

1. Why Convergence? Why Now?

This book describes and sets in context extraordinary recent events in policymaking for health in American states. Between 2001 and 2008, most states began to make policy as a result of which independent research informs decisions about coverage for pharmaceutical drugs for persons enrolled in Medicaid and the State Children's Health Insurance Program; and, in a growing number of states, for other health programs.¹ Spending for these programs totals billions of dollars each year. They pay for health care for almost a quarter of Americans.² Medicaid is, moreover, the largest payer for prenatal care, childbirth, and AIDS/HIV.

These events struck journalists, experts on health policy, and executives in the pharmaceutical industry as unusual because:

- Policymakers in the legislative and executive branches of state government made policy that facilitated applying findings derived from methods of research in which the United States had lagged behind many other industrial countries
- These policymakers adapted policy for using independent research to inform decisions about drug coverage from countries that offer universal entitlement to health care
- The policymakers countered strong opposition to the new policy from the pharmaceutical industry and its surrogates; even in states that were less rigorous than others in basing coverage decisions on independent research

Because I describe these events as the convergence of science and governance, I begin by defining these three terms. By "science," I mean the international body of independent research evaluating, ever more pre-

cisely and persuasively, the effectiveness, comparative effectiveness, and sometimes the cost-effectiveness of interventions to improve health. I accord particular emphasis to the science of research synthesis and to its principal product, systematic reviews, which offer unprecedented rigor in framing research questions, identifying relevant literature and assessing its quality, summarizing evidence, and interpreting findings.

By “governance,” I mean what public officials do to, for, and with colleagues in other agencies and branches of government, employees and stakeholders of business and nonprofit organizations, representatives of interest and advocacy groups, and voters. A leading scholar of governance describes it as “a technology of public action with its own history, structures and rationalities.”³

By “convergence,” I mean the use of science in governance: in formal deliberative processes through which state officials and the external advisers they choose collaborate to acquire and use the best available evidence to inform decisions about coverage for health services. For a substantial number of states, convergence also means that policymakers and their advisers are collaborating with researchers selected by public officials to plan, commission, evaluate, and communicate the findings of reviews of evidence of the effectiveness and comparative effectiveness of health services that are conducted according to internationally accepted standards of independence and rigor.

WHY STATES ACTED: IMMEDIATE CAUSES

The convergence described in this book had immediate and underlying causes. The most compelling immediate cause was the recession that began in the spring of 2000 and sharply reduced states’ revenues from taxes. This revenue shortfall continued into 2003.

Reducing or even containing the growth of state expenditures for pharmaceutical drugs became a high priority for many policymakers. They mobilized allies in order to deflect challenges from pressure groups, including threats to withhold campaign contributions. Spending for pharmaceutical drugs had been increasing faster than other health costs, which had been growing at double the rate of inflation in the general economy except for a brief pause in the mid-1990s. Because of the recession, policymakers could balance attacks on the new policy for making decisions about covering prescription drugs against demands from other groups advocating, for example, level or increased spending for education, roads, and public transportation.

The damaged reputation of the pharmaceutical industry was another immediate cause of these events. These corporations continued earning large and increasing profits despite the recession. Pharmaceutical manufacturers were charging the highest prices in the world to private employers who offered health coverage to their employees. These prices were often more than federal law permitted them to charge state Medicaid programs. Many manufacturers were also involved in well-publicized scandals about billing fraud, illegal promotion of off-label prescribing, exchanging meals for sales talks, and offering accommodations at lavish resorts ancillary to continuing medical education. Moreover, manufacturers' claims that rising drug prices were mainly a result of the cost of research and development proved to be inaccurate. Data that companies are required to submit to the U.S. Securities and Exchange Commission revealed that most pharmaceutical manufacturers spent more on lobbying and marketing than they did on research. Because of the diminished reputation of the industry, state policymakers could often count on support for, or at least neutrality about, their new coverage policy from leading private employers.

Michigan was the first state to establish the new policy for covering pharmaceutical drugs for enrollees in its Medicaid fee-for-service program. In the spring of 2001, Governor John Engler, a Republican, appointed a committee of physicians and pharmacists to examine evidence from independent research and then recommend for coverage the most effective drugs within each major class. The state would place these drugs on a preferred drug list (PDL) and would pay only the lowest price charged among manufacturers of equally effective drugs. Physicians could prescribe any drug on the list and could request exceptions to prescribe other drugs.

