Teacher's Guide
for

Health Care Regulation in America: Complexity, Confrontation and Compromise

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Overview of the Guide

Health Care Regulation in America: Complexity, Confrontation and Compromise is intended to present the sweep of American health care regulation in its broadest sense. It is structured according to various spheres of health care, and within each it presents the range of players, both governmental and private that are part of the regulatory process. Current regulatory programs are explained in historical context and in terms of underlying policy issues that shape them. Appreciation of these factors deepens the understanding of the reasons that programs take the forms that they do and of the interests that have influenced them. This teacher's guide describes the main points that each chapter is intended to convey and the central issues that can provoke productive student discussion.

The book's emphasis on policy issues and conflicts that underlie regulation is intended to facilitate an appreciation of the forces that perennially drive the regulatory system. Individual statutes, regulations, and agencies change over time, while underlying policy concerns exert an influence over the course of decades and sometimes much longer. This guide highlights key issues and suggests approaches to discussing them in class. The review of each chapter ends with suggested questions for class discussion that further distill the central policy questions in each sphere of regulation.

Chapter 1 - Introduction

This chapter provides an overview of the purposes of regulation, key components of the regulatory system, and the process by which regulations are developed and implemented. These are foundation elements in understanding regulation as a system rather than a disjointed set of rules. The discussion provides a context for considering individual spheres of regulation in the chapters that follow.

The conceptual lens through which the book considers the purposes of regulation is the constant need to balance the objectives of enhancing quality, expanding access, and controlling costs in health care. These objectives are all important, but they often work in opposition to one another. Addressing any single objective will inevitably harm one or both of the others. All regulatory programs can be seen as an attempt to bolster one of these goals. For example, medical licensure promotes quality; government insurance programs such as Medicare expand access; certificate-of-need programs that limit hospital construction seek to limit costs.

A helpful way for students to understand regulation from a policy perspective is to consider any individual regulatory program in terms of the goal that it addresses and the ways in which its unintended consequences hinder the others. By way of example, consider the licensure of allied health professionals. Each time another profession, such as psychology, is subject to formal licensure, the stated goal is to enhance quality through standardization and oversight of the training and conduct of its members. In applying a licensure requirement, the supply of practitioners in the field is invariably reduced, because some of them will fail to qualify under the new standards. This reduces access by patients and raises the cost of seeing those practitioners who achieve the new credential. A helpful classroom exercise would be to ask students to identify these effects in an area of regulation and to consider whether, on balance, the overall effect on health care is worth the trade-offs.

The discussion of pillars of the regulatory system on pages 9 – 11 highlights the breadth of kinds of regulatory authorities. It demonstrates that health care is regulated not only by the government but also by an assortment of private organizations. Few, if any, other industries are governed by such a range of different regulators, and few are overseen to the same extent by bodies that are controlled by the regulated entities, themselves. These include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the various medical specialty boards, and the National Committee on Quality Assurance (NCQA).

Consideration of this patchwork system introduces students to the notion that in health care, regulation is not simply a contest between government and industry. It is a much more complex and subtle interaction between players at different levels of government and in different kinds of private organizations. The patchwork leads to the complexity of the web of regulators, and to the confrontations and

compromises that ultimately permit the system to function, which is the theme of the final chapter.

Much of the discussion of key components focuses on the federal Department of Health and Human Services (DHHS), which houses most of the federal agencies that regulate health care in America. Since this body influences every sphere of regulation discussed in the book its history and structure are described in the introductory chapter on pages 10 - 11. This provides a context for considering its component agencies as they oversee different kinds of health care activities. In understanding the magnitude of the federal role in regulating health care, it is important for students to consider the enormity of the DHHS bureaucratic structure.

The discussion of the process of regulation on pages 11 - 15 introduces the central legal principles that govern regulation. It is important for non-lawyers to understand this legal context because it shapes much of the country's regulatory apparatus. Under the constitution, governmental regulators must provide "due process" to those who are directly affected by their actions, as they may limit the right to life, liberty, or property. The result is a long process through which those who are subject to regulation must be given notice of a proposed action, the evidence that supports it, the right to be heard, and the right to appeal. These elements apply to any regulatory action, whether it is the suspension of a medical license, the issuance of an environmental discharge standard, or the imposition of required procedures for testing new drugs.

The federal Administrative Procedures Act and similar state laws prescribe the ways in which these elements must be provided. The conceptual underpinning of all of these laws is that regulatory actions may not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." In practical effect, this means that agencies must have reasons for all actions that are backed up by evidence and that consider the positions of all affected parties. This brief overview of legal aspects of the regulatory process helps students to understand many aspects of the behavior of regulators that might otherwise seem unnecessarily bureaucratic.

The perennial policy conflicts discussed in this chapter are those that shape all spheres of health care regulation. They include the balance between relying on external regulation and on market forces to achieve policy goals, the interplay between governmental and private organizations in achieving oversight, and the relationship between different levels of government. Students should be sensitive to these issues as they consider each regulatory program discussed in the book.

Questions for Class Discussion

Consider the large number of uninsured Americans, a group that presently includes over 15 percent of the population. Can you think of a way to reduce that percentage without increasing costs or reducing quality? If you had to

choose, which of these two goals would you sacrifice in order to improve access to health care for those who lack health insurance?

In most industries, market-based competition is the primary incentive for sellers to maximize the quality of their product or service and to limit the cost. This is true to a much more limited degree in health care. To what extent can market forces achieve the goals of maximizing health care quality and access while controlling costs? In what ways do market concepts apply differently to health care than to other industries?

Which aspects of health care are best regulated by the states and which by the federal government? What are the strengths and weaknesses of placing primary regulatory authority at each level of government?

What are the arguments for and against private regulation of health care? Would you trust a private organization more or less than the government to oversee health care quality, cost, and access? Would your answer differ with regard to other industries?

Chapter 2 – Regulation of Physicians and Other Health Care Professionals

The oversight of physician practice is one of the oldest and most fundamental elements of health care regulation. It serves as a model for many other aspects of regulation that have followed. Among the distinguishing features of physician licensure is that it is accomplished at the state level, so there are 51 different bureaucratic structures. This results from the efforts of the profession to promote its own licensure in the late nineteenth century through the American Medical Association (AMA). A good topic for student discussion is to weigh the effects of licensure from the perspective of professional interest. It improves the quality of the physician pool, but by reducing the number of practitioners, it permits those remaining in the pool to raise prices.

