

**HEALTH CARE
MERGERS AND
ACQUISITIONS
ANSWER BOOK**

2018 Edition



PLI'S COMPLETE LIBRARY OF TREATISE TITLES

ART LAW

Art Law: The Guide for Collectors, Investors, Dealers & Artists

BANKING & COMMERCIAL LAW

Asset-Based Lending: A Practical Guide to Secured Financing
Consumer Financial Services Answer Book
Equipment Leasing—Leveraged Leasing
Financial Institutions Answer Book: Law, Governance, Compliance
Hillman on Commercial Loan Documentation
Hillman on Documenting Secured Transactions: Effective Drafting and Litigation
Maritime Law Answer Book

BANKRUPTCY LAW

Bankruptcy Deskbook
Personal Bankruptcy Answer Book

BUSINESS, CORPORATE & SECURITIES LAW

Accountants' Liability
Anti-Money Laundering: A Practical Guide to Law and Compliance
Antitrust Law Answer Book
Broker-Dealer Regulation
Conducting Due Diligence in a Securities Offering
Corporate Compliance Answer Book
Corporate Legal Departments: Practicing Law in a Corporation
Corporate Political Activities Deskbook
Corporate Whistleblowing in the Sarbanes-Oxley/Dodd-Frank Era
Covered Bonds Handbook
Cybersecurity: A Practical Guide to the Law of Cyber Risk
Derivatives Deskbook: Close-Out Netting, Risk Mitigation, Litigation
Deskbook on Internal Investigations, Corporate Compliance, and White Collar Issues
Directors' and Officers' Liability: Current Law, Recent Developments, Emerging Issues
Doing Business Under the Foreign Corrupt Practices Act
EPA Compliance and Enforcement Answer Book
Exempt and Hybrid Securities Offerings
Fashion Law and Business: Brands & Retailers
Financial Product Fundamentals: Law, Business, Compliance
Financial Services Mediation Answer Book
Financial Services Regulation Deskbook
Financially Distressed Companies Answer Book
Global Business Fraud and the Law: Preventing and Remediating Fraud and Corruption
Hedge Fund Regulation
Initial Public Offerings: A Practical Guide to Going Public
Insider Trading Law and Compliance Answer Book
Insurance and Investment Management M&A Deskbook
International Corporate Practice: A Practitioner's Guide to Global Success
Investment Adviser Regulation: A Step-by-Step Guide to Compliance and the Law
Legal Guide to the Business of Marijuana
Life at the Center: Reflections on Fifty Years of Securities Regulation
Mergers, Acquisitions and Tender Offers: Law and Strategies
Mutual Funds and Exchange Traded Funds Regulation
Outsourcing: A Practical Guide to Law and Business
Privacy Law Answer Book
Private Equity Funds: Formation and Operation
Proskauer on Privacy: A Guide to Privacy and Data Security Law in the Information Age
Public Company Deskbook: Complying with Federal Governance & Disclosure Requirements
SEC Compliance and Enforcement Answer Book
Securities Investigations: Internal, Civil and Criminal

Securities Law and Practice Deskbook
The Securities Law of Public Finance
Securities Litigation: A Practitioner's Guide
Social Media and the Law
Soderquist on Corporate Law and Practice
Sovereign Wealth Funds: A Legal, Tax and Economic Perspective
A Starter Guide to Doing Business in the United States
Technology Transactions: A Practical Guide to Drafting and Negotiating Commercial Agreements
Variable Annuities and Variable Life Insurance Regulation

COMMUNICATIONS LAW

Advertising and Commercial Speech: A First Amendment Guide
Sack on Defamation: Libel, Slander, and Related Problems
Telecommunications Law Answer Book

EMPLOYMENT LAW

Employment Law Yearbook
ERISA Benefits Litigation Answer Book
Labor Management Law Answer Book

ESTATE PLANNING AND ELDER LAW

Blattmachr on Income Taxation of Estates and Trusts
Estate Planning & Chapter 14: Understanding the Special Valuation Rules
International Tax & Estate Planning: A Practical Guide for Multinational Investors
Manning on Estate Planning
New York Elder Law
Stocker on Drawing Wills and Trusts

HEALTH LAW

FDA Deskbook: A Compliance and Enforcement Guide
Health Care Litigation and Risk Management Answer Book
Health Care Mergers and Acquisitions Answer Book
Medical Devices Law and Regulation Answer Book
Pharmaceutical Compliance and Enforcement Answer Book

IMMIGRATION LAW

Fragomen on Immigration Fundamentals: A Guide to Law and Practice

INSURANCE LAW

Business Liability Insurance Answer Book
Insurance Regulation Answer Book
Reinsurance Law

INTELLECTUAL PROPERTY LAW

Copyright Law: A Practitioner's Guide
Faber on Mechanics of Patent Claim Drafting
Federal Circuit Yearbook: Patent Law Developments in the Federal Circuit
How to Write a Patent Application
Intellectual Property Law Answer Book
Kane on Trademark Law: A Practitioner's Guide
Likelihood of Confusion in Trademark Law
Patent Claim Construction and *Markman* Hearings
Patent Law: A Practitioner's Guide
Patent Licensing and Selling: Strategy, Negotiation, Forms
Patent Litigation
Pharmaceutical and Biotech Patent Law
Post-Grant Proceedings Before the Patent Trial and Appeal Board
Substantial Similarity in Copyright Law
Trade Secrets: A Practitioner's Guide

LITIGATION

American Arbitration: Principles and Practice
Class Actions and Mass Torts Answer Book
Electronic Discovery Deskbook
Essential Trial Evidence: Brought to Life by Famous Trials, Films, and Fiction
Expert Witness Answer Book
Evidence in Negligence Cases
Federal Bail and Detention Handbook
How to Handle an Appeal
Medical Malpractice: Discovery and Trial
Product Liability Litigation: Current Law, Strategies and Best Practices
Sinclair on Federal Civil Practice
Trial Handbook

REAL ESTATE LAW

Commercial Ground Leases
Friedman on Contracts and Conveyances of Real Property
Friedman on Leases
Holtzschue on Real Estate Contracts and Closings: A Step-by-Step Guide to Buying and Selling Real Estate
Net Leases and Sale-Leasebacks