The pharmaceutical industry attacked. Pfizer, a major employer in the state, threatened to close its manufacturing plant in Kalamazoo. Engler then sequestered the committee that was analyzing evidence about the effectiveness of competing drugs in order to protect it from external influence. He also announced that he would not meet with lobbyists for the pharmaceutical industry before the committee reported. The Commissioner of Community Health, James Haveman, held a press conference during which he dumped on a table the contents of a shopping bag that contained one month's gifts and invitations to dine and travel from drug companies to a primary care physician in Grand Rapids. At the request of Engler and Haveman, Tommy Thompson, a former governor of Wisconsin who had recently become secretary of the federal Department of Health and Human

Services, waived Medicaid regulations in order to permit Michigan to establish its PDL. The industry sued Thompson; it eventually lost.⁴

In the fall of 2001, Haveman described these events to colleagues from other states at several meetings of the Reforming States Group (RSG). The RSG, organized in 1991, is a voluntary, nonpartisan association of leaders of the executive and legislative branches of the fifty states and, in recent years, Canadian provinces, Australian states and territories, England, and Scotland. His colleagues asked many questions, especially about the strength of the evidence for choosing preferred drugs and the involvement of leaders of the medical profession in selecting drugs and devising the mechanism by which physicians could request permission to prescribe nonpreferred drugs.

Some members of the RSG had learned about PDLs a year earlier. During its annual Western Regional Meeting in December 2000, John Santa, a member of the staff of Oregon Governor John Kitzhaber, a Democrat, had asked if anyone had information about the science-based Reference Drug Program in the Canadian province of British Columbia. A participant in the meeting (full disclosure: it was me, helping to staff the RSG) said that he had a case study of the program in his laptop, and that Bob Nakagawa, its lead author, was the policymaker who had designed and implemented it.

In February 2001, Nakagawa visited Salem at the invitation of Mark Gibson, Governor Kitzhaber's policy adviser for health and social policy. By midsummer, the Oregon Legislature had enacted a law that permitted the executive branch to create a preferred drug list and required it to assess the effectiveness of competing drugs. The examples of Michigan and British Columbia informed the policy crafted by Gibson and his colleagues.

That fall, Governor Kitzhaber, collaborating with AARP and the Milbank Memorial Fund, an endowed operating foundation based in New York City, convened a two-day open meeting in Portland. In his keynote speech, the governor said that the purpose of the meeting was to discuss ways to "globalize the evidence and localize the policy." Bill Novelli, the chief executive of AARP (formerly the American Association of Retired Persons) endorsed the governor's theme in a second keynote address. Several hundred state officials, lobbyists and experts on health policy from all over the country attended. Andrew D. Oxman, a researcher and public official in Norway, described the methodology of the science of research synthesis and how it was being used to evaluate the quality of studies of primary data and combine the results of acceptable studies in reports called

systematic reviews. Oxman and policymakers from Canada and the United Kingdom then described how systematic reviews were informing policy for covering prescription drugs.⁵

Representatives of the pharmaceutical industry criticized systematic reviews and PDLs in the discussion that followed these presentations. They said that systematic reviews were less informative and less rigorous than the well-designed clinical trials conducted by the companies themselves in order to obtain approval to market a drug from the Food and Drug Administration (FDA). Moreover, they said, PDLs would lower the quality of care, because they interfered with patients' and physicians' freedom of choice.

Other participants challenged these arguments. Persons familiar with the research that informed decisions about drug coverage in other countries explained why the findings of systematic reviews had greater statistical power than findings from even the best-designed randomized controlled trials (RCTs). Moreover, most of the trials financed by drug companies compared a new drug with a placebo in order to meet FDA requirements; but evidence about the comparative effectiveness of competing drugs was more useful for making coverage policy. Several participants said that "detailing" to physicians by industry salespersons and direct-to-consumer advertising probably threatened freedom of choice more than science-based coverage policy did.

In 2001 and 2002, in summary, one of the most conservative governors (Engler), and one of the most liberal (Kitzhaber), supported by a former centrist governor now serving in President George W. Bush's cabinet (Thompson), defied the pharmaceutical industry in order to establish policy to use the findings of independent research, and especially systematic reviews, to evaluate competing drugs in order to decide which of them to make available to persons eligible for Medicaid and the State Children's Health Insurance Program. In September 2002, the *Wall Street Journal* reported that "about a dozen" states "use PDLs or are in the process of setting them up," adding: "Michigan officials say its PDL is saving the state \$800,000 a week; Louisiana hopes to save \$60 million a year."⁶

THE UNDERLYING CAUSES OF CONVERGENCE

Persuasive Research on Fair Tests of Interventions

The rising cost of prescription drugs during a recession and the diminished reputation of the pharmaceutical industry made possible policy to establish PDLs. But this policy had four significant underlying causes. The first was

the development and implementation of research methods that, for the first time, permitted fair and persuasive tests of the effectiveness and comparative effectiveness of health services. The second was the representativeness, managerial competence and expertise in health policy of senior officials of state government. The third was frustration among policymakers about their failure to contain the growth of spending for health care. The fourth was the growing burden of chronic disease; a stimulus of increased spending but, equally important, a source of skepticism among policymakers about the priorities of physicians and hospitals and the organization of health services.

