Acknowledgments

I first became interested in the history of children and pharmacotherapeutics in 2002 when I served as a legislative fellow on Capitol Hill in the office of Minnesota Senator Paul Wellstone, and, by chance, attended a hearing related to the Best Pharmaceuticals for Children Act (BPCA). Christopher Dodd, then a senator from Connecticut and the hearing’s chair, emphasized our weak knowledge base with regard to pediatric drug dosing, side effects, adverse reactions, and other important scientific information. I was shocked. At that point, I had been a pediatric nurse and nurse practitioner for more than twenty years, and I had administered hundreds of different drugs to thousands of children. I had always assumed that the books and pediatric pharmacists I relied upon for my practice possessed evidence-based answers. But I had never really thought about the processes through which such evidence was generated. Senator Dodd and other BPCA supporters were convinced that, because of the limited legislative success of earlier laws, the nation needed a new one designed to address children’s unique needs. This topic seemed an ideal way to engage the nursing part of my life, in which I focus on twenty-first-century child health care delivery, and my historian’s propensity to examine the events, people, and beliefs that forged the contemporary template in which that care is delivered.

I had little idea how complicated this topic would be when I started what became *Children and Drug Safety: Balancing Risk and Protection in Twentieth Century America* in 2010. In fact, I was not even sure I could find enough material to write a book. Early support from the University of Pennsylvania Research Foundation, Trustees’ Council of Penn Women, American Institute of the History of Pharmacy at the University of Wisconsin School of Pharmacy (Sonnedecker Visiting Scholar Award for Pharmaceutical Historical Research), American Association for the History of Nursing, and the Karen
Buhler-Wilkerson fellowship from the Barbara Bates Center for the Study of the History of Nursing allowed me to gather enough preliminary archival data to convince me there was a story worth telling.

The historical actors who had considered pediatric drug-related issues and their ongoing debates, frustrations, and successes, gradually became visible when I received support in the form of a Robert Wood Johnson Foundation Investigator Award. This generous and unusually flexible funding allowed me to piece together the story in ways not otherwise possible. It is fascinating how the documents “dialogue” with one another, often referencing the same events, but from different perspectives. For example, in the Food and Drug Administration (FDA) records in the National Archives, letters from parents detail concerns about the safety of specific drugs prescribed or recommended for their children. At the same time, the American Academy of Pediatrics Committee on Drugs and United States Pharmacopeia records reflect organizational perspectives on pediatric drug development, safety, and efficacy. The FDA records reveal staffers’ attempts to address parents’ and clinicians’ concerns and a number of attempts to use the regulatory apparatus to make drugs safer for children. The papers of individual physicians such as Jay M. Arena and Horace L. Hodes illuminate pediatricians’ painstaking research and their interactions with regulatory agencies and drug companies. Fortunately, primary source data generated by the pharmaceutical industry can be found in all the above archives and were critical to piecing together the story, since I received no response to my queries to specific drug companies seeking access to relevant historical records. Finally, a National Endowment for the Humanities fellowship provided the time to draw all the threads together and complete the narrative.

I want to thank the many librarians and archivists without whose help I would never have located the sources I used over the course of many years. Russell S. Koontz, Duke Medical Center Library and Archives; Phoebe Letocha, Alan Mason Chesney Medical Archives, The Johns Hopkins Medical Institutions; Gregory Higby and Gregory Bond, American Institute of the History of Pharmacy; Tab Lewis, National Archives and Records Administration; Susan Bolda Marshall and Christopher Kwiat, American Academy of Pediatrics Division of Library and Archival Services; Jessica Murphy, Francis A. Countway Library of Medicine, Harvard University; Christopher Hoolihan, University of Rochester’s Miner Library Archives; Beth Lander, College of Physicians of Philadelphia; Marcia Meldrum and Russell Johnson, UCLA’s Center for the Study of the History of Neuropsycharmacology, History and Special Collections, Louise M. Darling Biomedical Library; Sheila Spaulding, Boston Children’s Hospital; Barbara Niss and Nicholas Webb, Icahn School of Medicine at Mount Sinai Archives, Gustave L. and Janet W. Levy Library; Stephen Greenberg, John P. Rees, and Crystal Smith, History of
Acknowledgments