TAX LAW

The Circular 230 Deskbook: Related Penalties, Reportable Transactions, Working Forms
The Corporate Tax Practice Series: Strategies for Acquisitions, Dispositions, Spin-Offs, Joint Ventures, Financings, Reorganizations & Restructurings
Foreign Account Tax Compliance Act Answer Book
Internal Revenue Service Practice and Procedure Deskbook
International Tax & Estate Planning: A Practical Guide for Multinational Investors
International Tax Controversies: A Practical Guide
International Trade Law Answer Book: U.S. Customs Laws and Regulations
Langer on Practical International Tax Planning
The Partnership Tax Practice Series: Planning for Domestic and Foreign Partnerships, LLCs, Joint Ventures & Other Strategic Alliances
Private Clients Legal & Tax Planning Answer Book
Transfer Pricing Answer Book

GENERAL PRACTICE PAPERBACKS

Anatomy of a Mediation: A Dealmaker's Distinctive Approach to Resolving Dollar Disputes and Other Commercial Conflicts
Attorney-Client Privilege Answer Book
Drafting for Corporate Finance: Concepts, Deals, and Documents
Pro Bono Service by In-House Counsel: Strategies and Perspectives
Smart Negotiating: How to Make Good Deals in the Real World
Thinking Like a Writer: A Lawyer's Guide to Effective Writing & Editing
Working with Contracts: What Law School Doesn't Teach You

**Order now at www.pli.edu
Or call (800) 260-4754 Mon.–Fri., 9 a.m.–6 p.m.**

**Practising Law Institute
1177 Avenue of the Americas
New York, NY 10036**

When ordering, please use Priority Code NWS9-X.

**HEALTH CARE
MERGERS AND
ACQUISITIONS
ANSWER BOOK**

2018 Edition

Edited by
Andrew L. Bab
Kevin A. Rinker

Debevoise & Plimpton LLP

Practising Law Institute
New York City

#239430

This work is designed to provide practical and useful information on the subject matter covered. However, it is sold with the understanding that neither the publisher nor the author is engaged in rendering legal, accounting, or other professional services. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

QUESTIONS ABOUT THIS BOOK?

If you have questions about billing or shipments, or would like information on our other products, please contact our **customer service department** at info@pli.edu or at (800) 260-4PLI.

For any other questions or suggestions about this book, contact PLI's **editorial department** at: plipress@pli.edu.

For general information about Practising Law Institute, please visit **www.pli.edu**.

Legal Editor: Keith Voelker

Copyright © 2014, 2015, 2016, 2017, 2018 by Practising Law Institute. All rights reserved. Printed in the United States of America. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of Practising Law Institute.

LCCN: 2014934916
ISBN: 978-1-4024-3128-9

About the Editors

ANDREW L. BAB is a corporate partner of Debevoise & Plimpton LLP, co-head of the firm's Healthcare Group, and a member of the Mergers & Acquisitions and Private Equity Groups. Mr. Bab has worked extensively on public and private acquisitions, divestitures, and joint ventures, including cross-border transactions for private equity and corporate clients, as well as licensing arrangements and other corporate transactions.

Mr. Bab has represented a number of health care companies and private equity firms investing in health care, including Allergan, Clayton, Dubilier & Rice, Diamond Castle, Envision Healthcare, Hisamitsu, Lanett, Mitsui, Noven Pharmaceuticals, P2 Capital, Sawai Pharmaceutical, and Stone Point Capital. In addition, he frequently advises investment banks on major health care transactions, including Guggenheim Securities, J.P. Morgan, Morgan Stanley, and Goldman Sachs.

Mr. Bab is recognized for M&A and private equity buyouts by *The Legal 500*, where he is described as a "leader in healthcare transactions." Clients have referred to him as "one of the sharpest legal minds [they] have ever worked with" and have noted that "[h]e consistently impresses with his legal and business instincts." He is named as one of the 500 leading lawyers in America by *Lawdragon* and is also recognized as a leading M&A lawyer by *Best Lawyers*.

Mr. Bab has written prolifically on a variety of M&A and health care-related topics, including "A Look at Recent Efforts to Contain Health Care Costs" (*Law360*, 2018), "How Section 1332 Waivers Could Impact Health Care Reform" (*Law360*, 2017), "Key Issues in U.S. Going Private Transactions" (*The M&A Lawyer*, 2016), "Lot of Inversion Talk, But Do You Know the Basics?" (*Law360*, 2014), "Got Financing? You May Have to Extend Your Tender Offer" (*The Harvard Law School Forum on Corporate Governance and Financial Regulation*, 2013), and "Contingent Value Rights in Healthcare M&A" (*Insights*, 2011).

Mr. Bab joined Debevoise in 1997 and became a partner in 2002. He received his B.A. magna cum laude from Yale University in 1986 and his J.D. from Columbia Law School in 1992, where he was a Stone

Scholar and Book Review Editor of the *Columbia Law Review*. From 1986 to 1989, Mr. Bab was an investment banker at Lazard Frères & Co.

KEVIN A. RINKER is a corporate partner of Debevoise & Plimpton LLP, co-head of the firm's Healthcare Group, and a member of the Mergers & Acquisitions and Private Equity Groups. Mr. Rinker has a broad-based transactional practice with extensive experience advising multinational corporations and private equity firms in structuring and negotiating mergers, acquisitions, divestitures, licensing arrangements, and other corporate transactions.

Mr. Rinker has represented a number of health care companies and private equity firms investing in health care, including The Carlyle Group, Clayton, Dubilier & Rice, Envision Healthcare, HCA, Hisamitsu, Johnson & Johnson, Nestlé, and PharMEDium.

Mr. Rinker is ranked as a leading M&A and private equity lawyer by *Chambers USA*, where he is described as "very strategic" and having "a deep knowledge of M&A transactions in the healthcare area." Clients note that he has a "unique combination of technical legal skill and business acumen" and that his negotiation skills make a significant difference in a transaction. He is also ranked by *IFLR1000* and is recommended for M&A and private equity buyouts by *The Legal 500*, where clients describe him as "very accessible and commercial," "a strong negotiator," "extremely client oriented," and "calm under fire," as well as noting that he has "great insight into healthcare." Clients say he has the "experience base, familiarity with market precedents and ability to help create unique structures to position clients to make the best deals they can."