Physician licensure also exemplifies the complex interaction between state and federal jurisdiction. The system of state-level medical boards has been disjointed, at best. The press has periodically carried reports of physicians losing their license for egregious conduct in one state only to gain a new license in another. Communication between state boards has been sporadic. Coordination is today accomplished through the federally-administered National Practitioner Data Bank (NPDB), which centrally stores information on disciplinary actions. However, studies suggest that the data is incomplete and that many deficient practitioners still fall below its radar.

Would a uniform national system be better? Policy debates on this issue generally focus on the ability of state boards to reflect local standards and customs in contrast to the greater consistency that federal oversight would bring. Another consideration is the susceptibility of state-level boards to capture by the profession, a phenomenon that consumer activists believe has already occurred in most states, balanced against the greater likelihood of bureaucratic unresponsiveness at the federal level.

Physician regulation beyond licensure is the paradigm example of a mixed public-private system. Private organizations develop the licensure examination and accredit the medical schools whose degrees are accepted by state authorities. They also certify the expertise of specialists. Once in practice, physicians are also regulated, sometimes quite aggressively, by the health maintenance organizations (HMOs) in which they participate, by the hospitals at which they maintain staff privileges, and by Medicare. Is this allocation of regulatory roles appropriate? Do the best kinds of organizations oversee each aspect of medical practice? Does the complexity of the system promote quality through the participation of a wide array of oversight bodies, or is it too inefficient to permit effective quality oversight? A full exploration of these questions is a useful exercise because it requires a thorough understanding of all moving parts in the system.

Many allied health professionals are regulated according to the same pattern as physicians, as described on pages 34 - 35. To name but a few, the list includes psychologists, pharmacists, physical therapists, and occupational therapists. In each case, the profession itself promoted its own regulation with an eye to the success that physicians achieved in enhancing their prestige and income. A good topic for class discussion or for student papers is to trace the route that an allied health profession took and the ways in which it has attempted to mimic the physician model.

Questions for Class Discussion

Why did the medical profession promote its own regulation? Would physician licensure be more or less effective if the government had acted on its own initiative?

What are the advantages and disadvantages of licensing a profession from the point of view of patients? Considering quality, cost, and access, in what ways are patients better and worse off in a profession in which entry is controlled?

Could the market effectively oversee physician quality? What elements of market competition would foster and what element would impede protection of the public from incompetent practitioners? Does the Internet change the role that the market could play?

Would physician licensure be more effective if it were moved to the federal from the state level?

Is there an inherent conflict of interest in entrusting much of the oversight of health care professionals to organizations that the professionals themselves control? What are the arguments for and against relying on private regulators as part of the oversight process?

Chapter 3 – Regulation of Hospitals and Other Health Care Institutions

A wide variety of regulatory programs that govern health care institutions address each of the three central policy goals. Most notable are programs to maintain quality. However major regulatory thrusts have sought to expand access and to limit costs, and all three kinds of oversight now govern hospital operations.

The regulation of institutional quality presents an opportunity to consider the challenges in the definition and measurement of this attribute. In tracing the evolution of the Joint Commission, as discussed on pages 43 – 46, it is possible to dissect the three aspects of measuring quality and their advantages and disadvantages. Structure is easiest to measure, but it reveals the least about actual patient care. Process is somewhat harder to measure but represents a closer reflection of actual quality of care. The ultimate goal of quality oversight is to examine variations in outcomes, but this is the most difficult to measure, and the technology to do so is still evolving.

The Joint Commission began its accreditation process in the 1950s by examining the physical structure of hospitals. Its auditors focused on features such as the width of corridors, the equipment in operating rooms, and the cleanliness of patient rooms. In the 1960s and 1970s, it began to look at the processes of hospital operations. This included the functioning of medical staff committees, the protocols that guide behavior in emergencies, and the work flow for nurses.

Over the past ten years, JCAHO accreditation audits have begun to examine outcomes of hospital care. This raises the issue of how outcomes can be measured. It would be difficult, if not impossible, to follow patients for months or years after an inpatient stay to monitor their recovery. Even shorter term results, such morbidity and mortality after surgery, can be confounded by variation in the severity of illness. To find useable metrics, JCAHO audits measure items that combine process and outcomes, such as the advice given to patients with certain conditions, such as smoking cessation after a heart attack, and adherence to clinical guidelines when they are available. The science of measuring quality is still in its infancy, so the standards used by JCAHO and other regulators of hospital quality will likely evolve substantially over the next several years.

Challenges to measuring outcomes of hospital care present themselves to a range of other regulatory authorities. Several states, most notably Pennsylvania, have agencies that compare morbidity and mortality for various procedures among hospitals. The findings are adjusted for severity of illness to account for differences in the kinds of patients who are treated. However, the results and the methodologies used to derive them are still highly controversial. Measurement and oversight of hospital quality is a fruitful area for delving into an issue that lies at the forefront of regulatory evolution.

Regulation of hospital access was most aggressively pursued through the Hill-Burton Act of 1946, which allocated substantial amounts of federal funding to hospital construction over the next 30 years. In addition to adding bed capacity, this law required open access based on race and the provision by hospitals receiving funding of significant amounts of indigent care. The planning process through which Hill-Burton funds were distributed evolved into certificate-of-need (CON) programs that determine the optimal geographic allocation of institutional resources in many states. The irony of this regulatory progression is that today CON programs seek to limit, rather than expand, supply in the interests of controlling costs. They were based on the observation that oversupply of institutional capacity can result in expensive over-utilization. This makes a good case study through which students can explore the difficulties of formulating viable public policy over the long term and the relentless strictures of the three competing policy goals. Success in expanding access brought new challenges in controlling costs.

The most significant hospital access program today is the federal Emergency Treatment and Active Labor Act (EMTALA). That law requires Medicare-participating hospitals, a category that includes almost all of them, to provide emergency room patients with a full medical screening regardless of ability to pay, and to refrain from transferring them until they have been stabilized. EMTALA has eliminated abuses in which some hospitals had turned away seriously ill patients based on lack of insurance. However it has created new policy dilemmas. Many indigent patients, knowing that they cannot be denied an assessment, visit emergency rooms for minor ailments. This introduces delay in treating legitimate emergencies, adds to hospital financial pressures, since the care is not reimbursed, and places new cost pressures on the overall health care system, as emergency care is extremely expensive. Once again, students can examine how difficult it is to expand health care access without impeding one or both of the other corners of the iron triangle composed of quality, access, and cost.

