Reviews in Medical Ethics

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

Health Care Regulation in America: Complexity, Confrontation, and Compromise by Robert I. Field (Oxford University Press, 2007): 352 Pages

Thaddeus Mason Pope

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.[1] One of the most significant contributions of the Expedition was a better perception of the geography of the Northwest.[2] Lewis and Clark prepared approximately 140 maps and "filled in the main outlines of the previously blank map of the northwestern United States."[3] 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[4] 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-

Thaddeus Mason Pope, J.D., Ph.D., *is an Associate Professor of Law at Widener University School of Law.* **Joshua J. Gagne, Pharm.D., M.S.,** *is a Research Student in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital and was a student intern in the Office of Surveillance and Epidemiology at the U.S. Food and Drug Administration.* **Aaron S. Kesselheim, M.D., J.D., M.P.H.,** *is an Instructor in Medicine at Harvard Medical School and an Associate Physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. He is also an AHRQ Post-Doctoral Fellow at the Department of Health Policy and Management, Harvard School of Public Health.*

About This Column

Robin Wilson, J.D., serves as the Review Editor for the *Journal of Law, Medicine & Ethics.* Professor Wilson is a Professor of Law at Washington & Lee University and presently serves as Chair of the Section on Law, Medicine and Health Care of the Association of American Law Schools. (rwilson@law.umaryland.edu)

tration of health care finance, (4) the regulation of drugs and health care products, (5) the regulation of public health, (6) the regulation of health care business relationships, and (7) the regulation and funding of research.

In the opening chapter, Field provides some foundational elements for best understanding the subsequent chapters. Specifically, he outlines the purpose, structure, 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.[6] 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 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 regulation 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. 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 health care finance. 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 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 Benefit 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

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.

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.

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.

While the primary mission and virtue of *Health Care Regulation in America* is its taxonomy of institutions, Field does have one objective distinct from mapping the history and structure of health care regulation. He also wants to articulate the underlying principles that explain the odd and complicated shape of health care regulation. And he delivers.

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

While the primary mission and virtue of *Health Care Regulation in America* is its taxonomy of institutions, Field does have one objective distinct from mapping the history and structure of health care regulation. He also wants to articulate the underlying principles that explain the odd and complicated shape of health care regulation. And he delivers.

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,[15] 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."[16] 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.[17] Field himself refers to this is "a prime example" of "chaotic results" from unclear division of authority.[18] 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.[19] 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,[20] state tort law causes of action against managed care organizations,[21] and state coverage expansion initiatives.[22]

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,[23] and (3) criminal liability.[24]

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."[25] 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."[26] 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.[27] To focus on only regulation that is "directly" targeted to health care is to miss a great deal of relevant and important regulation.[28]

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,[29] it should come as no surprise that the regulation of health care is not wholly independent from other industry sectors.[30] As Wendy Mariner observes, many "principles and doctrines as applied in the health law field…are not distinctive."[31] 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."[32] Private tort actions serve an important role in promoting the quality of health care products and services.[33]

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.[34] But its most significant application is to health care. There are almost as many health care false claims cases as all other types combined.[35] And the recoveries in health care

cases are substantially larger.[36] Furthermore, particularly with amendments through the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act of 2010,[37] 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.[38]

Criminal liability is often grounded in statutes closely related to the False Claims Act including: the criminal false claims statute,[39] the false submissions statute,[40] mail fraud,[41] and wire fraud.[42] While significant criminal regulation of health care dates only to the mid-1990s, there is no doubt that it plays a considerable role today.[43] For example, more than one-half of the recent $2.3 billion dollar settlement between the DOJ and Pfizer was a criminal fine.[44] Furthermore, criminal regulation is expanding at the state level, with the prosecution of offenses such as conspiracy and Medicaid fraud.[45]

