The Topography and Geography of U.S. Health Care Regulation

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Through the Louisiana Purchase in 1803, the United States expanded its size by over 800,000 square miles. But neither President Thomas Jefferson nor Congress knew exactly what they had bought until 1806, when Meriwether Lewis and William Clark returned from their famous expedition. One of the most significant contributions of the Expedition was a better perception of the geography of the Northwest. Lewis and Clark prepared approximately 140 maps and “filled in the main outlines of the previously blank map of the northwestern United States.” Robert I. Field has done much the same for the vast territory of U.S. health care regulation.

On the front cover of Field’s new book, Health Care Regulation in America: Complexity, Confrontation, and Compromise, is a picture of a giant three-dimensional labyrinth. Rarely is cover art so perfectly appropriate. A maze is surely the image that best symbolizes the core objective of Field’s book: to provide readers with a map and guidebook to the many interacting and overlapping private institutions and government agencies that regulate health care in America.

Like all primers, the book has its limitations, but it fulfills its mission most admirably. Health Care Regulation in America provides a thorough overview of the robust federal, state, and local government agencies. It also provides a thorough overview of the large assortment of private organizations that develop and enforce health care regulations against: hospitals, insurers, pharmaceutical companies, and other industry players. This array of oversight bodies, as Field reminds us many times, can be bewildering. But Health Care Regulation in America not only untangles this twisted web, it also clarifies the logic behind the regulatory complexity.

While Health Care Regulation in America contains little legal jargon and is directed beyond law students and legal professionals, novices and professionals in both law and other disciplines (e.g., public health, health administration, and health policy) will find it quite valuable. All these readers can profit by using the matrix offered by this book to get the “big picture” of the history, structure, rationale, and challenges of health care regulation in the United States.

Structure and Coverage

Health Care Regulation in America is comprised of nine chapters: an opening and closing chapter plus seven subject-specific chapters: (1) the regulation of physicians and other health care professionals, (2) the regulation of hospitals and other health care institutions, (3) the regulation and adminis-
tension points between different regulators.

In Chapter Two, Field discusses the regulation of physicians. He emphasizes the central role of state licensure, but also examines the role of the federal government both through the National Practitioner Data Bank and through Medicare oversight and reimbursement for training. Field also explores the significant role of private regulatory facilities. As throughout the book, the second half of the chapter is a delineation of the structure of the key regulatory agencies.

In Chapter Four, Field presents the regulation and administration of public health. He chronicles the history of private insurance from Blue Cross to managed care. He then relates the history of private insurance regulation. Field then turns to provide a history of

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and process of regulation. The purpose of health care regulation, Field explains, is to best achieve three fundamental policy goals: maximizing quality, maximizing access, and controlling costs. Field demonstrates how, over time, these different policy goals have motivated different regulatory programs, resulting in tensions and conflict. Field describes the structure of regulation as including a broad range of authorities categorized into three basic groups: state government programs, federal government programs, and private organizations. Finally, Field explains the process of regulation, by giving an elementary introduction to administrative law and procedural due process.

Each of the central seven chapters follows a three-part structure. Each begins, first, with a historical review both of the industry sector and its primary regulatory programs. Second, is a review of the size and structure of those programs. Third, closing each chapter, is a discussion of perennial policy conflicts, particularly the current and growing
tion both by private certification boards and through managed care and hospital credentialing. While the emphasis is on physicians, Field does briefly discuss the regulation of other (allied) health care professionals. In the second half of the chapter, Field turns to examine the structure and basic operation of the agencies mentioned in the first half of the chapter.

Chapter Three reviews the regulation of hospitals by function. The chapter covers regulation directed toward quality, including state data collection, Medicare oversight, and private Joint Commission accreditation. The chapter then turns to economic regulation to control costs, including state Certificate of Need laws and the Medicare prospective payment system. Next is regulation directed toward assuring access, including the Emergency Medical Treatment and Labor Act, the Americans with Disabilities Act, and the federal Hill-Burton funds. While the focus is on hospitals, Field briefly discusses the regulation of other health care institutions such as long-term care facilities.

public insurance. Here, the emphasis is on eligibility, coverage, and reimbursement under Medicare. But Field also describes the operation and influence of Medicaid and the Federal Employee Health Benefits Plan.

Chapter Five explains the regulation of drugs and health care products. This is the most cohesive chapter because, in contrast to every other chapter, it largely focuses on a single regulator: the Food and Drug Administration. As in the other chapters, Field's historical overview is often entertaining and full of colorful anecdotes. Here, Field explains the evolution of the FDA and how its implementing legislation was repeatedly precipitated by scandal. While discussion of the FDA is largely focused on quality issues, Field also examines both economic issues relating to intellectual property and access issues raised by genetically-tailored drugs.