Regulation of hospital costs has had a rocky history. The most direct approach, controlling prices, was tried and abandoned in several states. The bureaucracies needed to administer the systems incurred costs that exceeded any savings. The most successful approach to cost control has been the one instituted by Medicare in the mid-1980s, the use of prospective payment. A set fee, based on the patient's diagnosis, is paid regardless of the amount of care actually provided. This system, known as diagnosis-related group (DRG) reimbursement, is still used by Medicare, and copied by Medicaid programs in every state and by many private insurers. Over the past several years, the federal government has extended the concept of prospective payment to long-term care and to ambulatory care.

Regulation of inpatient costs has produced a range of unintended consequences that can be used to highlight how interconnected the health care system is. Reduction in payments under DRGs induced many hospitals to encourage more outpatient care. This resulted in technological advances that permitted some

kinds of surgery to be performed more quickly and efficiently. It also encouraged an assortment of business schemes to funnel kickbacks to physicians who referred patients for outpatient treatment.

Prospective payment for hospitals is also blamed for reductions in the quality of care, as patients are discharged as rapidly as possible. It has also encouraged many hospitals to select staff physicians based on economic considerations, such as efficiency and specialization in more profitable DRGs. This, in turn, has altered the underlying relationship between hospitals and physicians. All of these anomalous results in hospital regulation can engender class discussion of the pervasive effects of unintended consequences in regulatory policy.

Questions for Class Discussion

Is it appropriate that the core of hospital quality oversight relies on an organization, JCAHO, that the hospitals themselves control? What are the arguments for and against public protection by the industry itself? Can an organization that relies on its members for financial support be truly effective in policing those members?

How is hospital quality best measured? What kinds of patient outcomes should regulators seek to examine? What are the drawbacks to measuring them?

As regulators delve ever deeper into patient outcomes, collection and manipulation of data becomes increasingly central. Who should have access to the data? If the public and the press can view it, is there a risk of misinterpretation when sophisticated analytical techniques, such as severity adjustment, are used?

What should be the obligation of hospitals to treat patients who cannot pay for their own care? Should hospitals be required to assess everyone who enters the emergency room, regardless of how trivial their complaint may seem? How much charity care should hospitals be required to provide for non-emergency conditions?

To what extent does prospective payment of hospitals threaten quality of care? Are DRGs the best way to measure the value of the care that a hospital provides?

Chapter 4 – Regulation and Administration of Health Care Finance

The financing of American health care reflects most poignantly the disjointed nature of the overall system. It is called a "free market system", but, in fact, the government pays for almost two-thirds of all care. A third of the population is insured directly by government programs. For those who receive private coverage, about one-third of the bill is paid through a tax subsidy. And, of course, about 15 percent of Americans lack any health insurance at all.

Another layer of complexity is added by the assortment of different coverage arrangements. Some Americans, most notably those covered under traditional Medicare, still have conventional insurance under which they can see any provider they wish without the need for prior approval. Most private policies use a managed care system in which the insurer oversees coverage, but there is a variety of managed care arrangements. These range from restrictive HMOs to more flexible point-of-service plans. Patients are often bewildered by the intricacies of the coverage that they have.

The complex structure of American health insurance serves to highlight many important areas for class discussion. Three of the most interesting are the link between employment and coverage, the effect of financing mechanisms on the business side of health care, and the intertwined roles of government and the private sector. It is important for students to understand that financing is central to the overall health care system as it is in every other industry because any business is shaped by the flow of money.

The link between employment and private health insurance coverage in America resulted from historical accident, rather than explicit design. The history of health insurance from the first Blue Cross and Blue Shield plans of the 1930s to the World War II wage freeze that exempted health benefits from wages to the rise of commercial plans in the 1950s, which is described on pages 76 – 83, serves as a lesson in how incremental evolution over time can shape policy. It also exemplifies the importance of unintended consequences in policy decisions. This aspect of American health care can only be fully understood in historical context.

The employment-insurance link today produces several undesirable effects. These include the inaccessibility of insurance for those without regular employment at companies that offer health benefits and the often crushing financial burden on firms that do insure their workers. A good topic for student discussion is the search for alternatives to the present system. This can incorporate consideration of the factors that maintain a constituency for the present system, including the use of experience rating and the tax subsidy.

Discussion of the disadvantages of employment-based insurance inevitably leads to consideration of creating a universal system as an alternative that would cover everyone regardless of employment status. This offers a good context for discussing health care reform. A useful way to frame the discussion is to identify the interests on each side of the issue. This highlights divisions in the health care industry of which students may not have been aware. For example, physicians do not act as a monolithic block in this debate. Primary care physicians tend to favor a single payer national system while specialists tend to oppose the idea. Large employers increasingly favor a national system which would take the burden of coverage off of their shoulders, while smaller companies tend to fear the possible tax effects of a new government program. Hospitals generally favor a national system that would reimburse them for the uncompensated emergency room care that they must provide. A hidden and important force is insurance brokers, who exert significant political influence in support of the present employment-based system because it is the basis for their business.

A discussion of health care reform can also include a delineation of the distinctions between different approaches. Students may enter the debate believing that universal coverage necessarily means a single-payer, government-run system. However, this is only one kind of approach. The Clinton proposal of the 1990s called for multiple private players under federal coordination. A prominent current proposal would mandate that individuals purchase coverage for themselves in the private market. By presenting the many different ways in which universal coverage could be achieved and the advantages and disadvantages of each, students can see the complexities that reform presents.

The effects of financing on the business structure of health care are pervasive. In particular, managed care has introduced a new business dynamic. HMOs rely on networks of providers that agree to accept discounted reimbursement rates. If the providers in a region are disorganized, HMOs have bargaining leverage to play one off against another. This creates a clear incentive for providers to consolidate.

Consolidation by health care providers proceeded at a rapid rate during the 1990s, as the market penetration of managed care grew. Many hospitals merged with competitors or joined regional systems. Many physicians sold their practices to hospitals. Combinations of hospitals and physicians created integrated delivery systems that sought to offer all levels of care under global HMO contracts. As a result, the number of independent hospitals and physicians shrank noticeably during this time, so that independent hospitals and solo practice physicians have become quite rare.

The balance between the government and private roles in health care finance is particularly complex. The single most important government role is the administration of Medicare. An important topic for student discussion is the pervasive influence of Medicare on American health care beyond its insurance for the

elderly. After the successful implementation of DRG reimbursement in the 1980s, many private insurers followed suit. The business dynamics of DRGs have altered hospital-physician relations, with many institutions structuring their medical staffs based on utilization efficiency and profitability in addition to quality. Today, Medicare is piloting programs to rank hospitals according to quality criteria and to base physician reimbursement on performance measures. If successful, these innovations are certain to spread to private payers.