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

1. See J. L. Allen, "Geographical Knowledge and American Images of the Louisiana Territory," *Voyages of Discovery: Essays on the Lewis and Clark Expedition*, J. P. Ronda ed., (Helena: Montana Historical Society Press, 1998): 39-58.
2. See generally University of Nebraska-Lincoln, *Journals of the Lewis and Clark Expedition Online*, *avaialable at* <http://lewisandclarkjournals.unl.edu/index.html> (last visited May 4, 2010).
3. S. E. Ambrose, *Undaunted Courage: Meriwether Lewis, Thomas Jefferson, and the Opening of the American West* (New York: Simon & Schuster, 1996): at 483.
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.
5. R. I. Field, *Health Care Regulation in America: Complexity, Confrontation, and Compromise* (Oxford University Press, 2007).
6. Field discusses neither regulation pertaining to bioethics or the aging, nor the structure of regulatory entities such as state ombudsmen for the institutionalized elderly. Robert Gatter says this omission is understandable because such topics are "not essential to a survey of health law based on the themes of quality, access, and cost control." R. Gatter, "Health Care Regulation in America," (book review essay) *Journal of Legal Medicine* 28, no. 4 (2007): 593-599, at 598. I am not so sure. Quality, access, and cost control are often supplemented by a fourth key policy goal, autonomy. See, e.g., B. R. Furrow et al., *Health Law: Cases, Materials and Problems*, 1st edition (St. Paul: West Pub. 1987): xviii-xix; W. K. Mariner, "Toward an Architecture of Health Law," *American Journal of Law & Medicine* 35, no. 1 (2009): 67-87, at 83; M. A. Hall, "The History and Future of Health Care Law: an Essentialist View," *Wake Forest Law Review* 41, no. 2 (2006): 347-364, at 353. Since there was good reason to include the theme of autonomy, there was good reason to include a discussion of regulation associated with bioethics. See A. J. Rosoff, "Health Law at Fifty Years: A Look Back," *Health Matrix* 14, no. 1 (2004): 197-212, at 203 ("It is difficult to imagine a comprehensive health law text that would not have a substantial section devoted to these topics . . . ."); A. M. Capron, "A Bioethics Approach to Teaching Health Law," *Journal of Legal Education* 38, no. 3 (1998): 505-510.
7. See Field, *supra* note 5, at 191.
8. See, e.g., *Provena Covenant Medical Center v. Illinois Department of Revenue*, No. 107328, 2010 WL 966858 (Ill. Mar. 18, 2010); S. Strom, "States Move to Revoke Charities' Tax Exemptions," *New York Times*, Feb. 28, 2010: A21.
9. 31 U.S.C. §§ 3729-33. I discuss this omission in further detail, infra.
10. The entries would be more useful if each regulatory development were linked to a specific date, for example, "1965: Medicare and Medicaid enacted."
11. See G. D. Pozgar, *Legal Aspects of Health Care Administration*, 10th ed. (Sudbury, MA: Jones & Bartlett, 2007).
12. See R. D. Miller, *Problems in Health Care Law*, 9th ed. (Sudbury, MA: Jones & Bartlett, 2006).
13. R. I. Field, *Teacher's Guide for Health Care Regulation in America: Complexity, Confrontation, and Compromise* (version 1.0, Aug. 2007), *available at* <http://www.healthcareregulation.net> (last visited May 5, 2010). Ideally, this website would not only promote the book but would also supplement the book. Using a website in such a way is a model successfully implemented by other books in this area. See for instance M. A. Hall, M. A. Bobinski and D. Orentlicher, website for *Health Law and Ethics,* 7th ed. (Austin: Wolters Kluwer Law & Business: Aspen, 2008), *available at* <http://indylaw.indiana.edu/instructors/orentlicher/public_html/home.html> (last visited May 5, 2010). While not in the healthcare area, a particularly good supplemental website is that supporting W. A. Klein, J. M. Ramseyer, and S. M. Bainbridge, *Business Associations: Agency, Partnerships and Corporations*, 7th ed., (New York: Thomson Reuters/Foundation Press, 2009), avaliable at <http://www.business-associations.com> (last visited May 5, 2010).
14. See D. B. Dobbs, P. T. Hayden and E. M. Bublick, *Teacher's Manual to Torts and Compensation, Personal Accountability and Social Responsibility for Injury*, 6th Standard and Concise Edition (St. Paul: West, 2009).
15. 42. U.S.C. § 11101.
16. H. T. Greely, "Some Thoughts on Academic Health Law," *Wake Forest Law Review* 41, no. 2 (2006): 391-410, at 398 ("[H]ealth law is hard because it is largely state law.. ..."). Field does often use his home state of Pennsylvania as an example.
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).