In Chapter Six, Field provides a history of the regulation of public health in contexts ranging from food, to the environment, to the workplace. In contrast to Chapter
Five, the agencies described are numerous, including: the Environmental Protection Agency, Occupational Safety and Health Administration, Centers for Disease Control and Prevention, Health Resources and Services Administration, Department of Agriculture, as well as the new Department of Homeland Security, state agencies, and local agencies. It is a broad survey and surely Field could have legitimately covered even further public health issues such as automobile safety regulation and crime.

Chapter Seven reviews the regulation of health care business relationships. He focuses on four areas: antitrust, fraud and abuse, charitable tax exemption, and data privacy. Accordingly, he also examines the structure of the Federal Trade Commission, Department of Justice, Centers for Medicare & Medicaid Services, Internal Revenue Service, and Health and Human Services. Oddly, though, he barely discusses charitable tax exemption at the state level,7 even though this is an area of as much or even more significance.8 Nor does Field mention the number one tool against health care fraud: the federal False Claims Act.9

In Chapter Eight, Field summarizes the regulation and funding of research. This descriptive project is largely a history and delineation of federal government programs. Field rightly devotes primary attention to the intramural and extramural research coordinated by NIH. Still, he also briefly describes the role of agencies from the National Science Foundation to HRSA.

In the closing chapter, Field looks at future regulatory challenges. Here, he identifies three major trends: the maturation of information technology, the application of genomics, and an aging population. Field argues that an understanding of these three trends is essential to understanding the shape that health care regulation will take in the coming decades.

Appendices and Supplements

Health Care Regulation in America includes three short appendices. Appendix A is a four-page, three-column chart that lists: (1) the names of major health care regulatory agencies and organizations in the left column, (2) each agency’s primary health regulatory function in the middle column, and (3) the chapters of the book in which those functions are discussed in the right column. This can be useful either for review or for identifying which chapters to read.

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Appendix B is a chronology of major developments in public health regulation. Unfortunately, this chronology is only two pages in length and lumps several developments together under single, broad, decades-long date ranges. For example, one entry reads: “1960-1980: Medicare and Medicaid enacted; Civil Rights Act passed ....” Another reads: “1980-present: Managed care begins to proliferate; Americans with Disabilities Act passed; Health Insurance Portability and Accountability Act passed.” It would have been more useful to have listed each development on a separate line with a specific corresponding date.10

Appendix C is a four-page list of over 150 acronyms. The very length of this list illustrates just what a monumental task Field had in lucidly navigating the reader, in just 249 pages, through so many agencies. Still, the inclusion of this appendix of acronyms suggests that a glossary, as included in other health law primers,11 might also have been a useful appendix.

Health Care Regulation in America contains forty-four pages of notes and an eleven-page bibliography. Still, one might have hoped for even more cites and links from an overview text, to direct the reader to useful resources should he or she want to dig deeper.12 Furthermore, given the incredibly broad substantive scope of the book, it would have been useful to divide and label the bibliography sources by subject or regulatory function.

Finally, as a key use of Health Care Regulation in America will be as a textbook for students, it is important to mention that Field has prepared a separate teacher’s manual.13 At just twenty-nine pages, this teacher’s manual might strike some as being rather paltry. For example, the teacher’s manuals that accompany casebooks used in law schools are typically hundreds of pages in length.14 But Field’s teacher’s manual is actually more than sufficient. First, it describes the main points that each chapter is intended to convey and suggests approaches to discussing key issues...
in class. Second, the book itself is already written at an introductory level, so there is little need for a teacher’s manual to offer strategies on how best to unpack and present dense material. Third, since Health Care Regulation in America looks at health care regulation from a “zoomed-out” perspective, most teachers will probably use it as a supplement to other course material that focuses on particular issues in more detail.

**Underlying Themes**

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Field focuses on two classic themes: (1) balancing federal and state regulation and (2) balancing public and private regulation. He returns, throughout the book, to these two themes. For example, in Chapter One, Field explains how, by passing the Health Care Quality Improvement Act, Congress addressed concerns about a lack of coordination between states on physician licensure and discipline. And in Chapter Three, Field discusses the conflict between self-regulation and oversight in the regulation of health care institutions. Here, he aptly demonstrates the tension between the need for expertise from those actively involved in the field, on the one hand, and the need for impartiality, on the other hand.