To introduce the first of these underlying causes, I return to John Santa's question about policy in British Columbia during the meeting of the RSG in December, 2000. The draft case study was in my computer because Andrew Oxman and I had commissioned case studies of collaboration between policymakers and scientists in six countries in applying the findings of research on the effectiveness of health services. The policymakers and scientists who wrote the case studies had met in Cape Town, South Africa, two months earlier to review one another's drafts and seek consensus about lessons from them for colleagues.⁷

We chose Cape Town for the meeting because half the participants would be there to attend the eighth annual colloquium of the Cochrane Collaboration, the governing body of which Oxman chaired. The Cochrane Collaboration, named in honor of the British epidemiologist Archie Cochrane (1909–88), then comprised about 10,000 persons, mostly researchers, from more than eighty countries. Groups within the Collaboration set standards for systematic reviews, a significant advance in methodology for rigorous evaluation of health services, and then applied them. The Collaboration published the Cochrane Library, an electronic journal of reviews that met its standards, as well as abstracts of reviews in progress. It also supervised a global registry of published and unpublished clinical trials, the sources of primary data for most systematic reviews.⁸

Most of the founders of the Collaboration, like Archie Cochrane himself, had conducted RCTs that were independent of industry. These trials sought to avoid systematic bias in evaluating and comparing interventions through rigorous analysis of data collected from randomly selecting research subjects under procedures that prevented either the subjects or the persons treating them knowing who received which intervention. Trialists, as they called themselves, worried that observational research—mainly the analysis of data from clinical and billing records

(called administrative data)—risked several types of bias that could skew findings.

The United States lagged behind most other industrial countries in the priority it accorded, relative to other biomedical and health services research, to conducting independent RCTs and synthesizing their data in systematic reviews. Most of the Americans who studied the outcomes of health interventions used administrative data, of which, as a result of its fragmented payment system, the United States had more than any other country. American researchers devised subtle methods (to adjust for acuity and age, for instance) in order to reduce bias in studying these data. Their studies were generally less expensive and took less time than RCTs.

Americans who conducted independent RCTs had relatively less financial support and considerably lower prestige among health researchers than trialists in, for example, Australia, Canada, Denmark, and the United Kingdom. The National Institutes of Health and its most powerful constituents in academic medicine resisted the deflection or reallocation of funds from research on the pathophysiology of disease to independent RCTs. They did so mainly because they believed that research in the basic health sciences and traditional clinical investigation would lead more rapidly to improvements in population health than evaluation of the effectiveness of interventions. Moreover, the federal agencies and the few philanthropic foundations that sponsored research on health services had many competing demands on their budgets.

Many academic researchers, including those who evaluated health services, had other reasons to be critical of RCTs. They were expensive, time-consuming and often difficult to conduct. RCTs could violate ethical principles; especially if potentially effective treatment was withheld for the sake of comparison. Moreover, most RCTs evaluated interventions in carefully chosen patients in academic settings rather than in routine practice.

Many researchers also disparaged RCTs because they associated them with commercial interests. Pharmaceutical companies sponsored most American RCTs in order to obtain regulatory approval for new drugs. Many senior investigators at academic health centers had low regard for colleagues who administered research protocols that had been designed by pharmaceutical companies and then published articles about the trials that had been ghostwritten by company staff or contractors. Since the early 1990s, moreover, private firms had been conducting an increasing number of industry-sponsored trials, thus reducing still further their prestige among academic scientists.

A growing number of leaders in the legislative and executive branches of government in American states had, however, been learning about the methods, strengths, uses and limitations of independent RCTs and systematic reviews since 1990. By 2000, when approximately 2,500 systematic reviews that met the methodological standards of the Cochrane Collaboration had been published, a substantial number of influential policymakers understood how RCTs and systematic reviews could contribute to policy for coverage and for quality improvement; if, that is, it became politically feasible to use them.

These policymakers initially learned about the methods, strengths, uses and limitations of what came to be called, oversimply, evidence-based health research as a result of the work of the User Liaison Program (ULP) of the federal Agency for Health Care Research and Policy (now the Agency for Healthcare Research and Quality or AHRQ) and the Milbank Memorial Fund. Between its inception in 1976 and 1991, ULP had organized interactive workshops at which state (and some local) government policymakers learned about the methods and uses of research on health services. Until 1990 most of the research described in ULP workshops was observational; the methods and findings of investigators who used administrative data to study variation in the services offered to patients and the outcomes of treatment. I had helped to organize and defend ULP as a federal official and was subsequently a planner, presenter, and facilitator for many of its workshops. The Milbank Memorial Fund appointed me its president in the fall of 1989.

