursue broader goals.

In introducing the bill, Waxman noted not only that more funding was needed for health services research and research on patient outcomes but also that "the little that is being spent is currently without the kind of leadership and organization that could assure the most bang for the bucks."¹⁴ What was needed was a new agency that was "comparable to other agencies of the Public Health Service" and that "should strive to achieve the level of scientific prominence that the National Institutes of Health have accomplished in biomedical research." The Waxman bill amended the Public Health Service Act to create the Agency for Health Care Research and Policy, whose responsibilities would include outcomes research and guideline development. (The proposed name was later changed to the Agency for Health Care Policy and Research after the acronym potential of AHCRA^P was noticed.)

The Waxman bill became the primary basis for the legislation that eventually passed. The similarities are so extensive that a separate description here of that bill would be redundant. The changes that occurred between introduction of the Waxman bill and the passage of the legislation a few months later can be described succinctly.

Most differences involved minor editorial matters, clarifications, and changes to make certain provisions more inclusive (for example, consistently adding "preventing" and "clinically managing" to "diagnosing and treating"). The most significant differences between the Waxman bill and the enacted law were provisions in the latter that (1) set some additional reporting requirements to Congress, including deadlines for development of the first sets of practice guidelines, as in the Gradison bill; (2) increased recognition of and provision for the medical profession's role in the development of practice guidelines; (3) increased accountability regarding the needs of the Medicare program (for example, in setting priorities for research and guideline development); (4) added two "health professionals" to the three medical practitioners and eight health care researchers on the agency's national advisory council; (5) shifted many formal responsibilities from the agency's administrator to the HHS secretary; and (6) changed funding authorizations, including an increase (from 25 percent to 40 percent) of the so-called 1 percent PHS evaluation monies.

The relationship between these changes and the concerns of various parties at interest can be readily discerned. House Ways and Means and Senate Finance committee concerns about raids on the Medicare trust funds were addressed by provisions to assure that priority would be given to conditions that affect Medicare beneficiaries. The medical profes-

sion's role in the development of practice guidelines was affirmed. Non-physician health professionals gained a modicum of recognition. Provisions for accountability to Congress were strengthened. Although the changes in the bill that Waxman introduced 13 June were relatively modest, they show that the bill attracted attention as it moved forward and that several concerns had to be dealt with in committee markup and the budget reconciliation process.

The Kennedy bill. Kennedy's bill, the Health Care Policy and Research Amendments of 1989, was introduced very late in the process (21 November). However, its provisions had been included earlier in the Labor and Human Resources Committee's Omnibus Budget Reconciliation Act of 1989 (S. 1750), which was reported out 12 October. It closely followed the Waxman bill, including creation of a new agency (originally called the Agency for Health Services Research). Its impact on the final legislation was limited to broadening the focus of outcomes research and guideline development activities to include prevention.

Budget Reconciliation: Larger Forces Intervene

Negotiations and trade-offs on small, rather esoteric bills such as the outcomes research bills occur in several different contexts. (For convenience and because outcomes research was the driving force, I refer to these as versions of the outcomes research bill, although they all had different names.) The first is within the committees that have jurisdiction. Here the issues are hashed out among the members and staffers who may have a strong interest in the matter under consideration. Both large and small details may be negotiated. A second context is when different versions of a bill have come out of different committees in the same chamber (for example, the House Ways and Means and Energy and Commerce committees when Medicare Part B is involved) or in the House and Senate. Differences between members (and staffers) who have strong views may have to be resolved. In this case all four bills were approved by their respective committees.

The third context occurs in the later stages of the budget reconciliation process when trade-offs are made across major, often unrelated provisions of omnibus bills (for example, capital gains cuts versus physician payment reform versus Medicaid expansion). The individuals who have seen a bill through the committee process and approval by the House and Senate and who have negotiated differences with their counterparts on other committees or in the other chamber may find that their bill has become a bargaining chip in a high-stakes game among opponents who see the bill primarily in symbolic and budgetary terms and

who have little or no interest in its substance or details.

Thus the passage of a bill is determined by much more than numbers of supporters and opponents. Their influence is greatly outweighed by the forces that operate in the budget reconciliation process. These forces can prevent passage even of bills that have attracted no serious opposition. This nearly happened to the outcomes legislation.

The outcomes research bill was never the subject of a separate vote in either chamber of Congress. As has become common in the legislative process, outcomes research was folded into an omnibus bill that bundled together the separate bills that have been passed by numerous committees. The scale of omnibus bills can be forbidding. Because budget reconciliation bills are “must-pass” legislation, large numbers of provisions are commonly added on in committee.