Mr. Rinker is an editor of the *Debevoise & Plimpton Private Equity Report* and a frequent author and speaker on legal developments affecting M&A and health care, including "A Look at Recent Efforts to Contain Health Care Costs" (*Law360*, 2018), "How Section 1332 Waivers Could Impact Health Care Reform" (*Law360*, 2017), "Lot of Inversion Talk, But Do You Know the Basics?" (*Law360*, 2014), "MAC Clauses in the U.K. and U.S.: Much Ado About Nothing?" (*The M&A Lawyer*, 2014), and "Imitation is the Sincerest Form of Flattery: Continued Use of Private Equity Technology in Acquisitions by Strategic Buyers" (*The M&A Lawyer*, 2013).

About the Editors

Mr. Rinker joined Debevoise in 2000 and became a partner in 2007. He received his B.A. from Tufts University in 1994 and his J.D. from the Georgetown University Law Center in 1999, where he was on the editorial board of *The Tax Lawyer* and served as a Teaching Fellow in the LL.M. program. Mr. Rinker is a member of the Board of Directors of Partnership with Children, a nonprofit organization that assists at-risk youths in the New York City area.

About the Contributors

DANIEL M. ABUHOFF is a partner of Debevoise & Plimpton LLP and a member of the firm's Litigation Department. He has tried cases in courtrooms across the country and in arbitrations in the United States and abroad. Mr. Abuhoff received his A.B. magna cum laude from Princeton University in 1975 and his J.D. from Columbia Law School in 1978, where he was a Kent Scholar. Mr. Abuhoff is admitted to appear before the Southern and Eastern Districts of New York, the Second Circuit Court of Appeals, and the United States Supreme Court.

CHRISTOPHER ANTHONY is a partner of Debevoise & Plimpton LLP and a member of the firm's Mergers & Acquisitions Group. He has worked extensively on acquisitions, divestitures, and joint ventures for both private equity and corporate clients. Mr. Anthony joined Debevoise in 2009. He received a J.D. from Columbia Law School in 2009, where he was a Harlan Fiske Stone Scholar, and a B.A. from Duke University in 2005.

JOHN L. BABITT is the Life Sciences Industry Sector Leader for financial and accounting due diligence for EY LLP's North America Transaction Advisory Services Practice. Mr. Babitt has more than twenty years of experience in the health care and life sciences deal space providing advice to both private equity firms as well as strategic investors. Mr. Babitt has also served as CFO of a publicly traded medical technology company, where he was responsible for all financial and operational aspects, including capital raising and negotiating and structuring numerous collaborations and licensing arrangements. Mr. Babitt received a B.B.A. in accounting and an M.B.A. in finance from the University of Miami and is a certified public accountant in New York.

SAMANTHA L. BERKOVITS is a corporate associate of Debevoise & Plimpton LLP and a member of the firm's Mergers & Acquisitions Group. She received a J.D. from the University of Chicago Law School in 2016, where she served as a Comments Editor for *The Chicago Journal of International Law*. Ms. Berkovits received an A.B. with honors from the University of Chicago in 2011.

MICHAEL BOLOTIN is a partner of Debevoise & Plimpton LLP and a member of the firm's Tax Department. His practice focuses on private equity fund formation, targeting both foreign and domestic investors, real estate joint ventures, the formation of real estate investment trusts, and equipment finance. Mr. Bolotin received his B.A. from Columbia University in 2001 in History and Economics, and his J.D. magna cum laude from New York University in 2004, where he was inducted into the Order of the Coif.

SARAH BRICKNELL is a legal director of Blake Morgan LLP and a member of the firm's Health and Social Care Group, having spent over twenty-five years working as General Counsel across three sectors, aerospace, Internet technology and telecoms test equipment, and lately health care. For over twelve years as an Executive Director of a private UK health care provider, her responsibilities included the legal team's role in delivering corporate growth and strategy, and at various stages, operational and P&L responsibility for delivery of clinical services in radiology and cardiac diagnostics. Her work has involved structuring transactions to acquire and divest health care businesses and for organizational development, public sector tendering transactions relying on the UK Private Finance Initiative and public private partnerships, and a corporate development role liaising with health sector stakeholders at government and regulatory level. She has particular insight in living with the contractual consequences of promises made at a tender stage, and also in post-acquisition integration. At Blake Morgan, Mrs. Bricknell supports corporate transactions, infrastructure projects, and public private partnerships in the health care sector as well as advising NHS and independent sector clients on the current UK health care agenda. She has spoken at various health care conferences on the role that private companies can have in supporting the evolution of the public health service in England. She studied law at the University of Exeter. She is particularly grateful for the support of Madeleine Mould, a trainee solicitor at Blake Morgan who has recently joined the Health and Care Team, for her assistance in compiling content for this publication.

SCOTT A. CHAMBERS is a principal in the Washington, D.C. office of Porzio, Bromberg & Newman, P.C. He has worked extensively in district court litigation, patent appeals, Hatch-Waxman patent term extensions,

patent prosecution, licensing, and M&A due diligence. Dr. Chambers previously served as an Associate Solicitor for the Patent and Trademark Office (PTO), where he defended the PTO's patentability determinations and statutory interpretation before the U.S. Court of Appeals for the Federal Circuit and district courts in matters involving biotechnology, chemistry, and drug term extensions. As Associate Solicitor, he worked on drafting and implementing Examination Guidelines and drafted congressional testimony for the agency. Dr. Chambers has written and lectured on legal topics relating to intellectual property protection in chemistry and biotechnology. He is an Adjunct Faculty Member at the Georgetown Law Center, Catholic University Law School, and the George Washington University Law School. Dr. Chambers was previously a Senior Staff Scientist at the National Institutes of Health. He earned his J.D., magna cum laude, from George Washington University in 1993, his Ph.D. from Florida State University in 1981, and his B.S. from Ohio State University in 1974.