Because of the work of ULP and Milbank, state policymakers learned about the methods and uses of RCTs and systematic reviews conducted in other countries. At the end of 1989, Iain Chalmers, a Scot based in Oxford, published, with collaborators principally from Canada and the Netherlands, two volumes on *Effective Care in Pregnancy and Childbirth*.⁹ This was the first demonstration that systematic reviews could be used to evaluate an entire field of health care. Three years later Chalmers, who had been close to Archie Cochrane, was the principal organizer of the Collaboration.

Chalmers showed me the volumes in January 1990. I paged through them as he talked about his plans to organize an international collaborative network of investigators who would conduct systematic reviews of health services. At the end of the second volume, I found several appendices; lists of interventions of proven effectiveness; of those that should be discontinued; and of others with uncertain effects that required further research.

Several months later, the director of ULP asked me to help plan and then lead the closing session of a three-day workshop for some forty state

polymakers about research on the outcomes of health services. When my turn came, I asked the participants to assume for a moment that the slides I would now show them listed findings that met the highest international standards for research. I promised that I would describe the methodology of this research after they had responded to the slides.

My slides were the first pages of each of the appendices of *Effective Care in Pregnancy and Childbirth*. But when I spoke I changed the scientific language that Chalmers and his colleagues had used to describe each list. I said that the slides could be headed stop doing this, do that differently, cover these interventions when you have extra money, and do more research.

Most of the polymakers in the room said they were intrigued. Lee Greenfield, then chair of the committee of the Minnesota House of Representatives that financed health services and public health, called the lists "an answer to a policymaker's prayer;" depending, he added, on the persuasiveness of the methodology on which they were based. Greenfield had studied physics and engineering at Purdue and the philosophy of science at the University of Minnesota.

A conference in Washington, DC, early in 1991 contributed additional evidence that systematic reviews and research that met rigorous criteria for inclusion in them could help to improve the effectiveness of health services. The International Association for Healthcare Technology Assessment (now Health Technology Assessment International), several federal agencies, the American College of Obstetrics and Gynecology and the Milbank Memorial Fund convened the conference to discuss the significance of *Effective Care in Pregnancy and Childbirth*. Several hundred participants heard presentations about systematic reviews and how they could be used to improve clinical and financing policy for perinatal care. In a keynote speech, the senior health official in the federal government, Assistant Secretary of Health James Mason, endorsed the science of research synthesis and its applications.

Early in 1993 a cover story in *Parade* described the benefits to consumers of the findings and methods of *Effective Care in Pregnancy and Childbirth*. Earl Ubell, a senior editor at the magazine who had been a pioneering science reporter on network television, instigated and wrote the story.¹⁰ Ubell quoted me in the second jump, which was buried among classified advertisements. By the next morning, however, the voice mailbox at the Milbank Fund had received many inquiries from women all over the country wanting to know more about the book.

Because the Fund's mission is to help decisionmakers apply the best available evidence and experience in order to improve health policy, its

response to these consumers was to tell them how to acquire the paperback condensation of the book. Fund staff then began a multi-year initiative to inform policymakers about the methods and potential uses of systematic reviews.

The Competence of State Government

The second underlying cause of convergence was the competence of senior state officials in making health policy. Legislative leaders and members of their staff, governors and persons they appointed led in developing this competence over many years. I call these people “general government” in order to distinguish their responsibilities from those of persons I call “specialized government.” General government allocates resources among competing claimants, who include agencies of the executive branches, public benefit corporations, local government, interest groups, and citizens. Specialized government advocates; its employees compete to increase the resources allocated to their agencies by general government, at whose expense is not their concern. General government made convergence possible.

Many historians, journalists, and political scientists, as well as many federal officials, have argued since the late nineteenth century that states hindered the inevitable centralization of the economy and domestic policy. Many of these critics also complained about the incompetence and dishonesty of state officials. But state officials were never as irrelevant or as incompetent as their detractors claimed. Moreover, government in the states has become increasingly effective since World War II in response to growing responsibilities and spending to fulfill them, especially in health affairs.

The vast expansion of public higher education for the health professions after 1945 drew state officials into other aspects of health policy. States had for more than a century been responsible for public health, for inpatient treatment for persons who were mentally ill and disabled, for inspecting hospitals and, in many states, for supplementing charity in paying for the care of the indigent. By the late 1940s, states were subsidizing capital and appropriating operating funds to build and expand public and non-profit teaching hospitals. State officials were leading participants in implementing an internationally accepted theory that population health would improve if health care were organized in hierarchical pyramids topped by academic institutions and clinical facilities they controlled.¹¹

This theory, which I call hierarchical regionalism, also influenced legislation in 1946 establishing the federal Hill-Burton program to construct

hospitals. Because Hill-Burton funds flowed in response to state plans, states' responsibilities for inpatient care expanded beyond the hospitals they owned or whose capital they subsidized.

Because of Hill-Burton and other federal grant programs, every state expanded the size and sophistication of its civil service in order to comply with federal regulations for reporting and accounting. The extramural program of the National Institutes of Health, for example, began to award grants in 1946; many of them to state universities. Within a few years, states also received new federal funds to provide financial support to poor children and elderly persons and for payments to vendors of health services to these populations.