The budget reconciliation process is supposed to integrate the work of all of the committees that have jurisdiction over spending programs and revenue-raising activities. Each year, each committee is given budget targets by both houses’ budget committees, which have considered the president’s budget, the targets agreed to in the Gramm-Rudman-Hollings deficit reduction legislation, the constraints set by entitlements and interest on the national debt, and members’ individual interests.

Budget reconciliation was particularly contentious in 1989. The primary purpose of OBRA 1989—and the rubric under which legislative activity was categorized by the *Congressional Quarterly*—was deficit reduction. The Gramm-Rudman target called for reduction of \$28 billion in the fiscal year 1990 deficit to \$110 billion or less by 15 October, or the “sequestration” process would kick in, which would make across-the-board cuts (half in defense, half in domestic programs). Under a bipartisan budget agreement reached in April 1989, about half of the savings were to come through cuts in the thirteen appropriations bills. Specific targets for achieving the other half were assigned to the eighteen committees that had jurisdiction to make changes in areas and programs covered by the budget agreement. The budget reconciliation process, therefore, was oriented toward taking actions that would produce almost \$14 billion in deficit reduction.

Under the original schedule, Congress was to deal with budget reconciliation in June, but disagreements—particularly over President Bush’s proposal to cut the capital gains tax—delayed matters. The tax-cut proposal raised disputes over its effects, over its equity, and over the fact that under the constraints of the budget process, cuts in existing programs would have to make up for the revenue loss from the tax cut.

The atmosphere grew increasingly grim during the fall. President Bush vetoed the appropriations bills for Labor, Health and Human Services,

and Education over the abortion issue. Emergency funding measures had to be passed twice to keep the government running until regular appropriations bills were finished. The president threatened to veto the budget reconciliation bill unless it contained a capital gains tax cut, but Democratic leaders resisted. The House version of the budget reconciliation bill passed 5 October, and the Senate version passed 13 October. Neither cut the capital gains tax. By then it was too late to resolve the differences between the House and Senate bills before the sequestration deadline (15 October), and President Bush signed the order imposing the mandatory cuts 16 October.

The House/Senate conference on the budget reconciliation bill in 1989 thus began late in the year, with the mindless cuts of sequestration having already kicked in, with President Bush having shown his willingness to use the veto, and with the president and Senate Republicans still holding out for a capital gains tax cut. The key negotiations took place in a small leadership group, with participation by officials from OMB. The process lasted more than a month and involved numerous ploys, strategies, alliances, and negotiations. The president reluctantly dropped the capital gains fight on 2 November, but he threatened to veto the budget reconciliation bill and leave the sequestration cuts in place unless Congress passed a “truly clean” bill with hard savings of \$14 billion or more. (Rep. Dan Rostenkowski [D-IL], chair of the House Ways and Means Committee, also threatened to allow sequestration to remain in place.) With a Thanksgiving adjournment set, the conferees pursued the goal of a \$14 billion savings. They were faced with two extraordinarily different versions of the budget reconciliation bill.

The version that passed the House on 5 October and went to the Senate for consideration contained 1,878 pages. Its provisions were grouped according to the ten committees that had passed them. Even though numerous accounting gimmicks were used, the \$11 billion in deficit reduction provisions in the House bill fell far short of the requirements of the budget resolution, but it passed by a vote of 333 to 91. Both the Energy and Commerce and Ways and Means versions of the out-comes research legislation were included.

Faced with budget instructions of \$14 million in deficit reduction, the massive House bill, and continuing pressure by the president and Senate Republicans to fulfill the president’s campaign pledge of a capital gains tax cut, Senate Majority Leader Mitchell offered Senate Republicans a deal.¹⁵ The hundreds of provisions that added to the deficit would be stripped from the bill in exchange for the Republicans’ dropping the capital gains cut proposal. The deal was agreed to after the Democrats agreed to remove all provisions that would not help reduce the deficit.¹⁶

As a result, the budget reconciliation bill that passed the Senate on 13 October was almost 1,700 pages shorter than the version that had passed the House the week before.

Mitchell's own outcomes research provisions were among the items that were stripped from the bill. Outcomes research and the new agency appeared to be dead at that point because they did not exist in the Senate version of the bill. The way it survived was rather complicated and involved the enormously important physician payment reform bill, which had also been stripped from the Senate bill.

The reasons that these provisions had no deficit impact and were therefore stripped were different. The outcomes research provisions involved only authorizations, not appropriations, and so they had no effect on the deficit for fiscal year 1990.¹⁷ Physician payment reform had no deficit impact because budget-neutrality had been integral to the very logic of rationalizing the payment system by reducing inequities across medical specialties and procedures. Physician payment reform had gained much of its legitimacy by not being a pretext for cutting Medicare payments to physicians. The goals were equity and rationalization, not deficit reduction. Thus it was stripped from the Senate budget reconciliation bill, to the enormous distress and frustration of its chief sponsor, Sen. John D. (Jay) Rockefeller IV (D-WV), chair of the Senate Finance Subcommittee on Medicare and Long-Term Care.