JENNIFER L. CHU is a corporate partner of Debevoise & Plimpton LLP and a member of the firm's Mergers & Acquisitions and Healthcare Groups. Her practice focuses on advising corporations and private equity firms in mergers and acquisitions, joint ventures, and other corporate matters, with a particular focus on transactions in the insurance and health care industries. Ms. Chu received her J.D. cum laude from Harvard Law School in 2006, where she served as co-Editor-in-Chief of the *Harvard International Law Journal*. She received her M.A. with distinction from the University of London in 2002, and her A.B. magna cum laude from Harvard College in 2001.

JOHN M. (CHIP) CLARK III is the Healthcare Services Sector Leader for EY LLP's North American Transaction Advisory Services Practice. He has more than fifteen years of experience in the health care industry and advises corporate entities and private equity funds in connection with health care transactions. Earlier in his career, Mr. Clark served the health care audit and transaction advisory services practices of EY and Arthur Andersen. Mr. Clark received a B.S. in Business Administration and a Master of Accountancy from the University of Tennessee.

GUY CONSTANT is a partner in Blake Morgan LLP's corporate team. He deals with a full range of corporate transactions for clients, with a special emphasis on those within the health care sector. This includes

mergers and acquisitions, joint ventures, equity finance, debt finance, and IPOs. *The Legal 500* describes him as “very easy to approach, calm and knowledgeable.” He graduated with a BA (Hons) in History at the University of York and obtained his professional qualifications at the College of Law.

JEFFREY P. CUNARD is the managing partner of the Washington, D.C. office of Debevoise & Plimpton LLP. He leads the firm’s corporate intellectual property and information technology practices and has broad experience in transactions, including mergers and acquisitions, licenses, joint ventures, and outsourcing arrangements. Mr. Cunard represents companies in connection with reviews by the Committee on Foreign Investment in the United States. He also works on copyright litigation matters and is a member of the firm’s Privacy and Data Security practice. Mr. Cunard’s practice also encompasses U.S. and international media and telecommunications law, including privatizations and regulatory advice. He is an internationally recognized practitioner in the field of the Internet and cyber law. Mr. Cunard is the author of, and contributes to, books and articles on communications and intellectual property law, and he speaks widely on both subjects. He is also a co-author of two seminal books on international communications law and taught for several years at Harvard Law School. Mr. Cunard graduated summa cum laude in English and Political Science from the University of California at Los Angeles in 1977 and received a J.D. in 1980 from the Yale Law School, where he was an Editor of the *Yale Law Journal*.

JOHN S. (JAY) DARDEN is a partner in the Government Investigations and White Collar Defense Practice Group in the Washington, D.C. office of Paul Hastings LLP. Mr. Darden’s practice includes defending individuals and companies against allegations of health care fraud and abuse, including actions and investigations under the False Claims Act. His practice also includes internal investigations and defense of clients in government investigations under the Foreign Corrupt Practices Act (FCPA), as well as other white collar criminal matters. Previously, Mr. Darden was the Assistant Chief for Health Care Fraud at the Criminal Fraud Section of the Department of Justice. Mr. Darden received his undergraduate degree from Washington & Lee University and his law degree from the University of Virginia School of Law, where he served as managing editor of the *Virginia Law Review*.

SARAH A.W. FITTS is a partner at Schiff Hardin LLP. She works in the United States and internationally advising clients on M&A transactions, projects, and restructurings, with particular experience in joint ventures and other multiparty governance arrangements. Ms. Fitts is a Vice Chair of the Renewable and Demand Energy Resources Committee of the Section on Environment, Energy and Resources of the American Bar Association, a member of the Leadership Council of the American Council on Renewable Energy (ACORE), and a director on the boards of Scenic Hudson, Inc. and Urban Teaching Corps, Inc. She is also a Fellow of the American Bar Foundation and a member of the Council on Foreign Relations. Ms. Fitts received her B.A. magna cum laude in History and Oriental Studies from the University of Pennsylvania in 1987, where she was elected to Phi Beta Kappa, her M.A. in East Asian History from the University of Pennsylvania also in 1987, and her J.D. cum laude from Harvard Law School in 1990.

GARY M. FRIEDMAN is a partner in the Tax Department of Debevoise & Plimpton LLP whose practice focuses on the U.S. and international tax aspects of complex, multi-jurisdictional mergers, acquisitions, and financings. Mr. Friedman has contributed to the New York State Bar Association Reports on transfer pricing, the U.S. foreign tax credit, and passive foreign investment companies. Mr. Friedman is a member of the New York Tax Club and the Taxation Section of the American Bar Association. He was also a member of the Executive Committee of the Taxation Section of the New York State Bar Association from 2000 to 2003 and the Co-Chair of the Committee on U.S. Activities of Foreign Taxpayers for 2003. Mr. Friedman graduated from Princeton in 1979 and earned a J.D. from the University of Chicago Law School in 1983, where he served as Comments Editor of *The University of Chicago Law Review*. In 1990, Mr. Friedman earned an LL.M. in Taxation at New York University.

MELODI (MEL) M. GATES is a senior associate at Squire Patton Boggs (US) LLP, where she counsels clients in data privacy, cyber security, and regulatory compliance matters, helping organizations to achieve an effective balance between data protection and business capabilities. She holds a Certified Information Privacy Professional (CIPP/US) certification from the International Association of Privacy Professionals. Ms. Gates works with a variety of health care clients and service

providers, including state health information exchanges and all payor claims databases, in managing contracts and developing policies and practices to meet their HIPAA and HITECH obligations. Ms. Gates worked in telecommunications and information technology for more than twenty years prior to joining the legal field, including as chief information security officer for Qwest Communications, where she managed information security controls around the world and created a specialized team of technology professionals dedicated to protecting both enterprise and customer assets. She received a B.S. with distinction from California State University, Long Beach, an M.S. from the University of Colorado, and a J.D. from the University of Denver Sturm College of Law.