Demographic trends will add to Medicare's importance over the coming decades with the aging of the baby boom generation. Today, the program insures about 42 million Americans. In the next 30 years, that number will grow by over 50 percent. In addition to raising questions of financial stability, this growth will add to the government's share of overall health care spending and the influence that comes with this.

Medicare's larger influence raises important questions about the appropriate role of the federal government in health care. In theory, business matters such as physician practice and hospital operations are regulated by the states under America's federalist system. However, Medicare, as a federal program, has an important role in overseeing physician and hospital quality and implements rules concerning emergency room access through its ability to allocate and withhold funding. Is this role appropriate? It represents a good case study for weighing the proper balance between federal and state authority.

A final area that highlights the difficulty of formulating Medicare policy is the coverage for prescription drugs that began in 2006. The mechanism used to effectuate coverage is extremely complex with private companies administering the benefit under federal oversight and beneficiaries permitted to decline to participate. This arrangement was the result of numerous political and policy considerations.

Students can analyze the coverage plan in terms of both of these kinds of considerations. For example, there is a penalty for delaying participation in the benefit to discourage low utilizers of medications from opting out of the risk pool, thereby contributing to adverse selection. There is a "doughnut hole" between the primary and catastrophic layers of coverage, because Congress did not allocate enough funding for both purposes so it essentially split the program into two. Coverage is provided through private plans, including managed care arrangements, to encourage a strong private sector role. Reviewing each key aspect of Medicare Part D, which is described on pages 93 – 95, and asking students why they think each was included is a useful way to show how considerations such as moral hazard, adverse selection, universality of coverage, and politics play into the construction of any kind of government health care finance program.

Medicaid is the ultimate example of a complex federal-state relationship. Understanding the complicated arrangements through which the states administer Medicaid benefits under federal oversight is a daunting task. Medicaid is now

supplemented by state Children's Health Insurance Programs (SCHIP). It can be used to explore the balance between state-level flexibility and federally-imposed consistency that pervades much health policy.

Regulation of the private insurance market best demonstrates the interconnectedness of disparate regulatory roles in this sphere. In theory, private insurance is regulated by the states. However, in health care, the situation is far from straightforward. The federal Employee Retirement Income Security Act of 1974 (ERISA) exempts many aspects of coverage from state jurisdiction in a convoluted manner that defies clear legal analysis. Federal mandates through COBRA and HIPAA govern key aspects of the initiation and termination of employment coverage. Perhaps most importantly of all, federal and state tax exemptions for premiums paid by employers and employees fund almost one-third of all premiums. A taste of this complexity will help students to appreciate the difficulties that all parties, providers and patients alike, have in navigating the system.

Questions for Class Discussion

Has Medicare become too influential in shaping American health care? To what extent has it produced benefits in terms of innovations in reimbursement and quality oversight? To what extent has it usurped roles that the private sector and the states should play?

Should employment-based insurance be retained as the primary means for private coverage? What are its advantages and disadvantages?

Does America need a system of universal coverage? If so, what kind? Should it be government or privately based?

How active should private insurance be in managing care? Do HMOs go too far in restricting access to services, or is this a legitimate use of their power as payers of the bills?

Chapter 5 – Regulation of Drugs and Health Care Products

Regulation of the safety of foods and drugs dates back thousands of years. It is described in texts of ancient Greece and Rome. Today, it is widely accepted as a central government role. Since it involves oversight of products, rather than of health care services, the mechanisms involved and issues that they raise differ from those that control quality in physician practice and hospital operations.

A helpful way to introduce the topic is to ask students how the regulation of pharmaceuticals differs from that of health care services and differs from the regulation of non-medical products. In overseeing a product, there tends to be less ambiguity about the characteristics of quality than in judging a service. Assessing physician performance can be an extremely subjective exercise. Evaluating institutions raises the dilemma of balancing structure, process, and outcome measures. There is somewhat more consensus on how to measure the safety and efficacy of drugs using randomized controlled clinical trials.

The primary difference between regulation of drugs and of non-medical products is that drugs are evaluated by regulators before they reach the market. This is true for medical devices, as well. Most other products are subject to oversight only after they become available to consumers. The reason is that defective drugs can cause considerable harm, including death, if they reach consumers before regulators have had a chance to act.

The process through which the FDA assesses drugs and devices before marketing is long, rigorous, and expensive from the point of view of manufacturers. It can take up to ten years and cost close to a billion dollars. The Prescription Drug User Fee Act (PDUFA) passed in 1992 sped up the final step in the process by collecting fees from companies to fund FDA reviews. A good issue for student discussion is the balance in the process between speed and safety. If the process were faster, many drugs would reach patients who need them sooner, but more risks would go undetected. The proper balance ultimately depends on societal preference. There is not absolute right answer, as students may discover as they debate the issue.

Once drugs reach the market, the regulatory process for spotting hazards that pre-market review may have missed is spotty. The FDA is often criticized for acting too slowly when risks become apparent. There is little post-market testing for safety, although many side effects do not become evident until a drug has been used over time in a large and diverse population. Many proposals have been put forward for improvement, including enhanced enforcement by the FDA, creation of a second drug safety agency, and better use of large databases containing patient information. Consideration of the relative merits of these approaches can help to illustrate how

difficult it is to monitor the safety of products on the market, especially when the balance between safety and access to medicines must always be kept in mind.

The history of drug regulation in America presents an interesting counterpoint to that of other spheres of regulation. The three most significant federal food and drug laws were all enacted in reaction to public scandals. The 1906 law responded to numerous revelations of food and drug hazards culminating in publication of *The Jungle* by Upton Sinclair in 1904. The deaths of 107 people, mostly children, from an antibiotic contaminated with a toxic solvent led to passage of the 1938 law, which first instituted the process of pre-market approval. Reports of severe birth defects caused by the drug thalidomide in the early 1960s led to passage of amendments in 1962 that directed the FDA to consider efficacy as well as safety in new drug assessments. Why have scandals been so important in the evolution of this kind of government oversight? Are products more amenable than services to increased regulation in response to public outcries?