As the House/Senate conference got under way, Rockefeller set about convincing the leaders of the conference, Finance Committee chair Lloyd Bentsen (D-TX) and Ways and Means chair Rostenkowski, that physician payment reform should be restored. He had important allies in the House Ways and Means and Senate Finance committees, in the PPRC (which had recommended the plan on which the House and Senate bills had been based), and in the White House. In fact, of the items that had been stripped from the budget reconciliation bill in the Senate, physician payment reform was what the White House most wanted restored in the House/Senate conference. Such reform was seen as essential to future cost containment in Medicare.

Rockefeller and Mitchell thus both had initiatives that they wanted in the budget reconciliation bill, and the proposal was made that the physician payment and outcomes research initiatives be joined, with the latter becoming the fourth element of physician payment reform—along with the resource-based relative value scale (RBRVS), restrictions on balance billing, and volume controls. Some key players, including Bentsen and Waxman, were already thinking of outcomes research in these terms. Thus outcomes research became caught up in the politics of physician payment reform.

The main controversy in the physician payment reform package was about the volume control provisions. Under the leadership of the American Medical Association's (AMA's) nemesis, Pete Stark, the House Ways and Means Committee had approved a version of physician payment reform that included expenditure targets whereby the federal government would set annual targets regarding how much Medicare would pay doctors. The targets would reflect inflation, increases in the number and age of beneficiaries, and a judgment regarding appropriate increases in volume of services. If expenditures exceeded the target in a given year, fee increases the next year would be reduced accordingly.

The AMA, which had been generally supportive of physician payment reform, decided to fight the expenditure target provision on the grounds that it would force doctors to ration care. They had allies. Bentsen was sympathetic to the physicians' concerns. Moreover, the Waxman version of physician payment reform, which was part of the House Energy and Commerce Committee's version of budget reconciliation, did not include expenditure targets. Stark insisted on expenditure targets. This was to lead to some extraordinarily bitter exchanges between Waxman and Stark, the California Democrats whose subcommittees shared jurisdiction over Medicare Part B.

The battle over expenditure targets had important implications for the outcomes research bill. By embracing outcomes research and practice guidelines, the AMA could demonstrate its commitment to reducing waste and inappropriate use of medical resources. This could be done by finding out what does and does not work and educating physicians accordingly, not by such arbitrary means as expenditure targets. Thus the outcomes research legislation became part of physician payment reform very late in the game.

This was a mixed blessing. On the one hand, it provided a way for the outcomes research bills to reenter the budget reconciliation process, since all parties to the negotiation—including the White House—saw physician payment reform as extremely important. The principal Democratic negotiators—Bentsen, Rostenkowski, and Rep. John Dingell (D-MI)—used the leverage supplied by the White House's strong desire for physician payment reform by taking the stance that they were willing to forgo such reform unless the White House agreed to allow several other issues, including outcomes research and Medicaid expansion, to remain in the bill without a presidential veto. On the other hand, physician payment reform seemed certain to fail at several points because of bitter disagreements among the key players.¹⁸ To the consternation of those who had seen the outcomes research legislation through to this point, their bill, which had attracted no opposition, seemed to be going down

with a bill with which it had originally had no connection.

As the budget reconciliation process groaned forward, Rockefeller and Durenberger sought middle ground between the two versions of physician payment reform that had passed the House. They came up with the Medicare volume performance standards that were eventually included in the bill. Although some individuals, such as Gradison, saw little difference between such standards and the expenditure targets, the AMA found them more acceptable. However, more hardball politics and marathon negotiation sessions were still to come.

The largest crisis occurred on 17 November, with the adjournment deadline approaching. After a fifteen-hour negotiation session involving Ways and Means chair Rostenkowski, Senate Finance chair Bentsen, and Tom Scully from OMB, among others, Rockefeller was told that physician payment reform was no longer in the budget reconciliation bill. Finding this “ridiculous,” Rockefeller called a meeting for the next day of the principal members and staffers from both chambers, both parties, and OMB.¹⁹ Departing from his usual practice on the Jewish sabbath, Waxman stayed for part of the meeting, which lasted into the night. The staff that had to prepare legislation that reflected the agreements kept working thereafter and for the next couple of days.

By numerous accounts, several different agreements were reached and then fell apart during this marathon. Several issues pertained to physician payment reform, but other issues were also involved, including the size of the cuts that would be sought by leaving sequestration in place. Finally, an agreement was reached and turned over to staff to be put into legislative language. Even then there was a final crisis, when it was discovered that the bill drafted by legislative counsel in the House, under the supervision of Ways and Means Committee staff, did not accurately reflect a key point of agreement on the formula for updates in physician payment rates. However, behind the scenes, Rostenkowski had secured House Speaker Thomas S. Foley’s (D-WA) support in the potential dispute with House Energy and Commerce Committee chair Dingell, and Bentsen decided to go along. So the conference committee approved a bill with disputed language on a key point.