MARK P. GOODMAN is a litigation partner at Debevoise & Plimpton LLP and is a member of the firm's (1) Health Care Litigation, Enforcement, and Compliance, (2) Products Liability, and (3) White Collar practice groups. He regularly represents clients in the health care industry in a broad variety of matters, with particular emphasis on white collar criminal defense, internal investigations, internal compliance, and complex civil litigation, including securities litigation and products liability defense. Mr. Goodman has represented companies and individuals in grand jury and regulatory investigations and criminal proceedings involving allegations, among others, of health care fraud, *Park* liability, securities fraud, antitrust violations, and violations of the Foreign Corrupt Practices Act. He routinely represents corporate boards and board committees and provides litigation advice in connection with mergers and acquisitions. He is currently counsel to the Regulatory and Compliance Committee of the board of one of the world's largest pharmaceutical companies. Mr. Goodman has been lead counsel in many trials and arbitration proceedings, including the successful defense of Bristol-Myers Squibb at a jury trial in March 2013 in which plaintiffs sought \$3.5 billion in damages. Mr. Goodman is a co-editor and co-author of *Defending Corporations and Individuals in Government Investigations* (West 2d ed. 2012–13). From 1992 to 1995, Mr. Goodman served as Assistant U.S. Attorney for the Southern District of New York (Criminal Division). Mr. Goodman graduated from Sarah Lawrence College in 1983 and from the New York University School of Law in 1987, where he served as a Senior Editor of the *New York University Law Review*. He served as a law clerk to the Honorable

Leonard I. Garth of the U.S. Court of Appeals for the Third Circuit (1987), currently serves on the boards of the Legal Aid Society and Sarah Lawrence College, and is a member of the Management Committee at Debevoise.

ERICH O. GROSZ is counsel in the Litigation Department of Debevoise & Plimpton LLP. Mr. Grosz focuses his practice on white collar and regulatory defense, internal investigations, compliance advice, and complex commercial litigation. He has represented companies and individuals in criminal, civil, and SEC investigations and enforcement proceedings involving allegations, among others, of violations of the U.S. Foreign Corrupt Practices Act, securities and accounting fraud, and employee misconduct. He also regularly advises companies on compliance matters as well as risk mitigation in connection with potential transactions. Mr. Grosz received his J.D. in 1999 from Stanford Law School, where he was awarded the Order of the Coif and was an Articles Editor of the *Stanford Law Review*. He received his B.A. magna cum laude from Princeton University's Woodrow Wilson School of Public and International Affairs in 1996. From 2000 to 2001, he served as a law clerk to the Hon. Alvin K. Hellerstein, U.S. District Court for the Southern District of New York. From 2001 to 2002, he served as a law clerk to the Hon. Chester J. Straub, U.S. Court of Appeals for the Second Circuit.

STUART HAMMER is counsel in the Corporate Department of Debevoise & Plimpton LLP and a member of the Environmental Practice Group. He represents U.S. and international companies, financial institutions, and other entities on environmental matters in mergers and acquisitions, joint ventures, financings, securities offerings, and other corporate transactions. Mr. Hammer received a B.A. from Yeshiva University and a J.D. from Cardozo Law School.

SEAN HECKER, formerly a partner of Debevoise & Plimpton LLP, is a partner of Kaplan Hecker & Fink. He is an experienced trial lawyer whose practice focuses on white collar criminal defense, internal investigations, and complex civil litigation. He has tried numerous cases to juries in federal and state court and regularly defends individuals and companies in grand jury and regulatory investigations and criminal proceedings involving allegations of securities fraud, money laundering, and criminal antitrust violations. Mr. Hecker has

conducted numerous internal investigations of alleged Foreign Corrupt Practices Act violations and regularly advises companies on anticorruption compliance issues. He also represents clients in complex civil litigation, including cases involving alleged securities fraud and other commercial disputes. Mr. Hecker received his J.D. in 1997 from Stanford Law School, where he graduated Order of the Coif and was the Senior Note Editor of the *Stanford Law Review*. He received a Master's degree in public policy from the John F. Kennedy School of Government at Harvard University in 1994. He graduated magna cum laude from Columbia College in 1992. He was a trial lawyer with the Federal Defenders of New York from 2003 to 2006.

URI HERZBERG is a corporate partner of Debevoise & Plimpton LLP and a member of the firm's Mergers & Acquisitions and Private Equity Groups. Mr. Herzberg is a contributing author of the *Debevoise & Plimpton Private Equity Report* and co-authored "Imitation is the Sincerest Form of Flattery: Continued Use of Private Equity Technology in Acquisitions by Strategic Buyers," in *The M&A Lawyer* (January 2013). Mr. Herzberg received a J.D. from the University of Pennsylvania Law School in 2007, as well as a Certificate in Business and Public Policy from the Wharton School of the University of Pennsylvania. He received a B.A., cum laude, from Yeshiva University in 2004.

PETER HORNECKER is a partner in EY LLP's Financial Accounting and Advisory Services practice and covers health care and life sciences.

TAISUKE IGAKI is a corporate partner of Nishimura & Asahi, and a member of the firm's Life Science and Healthcare Practice Group. He focuses on cross-border commercial transactions, mergers and acquisitions, licenses, joint ventures, commercial disputes, and insolvency and restructuring. He has experience across many industries, but is particularly active in the medical, pharmaceutical, and health care industry. He also regularly represents investment banking firms in their roles as financial advisors in major transactions. Mr. Igaki received his LL.B. from the University of Tokyo in 1998 and his LL.M. from Northwestern University School of Law in 2007.

PETER J. IRWIN is a corporate partner of Debevoise & Plimpton LLP and is chair of the firm's Real Estate Group. He regularly advises clients on real estate acquisitions, dispositions, joint ventures, financings,

restructurings, and net lease transactions. Mr. Irwin received a B.S. from Cornell University and a J.D. from St. John's University School of Law.

YOKO KASAI is an associate at Nishimura & Asahi. Her practice focuses on the representation of life sciences and technology companies developing and marketing pharmaceuticals, biologics, vaccine, diagnostics, medical devices, and digital health products. She specializes in corporate transactions involving complex intellectual property and pharmaceutical regulatory issues, including mergers and acquisitions, joint ventures, strategic alliances, and asset transfers. In addition, she counsels clients on matters involving research and development collaborations, clinical trials, technology licensing, supply and distribution agreements, and co-promotions arrangements. She also advises clients in connection with privacy and personal data protection matters. Ms. Kasai received her J.D. from the University of Tokyo, Graduate Schools for Law and Politics and her LL.M. in Law, Science and Technology from Stanford Law School. She received her B.S. in Pharmaceutical Sciences from the University of Tokyo in 2005.

