CHAPTER 1

Introduction

FDA-regulated products account for an estimated one-fifth of overall economic activity in the United States of America.[1] Since the Dalkon Shield and DES episodes of the late 1970s and early 1980s, product liability litigation involving FDA-regulated prescription products—drugs, medical devices, vaccines, and the like—has exploded. As indicative of the magnitude of this explosion, consider that in early 2008 the federal Judicial Panel on Multi-District Litigation was overseeing seventy-one active product liability related multi-district litigations. Of those seventy-one, thirty-seven—more than half—involve an FDA regulated prescription product.[2]

Thus, when we were contacted to write a book on prescription medical product liability litigation, it was with considerable trepidation that we agreed to undertake what we knew would be a Herculean task. That task has now been completed, and the result is the *Drug and Medical Device Product Liability Deskbook*.

Chapter 2, the first substantive chapter, addresses the question of warnings, since one constant of prescription medical product liability litigation throughout the years is the preeminence of warning-related claims as the favored theory of liability. In addition to ordinary warning claims, and the principal defense to such claims—the

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[1] April 1, 2003 Remarks by Mark B McClellan, M.D., Commissioner, Food and Drug Administration, before the Food & Drug Law Institute, at 1. (available at http://www.fda.gov/oc/speeches/2003/fdli0401.html).

[2] The federal courts maintain a Web site listing all active product liability-related multi-district litigation. See http://www.jpml.uscourts.gov/Pending_MDLs/Products_Liability/products_liability.html. A thirty-eighth multi-district litigation concerned an ingredient, phenylpropanolamine, used primarily in FDA regulated non-prescription drugs. A list of these multi-district litigations, current through the end of 2008, with links to the Web sites of those that have them, is available at http://druganddevicelaw.blogspot.com/2008/07/what-are-drug-and-device-mass-torts.html (last visited Feb. 26, 2009).

learned intermediary rule—this chapter addresses other information-based theories such as overpromotion, express and implied warranty, fraud, and unfair trade practice.

Chapter 3 examines non-informational liability theories, such as strict liability, design and manufacturing defect, medical monitoring, failure to test, and liability under certain statutes. The impact of the Second and Third *Restatements of Torts*[3] is addressed in this chapter. Non-informational theories have become increasingly popular in this type of litigation, and most sophisticated plaintiffs now include one or more of them in their complaints.

Chapter 4, on the impact of FDA regulation on prescription medical product liability litigation, addresses two primary topics. The first is a series of discussions that cumulatively can be described as "what a litigator needs to know about the FDA." There are entire books devoted to FDA regulation, so the intent here was not to be comprehensive, but rather to highlight those aspects of FDA regulation that tend to arise in litigation. The other part of this chapter addresses FDA-related per se liability—claims that violations of FDA regulations in and of themselves establish either the negligence of the defendant or the defectiveness of the product, and the defenses to those claims.

Chapter 5 takes a close look at preemption of common law tort claims by the Food, Drug & Cosmetic Act and FDA regulations. The rise, fall, and partial resurrection of express federal preemption in the medical device field is examined, as are less common forms of statutory preemption. The more recent rise and partial fall of implied preemption as a viable theory in product liability litigation involving prescription drugs is detailed, as is the application of implied preemption to claims involving allegations of fraud on the FDA.

Chapter 6 addresses a critical, but often overlooked, aspect of prescription medical product liability litigation—what plaintiffs and defendants can do to enhance their chances for success before litigation is ever filed. A number of prophylactic steps that manufacturers can take to reduce the likelihood of litigation and liability are discussed.

Chapter 7 focuses on use of the class action device in prescription medical product liability litigation. It discusses the types of class certification and the various factors in this type of litigation that favor and hinder certification of both litigation and settlement classes. This chapter covers both federal and state class certification decisions.

Chapter 8 addresses theories of liability asserted in prescription medical product liability litigation against entities other than manufacturers.

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[3] See *Restatement (Second) of Torts* § 402A, comment k (1965), and *Restatement (Third) of Torts, Products Liability* § 6 (1997).

The chapter examines product liability theories asserted against distributors, bulk suppliers, pharmacists, hospitals, physicians, contract research organizations, product promoters, brand name manufacturers in cases involving generic drugs, the FDA itself, corporate entities related to other potentially liable parties, and manufacturer representatives.

Chapter 9, concerning management of litigation, addresses a variety of litigation-related issues of a practical nature: aggregation of claims, collateral estoppel, removal to federal court, and multi-district litigation, including document preservation and production, privileges, use of special masters, discovery, and confidentiality of trade secrets in such litigation.

Chapter 10 addresses a burgeoning sub-topic in prescription medical product liability litigation—the permissible and impermissible uses of expert witnesses. Litigation involving prescription medical products has always been driven by experts and their opinions. Since the Supreme Court's landmark *Daubert* decision,[4] however, challenges to the admissibility of expert testimony have become ubiquitous, especially in the federal courts, but in state court litigation as well. The subject of expert witnesses thus merits its own separate chapter.

Chapter 11 addresses a number of matters that arise at trial. Evidentiary issues peculiar to cases involving FDA-regulated products are examined, as are the admissibility of evidence of subsequent remedial measures and restrictions on evidence of similar incidents, and testimony of former FDA employees on FDA-related topics. Issues related to bifurcation and punitive damages are also discussed.

This book has taken over a year to write. We believe we can look back over that process with justified satisfaction. The effort has produced a first of its kind—a comprehensive guide to all that is important in prescription medical product liability litigation, from before litigation even starts through the trial of the case, with everything compiled in a single, readily-accessible volume.

Finally, a work of this scope could not have been undertaken without the help of many other people. We therefore wish to express our thanks and gratitude to: James Berger, M.D., Anthony Bolzan, Tara Kelly, James Mirro, Joseph O'Connor, and Peter Shindel of Dechert, LLP, and Brian Carmody, Matthew Hamilton, and Laurel Siegel of Pepper, Hamilton LLP.

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[4] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).