Several times during the long weekend that began in Durenberger’s conference room on Saturday morning and ended when the conference report went to the House and Senate after a marathon drafting session by staff, the word went out to supporters of the outcomes research legislation that it was, once again, dead. Nevertheless, physician payment reform and the outcomes research bill were contained in the conference committee report that the House passed late on 21 November and that the Senate passed after midnight the next day. It was fitting

that the ordeal ended in the middle of the night, because it had been a nightmare for everyone involved.

But What Was Passed?

The account of how the outcomes research legislation went into and came out of the House/Senate conference on the budget reconciliation bill has everything to do with the fact that it passed and almost nothing to do with its content. For content, one needs to look at negotiations primarily among staff of the members and committees that had an interest. The problem they faced was how to negotiate the differences among the various versions of the bill. Two were included in the budget reconciliation bill that had been approved by the House.²⁰ The others had been approved by the Senate Finance and Labor and Human Resources committees but had been stripped out of the Senate's budget reconciliation bill.

A total of 232 members were appointed to the overall conference committee to resolve the differences between the Senate and House versions of the budget reconciliation bill. Although the conference committee was broken up to consider different parts of the bill, the conferees on the outcomes research provisions nevertheless included thirty-two senators from three committees (Finance, Labor and Human Resources, and Budget) and thirty-three representatives (from Ways and Means, Energy and Commerce, and Budget). The conference on the outcomes research proposals was labeled "Medical Care Quality" after the Ways and Means (Gradison) version of the bill; it did not include the physician payment reform provisions, which were being considered by another, overlapping committee.

Even in the context of 1989's strange budget reconciliation process, this group of conferees faced an odd task. They had to reconcile a Senate-passed budget reconciliation act that contained no outcomes research provisions with the House-passed bill that contained two versions. Thus the official side-by-side comparison that was prepared by the Congressional Research Service for the use of the conferees had eighty-nine pages of white space in the column marked "Senate Amendment" and frequently had two different provisions in the column marked "House Bill." However, at Bentsen's request, an "unofficial" side-by-side comparison was also prepared that included in the Senate column the provisions (both Mitchell's and Kennedy's) that had been passed by the Finance and Labor and Human Resources committees and included in the bill that had been reported out by the Senate Budget Committee. This document was also used by the conferees.

The provisions that emerged from the House/Senate conference included virtually all of the Energy and Commerce (Waxman) bill plus a few additions. The differences had almost all been resolved within the framework of the Waxman version, which included creation of a new agency. Indeed, a comparison of the bill that Waxman had introduced on 13 June and the versions that existed at various stages shows that most of the changes were made within the House Energy and Commerce Committee itself, before the bill was thrown into the budget reconciliation and conference committee processes with the other bills.²¹ Most of the changes that came from other bills came from the Gradison/Stark bill, and most were minor.²²

Why was the Waxman bill so dominant? For one thing, it was written to include the key provisions of the original bills, so Gradison and Mitchell and their staffs were not asked to yield on fundamental matters. Gradison would have preferred to let the HHS secretary determine where the outcomes research program would be located, but this was not an issue to fight for at that stage of the game. Other, more contentious negotiations were going on at the same time—physician payment reform, repeal of the Medicare Catastrophic Coverage Act, and the deficit reduction bill. The outcomes research negotiations largely took place at the staff level, which gave the Waxman bill a significant advantage.

Two very experienced and highly committed staffers—Peter Budetti and Peter Bouxsein—worked on the bill from the House Energy and Commerce side. They were able to devote much time and energy to this legislation not only because they cared—Budetti about the new agency and Bouxsein about practice guidelines and the Forum for Quality and Effectiveness in Health Care—but also because they came from the majority side of a very well staffed committee. The staff negotiator from the House Ways and Means side, Chip Kahn, was no less experienced than the Waxman staffers, and he had a serious long-term interest in outcomes research legislation. However, as minority counsel on the Ways and Means health subcommittee, he was part of a small staff and was responsible for many issues, including physician payment reform and the repeal of the catastrophic legislation. As long as Waxman's staff were willing to give Kahn the provisions about which his boss, Gradison, cared most, then he was willing to accede to Budetti's and Bouxsein's wishes on the matters about which they felt strongly. By all accounts, Kahn played a key role in assuring that formulations regarding the use of the Medicare trust fund monies were acceptable to Ways and Means.