The nature of drug regulation is presently undergoing profound changes on at least two fronts. The first is the rise of economic oversight. As drugs have become an increasingly important component of health care, their costs have risen dramatically because of increases both in their prices and in the amount of their use. Regulatory efforts to control costs have focused on encouraging the availability of generics. The Hatch-Waxman Act, passed in 1984, eased the entry of generic copies of drugs onto the market after the patent on the original product had expired. This law is extremely complex, and it includes elements that help both brand name and generic manufacturers. Major aspects of the law are described on pages 125 – 127. Of particular significance, it requires the FDA to maintain a registry of all patents related to approved drugs, including those covering fillers, coatings, and colors. Brand name manufacturers can sue generic companies for infringement of any of these patents, thereby delaying competition. The FDA has been caught in the middle of some of these disputes.

Should the FDA play a role in the economic regulation of drugs, or should its activities be restricted solely to overseeing safety and efficacy? Some feel that the agency should use pharmacoeconomic analyses to judge new drugs according to cost effectiveness, in addition to the traditional criteria, but the FDA is not eager to take on such a new set of responsibilities. Students can consider whether the high cost of drugs argues in favor of a larger economic oversight role for the FDA, or whether this would confuse the agency's mission.

A particularly contentious aspect of drug regulation is the oversight of marketing. Several kinds of activity have generated public concern, including the use of direct-to-consumer (DTC) advertising and the promotion of off-label uses, which are described on pages 130 - 132. DTC advertising encourages patients to assertively seek a drug from their physicians. Off-label uses are applications of a drug in ways that were not specifically covered by its FDA approval. Drugs are often prescribed for new uses as part of standard medical practice, however companies

are restricted in their ability to promote these uses until the FDA has evaluated them. These marketing practices bring a range of information to patients and physicians and, at least in theory, permit them to make more informed choices. However, they also encourage greater use of prescription drugs and consequently more spending on them. Discussion of the appropriate roles of manufacturers, patients, physicians, and regulators can make for useful student debate that can elucidate the difficult balance between private activity and government oversight.

The second new challenge for drug regulation is the changing nature of pharmaceutical development. The revolution in genomics has begun. Drugs are increasingly designed based on genetic markers and will increasingly be tailored to the characteristics of individual patients. This change promises tremendous therapeutic potential, but it brings a range of challenges. If drugs are directed only to patients with specific genetic traits, then their potential markets will be small. How will companies afford to develop products with limited sales potential? How will the FDA assess such products, if only a small number of subjects are available for clinical trials? Should companies be permitted to hold patents on genetic sequences that are part of the human genome? Regulatory responses are in their infancy, which makes this a good area for wide-ranging student debate.

Questions for Class Discussion

What limits are appropriate on pharmaceutical marketing? To what extent do DTC advertising and promotion of off-label uses represent legitimate tools to better inform consumers, and to what extent do they engender unnecessary utilization?

Should the FDA consider economic factors in new drug approvals? Should the cost of drugs be part of the FDA review process, a concern for other agencies, or an aspect of drug use best left to the market to decide?

How closely should drugs be monitored for safety hazards after they reach the market? Should the FDA have enhanced ability to pull drugs that it has already approved? Where would this leave patients who have come to rely on those drugs?

How should drug regulation balance the risks of new products against the needs of patients who might use them? Is it better to err on the side of caution, given experiences with products such as thalidomide and Vioxx, or to accept risks in the interests of giving patients better access to medications?

Chapter 6 – Regulation of Public Health

The oversight of public health has a longer history than that of any other sphere of health care regulation. Programs in the mid-nineteenth century promoted sanitation, clean drinking water, and vaccinations to protect the population from large-scale health threats. All of these programs exist today, but they tend to evade public consciousness until crises arise.

Public health regulation raises numerous issues for student discussion. Among the most prominent is the contest between protecting the health of populations and the health of individuals. This is often framed as the difference between protecting statistical lives and individual lives. There is no question that population-based programs are more cost effective, because they tend to focus on prevention. Every dollar spent on vaccinations for polio, for example, prevents substantially more suffering and death than dollars spent on treatment. The difficult part is that it is impossible to know whom a vaccination has saved. Statisticians can estimate the number of children who would have developed polio had they not been immunized, but is not possible to determine which ones they are. Individual health saves identified people who are ill and in need. Shifting resources to public health may force the health care system to deny treatment to vulnerable people whose identities are known.

Students can consider how they would weigh the two aspects of health care. Only about three percent of health care spending in the United States goes to public health. If we were to spend more, some programs for people in need might have to be curtailed. If we were to spend less, the aggregate health of the population could suffer. In addition to the moral dimension, there is a political element to this debate. It is difficult for politicians to divert spending from identified vulnerable constituents.

Another important area of debate is the balance between public programs to address acute and chronic diseases. The earliest public health programs dealt primarily with acute infectious threats. This remained the focus until the end of the twentieth century, when research began to indicate that risk factors for chronic conditions could be controlled. For example, during the 1960s and 1970s, scientists discovered links between various forms of cancer and environmental exposures. These findings led Congress to create the Environmental Protection Agency (EPA) in 1970 and the Occupational Safety and Health Administration (OSHA) in 1971 to regulate exposure to these substances in the general environment and in the workplace. The standards set by these agencies proved to be extremely controversial, because they can be extremely expensive to implement.

In the 1980s and 1990s, the focus of chronic disease prevention began to shift to lifestyle factors that individuals can, for the most part, control. Starting with the Surgeon General's Report in 1964, evidence accumulated rapidly that linked

smoking with cancer and with heart disease. Smoking cessation became a major focus of the medical community. In response, local and state governments began to ban smoking in public places. A body of scientific evidence also grew that linked heart disease and diet. Healthy eating and weight loss programs proliferated, as a result. Today, the focus is on obesity, which is blamed for a range of diseases.

Public prevention of chronic diseases tends to be much more expensive than prevention of infections. Regulatory programs have, therefore, met with greater political resistance. How much economic cost should we be willing to bear in order to make our industrial activity and lifestyles safe, knowing that perfect safety can never be assured? Should regulators devote their efforts to trying to control lifestyle factors, or are these risks a matter of individual responsibility?

The contest between federal and state jurisdiction plays itself out with particular vigor in the sphere of public health. Since the earliest programs of the nineteenth century, the two levels of government have vied for supremacy. The first programs were all administered on the local level. However, as understanding of the nature of infections grew, a federal role became inevitable. Germs easily spread from state to state and easily enter the country from abroad. The first federal public health programs involved immigration controls and the administration of maritime hospitals. Today, the Centers for Disease Control and Prevention (CDC) is the key source for national public health data and disease investigation.