Like all writers on health care regulation, Field struggles to adequately elaborate and illustrate state government regulation. Field repeatedly reminds us that, in some contexts like the regulation of private health insurance, state regulation is comparatively more important. Yet, his actions may speak louder than his words. In almost every chapter, the lion’s share of the discussion and examples concern either federal or national-level private regulation. Admittedly, a less comprehensive discussion of state-level regulation is understandable. “Analyzing information from more than fifty jurisdictions and then presenting it in a useful and interesting way [is] challenging.” Nevertheless, a reader could easily get the (mis)impression that the federal government’s role is far larger than it actually is.

Field does give many examples of tension and conflict between state and federal regulation. But given the centrality of this theme, it is odd that there is such a limited discussion of the archetype illustration: Employee Retirement Income Security Act (ERISA) preemption. Field himself refers to this as “a prime example” of “chaotic results” from unclear division of authority. Granted, it would be too much of a detour for this book to rigorously explain both the operation and rationale of preemption under Sections 502 and 514 of ERISA. After all, if it is difficult for federal appellate courts to explain ERISA clearly, then perhaps it does not belong in an introductory primer. Still, ERISA is more than an apt example of the underlying themes. It also exerts a significant impact on, and is a major obstacle to, the regulation of health insurance, state tort law causes of action against managed care organizations, and state coverage expansion initiatives.

**Limitations**

Since Health Care Regulation in America’s mission and value is in providing a concise overview, the omission of a more detailed explanation of ERISA preemption is perhaps understandable. But, more puzzling, is the omission of even survey-level treatment of three key areas of health care regulation: (1) medical malpractice and products liability, (2) the False Claims Act, and (3) criminal liability.

To be fair, Field acknowledges that “because of the tremendous breadth of the subject, it is impossible to cover every regulatory program that relates to health care.”

Still, he promises “to be as comprehensive as possible and to describe every significant kind of regulation that is directly targeted to the provision or financing of health care.” I do not claim that Field has broken his promise. Rather, I argue that he has set his sights too low, and has promised too little. To focus on only regulation that is “directly” targeted to health care is to miss a great deal of relevant and important regulation.

Certainly, tort law is not unique to health care. But uniqueness is an inappropriate test. Because health care covers nearly one-fifth of the entire economy, it should come as no surprise that the regulation of health care is not wholly independent from other industry sectors. As Wendy Mariner observes, many “principles and doctrines as applied in the health law field...are not distinctive.” Tort law is a perfect example. While it obviously applies to domains far outside health care, that hardly undermines its position as a “key element of the [health care] regulatory regime.”

Similarly, the federal False Claims Act is not uniquely targeted to health care. It also applies to other areas of commerce such as housing, student loans, and defense procurement. But its most significant application is to health care. There are almost as many health care false claims cases as all other types combined.

And the recoveries in health care
cases are substantially larger. Furthermore, particularly with amendments through the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act of 2010, the False Claims Act remains the government’s “chief weapon and enforcement tool against the healthcare industry.” Consequently, the FCA will remain a major impetus to the development of comprehensive and effective compliance programs.

Criminal liability is often grounded in statutes closely related to the False Claims Act including: the criminal false claims statute, the false submissions statute, mail fraud, and wire fraud. While significant criminal regulation of health care dates only to the mid-1990s, there is no doubt that it plays a considerable role today. For example, more than one-half of the recent $2.3 billion dollar settlement between the DOJ and Pfizer was a criminal fine. Furthermore, criminal regulation is expanding at the state level, with the prosecution of offenses such as conspiracy and Medicaid fraud.

I look forward to a second edition of Health Care Regulation in America, and hope that it includes a discussion of tort litigation, the False Claims Act, and criminal prosecution, as well as a description of the corresponding regulatory agencies: Recovery Audit Contractors (RACs), Medicaid Fraud Control Units, the Health Fraud Prevention and Enforcement Task Force (HEAT), and related entities. Still, even with these omissions, Field has succeeded in providing an accurate and concise review of the broad (and ever-growing) landscape of health care regulation.

Conclusion

Health Care Regulation in America is a pleasure to read. It is well-organized and well-written, and offers a succinct yet comprehensive overview of health care regulation. I recommend this book both to absolute beginners as well as to those seeking to consolidate their knowledge.

References


4. At the time the book was published, Robert I. Field, J.D., M.P.H., Ph.D. was Chair of the Department of Health Policy and Public Health at the University of the Sciences in Philadelphia. Field is now Professor of Law at the Drexel University Earle Mack School of Law and Professor of Health Management and Policy at Drexel University School of Public Health.