States' responsibilities in health affairs grew as the health sector expanded. They regulated many more hospitals and nursing homes, whether public, nonprofit, or proprietary. They oversaw the construction and expansion of health facilities and provided increasing amounts of subsidized capital to nonprofit hospitals and nursing homes. As enrolment in voluntary health insurance plans increased, so did states' responsibility to regulate the solvency, market conduct, and products of the commercial and nonprofit firms that sold it. The insurance industry persuaded Congress to pass a law that clarified and strengthened states' authority to regulate insurance, even companies in interstate commerce.

Many experts in universities, research organizations, and the federal government continued to proclaim the inevitability of greater centralization in the decades after World War II. For many academic political scientists, centralization was the domestic counterpart to the increased power of the presidency in foreign and defense policy. They adduced evidence from the poorest (which were also, not coincidentally, the most defiantly racist) states to support their claim that states would (and should) wither away. Generations of students of American government learned that the "Alabama problem" was an example of the need to centralize domestic policy.

Only a few proponents of the inevitability of centralization noticed the consequences for state government of changes in where people lived. Mainly as a result of employment opportunities during and after World War II, many people, both black and white, migrated from the South and border states to the Northeast, Midwest, and Pacific West. Many African Americans had their first opportunity to participate in politics; many whites had a choice among competing candidates for public office for the first time.

Many people from the Midwest, Mid-Atlantic, and New England states also moved, seeking jobs and a more benign climate, to metropolitan

regions in the South and Southwest. Many of these migrants had higher expectations about the scope and efficiency of public services than many of their new neighbors.

The prosperity of mobile Americans stimulated the growth of suburbs and of the influence of their residents on state politics and government.¹² Most of the new suburbanites were homeowners who held mid-level jobs in the public and private sectors. They wanted a great deal from government, including schools and universities that would increase their children's opportunities, roads, bridges, and in some places mass transit that would reduce the time they spent commuting and shopping, hospitals that had the latest technology and offered rapid access in emergencies, and zoning that enhanced or at least protected the value of their homes. Many of them were willing to pay more state and local taxes to achieve these benefits. They began to elect people like themselves to legislatures.

The U.S. Supreme Court soon helped to redistribute political power in the states from rural areas to suburbs. Most state legislatures had traditionally established the boundaries of districts for electing their members and members of the U.S. Congress in ways that skewed power to voters in rural areas. This situation changed rapidly after 1962 when, in two landmark decisions, the U.S. Supreme Court established and then applied the constitutional principle of one person, one vote.

The characteristics of legislators changed after states redistricted. Many of the new legislators from urban and suburban districts had more education, and more of them were professionals, women, and members of minority racial, religious, and ethnic groups than many of their rural predecessors.

Redistricting coincided with the expansion of public spending for health by the federal government and the states as a result of the enactment of Medicare and Medicaid in 1965. Medicaid was a federal-state program. Medicare, although entirely a federal program, combined with Medicaid to transform the financing of hospital and medical services for the poor and for elderly persons with modest incomes. Patients whose care had previously been subsidized by government and philanthropy became significant, and often the most prompt and reliable, sources of reimbursement for hospitals and physicians.

State officials were now responsible for access to appropriate care for a huge percentage of the population. They continued to regulate hospitals, nursing homes, and health insurance, to subsidize care in teaching hospitals, and to provide care for special populations. Now states also had responsibility for patients covered by Medicaid for acute and long-term

care, and shared with the federal government responsibility for seniors and persons with disabilities whose low incomes entitled them to both Medicaid and Medicare.

States' spending for health, including public health activities and education and training for the health professions, became a huge percentage of their budgets. Medicaid became a larger budget item than education in many states. States that deinstitutionalized most services for persons who were mentally ill and developmentally disabled could, under federal regulations, substitute Medicaid for what had been state-only funding. Moreover, Medicaid became the largest payer for long-term care. Because of "spend down" provisions to implement the legal construct of "medical indigence," long-term care became an entitlement for people with higher income and more assets than other Medicaid recipients.

Increased Spending, Uncertain Revenue

Spending for health services, in total dollars and as a percentage of gross national product, has grown in every industrial country during the past half century, but most rapidly in the United States. Expenditures for health services for the first time exceeded spending for national defense during the 1960s. In most subsequent years, the rate of inflation in spending for health services has exceeded the rate of general inflation.