However, the balance between state and federal public health jurisdiction is subject to continual adjustment. Preparedness for a pandemic or bioterrorist attack presents a good case study. While care for those who become ill and administration of vaccinations would be handled at the local level, who would oversee the distribution of supplies? This would require a national effort. Who would coordinate actions by different states? Lax vigilance in one state could counteract the public protection efforts of its neighbors.

Another area of current interest is the resurgence of infectious threats. After readjusting the focus of public health to chronic conditions, it began to become evident in the 1990s that some infectious agents are fighting back. The most notable example is tuberculosis, which can now strike in antibiotic resistant forms. In addition, E. coli infections from food have become increasingly common. New threats, such as pandemic influenza, may be ready to arise.

Why are we still fighting these kinds of conditions, which were thought to have been conquered several decades ago? Much of the answer lies not in a lack of scientific knowledge but in a lack of behavioral controls. Drug-resistant tuberculosis results from the failure of many patients to adhere to treatment regimens. Food-borne illnesses result from a lack of care in food handling. The threat of pandemics increases with air travel and lack of individual protective measures such as vaccinations.

The importance of behavioral factors in protecting public health can engender interesting class discussion on the role of regulation. How important is it to promote and disseminate better science as opposed to maximizing the benefits of the scientific knowledge that we already have. Overseeing behavior can be extremely difficult. How do we insure that patients take their medication, that food handlers use proper precautions, or that vulnerable individuals obtain vaccinations? In considering regulatory options, students can see how difficult it is to manage public behavior.

This leads to a final area for debate, the contest between public health and civil liberties. Quarantine can be an effective approach in some circumstances to controlling infections, but its use is highly controversial. Civil liberties advocates worry that individual freedom is curtailed without adequate protections. Mandatory vaccinations raise similar concerns. Our society places tremendous value on individual liberty. When does a public health threat take precedence? The best balance between the level of threat and amount of government intrusion is a fascinating topic for student debate.

Questions for Class Discussion

What is the best level of government to address public health concerns? Should primary reliance be placed on the states, which are closest to the threats and the populations in need or on the federal government, which has the resources to address health needs nationally?

Does the United States spend the right amount on public health? Should we spend more, if it means taking funding away from patients who have already become ill?

What is the appropriate balance between government efforts to improve health behaviors and reliance on individual responsibility? Is it society's problem if someone places themselves at greater risk by smoking, eating fatty foods, or failing to wear a seatbelt? Is there a societal benefit to controlling individual health behaviors? Is there a risk of excessive government intrusion into individual lives?

To what extent should the government curtail individual liberties in the interests of public health protection? When, if ever, are quarantine, mandatory vaccination, and mandatory drug treatment appropriate? How should we balance respect for individual autonomy and control of socially irresponsible behavior?

Chapter 7 – Regulation of Health Care Business Relationships

The regulation of the business side of health care raises important issues because of the fundamental differences between health care and other kinds of commercial activity. This chapter focuses on four types of regulation that are either unique to health care or that apply to it in distinctive ways. These are antitrust, restrictions on referrals, tax-exempt status, and data privacy. The important overarching theme is how the nature of health care requires special policy considerations.

Four aspects of health care differentiate it most starkly from other businesses. These differences can be analyzed on an operational level or in economic terms. The first and most significant is the presence of third party reimbursement. The ultimate consumer, the patient, usually pays only a small portion, or none, of the cost of services received. This eliminates the incentive to be a prudent purchaser, a phenomenon that economists call moral hazard. Purchasing decisions are further confounded by the intercession of physicians or other health care practitioners who act, in effect, as agents for the consumer. They are often referred to as learned intermediaries. Even when patients share in the decision making, they are rarely able to competently weigh the opinions of their physicians because of the huge gap in knowledge. Economists call this asymmetry of information. Finally, were patients to make their own purchasing decisions, true market-based price competition would still be unlikely because of the life and death nature of the services involved. If a patient needs a life saving service, he or she is likely to purchase it regardless of price, a situation that economists describe as limited price elasticity of demand.

It may be helpful to ask students to identify differences between the market for health care and for other kinds of services using an example such as automobiles. What would happen to the price of cars if an insurance company paid 80 percent? How would that affect your decision about when to buy a new car and what kind of car to get? What if, in addition, the car dealer decided for you when you needed a new car and the model that best meets you needs? And what if you had to buy a car in order to earn a living and could not delay the decision to consider options? Students who have studied economics can be asked to compare this situation with the standard model of microeconomics that they were taught.

Antitrust enforcement highlights most starkly the differences between health care and the traditional business model. The roles of buyers and sellers are reversed from the situation that the architects of antitrust law envisioned. The federal Sherman Act was passed in 1890 to protect small purchasers from large monopolies that fixed prices, limited supply, and engaged in predatory practices. In many aspects of health care, however, the actual buyers are not the patients but rather large insurance companies, which often have monopoly power in their markets. The

sellers are often small providers, such as physician practices. The potential for abuse is mostly on the buyer side, yet the Sherman Act mostly restricts the sellers. For this reason, physicians are limited in their ability to collectively bargain with HMOs over reimbursement rates and health systems are limited in the amount of market share they can acquire to gain bargaining leverage.

This anomaly raises important policy questions. Many analysts and courts have viewed the antitrust tilt toward insurance companies as appropriate because it supports efforts to control costs. Others counter that it stifles competition, which impairs quality. Students can consider whether antitrust law should generally favor buyers over sellers according to the conventional model of the Sherman Act or whether health care requires a different approach.

Restrictions on referrals are contained in the fraud and abuse provisions of the Medicare Act and in the Stark Amendments. They prohibit financial inducements to refer patients to another provider for services that are reimbursed by Medicare or Medicaid. They raise the question of why such arrangements are outlawed in health care but are quite common in many other kinds of industries. Real estate agents, for example, receive explicit compensation for referring potential buyers to particular sellers.

The reason that the law treats health care differently is the effect of moral hazard. Patients have less incentive to question the necessity of additional services when an insurance company is paying most of the bill. Asymmetry of information also plays a role, because patients are often unable to determine on their own when a referral from their physician is unneeded or is to an inappropriate provider. This gives unscrupulous physicians the opportunity to abuse their authority. Discussion of this aspect of the physician-patient relationship can highlight important underlying dynamics in health care economics.