KRISTIN D. KIEHN is counsel in the Litigation Department of Debevoise & Plimpton LLP. Her practice focuses on health care–related enforcement, litigation, and compliance, including in the areas of white collar and regulatory defense, government and internal investigations, general commercial litigation, and compliance and regulatory advice. She has broad experience representing clients in a variety of health care–related matters, including representing pharmaceutical companies and individuals in government investigations relating to sales and marketing practices, manufacturing and distribution issues, clinical trials, health care program reporting, and individual *Park* liability; in consumer fraud class actions arising from the sale of pharmaceutical products; and in international arbitration disputes relating to drug development, manufacturing, and safety. Her experience includes health care program exclusion matters and corporate integrity agreement negotiation and implementation. She regularly advises clients—including major pharmaceutical companies—on corporate compliance standards and best practices in the pharmaceutical industry. Ms. Kiehn received a B.A. from Smith College in 1992, an M.A. from New York University in 1996, and a J.D. cum laude from Fordham University

School of Law in 2000, where she was Writing & Research Editor of the *Fordham Law Review*.

ANTOINE F. KIRRY is a partner based in the Paris office of Debevoise & Plimpton LLP and a member of the firm's Litigation Group. Mr. Kirry has substantial litigation and arbitration experience, with particular emphasis on M&A-related disputes. He has argued numerous cases in most courts in the Paris area and in many courts elsewhere in France. He has also handled arbitrations under the auspices of the International Court of Arbitration of the International Chamber of Commerce, the Arbitration Institute of the Stockholm Chamber of Commerce, and the Arbitration Court of the Russian Federation Chamber of Commerce and Industry, as well as ad hoc arbitrations in various European countries. In addition, Mr. Kirry has broad experience in advising French and foreign clients with respect to acquisitions and dispositions in France and has advised clients on several of the most significant transactions of the past few years, involving both publicly and privately held companies. Mr. Kirry recently concluded a nine-year term as a member of the board of directors of Association Droit et Procédure, one of the oldest and most respected associations of litigation practitioners in France. He is also a member of Association Française des Avocats Conseils d'Entreprise and of the Swiss Arbitration Association. Mr. Kirry received a Licence d'Histoire and a Maîtrise en Droit des Affaires in 1981 and a D.E.A. en Droit Privé in 1982 from the University of Strasbourg, and an LL.M. from Columbia Law School in 1986.

ADRIANA D. KOHLER is a Public Policy Analyst at Planned Parenthood Federation of America, where she works on regulatory issues and policy advocacy related to implementation of the Affordable Care Act. Prior to Planned Parenthood, Ms. Kohler was an associate in the Health Care Practice Group at Patton Boggs LLP. At Patton Boggs, Ms. Kohler advised clients in a variety of health care legislative and regulatory issues, including Medicare and Medicaid coverage and reimbursement and implementation of the Affordable Care Act. Ms. Kohler has broad experience representing clients throughout the health care industry, including pharmaceutical and medical device companies, trade associations, patient and provider groups, and hospital systems. She has particular expertise developing and implementing legislative and regulatory strategies for individual

clients and coalitions and counseling clients regarding fraud and abuse laws and regulatory compliance matters. Ms. Kohler received her B.A. in History and Political Science, *summa cum laude*, from the University of Pennsylvania and her J.D. from the University of Pennsylvania Law School.

LACY L. KOLO is a partner in the Intellectual Property practice at Squire Patton Boggs (US) LLP. Dr. Kolo represents a range of clients, from pharmaceutical, medical device, and dietary supplements companies to high-technology corporations, on a full range of intellectual property matters. Dr. Kolo has particular expertise in conducting due diligence on intellectual property assets and counseling clients on the intellectual property rights, value, and risks associated with a merger or acquisition. Dr. Kolo received a B.A. in Psychobiology from the University of Virginia, a Ph.D. in Pharmacological and Physiological Sciences from Saint Louis University, and a J.D. from George Mason School of Law.

ALYONA N. KUCHER is a partner based in the Moscow office of Debevoise & Plimpton LLP. She has been principally involved in such areas as general corporate practice, construction (in particular, major infrastructure projects), lease of real estate and other immovable property, oil and gas projects, and M&A. Ms. Kucher has written a book on formation of contracts and negotiations procedures as well as several articles on foreign investments in Russia. She graduated from Moscow State University, Faculty of Law, in 2000 and from its Faculty of Foreign Languages in 1999. She received her Ph.D. in law from Moscow State University in 2002 and currently lectures on corporate and contract law in the Faculty of Law of Moscow State University.

ROSANNE LARIVEN is a Paris-based associate in the Corporate Department of Debevoise & Plimpton LLP. Ms. Lariven received her LL.M. from the London School of Economics and Political Science in 2014, and she also holds a master's in business law from the University Rennes I (2013).

HENRY LEBOWITZ is a partner in the Corporate Department of Debevoise & Plimpton LLP and a member of the Corporate Intellectual Property Group. He focuses his practice on leading the IP and technology aspects of mergers and acquisitions, financings, capital markets, and

other corporate transactions. Mr. Lebowitz has advised companies on complex transactions, litigation, portfolio development, and other IP matters in an array of industries. He also regularly assists clients in evaluating patents, trademarks, and other intellectual property, developing effective IP portfolios, assessing the merits of IP-related litigation and other disputes, and implementing strategies to avoid or favorably resolve such disputes. Mr. Lebowitz is a lecturer at Columbia University School of Law, where he has co-taught the advanced patent law seminar since 1997. Since 2012, he also has taught an IP legal practice workshop at the law school. He earned his J.D. in 1995 from Columbia University School of Law, where he was a James Kent Scholar, recipient of the Carroll G. Harper Prize in Intellectual Property, and a member of the *Law Review*. He received a B.S. in Electrical Engineering from Columbia University in 1989.