High expenditures for health services in the United States have many causes. The most important drivers of spending have been the introduction of new technology and the weakness of policy to restrain its proliferation. A related source of spending growth has been the overuse and misuse of some of this technology and the underuse of less expensive preventive and primary care services. Some of the increase is, moreover, a result of disease mongering by manufacturers of drugs and their allies among providers; the medicalization, for example, of anxiety, sadness, and stress. Much of the inflation has also resulted from the administrative complexity of billing and reimbursing for services in a sector with many public and private payers. Very little of the increase, however, is the result of the aging of the population; a counterintuitive finding first recognized in European countries and recently confirmed in the United States by the Congressional Budget Office.¹³

Much of the increased spending has been beneficial. More people have had access to more health services in recent decades than at any time in the past. Although there is strong evidence that increasing length of life over the past century has mainly been a result of other determinants of health than personal health services, advances in diagnostic, preventive,

and therapeutic technologies have had a significant effect on both the length and quality of life.¹⁴

As health care became the largest sector of the American economy, increasing payments by government, health insurance plans and consumers generated considerable personal and corporate income. Pressure from interest groups whose members benefited from rising expenditures has made it easier for policymakers in the states and the federal government to increase the supply of services than to restrain spending for redundant and ineffective services in order to subsidize access to essential care for more people.

Rising expenditure for health services has placed an increasing burden on the states, the federal government, and business firms. Expenditure growth is a particular problem for states because their annual revenue from taxes and fees varies within each business cycle, while their constitutions, with the exception of Vermont's, require them to balance their budgets annually.

Policymakers in the public and private sectors have tried to restrain spending in a variety of ways. Their strategies have included capping and freezing reimbursement to institutions and professionals; encouraging competition among providers; requiring prior approval for patients to receive drugs and surgery; limiting patients' coverage and raising deductibles and copayments; reducing or refusing to increase educational opportunities for aspirants to the health professions; and restraining the building and expansion of facilities.

Interest groups threatened by each of these strategies have complained that they compromise patients' access to health care of the highest quality. Policy for spending less, increasing spending more slowly, and spending better became inseparable from policy for access and quality. Any proposal for policy to restrain spending stimulated debate about access and quality. Similarly, any policy to address quality stimulated charges by interest groups and advocates that it was a covert attempt to reduce spending.

Physicians and the organizations that represent them have since the 1920s interpreted most proposed policy to address access, quality, and cost (defined as spending that they ordered for particular patients) as threats to their professional autonomy. Because many of these proposals have been informed by research on health services, most physicians and the organizations that represent them have been severe critics of the methods and findings of such research. This criticism has affected funding for the field, researchers' careers, and the framing of questions for research.

The politics of physicians' autonomy has profoundly affected the history of convergence. The legislation that established Medicare and Medicaid in 1965 accorded considerable autonomy to physicians in both treating patients and setting fees. The politics of cost containment over the next half century diminished but never eliminated this autonomy. The preferred drug lists (PDLs) that are the focus of this book, for example, substitute policy informed by independent research for physician autonomy in prescribing drugs. PDLs are an aspect of a gradual process by which public officials and corporate executives have become less solicitous of physicians' preferences.

Although physicians and many of the associations that represent them still use the rhetoric of autonomy, the politics of medicine is changing. Leaders of the major associations of the profession (who call themselves the House of Medicine) have explored strategies to preserve substantial autonomy by accepting more accountability to government and private employers. These leaders are promising increased accountability to the public for the quality and safety of medical practice in exchange for the profession's continued dominance of medical education, licensure and discipline, and specialty certification. Nevertheless, the politics of medical autonomy still has substantial influence on policymaking to restrain spending and improve quality.

Chronic Disease and the Inefficiency of Health Care Delivery

Until roughly the 1960s, it seemed reasonable to most people that public and private sector coverage should accord the highest priority to resource-intensive care during acute episodes of illness, whether patients suffered such episodes as a result of infections, injuries, or chronic disease. Since the early twentieth century, there had been consensus that the principal determinants of life and death were whether, how promptly, and how effectively providers of health services addressed these episodes. Because hospitals provided the most effective care during acute episodes it was logical for policymakers to prioritize increasing the supply of hospital and specialized services rather than of primary care. Similarly, payers reimbursed providers more generously for inpatient than for ambulatory care, and particularly for invasive procedures. Few diseases could be prevented by medical intervention until after mid-century. Moreover, only a few drugs cured infections or slowed the course of chronic disease before the 1940s.¹⁵

A widely accepted assumption about biomedical science reinforced for many years the priority accorded to treating acute episodes of illness. Most

scientists, journalists, and members of the public assumed that the germ theory of infectious disease would be the model for understanding the natural history of chronic disease, and thus of research to prevent and eventually to cure it. The microscopic agents that caused chronic disease would be isolated in laboratories. Physicians who worked in laboratories and treated patients, assisted by scientists in other disciplines, would devise simple preventive measures and cures. These interventions were sometimes called, usually admiringly, “magic bullets” during and even after the first half of the twentieth century. Magic bullets would proliferate and gradually lead to improvement in the health of populations. As recently as 1971, for example, an influential medical scientist and pundit disparaged interventions that merely postponed death rather than curing disease as “half-way technologies.”¹⁶

Chronic disease became the leading cause of death in the United States by the 1920s. In the mid-1930s, a cross section of Americans told federal surveyors that their most important health concern was mitigating the disabling effects of chronic disease. But health policy continued to prioritize interventions during acute episodes of disease. The few effective interventions for chronic disease seemed to be magic bullets, notably, insulin treatment for diabetes and vitamin therapy for pernicious anemia. Surgeons were intervening more effectively, especially to treat cancers. Chronic disease, most experts had reason to believe, would eventually yield to drugs and surgery.

