

Preface

Medical Biotechnology: Premarket and Postmarket Regulation provides an introduction to U.S. Food and Drug Administration (FDA) and related federal regulation of medical devices, drugs, and biological products derived from biotechnology. It is intended to help general practitioners understand the regulatory infrastructure that embraces and governs their biotechnology clients. The authors believe that nearly every practice of law involving a biotechnology client is ultimately informed by, or influenced by, the governing regulatory framework. Whether you prosecute biotechnology patents, negotiate intellectual property licenses, handle corporate mergers and acquisitions, negotiate clinical trial agreements, supervise securities disclosures, litigate securities case, or handle products liability issues for these companies, we believe that understanding the federal regulatory framework will help. This book is intended to give you that framework.

This volume follows on the heels of the Section of Science & Technology Law's successful and well-regarded 2007 volume, *Biotechnology and the Law*. **Dan Pancamo**, of counsel at Phelps Dunbar, has updated and expanded his chapter on federal regulation of preclinical research. A significantly updated chapter on FDA regulation of clinical trials has new authors: **Erika Lietzan**, a professor at the University of Missouri School of Law and former FDA partner at Covington & Burling LLP; and **Afia Asamoah**, product counsel at Google Inc. and former FDA attorney at Covington & Burling, as well as former Special Assistant in the Office of the Commissioner at FDA. **Areta Kupchyk**, an FDA partner at Nixon Peabody and former Associate Chief Counsel for Drugs and Biologics and Assistant General Counsel for Litigation at FDA, has updated and expanded her chapter on pathways to market for biotechnology-derived drugs and devices as well as her chapter on postmarket FDA regulation of these products. The authors of these chapters are national experts in their fields; every author is either an alumnus of the FDA or ranked a "Best Lawyer in America" in biotechnology law, or both. All have substantial experience advising clients on these issues.

The SciTech Section plans to publish a new edition of *Biotechnology and the Law*, which will include these four chapters. The larger (nearly 1,000-page) book is a flagship publication of the section, which leads the way nationally and globally on emerging issues at the intersection of law, science, and technology. The section provides a collaborative, wonderfully diverse, intellectually curious, and inclusive environment for its members to connect and explore issues of common interest at the intersection of science and technology.

Various committees within the section's Life and Physical Sciences Division may be of interest to readers of this volume, including the Biotechnology Law Committee and the Medical Devices Committee—as well as the committees exploring Behavioral and Neuroscience Law, Nanotechnology Law, and the Rights and Responsibilities of Scientists. These committees provide their members with opportunities to network, discuss hot topics, plan and participate in a variety of programming, and engage in informal conversations over Listservs on a regular basis. The section also has a variety of additional publications that may be of interest to readers. These include *Science for Lawyers*, which explains and discusses 13 applied scientific disciplines in jargon-free language that is specifically geared toward lawyers, and our quarterly newsletter, *The SciTech Lawyer*. I encourage readers of this volume to explore membership in the section and the many committees it offers.

Although I took responsibility for editing the entire volume as well as co-authoring one chapter, others played instrumental roles in this project. Bob Copple and Hugh Welons reviewed early versions of some of the chapters. Krista Carver provided invaluable substantive comments on all of the draft chapters while on vacation, greatly improving the finished product. And publication of the volume would not have happened without the assistance of Michael Hawes and Bonnie Fought, as well as the hard work (during the year-end holidays) of Sarah Orwig, Ben Wilson, and Caryn Hawk.

—Erika Lietzan