Budetti and Bouxsein were also in a strong position vis-à-vis the Senate side, in part because the Senate's "stripping" process had included the outcomes research provisions. The primary staffer from the

Senate side, Margaret VanAmringe, was new to Capitol Hill (she had arrived in February 1989), having moved into Democratic Senator Mitchell's office from Secretary Bowen's office at the end of Ronald Reagan's Republican administration. Her autonomy was limited in the staff-level meetings in which differences in the outcomes research bills were negotiated out. Moreover, the Waxman bill accomplished the major purposes of the Mitchell bill: practice guidelines development and larger authorizations for outcomes research.

After an extraordinarily contentious process, agreement was reached on the conference report on the budget reconciliation act in the middle of the night, the Tuesday before Thanksgiving. The outcomes research program was included, in the context of the new Agency for Health Care Policy and Research, as was physician payment reform and some important Medicaid amendments. The White House had given way on numerous issues—the capital gains tax, the watered-down volume control provisions in the physician payment bill, and the inclusion of provisions that did not adhere to deficit reduction mandates, including outcomes research. However, the bill did meet President Bush's deficit reduction target, and he signed it a month later, 19 December 1989.

Implications For Health Policy

Compared with such major health policy issues of the 1980s as the passage of Medicare prospective payment and physician payment reform, Medicaid expansions, and the passage and repeal of the catastrophic insurance legislation, the enactment of Section 6103 of OBRA 1989 was a minor matter. It involved a relatively small amount of money, was never separately debated on the floor of either house, and never received media attention outside of some trade publications. Yet it did some things that advocates hoped would have a deep effect on medical care. It created a higher-level agency to take the lead on research on health services and policy, and it accepted the idea that the federal government should devote significant resources to researching the outcomes and effectiveness of medical procedures and to developing practice guidelines for use by practitioners, payers, and patients.

In many ways, the passage of this legislation was an improbable event. In a year of budgetary crisis, the legislation provided substantially more financial support for research in a field that had historically either lost ground or struggled to stay even. The idea of the federal government's becoming an arbiter of the content of medical practice had been abhorrent to the medical profession, yet several professional associations, including the AMA, actively advocated inclusion of practice guideline

development in the legislation. The creation of a new public health service agency was itself improbable, since there was no serious advocate of this idea among the membership of either chamber of Congress.

Implications for health services research. The passage of the legislation did not signal broad new congressional interest in health services research. The legislation passed because it had the support of some key members and received an important boost from the PPRC. Even the two key supporters—Mitchell and Gradison—had not developed a general appreciation for health services research. Their interest had been captured by one particular problem, as was clear when they introduced their respective bills. Citing Wennberg’s work on practice variations and Brook’s work on inappropriate use of procedures, Gradison described the problem thus: “Questions are being raised about the value of the outcomes of the expanding number of medical treatments.”²³

In harnessing some key members’ interest in outcomes research, advocates of health services research studiously avoided using that term. This strategy, however, risked stimulating a major redefinition of the field and its purpose. As a result of the legislation, federally supported health services research became more like clinical research and, therefore, the province of physicians rather than of the economists and social scientists who were interested in payment systems and the organization of care. The purpose of the research shifted away from the scientific ideal of investigator-initiated research toward program-oriented research in support of the government’s activities as purchaser of medical care. The problem that had caught the attention of Mitchell and Gradison was important, but it involved a narrow slice of the concerns of the field of health services research and the organizational, financing, and patient care problems faced by the nation. Even as the outcomes research bill with all of its funding provisions was passing, an appropriations bill was passing that actually reduced the general appropriation for NCHSR.²⁴

Implications of funding strategies. The solutions that were used to gain increased funding in the face of budgetary constraints and frank skepticism in both OMB and the House Appropriations Subcommittee on Labor, Health and Human Services, and Education about the value of health services research have important implications.

The decision to allocate 40 percent of the 1 percent evaluation funds for AHCPR’s research agenda had enormous advantages. It made use of funds that OMB believed were not being spent well. More importantly, it was budget-neutral—a key matter in the Gramm-Rudman era—and it produced immediate funding over and above the fiscal year 1990 appropriation for NCHSR, which was signed into law on the same day that the conference report on the budget reconciliation bill went to the two

chambers for final approval.

However, despite superficial appearances to the contrary, this was not free money. Although the funds were ordinarily allocated by the HHS assistant secretary for health, the primary source was the largest PHS agency—NIH, the darling of the Appropriations committees. Any hope that NIH, with its \$6.5 billion budget, would hardly notice the loss of a mere \$40 million in evaluation funds was quickly dashed. NIH noticed—after the fact—and complained to friends on the House Appropriations Committee, who also perceived a bit of imperialism in Waxman's funding ploy. They saw the budget reconciliation bill's allocation of the 1 percent funds as an appropriation and thus a clear invasion of the Appropriations Committee's territory. The Appropriations Committee chose to treat the provision like an authorization—for which it made no appropriation the next year. Even so, it appears that by setting an overall funding level, the 1 percent solution was a net gain in AHCPR's funding. Yet future years' appropriations may be affected by the anger that was provoked, since the same Appropriations committees will make future funding decisions for AHCPR.