18. R. I. Field, "Why Is Health Care Regulation So Complex?" *Pharmacy & Therapeutics* 33, no. 10 (2008): 607-608, at 608.
19. The ERISA enforcement scheme, as interpreted by the courts, is bewilderingly complex. Judge Edward Becker described the ERISA regime as "unjust and increasingly tangled" and a "Serbonian bog." *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 453-54 (3d Cir. 2003) (Becker, J., concurring); see also *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 222 (2004) (Ginsburg, J., concurring) (quoting Judge Becker's concurrence in *DiFelice*).
20. See, e.g., *American Medical Sec., Inc. v. Bartlett*, 111 F.3d 358 (4th Cir. 1997).
21. See, e.g., *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004).
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).
23. Field does briefly mention qui tam actions in a discussion of the anti-kickback statute and Stark Amendments. Field, *supra* note 5, at 187. But he omits any mention of the False Claims Act.
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 6, at 597.
28. In addition to omitting significant indirect regulation of health care, Field omits discussion of some regulation that is specifically targeted at health care: international health law. See for instance T. S. Jost, "Comparative and International Health Law," *Health Matrix* 14, no. 1 (2004): 141-147; L. O. Gostin and A. L. Taylor, "Global Health Law: A Definition and Grand Challenges," *Public Health Ethics* 1, no. 1 (2008): 53-63.
29. Centers for Medicare and Medicaid Services, National Health Statistics Group, National Health Expenditure Data, *available at* <http://www.cms.hhs.gov/NationalHealthExpendData/> (last visited May 7, 2010).
30. M. G. Bloche, "The Invention of Health Law," *California Law Review* 91, no. 2 (2003): 247-322, at 249-50; Mariner, *supra* note 6, at 68 ("[D]octrines and principles grounded in other legal domains have come to apply to health problems with less and less special adaptation . . . .").
31. Mariner, *supra* note 6, at 69.
32. C. C. Havighurst and B. D. Richman, "Distributive Injustice(s) in American Health Care," *Law & Contemporary Problems* 69, no. 4 (2000): 7-82, at 65 ("It is conceptually sound to view the malpractice system as a key element of the regulatory regime . . . as a form of regulation."); R. A. Epstein, "The Unintended Revolution in Products Liability Law," *Cardozo Law Review* 10, no. 8 (1989): 2193-2226, at 2193 ("There is an even greater recognition that tort law writ large is a form of government regulation . . . .").
33. See T. A. Brennan, "The Role of Regulation in Quality Improvement," *Milbank Quarterly* 76, no. 4 (1998): 709-731, at 720 ("Many do not consider tort law when addressing regulation of health care quality, despite the fact that this branch of law has as one of its major social goals . . . the deterrence of behavior that leads to medical injuries."); A. D. Eremia, "When Self-Regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care," *Annals Health Law* 11, no. 1 (2002): 93-124, at 104 ("[S]elf-regulation, market forces, and private tort actions all serve important roles in the promotion of quality . . . ."); B. Furrow, "The Legal Implications of Health Care Cost Containment: Medical Malpractice and Cost Containment, Tightening the Screws," *Case Western Law Review* 36, no. 4 (1986): 985-1032.
34. GAO, *Information on False Claims Act Litigation*, GAO-06-320R (Jan. 31, 2006).
35. *Id.*; see also C. M. Sylvia, *The False Claims Act: Fraud Against the Government* § 2:14 (St. Paul: Thomson/West 2009).
36. GAO, *supra* note 34; Sylvia, *supra* note 35.
37. Pub. L. No. 111-21 (May 20, 2009); H.R. 3590, 111th Cong., 1st Sess. (2009) § 6402, *enacted as* Pub. L. No. 111-148 (Mar. 23, 2010).
38. S. Carhart et al., "Restructuring, Consolidation in Healthcare Make Reform Top Health Law Issue for 2010," *BNA Health Law Reporter* 19 (Jan. 7, 2010): 5-16; R. T. Rhoad and M. T. Fornataro, "A Gathering Storm: The New False Claims Act Amendments and their Impact on Healthcare Fraud Enforcement," *Health Law* 21, no. 6 (2009): 14-22.
39. 18 U.S.C. § 287.
40. 18 U.S.C. § 1001.
41. 18 U.S.C. § 1341.
42. 18 U.S.C. § 1343.
43. See, e.g., Miller, *supra* note 12, at 681 (noting an "explosive growth" in applying criminal law to health care providers); T. S. Jost, "Health Law and Administrative Law: A Marriage Most Convenient," *St. Louis University Law Journal* 49, no. 1 (2004): 1-34, at 9 ("Criminal prosecutions . . . have also taken on an increasingly important role in health care in recent years."); see also J. T. Boese, et al., "Healthcare Behind Bars: the Use of Criminal Prosecution in Forcing Corporate Compliance," *Journal of Health & Life Science Law* 3, no. 1 (2009): 91-131.
44. G. Harris, "Pfizer Pays $2.3 Billion to Settle Marketing Case," *New York Times*, Sept. 3, 2009: at B4.
45. See R. Frabrikant et al., *Health Care Fraud: Criminal, Civil, and Administrative Law* § 3.03 (New York: Law Journal Press 2009).