KATHLEEN J. LESTER is a principal at Lester Health Law PLLC. She provides legal and strategic advice to clients on legislative and regulatory matters involving Medicare and Medicaid coverage and reimbursement, quality, federal health care funding, health information technology, and medical and Internet privacy—including the Health Insurance Portability and Accountability Act (HIPAA) regulations, other federal and state privacy laws, and the European Union Privacy Directive. Ms. Lester has experience in all three branches of the federal government. Ms. Lester served as a privacy consultant in the Office of General Counsel to the U.S. Department of Health and Human Services (HHS), where she finalized the HIPAA Privacy Rule. Ms. Lester also served as law clerk to the Honorable Michael S. Kanne, Circuit Judge, U.S. Court of Appeals for the Seventh Circuit, and worked for Senator Richard G. Lugar (R-IN). Prior to opening her own practice, Ms. Lester was an equity partner in the Health Care Practice at Patton Boggs LLP in Washington, D.C.

ANDREW M. LEVINE is a partner in the Litigation Department of Debevoise & Plimpton LLP who focuses his practice on white collar and regulatory defense, internal investigations, and a broad range of complex commercial litigation. He regularly defends companies in criminal, civil, and regulatory enforcement matters and has conducted numerous investigations throughout the world. Mr. Levine frequently advises

companies on compliance matters, including with respect to the U.S. Foreign Corrupt Practices Act, and the assessment and management of risks presented by potential mergers, acquisitions, and other transactions. He is a Co-Editor-in-Chief of the firm's *FCPA Update* newsletter and a Co-Contributing Editor of the Anti-Corruption Section of the *Latin Lawyer* Reference Series, and has published widely on anticorruption and other compliance topics. Mr. Levine received his J.D. from Yale Law School in 2002, where he was a Senior Editor of the *Yale Law Journal* and Submissions Editor of the *Yale Journal of International Law*. He obtained his B.A. summa cum laude and Phi Beta Kappa from Yale College in 1997. Before joining Debevoise in 2006, Mr. Levine served as Deputy Counsel to the Independent Inquiry Committee into the United Nations Oil-for-Food Programme, led by Paul A. Volcker, from 2004 to 2005.

JONATHAN F. LEWIS is a partner in the Executive Compensation & Employee Benefits Group of Debevoise & Plimpton LLP. His practice encompasses a broad range of executive compensation and employee benefits matters including public and private mergers and acquisitions; the design, operation, and disclosure of executive compensation plans and programs, with a focus on management equity arrangements; and formation of investment funds, such as hedge funds and private equity funds, and the investment in the funds by ERISA pension plans. Mr. Lewis received a B.A. from Harvard College in 1990 and a J.D. from the George Washington University Law School in 1994.

G. CHRISTOPHER LOUIS, ASA (Business Valuation), MAI (Real Estate), was formerly a principal with Marshall & Stevens Incorporated. He served as national leader for the Healthcare Practice and as a senior member of the Financial Valuation and Consulting and Real Estate Services Practices. Mr. Louis has been in the valuation business since 1979. He specializes in complex valuation studies requiring a financial, real estate, or multidiscipline approach for transaction consulting, project financing, regulatory compliance, ad valorem, bankruptcy, litigation support, wealth/tax transfer, and financial reporting. Mr. Louis holds a B.A. in Economics from Westminster College in Fulton, Missouri, and an M.A. from Case Western Reserve University in Cleveland.

JONATHAN L. LUBIN, formerly a corporate associate of Debevoise & Plimpton LLP, is counsel at MHR Fund Management. In his six years at Debevoise through 2014, Mr. Lubin focused on domestic and cross-border mergers and acquisitions, investment management, and corporate governance. At MHR, Mr. Lubin structures, negotiates, and executes private equity-style investment transactions. He received a J.D. degree from Yale Law School in 2008 and a B.A., *summa cum laude*, in Economics and Classical Studies from the University of Pennsylvania in 2005, where he was elected to Phi Beta Kappa.

ALEXANDRA S. MARZELLI is regulatory counsel at BD, where she provides advice on Food and Drug Administration and other U.S. and international regulatory, quality, and related matters. Prior to joining BD, Ms. Marzelli was an associate in the Food and Drug practice at Patton Boggs LLP. Ms. Marzelli received a B.A. from Brown University and a J.D. from the University of Virginia School of Law.

ROBERT MASELLA is one of Shearman & Sterling's Healthcare Industry Leaders and a partner in the Mergers & Acquisitions practice. He has extensive experience in complex U.S. and cross-border corporate transactions, securities law issues, and corporate governance matters. Mr. Masella's transactional work includes public and private mergers and acquisitions, sell-side and buy-side transactions, dual-track M&A/IPO processes, joint ventures, collaboration and licensing agreements, divestitures, debt and equity investments and issuances, spin-offs, and other forms of corporate transactions. He received a J.D. *magna cum laude* from the University of Pennsylvania Law School, an M.B.A. with distinction from the Wharton School at the University of Pennsylvania, and a B.A. *magna cum laude* in Economics from the College of William & Mary.

ANNA V. MAXIMENKO is a Russian-qualified international counsel in the Moscow office of Debevoise & Plimpton LLP. She is a member of the firm's Corporate Department. Ms. Maximenko focuses on advising companies operating in the health care sector, including advising mergers and acquisitions, establishment of strategic partnerships, and advising on various operational and regulatory matters, including distribution arrangements and regulatory compliance. Ms. Maximenko graduated with honors from the Saratov State Academy of Law in 1999. She is

admitted to practice in Russia and is a member of the Non-commercial Partnership for the Support of Competition in Russia.

ILIR MUJALOVIC is a partner in Shearman & Sterling's Capital Markets Group. Mr. Mujalovic has extensive experience in capital markets transactions and advises investment banks and corporations on a wide variety of matters, including IPOs, follow-on offerings, convertible bonds, high yield and other debt offerings. From August 2010 through February 2014, Mr. Mujalovic was a Director and Assistant General Counsel at Bank of America Merrill Lynch where he advised on a broad range of equity and high-yield capital markets transactions. Prior to that, Mr. Mujalovic was an associate in Shearman & Sterling's Capital Markets Group.