The second funding solution followed Willie Sutton's maxim of going where the money is. The law specified that 70 percent of the funds for the outcomes research program—authorizations that began at \$50 million in 1990 and increase to \$185 million in 1994—were to come from the two Medicare trust funds. Other provisions were built into the law to assure that a substantial share of AHCPR's outcomes research and guideline development activities would focus on problems of particular relevance to Medicare. There was considerable logic behind these provisions, in that the Medicare population accounts for a large share of the nation's health costs. But again, there is a price to be paid.

For one thing, it heightened the sense that the federal government's health services research program—unlike, say, its biomedical research program at NIH—exists essentially to provide support for other federal programs. The premise of the National Cancer Institute's research activities, for example, is not to help HCFA spend its dollars more wisely, but that was the expectation for the outcomes research legislation.

The use of the Medicare money presented the new agency with some future complexities. Because Medicare and PHS funds are authorized, two different committees in both the House and Senate will be involved in future reauthorizations for the outcomes research program. More members will have a say, and differing evaluation criteria may be applied. Whereas the health subcommittee of the House Energy and Commerce or Senate Labor and Human Resources committees may evaluate AHCPR's accomplishments in terms of contributions to biomedical

knowledge or public health—much as NIH might be evaluated—the House Ways and Means and Senate Finance committees can be expected to have more practical concerns regarding Medicare costs.

There would be considerable justice in that, and not just because Medicare funds were used. Year after year AHSR sought increased funding for health services research by citing all of the money that PPS had saved the Medicare program. An original premise of Wennberg's appeal for increased federal funding, as stated in his testimony before the Senate Appropriations Committee in 1985, was as follows:

The extent of variation in [Medicare] reimbursements to hospitals . . . is such that if the low cost patterns of care were the norm, we would not be faced with the pending bankruptcy of the Medicare Trust Fund, nor would we now be concerned with the specter that medical care must be rationed. For many medical and surgical conditions, the variations suggest opportunities to reduce expenditures under the Medicare and Medicaid programs without reducing the benefits of medical care.²⁵

The legislation that created AHCPR was driven substantially by outcomes research and the hope that such research might help to prevent unnecessary Medicare spending. Even if the most sophisticated legislators understood that the research into the outcomes and effectiveness of care might never be able to demonstrate financial savings, this was a point that could be kept quiet. It is likely that some votes were based on the original premise that the savings potential was substantial, as it would have to be if it were to prevent the bankruptcy of the program. If that was the expectation, then the name change may not protect the new agency from the same treatment on Capitol Hill that NCHSR had experienced over many years.

Implications of a new agency. The decision to create the new agency came about not because key policymakers strongly sensed that health services research (in its new guises) deserved to be elevated to a higher bureaucratic level but because of dissatisfaction with the existing situation. NCHSR lacked credibility on Capitol Hill and visibility in the outside world. The stimulus for change came from AHSR.

AHSR's board deliberated on this topic for a half-dozen years. It was also being considered elsewhere. Some advocates of outcomes research, including Wennberg and some NCHSR staffers, saw NIH as the most appropriate location for health services research. Others saw the NIH power structure and constituency as too strongly oriented to basic biomedical research and feared that more applied research would always be very secondary. Some advocates within HHS believed that outcomes research belonged at HRSA, but AHSR and others felt that this location had insufficient prestige to attract strong leadership and would impart too much of a flavor of supporting a set of PHS programs that were outside the mainstream of U.S. health care.

HCFA was an obvious choice of where to locate the new agency, in view of Roper's advocacy of the "effectiveness initiative" and the fact that Medicare funds would of necessity be involved. But most friends of outcomes research within and outside Congress believed that location in HCFA would impart a cost containment flavor to the research and guideline development activities that would undercut their legitimacy in the eyes of physician groups. Ultimately, the creation of an agency-level organization became plausible, despite the comparative modesty of its budget, because no other place could be found for it. The same committee chairman—Henry Waxman—who had opposed the move to office of the HHS assistant secretary for planning and evaluation in 1987 agreed to the proposed new arrangement in the legislation that he introduced and saw through passage.