7. See Field, supra note 5, at 191.


10. The entries would be more useful if each regulatory development were linked to a specific date, for example, “1965: Medicare and Medicaid enacted.”


17. Another great example of federal-state tension, not discussed in Health Care Regulation in America, concerns the regulation of medical marijuana and the drugs used in physician-assisted suicide. See generally Gonzales v. Raich, 545 U.S. 1 (2005); Gonzales v. Oregon, 546 U.S. 243 (2006).
20. See, e.g., American Medical Sec., Inc. v. Bartlett, 111 F.3d 358 (4th Cir. 1997).
22. See, e.g., Golden Gate Restaurant Ass’n v. City & County of San Francisco, No. 08-1515 (U.S. June 5, 2009) (petition for a writ of certiorari filed); Retail Industry Leaders Ass’n v. Fielder, 475 F.3d 180 (4th Cir. 2007).
24. Field incidentally mentions criminal liability when briefly mentioning that the Department of Justice supplements the enforcement actions of the Office of Inspector General in the Department of Health and Human Services. Field, supra note 5, at 188-89. Unlike the Office of Inspector General, he looks at neither the structure of the Department of Justice nor the nature of its regulation.
25. Field, supra note 5, at viii.
26. Id.
27. Gatter calls this a “critical hole.” Gatter, supra note 5, at 597.
31. Mariner, supra note 6, at 69.
34. GAO, Information on False Claims Act Litigation, GAO-06-320R (Jan. 31, 2006).
36. GAO, supra note 34; Sylvia, supra note 35.
41. 18 U.S.C. § 1341.
42. 18 U.S.C. § 1343.


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On November 9, 2009, Maclaren USA, a manufacturer of children’s strollers, announced a recall of approximately one million strollers because it had received 12 case reports of amputation of children’s fingertips by the hinges of the strollers’ umbrella feature.1 That the strollers had a direct causal role in the amputations is unequivocal. In the field of health care, identifying causal relations between medical products, such as prescription medications, and adverse events can be equally unambiguous, as in the case of patients who take a dose of penicillin and immediately develop anaphylaxis. Most cases, however, are not so simple. If a patient with diabetes is prescribed an oral hypoglycemic agent to take on a daily basis and the patient experiences a myocardial infarction (MI) two months later, how can we tell whether the MI was caused by the drug, by the patient’s underlying diabetes, or by
any number of other potential risk factors for coronary artery disease, including obesity, cigarette smoking, or lack of physical activity? As discussed in vivid detail in Professor Marshall S. Shapo’s Experimenting with the Consumer, patients rely on the regulatory bodies such as the US Food and Drug Administration (FDA) and other safety experts to examine this intricate milieu and identify dangerous adverse effects of drugs and other medical products. This environment is further complicated, as Shapo points out, by pre-marketing regulatory hurdles that can take longer than patients have to live (as detailed in the history of HIV/AIDS drug approvals in Chapter 2), sensationalized reports in the lay media, consumerism fostered by direct-to-consumer advertising, and the financial self-interest of for-profit drug manufacturers.

The book opens with a fair number of pages dedicated to the legal evolution of the role and importance of informed consent in clinical research. After that, Shapo outlines his primary thesis, which he then illustrates through several detailed examples in the rest of the book: the study of the safety of medical products does not end upon FDA approval. The current medical product research, development, and approval system requires that many drug safety issues be identified in the post-marketing setting. “Mass market experimentation,” as Shapo describes it, is necessary because early-stage clinical trials are generally too small, too short, too few, and include too narrowly defined a population to identify serious, rare adverse events or common events that occur in very specific patient populations. Shapo goes to great lengths to persuade the reader, correctly, that even though the FDA’s mission is to ensure the efficacy and safety of medical products, we should not be misled into thinking that these products are safe in the literal sense — that is, free from harm or risk — when they receive FDA approval.

Shapo engages in a well-researched, well-documented legal and historical journey through some of the most important medical product safety controversies of the past half-century — stories shaped not only by science, but also heavily by tort law, commercial interests, consumerism, patient advocacy, and even the desire for improved sexual performance (as described with adequate innuendo in Chapter 4). Although Shapo presents a good deal of scientific detail, he does so in a non-critical manner, letting history determine which studies succeeded at ascertaining scientific truths and which did not. This scientific review is accomplished by sewing together quotes from authors of primary research articles and commentators on those articles, rather than a more in-depth review of the merits and limitations of that science.