A few epidemiologists and medical scientists had, however, begun in the 1920s to array evidence that chronic disease presented different challenges for research, practice, and policy than infectious disease. Working in laboratories and applying advances in statistical methods, they demonstrated that chronic diseases had a variety of causes, often linked, which included bacteria, viruses, genes, environmental toxins, personal behavior, injuries, and the biology of aging. This research eventually established the conceptual basis for policy and practice to prevent or delay acute episodes of chronic disease and alleviate pain and other symptoms through more effective management of patients’ disease. Prevention, research indicated, should also include reducing environmental hazards, particularly those resulting from industrial processes, and persuading people to modify their behavior.

Policy for health services accommodated gradually to the growing prevalence of chronic disease. Hierarchical regionalism, the dominant theory of the organization of services, had been devised early in the twentieth century to treat infectious disease and casualties of war. The politics

of physicians' autonomy thwarted hierarchical regionalism in the United States. These politics also gave community hospitals and the specialists who practiced in them financial incentives to treat acute episodes of chronic disease. Most of these physicians, as well as public and private payers, were slow to implement advances in managing care for chronic disease in outpatient settings.

During the first decade after World War II, the priorities of health policy and Americans' experience of illness diverged more widely than at any time before or since. Americans had more chronic disease and hence suffered more disability than ever before. As a result of the growth of employment-based health insurance, they also had more access than ever before to more care for infectious disease, injuries, and acute episodes of chronic disease. New government subsidies increased the supply of acute care hospital services and offered advanced training to more specialists, especially in invasive disciplines, than to primary care physicians.

Beginning in the mid-1950s, health policy began to accommodate to the prevalence of chronic disease and advances in preventing and managing it. Major medical insurance, devised by commercial insurers, paid for and coordinated expensive outpatient and hospital care for chronic disease in exchange for higher deductibles and co-insurance. A decade later, Medicare began to reimburse more services for managing chronic disease than any previous insurance program, public or private. In 1972, the federal government extended Medicare coverage to persons eligible for Social Security Disability Insurance (which had been established in 1956) and socialized the cost of treating end-stage renal disease. Medicaid subsidized a vast increase in the availability of skilled nursing facilities and home health care.

A few reformers insisted that despite these incremental changes in the allocation of resources, the organization of health services and reimbursement for them required radical reform. They argued that, in the absence of major changes in how and where physicians practiced and how they applied evidence about the effectiveness of interventions, health spending would rise more quickly than necessary. Moreover, the outcomes of care would not justify these expenditures.

Leaders of many powerful interest groups in health affairs agreed that the delivery system and reimbursement policy should accommodate to the prevalence of chronic disease. But they also represented their members and constituents. Specialists in surgery, interventional subspecialties of internal medicine, and radiology continued to be more highly paid than their colleagues who managed the chronic disease of their patients. Episodic

management of patients' diseases and overprescribing of tests, drugs, and invasive treatment continued.

Many officials of general government in the states acknowledged serious flaws in the organization of health services. They knew that many hospitals were overequipped and underutilized and that government agencies and private health insurance plans reimbursed physicians for many procedures of dubious effectiveness. Voters frequently complained to them about their lack of access to primary care. Officials observed that much of the increased spending on prescription drugs was a result of overprescribing, often in response to demand generated among physicians and consumers by pharmaceutical companies. Many of them talked to one another about the excess suffering and waste of resources that resulted from services that were inefficient and ineffective. The convergence of science and governance described in this book became a small, but significant, way to address some of these problems.

HOW THIS BOOK IS ORGANIZED

The chapters that follow amplify and continue through the spring of 2009 the stories I have summarized in the preceding pages. The next chapter describes how the politics of health policy has shaped the scope, priorities, and methods of research on health services. This chapter begins in the early twentieth century in order to document the persisting influence of past politics on subsequent events; particularly the politics of asserting, defending and negotiating the autonomy of the medical profession.

The subject of Chapter 3 is how and why leaders of state government became receptive to research on health services and especially to the research that makes convergence possible. The chapter describes the growing capacity of states in making and implementing policy; initially for public health, then for higher education for the health professions, and since the 1950s, for personal health services.