Debates about the best location for health services research had gone on for more than a decade.²⁶ However, once AHSR decided to push for a new agency and Waxman included the idea in his bill, virtually no resistance was encountered in the legislative process. There was, however, resistance at another level. To create a new agency is not to start at ground zero. AHSR's hopes that a new agency would put the federal government's health services research program into the hands of nationally recognized researchers of the sort who serve on AHSR's board met a quick reality test. For many practical reasons, including appropriations under existing authorizations, the law that created the new agency transferred all of NCHSR's functions and programs to AHCPR. There was no shift in power away from career government employees. AHSR's hopes of seeing a national leader in the field named as the agency's director were thwarted when a career PHS officer, Jarrett Clinton, was named acting director and then director, winning the position over former and future AHSR presidents, Donald Steinwachs and John Eisenberg. Even the national advisory council, which was supposed to have heavy representation of distinguished researchers, was largely filled with names that were unfamiliar to most health services researchers.

Yet even if some changes have been less than dramatic and even if there is no evidence of greater congressional support for health services research, the 1989 legislation is still significant. It is more than a "gnat on a screen door," as one jaded congressional staffer described it in the context of the overall budget reconciliation process in 1989. By giving the new agency a mission that has direct consequences for the flow of funds from the nation's largest governmental health programs, the law guaranteed that some new parties would pay attention. By early 1992 a new organization—the Friends of AHCPR—had been formed. Members included the AMA and several specialty societies, major trade associa-

tions (such as the Health Insurance Association of America and the Health Industry Manufacturers Association), the Washington Business Group on Health, and the American Association of Retired Persons, among many others. Such involvement is a measure of power far beyond what NCHSR ever enjoyed.

The changing basis of medical decision making. The law's passage also represented an important step in the evolution of medical decision making—from judgment to standards, from expert to science, from the individual physician to objective criteria agreed upon by expert panels. With growing rapidity in the 1970s and 1980s, patient care decisions moved from the domain of the treating physician (perhaps in conjunction with the patient) to being the domain of objective knowledge, and from a matter of great subjectivity (“clinical judgment”) to a matter of such objectivity that patient care decisions could be reviewed and affirmed or denied by individuals who did not even see the patient. The application of objective criteria was replacing the treating of physicians’ judgment as the key event in patient care. In this sense, the law’s provisions regarding studies of outcomes, effectiveness, and appropriateness and the development of “practice guidelines, quality standards, performance measures, and medical review criteria” reflect the broad trend toward managed care.

Not so obvious in the excitement about the law’s passage was the fact that leading advocates had different ideas about how their research efforts might be applied. Wennberg talked of developing sufficient data to be able to calculate the probabilities of all relevant outcomes, so that patients could make informed decisions. Brook’s approach was to develop clear distinctions between appropriate and inappropriate care, so that doctors and third-party payers would know what services were needed. The choice between research in service of empowering patients and research to help third parties manage patient care will be raised but not resolved by the products of the work supported by AHCPR.

Conclusion

The story of the outcomes research legislation does not inspire optimism regarding the federal government’s ability to make health policy. This was a legislative proposal that seemed to be a rational response to a significant problem. It was introduced or cosponsored by Democratic and Republican leaders on the key committees. It attracted no opposition. Differences among the committees that had jurisdiction were resolved relatively easily. The bill was reasonably consistent with the president’s budget. It had support from the only two constituencies that

cared: health services researchers and organized medicine. Yet, with all of these advantages, it came dangerously close to dying.

In some ways, this situation is just another example of the contentiousness that existed between the Republican White House and the Democratic Congress. But it is also a reflection of how the legislative process works. The budget reconciliation process requires that bills that have been passed by committees be considered in relationship to bills that have been passed by other committees. This means that multiple differences across committees get considered simultaneously, and one bill may be held hostage to another, even if it has no serious opponents. Adding to the potential for stalemate is the fact that three committees have jurisdiction over Medicare and the fact that, as a practical matter, the White House can become a party in congressional negotiations via the threat of veto. The close examination of this particular piece of legislation makes one marvel that any legislation ever gets passed.