Some readers may be surprised to learn about the realities of the study of medical product safety in the post-marketing setting. For example, Shapo emphasizes that when drugs and other products reach the mass market after regulatory approval, much rigorous scientific inquiry into the safety of these products continues from many angles and, as with the case of hormone replacement therapy, knowledge about the product is often still in its infancy at the time of marketing authorization. Although hormone replacement therapy has been used in practice for more than 60 years, a large amount of clinical trial and even animal model research continues to disentangle its benefits and risks, resulting in an ever-changing conceptualization of its use in patient care.

Another striking point Shapo emphasizes is the lack of understanding, not only about unintended effects of drugs, but also sometimes about the drugs’ properties themselves and about how they exert their intended effects. For example, Shapo quotes FDA’s director of the Center for Drug Evaluation and Research as stating that “the active ingredients of Premarin (a hormone replacement product) cannot now be definitely identified,” even though the drug has been marketed since 1942. It is also not uncommon to read in an official drug label that the precise mechanism is unknown by which a given drug exerts its effect.

While much of the book focuses on the safety of prescription drugs (e.g., drugs for erectile dysfunction and estrogens as hormone replacement therapy), Shapo also explores the realm of medical devices through the history of the safety of breast implants, and closes with a cautionary tale “at the billionth level”: nanotechnology and what regulators and scientists involved with nanotechnologies can learn from precedence set on the macro level of medical product safety.

Meanwhile, the next chapter in the story on mass experimentation of medical products is currently being written. In his conclusion, Shapo describes the general framework, and a major limitation, of the current drug safety surveillance mechanism, which relies primarily on case reports similar to those used to identify the link between umbrella strollers and fingertip amputation. “If on the basis of relatively thin data,” he writes, “a product does enter the mass market, with many thousands or even millions of people exposed to its risks, rather than only hundreds of experimental ‘subjects,’ it may be difficult at first to discern a problem requiring governmental attention.” The case of the anti-inflammatory drug rofecoxib (Vioxx) provides some additional insight into the imbalance in the numbers of patients exposed to
The Sentinel System promises to improve the way medical product safety is studied and promises to lead to improvements in the public’s health through earlier detection of problems associated with these products. Nevertheless, this system exploits Shapo’s notion of mass testing of risky products on the public and comes closer to formalizing it as a “mass market experiment.”

The Sentinel System is intended to complement AERS by addressing many of its limitations. Because data are collected on a routine-care basis and are typically collected for reimbursement purposes, underreporting is unlikely to be a major limitation. Also, the Sentinel System will address the limitations of the human element of AERS, which requires individuals — patients, physicians, and other health care providers — to identify specific cause-and-effect pairings and disentangle them from other potential causes of the effect prior to reporting. As highlighted by the association between penicillin and anaphylaxis, this is a relatively unambiguous task when the drug and adverse event pair satisfies typical criteria for causality determination.

However, many recent drug safety dilemmas that have been identified in the post-marketing setting, such as the cases of the hypoglycemic agent rosiglitzaone (Avandia) and cardiovascular events or antidepressants and suicidality, have eluded standard assessments of causality. For example, causality assessment criteria often give preferential weight to circumstances where alternate causes are absent and to cases where previous similar reports exist. However, these situations rarely present themselves in plain view in routine practice. The more likely scenario is that unanticipated drug effects occur in patients with the most complex constellations of comorbidities. Clearly, there is a large information gap for the Sentinel System to fill.

While FDA scientists, academicians, and legal experts deliberate on how to design the Sentinel System to maximize interoperability between databases, other questions of scientific and legal importance have arisen. For example, some commentators have contemplated “what to do with all those new numbers” to that the monitoring system will generate. As patterns of association emerge from the Sentinel System, it will be paramount to identify causal relations with a sufficient
degree of certainty. Important public health ramifications hinge not only on generating true signals, but also on doing so as quickly as possible, while minimizing the number of false alarms. A failure or delay in detecting a true signal between a drug and serious adverse event — for example, between an oral hypoglycemic agent and an MI — can result in unnecessary exposure to the drug and preventable MIs. On the other hand, sounding the alarm for a medication when no true signal exists could ultimately result in underuse of an appropriate and potentially life-saving treatment if regulatory action is taken to restrict access to the drug or if patients and physicians stop using or prescribing the drug based on faulty information. Methodological research into identifying the optimal point to trigger an alert in order to maximize true positives and minimize false positives is a topic of current scientific inquiry. Finally, it is unclear to what extent the other pressures, such as media, commercial interests, consumer choice, and tort law, which factored so strongly in shaping the stories in the chapters of Shapo’s book, will shape this unfinished chapter on the Sentinel System.

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References