I owe a special debt of gratitude to Patricia D’Antonio, who read multiple drafts of this manuscript, listened to me talk through my thoughts and arguments, and provided continual encouragement. John Swann gave generously of his time to review chapters, locate relevant materials, and tutor me in the complicated nuances of the FDA and American drug policy. Gregory Higby and John Parascandola facilitated my understanding of the history of pharmacy. Scott Podolsky suggested meaningful archival sources I would not have otherwise located and was a valuable sounding board on numerous occasions. A conversation with Susan Lederer sparked the idea for this project and her critique of the human experimentation chapters was very beneficial. My discussions with Julie Fairman surrounding the ways in which history is embedded in contemporary policy and practice deepened my analysis. Naomi Rogers’s insightful suggestions helped me plumb my data in new ways. Janet Golden offered a tireless sounding board for my ideas and I always left our time together with a deeper understanding of the history of children’s health care in the United States. I am especially grateful to the individuals with expertise in pediatric drug policy who made time to give me their perspective including Cheston Berlin, Dianne Murphy, Edward G. Feldmann, Marlene Haffner, Samuel Maldonado, Abbey Meyers, Allen A. Mitchell, Stephen P. Spielberg, Robert Ward, Sidney Wolfe, and Sumner Yaffe.

Colleagues whose support was invaluable along the way include Rima Apple, Joel Braslow, James Colgrove, David Herzberg, Joan Lynaugh, Lewis Leavitt, Beth Linker, Thomas Maeder, Gerald Oppenheimer, Heather Munro Prescott, David Rosner, Dominique Tobbell, Barbra Mann Wall, and John Harley Warner. Conversations with Jeffrey Baker, Jeffrey Brosco, Naixue Cui, Cindy Christian, Kara Finck, Richard Gelles, Janet Golden, Richard Meckel, Edward Schor, and Debra Schilling Wolfe sharpened my thinking about this history in the context of past and present children’s health care delivery and policy. Peter Mickulas, my editor at Rutgers University Press, continually encouraged me, was always available to listen, and was patient when circumstances delayed the manuscript’s completion.

This book could not have been completed without the collegiality, intellectual energy, and laughter that makes the Barbara Bates Center for the Study of the History of Nursing such a special place. It is my distinct honor to have been able to call each successive Bates Center director, Joan Lynaugh, Karen Buhler-Wilkerson, Julie Fairman, and now Patricia D’Antonio, a mentor and a friend. The vision and enthusiastic support of Penn Nursing dean emerita, Afaf Meleis, and my current dean Antonia Villarruel, create an academic space for the humanities to flourish and their support has transformed my personal and professional life. Bates Center colleagues Elisa Stroh and Jessica Clark are
never too busy to answer a question or help with something. Both make the Bates Center a fun and lively space. Current and former students John Barbieri, Jason Chernesky, Briana Ralston Smith, Virginia Schieck, and Benjamin Schneider provided assistance at various junctures of this project. Kimberley Byrd, Seymour Sejour and all the information technology staff at Penn Nursing responded to my numerous computer-related emergencies speedily and calmly, keeping my research and writing on track. The assistance of colleagues Christine Eisler, Sherri Kaplan, Jake Rutkowski, and Denise Scala also facilitated my ability to complete this book.

Friends who distracted, listened, supported, nurtured, and fed me during the many years it took to complete Children and Drug Safety include Carol Albert, Michael Albert, Michael Berthold, Gary Blum, George Bradt, Thomas Butler, Robert Elfont, Jeffrey Hartzell, Carolyn Reiners, Jeffrey Snyder, Lisa Stern, and Sharon Wolfson. Finally, I am deeply grateful to my family, my late parents Nicholas and Mary Connolly, sister Jackie, brother Nick, sister-in-law Linda, nephew Nicholas, and niece Lauren, whose sense of humor and love always keep me going.

This study received approval from the University of Pennsylvania Institutional Review Board. All Oral History Association guidelines were followed for interviews cited in this study. I received Privacy Board approval to view archival records in which Protected Health Information might be included from the Countway Library, The Johns Hopkins Medical Institutions, and the Duke University Medical Center. While the Sydenham Hospital records are open to researchers, the History of Medicine Division of the National Library of Medicine screens requests to review case files. I applied for and received permission. All names of patients or parents in archival records have been abbreviated or anonymized.