The regulation of tax-exempt status underscores the changing nature of the health care industry. Hospitals were created in the eighteenth century as charities that cared mostly for indigent patients who could not afford care at home. For-profit hospitals were unusual until the late twentieth century when they began to proliferate across the country. Today, many metropolitan areas have both nonprofit and for-profit institutions that compete for patients.

The first point that students should understand is the distinction between nonprofit structure and charitable status. Any business can incorporate as a nonprofit by dispensing with shareholders and retaining any excess income that it obtains. This does not guarantee recognition by the federal Internal Revenue Service (IRS) as a charity that is exempt from taxation. To gain this benefit, an organization must demonstrate that it serves a charitable mission. Health care is not considered, in and of itself, to constitute such a mission. To be considered a charity, a hospital must engage in additional activities to serve its community, such as providing

substantial amounts of indigent care or implementing significant community outreach.

For-profit hospitals contend that even with such additional activities, their nonprofit competitors receive an unfair advantage in their tax exemptions. They assert that the difference in community benefit between the two types of institutions does not warrant a special status that confers a large tax subsidy. A good topic for debate is whether tax-exempt status is still appropriate for hospitals, and if so, what level of community benefit they should have to demonstrate to achieve it.

This can lead to an important underlying point. What is the fundamental difference between nonprofit and for-profit hospitals? Is it simply the level of community involvement and the amount of taxes paid? A more important distinction may lie in their organizational structures. For-profit companies are ultimately accountable to shareholders, while nonprofit organizations report to boards composed of community members. Does this difference affect actual patient care?

The regulation of data privacy is a new area of government concern. It reflects a technological revolution that is changing health care, as it is much of the rest of American industry. Increasingly, care is based on the collection and manipulation of information. This requires that data on individual patients be compiled and stored so that it can be shared among treating clinicians, easily accessed wherever a patient receives care, and analyzed in research to improve overall care. However, patient data is extremely sensitive. It can cause embarrassment and financial harm if it is inappropriately released. The benefits of information-based health care will not be achieved if patients fear that candor with their physicians will place them in jeopardy.

The major regulatory program that addresses data privacy is the Health Insurance Portability and Accountability Act (HIPAA). That law addresses several concerns, only one of which tends to receive public attention (other than the insurance provisions that are considered in chapter 4). Most providers, and much of the public, are aware that HIPAA restricts the release of patient information. The law also standardizes the collection of information to facilitate billing and other functions and guarantees patients access to their medical records, replacing a patchwork of inconsistent protections contained in state laws. This enables patients to check the accuracy of their own information and to request corrections.

HIPAA raises many interesting issues related to the balance between the competing needs for privacy and for data sharing. Who should have access to patient information without the patient's explicit consent? HIPAA permits access related to care provision, health care administration, and claims payment. Should patients have more of say when their data are shared for these purposes, or would that impede effective information use? What kinds of information should be shared for other uses, such as research and marketing? Exploration of these questions

helps to illustrate some of the challenges that lie ahead as information technology advances.

Questions for Class Discussion

Should the antitrust laws treat health care providers the same as sellers of other kinds of goods and services? How does doing so affect the three policy goals of controlling quality, access, and cost? How, if at all, should antitrust enforcement be tailored to accommodate the dynamics of the health care industry?

When, if ever, is it appropriate for those who make and those who receive referrals to have a financial relationship? The safe harbor regulations for fraud and abuse enforcement and the exceptions to the Stark Amendments legitimize a number of economic arrangements. Are these rules too restrictive? What would be the effect on the health care industry of loosening these restrictions?

Should tax exempt status be available to hospitals? It is not generally available to other components of the health care industry, such as physician practices and drug companies. How might health care change if all hospitals were organized as for-profit businesses?

What kinds of patient information should be available to clinicians, insurers, and researchers without the patient's consent? What is the best balance between protecting patient privacy and facilitating the full potential of information-based health care?

Chapter 8 –Regulation and Funding of Research

Biomedical research represents one of the great success stories of American medicine. It has produced advances that have transformed the field, and in the process saved countless lives and prevented immeasurable suffering. By leading in this endeavor, America has brought the fruits of research to the rest of the world.

The major conduit for funding biomedical research is the National Institutes of Health (NIH). From a policy perspective, this agency is interesting in the unique collaboration of public and private interests that it effectuates. Most NIH research is conducted not in government laboratories but in private institutions that receive the agency's funding. Two-thirds of the NIH budget goes to investigators at universities and independent laboratories who submit proposals for studies. The proposals are evaluated by peers of the investigators from other institutions. NIH shapes the overall research agenda indirectly by allocating its budget among its component agencies and toward specific kinds of studies, but it is nongovernmental scientists who directly determine that agenda's details.

This public-private collaboration is distinctively American. It permits a substantial level of government oversight but with a primary decision making role for the private sector. The growth of NIH in terms of its budgets, personnel, and research productivity between the end of World War II and today, which is described on pages 209 – 213, has been tremendous.

A significant issue for student consideration is the role that remains for politics. Congress has intruded on several occasions to either promote or discourage some kinds of research. Advocates for patients with certain kinds of diseases, such as Parkinson's disease and AIDS, have successfully lobbied for greater funding. While few would question the motive of supporting more research to aid patients with devastating diseases, debates have focused on the proper role of politics in influencing such decisions. There are many devastating conditions. Who should determine which receive priority in research funding? Politicians have the least expertise, but they are the most responsive to public sentiment. Scientists are the most knowledgeable, but they tend to have a self-interest in favoring their own areas of specialization. The best way to allocate the NIH budget involves complicated considerations and can engender vigorous discussion.

Students can also consider the reason for such a high level of government involvement. The pharmaceutical industry represents a substantial research engine that now spends more than NIH. With private industry research operating at such a high level, why not leave biomedical research to the market? The answer lies in the underlying nature of medical inquiry. Private companies must focus on applied studies that lead to identifiable returns for investors. However, applied research is only possible when it can build on basic inquiries that came before. The search for

basic biomedical knowledge is an extremely long-term process in which a line of exploration may take decades to bear fruit, if it bears any fruit at all. Private companies do not have this patience and cannot take such chances. Therefore, it is left to the government to promote basic research that lays the foundation for applications that only become evident over time.

Despite the successes, biomedical research does have a dark side. A major concern for regulators has been abuses of research subjects, which are discussed on pages 215 - 217. In several highly publicized scandals, subjects experienced harm in dangerous experiments after investigators failed to inform them of the risks. The most prominent of these is the Tuskegee experiment that lasted from the 1930s through the early 1970s. The natural progression of syphilis was observed in a group of poor black men, who were denied treatment, without their knowledge, so that the disease could follow its full course.