Chapter 4 describes the convergence of science and governance in American states through a history of the origin, work, and effects of the Drug Effectiveness Review Project (DERP). The chapter describes the process of mutual assistance that DERP's member states and a Canadian intergovernmental organization devised and how researchers and state officials collaborate to produce systematic reviews. The history of health services research and of state government in health policy described in the preceding chapters made DERP possible. Immediate events and underlying

causes made it feasible. Particular policymakers and their staff made DERP happen.

The final chapter assesses the sustainability of the convergence of science and governance exemplified by DERP. It emphasizes the fragility that threatens the partial success to date. The chapter also raises issues that policymakers and researchers could address as they prepare for contingencies that either threaten convergence or offer opportunities to expand it.

A COMMENT ON SOURCES AND METHODS

Many of the sources for this book could be described in conventional scholarly language: interviews, participant observation, published primary and secondary sources (articles in print and electronic media, publications by researchers), published documents (reports, bills, laws, court decisions) and unpublished documents (letters, e-mail messages, internal memoranda, draft legislation and regulations, legal briefs).

These conventional words misstate how I acquired most of my sources. My “interviews” were mainly privileged conversations with policymakers and researchers. I was a “participant observer” because I had to listen attentively (and consider my responses carefully) in order to offer advice that policymakers might find useful or to assist them in drafting memoranda, legislative specifications, budget documents, and official publications. I had access to unpublished documents about politics and policy—documents that would subsequently be deposited in archives—because they were part of my daily work with colleagues in government. I read published sources because policymakers asked me to or because reading them was preparation for what policymakers might ask me to do.

I have been talking with policymakers and members of their staff and reading internal and published documents on the subjects I address in this book for four decades. I have been fortunate to experience public life in quite different environments and thus to learn about the priorities, processes, and predilections of people who work in them. These environments include three federal agencies, government in two states, two universities, and an endowed operating foundation.

As a result of how I acquired information, I have different ethical obligations than most scholars who write about politics and policy. I did not seek informed consent before engaging in any of the conversations that inform this book. I had access to confidential information because

policymakers and their staff as well as colleagues in the field of health services research assumed that I could be trusted. Many of the primary data in this book were confidential until released by the persons who provided them.

For many years I have solicited comments on excerpts from and sometimes entire drafts of articles and book chapters from the policymakers whose experience I report and interpret. I invite them to request complete anonymity or imprecise attribution for any quotation or paraphrase of what they say. I also promise to take account of each comment they make about how I interpret their statements or behavior.

I stipulate, however, that taking account of comments does not necessarily mean that I will change my interpretation of sources. A co-author and I once revised the conclusion of an article to add that a former policymaker took exception to our interpretation of his purpose in crafting an amendment to the Internal Revenue Code. We revised again when the policymaker wrote us that, on reflection, he agreed with our interpretation.¹⁷

The citations in this book reflect this interpretation of my ethical obligations. I cite published and archival sources in the conventional way. Whether I name an informant or attribute a quotation or an anecdote by title (for example, to a committee chair, a senator, or the executive of a professional association), I usually do not provide the precise date or setting of the comment. I omit this information in order to enable my colleagues in public service to maintain ownership of information about what they said to whom, where, when, and under what circumstances. The absence of a citation signifies that my source chose anonymity.

I am sometimes the source of an uncited quotation, paraphrase, or description of an event. I identify myself as a source only when I am a character in a story. In this chapter, for example, I described why I had a draft case study of the PDL in British Columbia when a state official asked about that policy and my role in introducing systematic reviews to state policymakers. When my presence did not affect a story, however, I report, without attribution, what I heard. In borderline cases, when my presence had only a modest affect, I usually choose anonymity in order to maintain narrative focus on more important characters.

I hope my strategy for describing and citing sources also meets my ethical obligations to persons whose permission to quote or paraphrase them I did not seek. These people made ill-considered, or deliberately misleading, or self-serving, or merely outrageous comments in conversation with me or at a meeting I attended. I have tried to prevent even the most knowledgeable readers from identifying these sources.

Another ethical issue is my decision not to discuss with policymakers my interpretations of the causes of political events. To do so would impose the preoccupations of scholars on people who have other interests and many demands on their time. Only once during my career has a policymaker found and read a book I wrote and commended it to colleagues.

I have sometimes, however, told a few policymakers about interpretations of mine that academic colleagues have dismissed. Each time the policymakers replied that my interpretation was obvious to them. An example is the distinction between general and special government introduced in this chapter and elaborated in Chapter 3.

In contrast to my reticence about discussing interpretation with policymakers, I have asked many of them about the political and financial costs and potential benefits of many policies. That is their business, and I am grateful for their guidance, which is, I hope, reflected in this book.

My greatest ethical regret is that the conventions of writing a book require me to imply that the politics of policymaking is more coherent than it actually is. Much of what I ascribe to causation could also be interpreted as responses to contingency.