Experimenting with the Consumer: The Mass Testing of Risky Products on the American Public by Marshall S. Shapo (Praeger, 2008): 304 Pages

Joshua J. Gagne and Aaron S. Kesselheim

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

potentially risky products in early clinical trials and the post-approval setting. It is estimated that only 500 to 3000 patients are exposed to prescription medications before they are approved by FDA.[2] At the time Merck withdrew rofecoxib from the market, the company estimated that 84 million people around the world had used the drug.[3] Shapo goes on to state that with "An 'adverse event' in California, a 'side effect' in Kentucky; it may take a while for enough red pins to dot the map for observers to find a more macro pattern." Indeed, because of the difficulty in determining whether a drug exposure caused a specific adverse health outcome in a patient with many other risk factors, the FDA's MedWatch and Adverse Event Reporting System (AERS) is limited by gross underreporting, despite the fact that millions of patients may be taking the drug. AERS is also limited by absence of known denominators of numbers of patients exposed to the drug of interest and limited ability to adjust for other potentially confounding factors.[4]

Recognizing the limitations of the current drug safety surveillance paradigm, Congress passed the FDA Amendments Act in 2007, mandating FDA to establish an active surveillance system to monitor, in real-time, the safety of medical products using data from routine care that are collected in large administrative databases, such as health insurance claims databases. FDA's initial response to this mandate has been to start to organize a "Sentinel System" that will link databases from several private-sector US health insurers covering millions of Americans.[5] These databases, in which data are anonymized to be compliant with the Health Insurance Portability and Accountability Act (HIPAA), serve as the primary data source for contemporary research in pharmacoepidemiology,[6] a field of scientific inquiry that focuses largely on the safety and comparative effectiveness of therapeutics in the post-marketing setting. With the advent of electronic claims databases, advanced pharmacoepidemiologic techniques used to analyze the data have proliferated in recent years.[7] The goal of this field of study is to recognize the magnitude of "mass market experimentation" and try to cull as much information as possible about the effects of such experimentation, so that the benefits of therapeutics can be maximized and their risks minimized.

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.[8] 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.

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."

While FDA scientists, academicians, and legal experts deliberate on how to design the Sentinel System to maximize interoperability between databases,[9] other questions of scientific and legal importance have arisen. For example, some commentators have contemplated "what to do with all those new numbers"[10] 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.

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." Much in the same way that Shapo recognizes that "It has never been suggested that once the FDA clears a product for the market, manufacturers should be required to have consumers sign formal informed consent forms," it has not been suggested that patients prescribed a drug that will be monitored within the Sentinel System will be reqired to sign formal informed consent forms for the research study they are about to begin. Despite such concerns, the Sentinel System will address an important goal tht Shapo has also undertaken — increasing the public's awareness of the lack of safety knowledge about prescription medical proucts even when they are approved for us.

References

1. "Maclaren USA Recalls to Repair Strollers Following Fingertip Amputations," NEWS from CPSC: U.S. Consumer Product Safety Commission, Release # 10-033 (November 2009), *available at* <http://www.cpsc.gov/cpscpub/prerel/prhtml10/10033.html> (last visited May 6, 2009).
2. B.L. Strom, "How the US Drug Safety System Should be Changed," *JAMA* 295, no. 17 (2006): 2072-2075.
3 R. Knox, "Merck Pulls Arthritis Drug Vioxx from Market," National Public Radio, September 30, 2004, *available at* <http://www.npr.org/templates/story/story.php?storyId=4054991> (last visited May 7, 2010).
4. T. Brewer and G. A. Colditz, "Postmarketing Surveillance and Adverse Drug Reactions," *JAMA* 281, no. 9 (1999): 824-829.
5. "FDA's Sentinel Initiative," U.S. Food and Drug Administration (December 2009), *available at* <http://www.fda.gov/Safety/FDAsSentinelInitiative> (last visited May 7, 2010). .
6. S. Schneeweiss and J. Avorn, "A Review of Uses of Health Care Utilization Databases for Epidemiologic Research," *Jorunal of Clinical Epidemiology* 58, no. 4 (2005): 232-237.
7. S. Schneeweiss, "Developments in Post-Marketing Comparative Effectiveness Research," *Clinical Pharmacology & Therapeutics* 82, no. 2 (2007): 143-156.
8. M. García-Cortés, M. I. Lucena, R. J. Andrade, R. Camargo, and R. Alcántar, "Is the Naranjo Probability Scale Accurate Enough to Ascertain Causality in Drug-Induced Hepatotoxicity?" *Annals of Pharmacotherapy* 38, no. 9 (2004): 1540-1541.
9. J. C. Maro, R. Platt, J. H. Holmes, B. L. Strom, S. Hennessy, R. Lazarus, and J. S. Brown, "Design of a National Distributed Health Data Network," *Annals of Internal Medicine* 151, no. 5 (2009): 341-344.
10. J. Avorn and S. Schneeweiss, "Managing Drug-Risk Information – What to do With All Those New Numbers," *New-England Journal of Medicine* 361, no. 7 (2009): 647-649.