The regulatory response followed the pattern of mixing government oversight with private implementation. All studies that either receive NIH funding or that contribute to the assessment of a drug by the FDA must be reviewed and approved by an Institutional Review Board (IRB) at the sponsoring institution. IRBs are composed of researchers, experts in ethics and in law, and members of the community. When they review study protocols, they usually give greatest attention to the process of obtaining informed consent from subjects, so that any risks of participation are accepted knowingly.

A good question for discussion is whether this regulatory approach is sufficient. IRBs are often composed of colleagues of the investigator of a proposed study, which creates a potential for a conflict of interest. In several instances, they have approved questionable studies. Would direct government oversight be more effective? On the other hand, might it stifle important research with bureaucratic impediments?

A more overarching issue is the balance between protecting subjects and advancing knowledge. Risk to subjects is inherent in much research. If regulation is too heavy handed, important investigations might become impossible to conduct. On the other hand, the potential for serious abuses, first chronicled in descriptions of Nazi horrors, must be controlled. Debates on this topic can touch on the nature and value of research and the balance between individual rights and societal benefit.

Questions for Class Discussion

What role should Congress play in determining the details of NIH budgets? Once a total amount has been determined, should it be allocated according to the judgments of experts alone, or should politicians who are responsive to public sentiment also play a role?

What is the appropriate balance between government and privately funded research? If left on its own, it is unlikely that private industry would be able to support enough basic research to sustain the next generation of applied discoveries. To the extent that it develops products from the fruits of government-funded research, should it have to repay some of the government's cost? In contrast, should government-supported findings be considered a public good for anyone to use?

How certain should regulators be that research subjects understand all risks before a study is permitted to proceed? If regulatory oversight becomes too onerous, life saving discoveries could be stifled. On the other hand, serious abuses can, and do, occur.

Chapter 9 – New Regulatory Horizons and Old Policy Conflicts

As rapidly as American health care has evolved over the past few decades, it is at the start of an era of even greater change. Three major trends, two technological and one social, are about to alter its foundations. The scientific trends are the maturation of information technology and the application of genomics. Information technology will change the way health care is provided and ways in which patients communicate with physicians and clinicians communicate with one another. Genomics will permit medicine to be personalized, with drugs and procedures tailored to each patient's genetic profile. The social trend is demographic. The population is aging with the large cohort of Americans born during the baby boom years reaching retirement age. This will change the demands on the health care system and the financing of care for the elderly through Medicare.

To understand the shape that health care will take over the coming decades, it is essential to understand these trends. Students can consider the ways in which their interactions with clinicians will change as tools such as electronic medical records, mobile communications, and Internet-based diagnosis and treatment become more widespread. They can assess the challenges facing the pharmaceutical industry as current methods of drug development become obsolete and genetic sequences become the basis for devising new treatments. They can analyze the ways in which demand for health care services will be different in a society with a larger proportion of elderly patients and the difficulties of financing those services.

It is possible to catch a glimpse of the ways in which regulation will respond. On the one hand, new regulatory programs, such as HIPAA, will appear to protect patient privacy in an information-based system. On the other hand, much regulation will itself begin to rely on information technology. This is seen in several new programs that analyze health care outcomes to improve quality and reduce errors. The state of Pennsylvania is particularly active in this regard with two agencies that use data in these ways, the Pennsylvania Health Care Cost Containment Council and the Pennsylvania Patient Safety Authority.

What are the challenges in implementing information-based regulation? One is the issue of accounting for case mix. How do you accurately compare providers whose patients differ in the degree of severity of their illnesses? Another is in the uses of data analyses. Should their dissemination be limited to the regulators and providers involved or should the public have access, as well? Patients have a clear interest in knowing how their physicians and hospitals perform, but they may not have sufficient understanding of the intricacies of statistical analyses to form educated judgments based on them. It is important that students understand these issues, because they are certain to become increasingly central to regulatory policy across a range of health care spheres.

The final theme of this chapter is the aspects of regulation that are likely to remain the same even as health care evolves. First, there is the constant need to balance the competing goals of controlling quality, cost, and access. This will also be the underlying role of regulatory policy. Second, there is the distinctively American structure of competing regulators. Federal agencies struggle with state and local bodies, agencies at the same level of government often conflict with one another, and government regulators compete with private organizations. As discussed on pages 244 – 248, these contests make the system complex and engender confrontation but also usually result in compromise. This is, of course, the underlying theme of the book. A fertile field for student debate is the extent to which this system is beneficial, in terms of bringing a range of different kinds of expertise and perspectives to bear, or inefficient in creating unnecessary bureaucratic overlap.

Questions for Class Discussion

Should private regulatory bodies, such as the JCAHO and medical specialty societies, play a central role in overseeing health care, or is the conflict of interest too great?

Might statistical analyses of provider performance eventually permit patients to make market-based choices of what health care services they will obtain and from whom? Would this be a desirable result? What is the proper balance between market-based and regulatory mechanisms to protect patient interests?

Does a system of multiple regulators create an effective system of checks and balances that limits potential abuses and incompetence by each component body? On the other hand, does is create inefficiencies and place undue burdens on those who are regulated?

Overall, to what extent does regulation create a drag on the efficiency and productivity of the industry and to what extent does it lay a foundation upon which the industry can generate sufficient public trust to enable it to flourish?

Appendices

The book contains three appendices. They are intended primarily as references, but they can also serve a teaching purpose. Appendix A lists all major regulatory agencies that are discussed in the book. They are grouped according to the level of authority at which they operate – federal, state, local, or private. An overview of the table provides a sense of how much of American health care regulation resides at the federal level. It reflects the significant role of the Department of Health and Human Services but also indicates how many other federal agencies are players, as well. The list of private organizations demonstrates how important nongovernmental regulation is in many spheres of health care.

Appendix B presents a chronology of public health regulation. This sphere of regulation has the longest history and is the most varied in scope. The table reflects the shift in importance from state and local health departments, among which major policy development subsided after about 1940, to various federal agencies, including CDC, EPA, USDA and HRSA. The chronology of other significant developments indicates how many different kinds of programs and players participate in shaping public health in America.

Appendix C includes an exhaustive list of acronyms used in the book. It is a resource for readers who can use reminders and also for those who find references to health care agencies and terms in other sources and need definitions. The length of the list reflects the large number of organizations that are part of the American regulatory system.