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Health Law (Hornbook Series)

Robert Schwartz
*University of New Mexico - Main Campus, schwartz@law.unm.edu*

Barry R. Furrow

Thomas L. Greaney

Sandra H. Johnson

Timothy Stoltzfus Jost

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HEALTH LAW

Third Edition

by

Barry R. Furrow
Professor of Law and Director, Health Law Program
Drexel University Thomas R. Kline School of Law

Thomas L. Greaney
Chester A. Myers Professor of Law and
Co-Director, Center for Health Law Studies
Saint Louis University School of Law

Sandra H. Johnson
Professor Emerita of Law and Health Care Ethics
Center for Health Law Studies
Saint Louis University School of Law

Timothy Stoltzfus Jost
Robert L. Willett Family Professor of Law
Washington and Lee University School of Law

Robert L. Schwartz
Senior Visiting Professor
University of California Hastings College of the Law
Visiting Professor (Psychiatry)
University of California, San Francisco
Weihofen Professor of Law Emeritus
University of New Mexico School of Law

HORNBOOK SERIES®
To Donna Jo, Elena, Michael, Nicholas, Eva, Robert, Hayden, Aspen, Grey, and Olivia

B.R.F.

To Nancy, T.J., Kati, and Jorro

T.L.G.

To Bob, Emily, Kathleen, Colin, Nicholas, Zachary, and Abigail

S.H.J.

To Ruth, Jacob, Micah, David, Felix, and Emily

T.S.J.

To Jane, Mirra, and Elana

R.L.S.
Preface

This third edition of this Hornbook marks more than a quarter of a century that the authors have worked together on academic health law materials. When these materials were first published, they helped define the scope of the newly emerging discipline of Health Law. Over the intervening years, no part of the American landscape has changed more than the American health care system. The system has been stressed by demographic changes, buffeted by the winds of political change, and utterly transformed by scientific, social and economic developments. The formal structure of the business of health care was a small part of the subject of health law when we published our first edition; it is now the subject of entire graduate programs. The for-profit commercial sector of the health care economy sounded like a lamb twenty years ago; now it roars like a lion. Until a few years ago virtually no one attained elective office because of her position on issues related to health care; now health care reform is the most politically controversial issue in America. Indeed, we have delayed bringing out a new edition of the Hornbook because of the uncertain fate of health care reform, threatened first by a Supreme Court case, then by the 2012 elections, and then by continuing political and legal uncertainty. We can wait no longer, though. This book is current as of January 2014 with regard to most developments related to the ACA, Medicare and Medicaid; it is current by a few additional months with regard to other development.

While the perspective that we must bring to the legal analysis of health care is far broader now than it was when our first hornbook was published, the fundamental concerns on which that analysis is brought to bear are surprisingly unchanged. As was the case in 1987, we want to know what role the law might play in promoting the quality of health care, in organizing the delivery of health care, in assuring adequate control of the cost of health care, in promoting access to necessary health care, and in protecting the human rights of those who are provided care within the health care system.

Every section of this Hornbook has been reviewed and rewritten so that the organization of the text reflects new developments in American health care. This Hornbook is divided into four major sections. While some subjects are addressed in more than one section of the Hornbook, the first four chapters generally address ways in which the law contributes to the promotion of the quality of health care. This part of the Hornbook includes thorough treatment of governmental efforts to assure the quality of health care services, including licensing and accreditation programs, as well as extensive analysis of medical malpractice law.

The second part of the text (Chapters 5 through 9) broadly addresses the issues of access to health care and control of health care costs. These chapters address both private and public financing mechanisms in the many varieties that have been formed and reformed over the past few years, including Medicare and Medicaid and private health insurance. These chapters have been completely rewritten in this edition in response to the Affordable Care Act. In these chapters we also examine the continued evolution of managed care as well as the emergence of the consumer-driven health care movement. Finally, this material also addresses legal obligations to provide medical services under the Emergency Treatment and Labor Act and the common law.
The third part of the book (Chapters 10 through 13) describes the role of the law in organizing the health care enterprise. This section of the Hornbook includes a thorough analysis of the different ways in which the business of health care delivery can be organized, the potential legal relationships among different players in the health care enterprise, tax and corporate law and its consequences for the health care industry, health care fraud and the government regulation of financial relationships among providers, and the application of antitrust law to health care.

The last major section of the hornbook (Chapters 14 through 17) provides background on the role law plays in protecting the human rights of those who interact with the health care system as patients or as participants in medical research. This section of the book addresses the current status of laws regulating abortion, assisted conception, and human reproduction. We also address controversies over the definition of death, the propriety of organ transplantation, the law of health care decisionmaking, and medically assisted dying. The Hornbook concludes with a review of legal regulation of research involving human subjects.

We are grateful for the many comments and helpful suggestions that judges, health law academics and others across the United States (and from elsewhere, too) have made to help us improve this Hornbook. A large number of very well respected health law teachers have contributed a great deal to this and previous editions by making suggestions, reviewing sections, or encouraging our more thorough investigation of a wide range of health law subjects. We wish to thank those who provided support for our research and the preparation of the manuscript, including the Frances Lewis Law Center, the Robert L. Willett family, Joshua Deal, Laura Edwards, David Freeman, David Fuchs, Wes Hansen, Garrett Lambur, Madeline Morcelle, Nicole Moskowitz, Rachel Polzin, Monica Smith, Stephanie Young, Anna Zaret and Lora Zommer. We have appreciated the administrative support provided by Cheryl Cooper, Lesley King, and Katey Mason. We all have special appreciation for the tremendous publication assistance provided by Greg Olson, Pamela Siege Chandler, Louis Higgins, Rebecca Schneider, Pat Sparks and James Cahoy of West Academic. Finally, we wish to thank our deans, Nora Demleitner, Roger Dennis, David Herring, Elizabeth Hillman, Elizabeth Pendo, Mike Wolff, and Frank Wu.

It has been a splendid opportunity to work on this hornbook. After twenty-eight years of exchanging manuscripts and comments, we still both like and respect one another. Each time we have done a new edition of any title, it has been difficult to assess whether particular new developments will become more significant during the lifespan of the edition or whether they will quickly fade as legal issues. It is difficult to delete materials that required so much labor and that still remain relevant, but seem to have been eclipsed in importance by others. As you will notice, this edition required cutting several sections—all beloved by their original authors—that were included in the Hornbooks of years gone by. Maybe we got those cuts right; to the extent that we did not, we may have another opportunity to correct our error down the line.

BARRY R. FURROW
THOMAS L. GREANEY
SANDRA H. JOHNSON
TIMOTHY S. JOST
ROBERT L. SCHWARTZ

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**CHAPTER 13. ANTITRUST LAW** 

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