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NOTES

1. I am grateful to all who provided information in interviews: William Belden, Brian Biles, Peter Bouxsein, Robert Brook, Bonnie Brown, Peter Budetti, Thomas Burke, Barry Clendenon, Jarrett Clinton, Robert Crittenden, William Dorotinsky, Michael Fitzmaurice, Beth Fuchs, Donald Goldstone, Rep. Willis Gradison, Robert Graham, Michael Hash, Jan Heiniger, Alice Hersh, Darrell Jodrey, Judith Miller Jones, Charles (Chip) Kahn, John Kelly, John Kralewski, Ann LaBelle, Richard Lauderbaugh, Steve Lieberman, Tony McCann, Mary McGrane, John Marshall, Karen Nelson, Larry Patton, Gregory Pawlson, Karen Politz, Wendell Primus, Richard Rettig, Jamie Reuter, William Roper, Anthony Schwartz, Thomas Scully, Donald Steinwachs, Michael Stevens, David Sundwall, Margaret VanAmringe, Rep. Henry Waxman, Marina Weiss, Norman Weissman, John Wennberg, Christine Williams, and Karl Yordy. Because many asked not to be quoted, much information in this paper is not attributed.
2. Section 2611 of the Public Health Service Act provides that 1 percent of appropriated funds be available for evaluation studies. Although the HHS assistant secretary for health could use these funds for a variety of evaluation purposes, most have generally not been so used and have remained with the different PHS agencies for their own use.
3. NCHSR did receive substantially increased funding after 1986 because of the decision to conduct the National Medical Expenditure Survey using PHS evaluation funds for the purpose. However, AHSR was not able to convince Congress to make substantial increases in appropriations for general health services research funds that could be used for investigator-initiated projects. The increase between 1983 and 1990 (\$16.1 million versus \$17.1 million) did not even keep up with inflation.
4. This position was reached by AHSR early in 1989 after years of debate within its board over the best bureaucratic location for health services research.
5. The term *policy entrepreneur* comes from an editorial by D. Koshland in *Science* (17 July 1992): 307. Koshland wrote of NIH Director Bernadine Healy.
6. U.S. Congress, Senate Committee on Appropriations, *Variations in Medical Practice*:

- Hearing before a Subcommittee of the Committee on Appropriations, 98th Cong., 2d Sess.* (Washington: U.S. Government Printing Office, 1985).
7. J.E. Wennberg, "Dealing with Medical Practice Variations: A Proposal for Action," *Health Affairs* (Summer 1984): 6–32.
 8. L. Shaw, "Proxmire's Health Bill 'A Golden Egg'?" *Racine Journal Times*, 27 January 1986, 3.
 9. Physician Payment Review Commission, *Annual Report to Congress, 1988* (Washington: PPRC, 1988).
 10. PPRC, *Annual Report to Congress, 1989* (Washington: PPRC, 1989), 219.
 11. W.L. Roper et al., "Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice," *The New England Journal of Medicine* (3 November 1988): 1197–1202.
 12. B.H. Gray and M.J. Field, eds., *Controlling Costs and Changing Medical Practice? The Role of Utilization Management* (Washington: National Academy Press, 1989).
 13. O. Bowen and T. Burke, "New Directions in Effective Quality of Care: Patient Outcome Research," *Federation of American Health Systems Review* (September/October 1988): 50–53.
 14. *Congressional Record*, 13 June 1989, E-2107.
 15. Other Democratic leaders, such as Sen. Lloyd Bentsen (D-TX) and Sen. Robert Byrd (D-WV), supported stripping because they disliked the use of budget reconciliation as a legislative vehicle because it entailed restrictions on debate and floor amendments. This both elicited criticism from colleagues who felt shut out of the process and violated the Senate's tradition of reasoned debate without artificial restraint.
 16. There was public disagreement over whether the Republicans had merely accepted Mitchell's proposal or whether they had significantly enlarged its scope. J. Calmes and R. Elving, "Bipartisan Deal Set in Senate to Strip Down Deficit Bill," *Congressional Quarterly* (14 October 1989): 2691.
 17. There was also the provision regarding the 1 percent monies, but this involved a reallocation of funds already appropriated and thus had no effect on the deficit.
 18. J.K. Iglehart, "The New Law on Medicare's Payments to Physicians," *The New England Journal of Medicine* (26 April 1990): 1247–1252.
 19. J. Rovner, "Congress Agrees to Overhaul Medicare's Doctor Payments," *Congressional Quarterly* (25 November 1989): 3240.
 20. This was not unusual. Because the two committees operated independently but shared jurisdiction over Medicare Part B, they often both passed bills that addressed the same topic. Although this adds to the messiness of the House/Senate conference process, some people on the House side believe that having the two House versions improves their bargaining position with the Senate.
 21. Most changes took place between the original (13 June) version of the Waxman bill and the version that was included in the budget reconciliation bill (H.R. 2924), which Waxman introduced 18 July.
 22. The most notable was in the section on research in support of outcomes research, where Gradison-based provisions were added regarding grants and contracts to research centers, research using claims data, and research to enhance existing databases.
 23. *Congressional Record*, 5 April 1989, E-1082.
 24. E.R. Klebe, *Appropriations for Selected Health Programs, FY 1980–FY 1990* (Washington: Congressional Research Service, 1990), 8. Excluded are funds earmarked for specific purposes: the National Medical Expenditure Survey, the Patient Outcome Assessment Research Program, and training funds.
 25. *Variations in Medical Practice*, Senate Appropriations Committee hearing, 1985.
 26. Institute of Medicine, *Health Services Research* (Washington: National Academy Press, 1979).