CHAPTER ONE

INTRODUCTION

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New Issues in Product Liability

In the last decade, we have witnessed an unprecedented number of liability claims and extensive social upheaval from products with serious unintended consequences for workers, consumers, and the environment. In 2009, the ten largest jury verdicts in product liability cases totaled approximately $350 million.1 With large-scale investments in production and global marketplaces, even budding concerns about potential product liability can stimulate market responses that create large winners and losers. As a legal matter and in the global marketplace, product liability is a complex area that is becoming more so every day. The practical treatment of product liability by industries and societies demonstrates the influences of risk perception, public and private risk management, scientific foundations for risk assessment and causality, and socio-legal institutions.

This book presents business and policy advisory perspectives regarding a number of important issues in product liability that emerge from current but dramatically changing legal and global market conditions. The idea for this book was conceived in an era of headline product recalls that occurred simultaneously with calls for tort reform and liability limitations. Not surprisingly, in the last several years, product liability and product safety became high-priority issues for policy makers at state and federal levels (Burrows 2010).2 The tension between demands for increased product safety and decreased liability served to highlight the complexity of the issues that corporate risk managers, policy makers, business advisors, and consumers were wrestling with on a daily basis to manage product risks. Whether the enterprise is the corporation, the marketplace, or the household, product risks and their liabilities have become core drivers for the decision making that typically shapes

economic performance and well-being. As a result, product liability fits squarely in the scope of concerns for the general practice of enterprise risk management (ERM). This book was developed to be a resource for private and public-sector practitioners who want to understand the potential effects of recent market and regulatory developments in product liability risk management, especially as they might pertain to ERM analysis.

Product liability is an important area of the U.S. legal and regulatory systems, but it is also an area deeply informed by sophisticated risk and economic concepts. Chapter 2 provides an overview of risk assessment issues from the private and public points of view. Chapters 3 and 4 then detail the new rules governing consumer protection and product recall in the United States, with chapter 4 emphasizing the implications of product recalls for sound risk management with a focus on the food sector. As concerns about product liability logically give rise to demands for risk-spreading solutions and risk transfer, chapter 5 discusses innovations in insurance and financial solutions to manage these risks. To present a more global and comparative view of product liability, the insurance chapter is followed by a chapter on recent developments in Europe that have substantial implications for product liability in the global marketplace and ERM context. Subsequent chapters explore product liability issues and future directions in areas such as asbestos products, pharmaceuticals, chemical products, and finally nanotechnology.

**The ERM Context**

We begin with a general but useful definition of ERM:

Enterprise risk management deals with risks and opportunities affecting value creation or preservation, defined as follows:

Enterprise risk management is a process, effected by an entity’s board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.3

In recent years, ERM has gained wide acceptance as a method for assessing and responding to key risk sources and exposures for many public and private enterprises. A recent study found that approximately 80 percent of the 149 respondent companies from all over the world indicated their companies employ a formal ERM

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Moreover, approximately 40 percent of the respondents with no current formal ERM program had plans for implementing one within 12 months of the survey.

Importantly, ERM aims to proactively and systematically manage the risks of enterprises. In application, ERM typically addresses the challenges of risk in four main categories: strategic, operations, reporting, and compliance. ERM is distinguished from traditional approaches to managing risks by its systematic, comprehensive, and integrated focus. ERM strives to provide management with a portfolio view of risks affecting the organization.

In addition, ERM attempts to provide an understanding of potential barriers that must be recognized and managed in order to achieve the programmatic and strategic objectives of the organization. With its focus on the robust and systematic analysis of information, ERM is often implemented to inform decision makers of corporate challenges and mitigation strategies, and to provide a basis for risk-based executive-level decisions, both operational and strategic. Comprehensive ERM frameworks are expected to strengthen management’s ability to better anticipate internal and external risks, preserve a full range of mitigation options and responses, and generally reduce surprises and their associated costs. Not surprisingly, some obvious objectives of ERM are to identify and classify risks; to quantify risks using a number of risk metrics; to monitor risks; and to implement strategies for risk reduction, integration, diversification, and transfer. With this in mind, the chapters in this book provide a review and summary of events and trends in product liability risk management that relate directly to these fundamental ERM objectives.

IDENTIFYING AND CLASSIFYING RISKS

The sheer volume of risk-based decisions that are necessary in today’s society requires highly structured approaches to risk identification and classification. Although most risk assessment in the United States is done by private parties, government regulation exerts a huge influence on why and how these assessments are done. This point is emphasized in the chapters that address consumer-product protection and product recalls insofar as government regulation begins with definitions of substantial product hazards, unreasonable risk of serious injury or death, adulteration, and misbranding.

In the area of product liability, it is essential to find an ideal balance between too little and too much regulation because of the costs associated with under- and over-regulation, respectively. One alternative is to shape incentives in such a way that manufacturers will conduct tests before bringing the product on the market. Another alternative is for industries to self-regulate the process of pre-market due

diligence by developing a code of best practices or voluntary standards. Given that private risk assessments might be influenced by cost concerns and expediency at the same time that government oversight can be overly burdensome, what is the best course for effective risk identification? This book addresses a number of key issues in this regard such as private-product due diligence, government regulation, industry standards, and penalties for failing to disclose risk information.

Tort liability is, of course, an important incentive to conduct risk assessment in the context of ERM in the United States. In contrast, the implementation of the Regulation, Evaluation, Authorization and Restriction of Chemical substances (REACH) and similar regulations in the EU might support increased private risk identification and assessment through changes in the requirements to conduct business in that region. The European perspective on product safety provides a useful insight into the use and potential limitations of a collective approach to allowable and acceptable risks in the marketplace.

A further complication, however, for national and regional approaches to product safety, is outsourcing. This somewhat recent trend poses new challenges relating to the identification and classification of risk. In an effort to keep costs down, manufacturers are increasingly turning to outsourcing at different stages of the manufacturing process, from raw materials to the finished product. With the surge in outsourcing, there is less control of the information that supports risk identification and classification. Regulatory concerns about this source of risk have triggered supplier-targeted audit programs that allow monitoring of each supplier along the supply chain. For example, as discussed in chapter 8, Strategic Enterprise Risk Management and Pharmaceuticals, in January 2009 the U.S. Food and Drug Administration (FDA) launched a two-year Secure Supply Chain pilot program whereby the participating companies will have to maintain control of the drug from manufacture to its entry into the United States. If successful, this program may prove to be the precursor for an extensive program potentially covering all drugs that are partially or fully manufactured outside the country. Such an approach could not only minimize liability by enhancing drug safety but also minimize import delays that are costly for manufacturers. The enterprise risk management challenge is to reap the benefits of outsourcing and contain the liability. Notable recalls linked with outsourcing in the recent past have spanned a wide range of industries including pharmaceutical, food, and manufacturing industries. With increased outsourcing activity, it is evident that adequate supply-chain management procedures are essential and there are lessons to be learned across industries.