About the Authors

Joanne S. Hawana, MS, JD, is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC's FDA practice team. She counsels global clients on regulatory and distribution-related considerations to bringing a new FDA-regulated product to market and how to ensure continued compliance after a product is commercialized. Hawana also assists the Mintz corporate team by performing regulatory due diligence as part of potential mergers and acquisitions that involve regulated companies, and she often works in conjunction with the firm's intellectual property attorneys to ensure that patent and regulatory activities are strategically aligned. She holds an MS in molecular genetics and microbiology from the University of Medicine and Dentistry of New Jersey and a JD from the University of Maryland School of Law.

Benjamin M. Zegarelli, MS, JD, is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC's FDA practice team. He provides counsel on compliance and regulatory issues to clients in the medical device, pharmaceutical and biotech industries. With a clear focus on FDA regulatory counseling, Zegarelli advises a breadth of health care industry and life sciences clients on the federal and state laws surrounding medical product development and marketing. He also frequently leads regulatory due diligence reviews for transactions involving pharmaceutical and medical device manufacturers and provides regulatory advice to the Mintz corporate team on such transactions. Zegarelli holds an MS in organic chemistry from the California Institute of Technology and a JD from the Benjamin N. Cardozo School of Law.

Elizabeth K. Conti, JD, is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC's FDA practice team. She focuses her practice on regulatory compliance and enforcement defense matters for companies in pharmaceuticals, medical device, dietary supplement, cosmetics and food industries as well as pharmacies and distributors. Conti advises clients on FDA regulations related to labeling, advertising, importing and exporting, and manufacturing practices. Her practice also encompasses administrative matters and civil litigation related to DEA requirements. Conti holds a JD from the Catholic University of America.

Scott P. Dunberg, JD, is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC's corporate and securities practice team. He represents public and private companies in a broad range of transactions and corporate matters and focuses primarily on mergers and acquisitions, venture capital financings, capital markets transactions, securities law compliance and general corporate representation. Dunberg regularly represents technology-based companies, principally in the areas of biotechnology, med-tech, telecommunications, and software. He holds a JD from Suffolk University Law School.

A General Introduction to Due Diligence: Look Before You Leap

Introduction

An average consumer in today's digital age has greater access to information than at any time in the past. Before purchasing a bicycle, for example, a consumer can obtain detailed product information and technical specifications, read reviews and recommendations, and compare the bicycle with similar offerings from the manufacturer or its competitors. Using such information, the consumer can assess the bicycle's components and quality, consider the appropriateness of its price, identify any potential concerns (or "red flags") that would support a decision not to purchase the bicycle and, ultimately, make an informed decision—to buy or not to buy—without the fear of buyer's remorse. Today's consumers would undoubtedly agree that *scientia potentia est*, or "knowledge is power."

That Latin aphorism is no less true in the context of acquiring a business or making an investment decision. In the context of mergers and acquisitions (M&As) and venture capital or growth equity investing, potential acquirers and investors, respectively (referred throughout this chapter, collectively, as "acquirers"), are presented with business opportunities that would require significant investments of time, money and other resources, and each opportunity must be evaluated for its potential risks and rewards. However, unlike the bicycle, information about a potential target (e.g., financial information, business development plans, clinical trial data, etc.) is rarely publicly available (unless the target is a public company that files reports with the US Securities and Exchange Commission) and, in most cases, inaccessible to an acquirer without engaging in an information-gathering process directly with the target. That process is known as "conducting due diligence" and is the