STEPHEN P. NASH is a partner in the Denver office of Squire Patton Boggs (US) LLP and the co-leader of the firm's Global Healthcare Practice Group. Mr. Nash has represented health care organizations for more than thirty years. His clients include academic medical centers, hospitals and health systems, health information exchanges, medical groups and other physician organizations, health plans and other managed care organizations, long-term care organizations, ancillary health service providers, and health care investors. Mr. Nash counsels these organizations regarding governance, corporate, reimbursement, tax, privacy and security, fraud and abuse, and other regulatory compliance issues. These issues typically arise within the context of mergers, acquisitions, joint ventures, corporate reorganizations, complex contractual arrangements, and other affiliations and collaborative efforts, as well as in connection with tax-exempt revenue and refunding bond issues. Mr. Nash has also counseled a number of government-sponsored entities and sovereign wealth funds regarding health care transactions in the Middle East. In addition to his transactional and regulatory work, Mr. Nash has over twenty years of experience representing hospitals in single provider and group appeals for Medicare and Medicaid reimbursement, and serves as a strategic advisor on Medicare, Medicaid, and private payor matters such as coverage issues and payment methods. Mr. Nash also has substantial experience representing statewide health information exchanges and all-payor claims databases.

SEAN P. NEENAN, formerly a corporate associate at Debevoise & Plimpton LLP, is Assistant General Counsel at New York Life Insurance Company. At Debevoise, he was a member of the firm's Insurance and Financial Institutions group, focusing on financings and acquisitions in the insurance industry. Mr. Neenan received a J.D. from Rutgers University School of Law in Newark in 2008 and a B.A. in Economics and a B.A. in Psychology from Rutgers College in 1999. Prior to joining Debevoise, Mr. Neenan was a law clerk in the insurance law group of Prudential Financial, Inc.

CAREY B. NUTTALL is Senior Counsel at Takeda Pharmaceutical Company Limited. He was previously a partner in the FDA practice at Polsinelli PC, where he advised a diverse array of clients on a wide variety of FDA-related regulatory, public policy, and enforcement matters. Previously, Mr. Nuttall was Associate Chief Counsel for Enforcement in the FDA's Office of the Chief Counsel, where he represented the FDA in enforcement and defensive litigation matters. Mr. Nuttall received a B.A. in International Relations from Brigham Young University and a J.D., cum laude, from the J. Reuben Clark Law School at Brigham Young University.

ANTOINE D'ORNANO is a retired international counsel resident in the Paris office of Debevoise & Plimpton LLP and was a member of the firm's Corporate Department. His practice concentrated on mergers and acquisitions, financing transactions, and French and European commercial, labor, and tax matters. Mr. d'Ornano is the co-author of several articles on French corporate law and tax issues. He graduated from Université de Paris-X in 1973, Cambridge (UK) University in 1976, and New York University in 1985. He is a member of the Paris and New York bars.

TERRIANNE M. PATNODE, formerly a litigation associate of Debevoise & Plimpton LLP, is counsel at Clayton, Dubilier & Rice. She received her B.A. from Boston College in 1999 and her J.D. with high honors from Rutgers University School of Law in 2004, where she was Lead State Constitutional Law Editor of the *Rutgers Law Journal*.

NICHOLAS F. POTTER is a corporate partner of Debevoise & Plimpton LLP, where he is Co-Chair of the firm's Financial Institutions Group and a member of the firm's Mergers & Acquisitions and Securities Groups.

He also served as the Co-Chair of the firm's Pro Bono Committee from 2001–2012. Mr. Potter's practice focuses on corporate transactions in the insurance industry; he advises insurers and reinsurers, private equity firms, investment banks, and other industry participants on public and private mergers, acquisitions, restructurings, corporate governance, regulatory issues, and capital markets transactions and financings including life insurance "embedded value" and excess reserve financings. Mr. Potter received his A.B. magna cum laude from Harvard College in 1985 and his J.D. from Harvard Law School in 1988. He is a member of the Association of the Bar of the City of New York and the American Bar Association and regularly writes and speaks on insurance industry M&A and finance topics. Mr. Potter serves on the Board of Directors of Poets House, Inc. and Search and Care, Inc.

ERIC T. RASMUSSEN is the Senior Director of Federal Government Affairs for Sunovion Pharmaceuticals, Inc. In this role, he leads federal legislative and regulatory strategy and implementation for the company. Mr. Rasmussen was formerly an associate in the Health Care Practice Group at Patton Boggs LLP. Mr. Rasmussen previously worked for Senator Mike Crapo as the senator's lead policy advisor and legislative strategist in the areas of health care, education, labor, and Social Security. Mr. Rasmussen received a B.A., magna cum laude, from the University of Utah and a J.D. from the Georgetown University Law Center.

JEFFREY E. ROSS is a corporate partner of Debevoise & Plimpton LLP, co-chair of the firm's Finance Group, and a member of the Private Equity Group. His practice focuses on complex acquisition and leveraged financings. Mr. Ross publishes frequently on legal matters related to finance topics and is an editor of the Debevoise & Plimpton Private Equity Report. Mr. Ross received a J.D. cum laude from Cornell Law School in 1999, an M.A., first class honors, in International Relations from University of Melbourne, Australia in 1997, and a B.A. from Columbia University in 1995.

PAUL D. RUBIN is a partner in the Washington, D.C. office of Debevoise & Plimpton LLP. He chairs the firm's FDA regulatory practice, and is a member of the Healthcare Group. Mr. Rubin represents FDA-regulated drug and device companies on a wide range of regulatory issues ranging from strategic regulatory counseling to complex compliance and

enforcement matters. He also routinely conducts regulatory due diligence for private equity funds and strategic acquirers in corporate transactions. In addition to his FDA practice, Mr. Rubin has substantial experience helping clients navigate complex advertising and promotion-related issues including FTC investigations, negotiating FTC settlements/consent decrees, disputes before the National Advertising Division of the Better Business Bureau (NAD), and advertising lawsuits under section 43(a) of the Lanham Act. He received a B.S. in economics magna cum laude from the University of Pennsylvania Wharton School of Business and a J.D. cum laude from the University of Pennsylvania Law School.

MELISSA B. RUNSTEN is an associate in the Corporate Department of Debevoise & Plimpton LLP and a member of the Healthcare Group. Her practice focuses on FDA/FTC regulatory matters and includes the representation of drug, device, food, cosmetic, and other consumer product companies. Ms. Runsten also routinely conducts regulatory due diligence for private equity funds and strategic acquirers in corporate transactions. She received a J.D. from Stanford Law School in 2015, where she was co-president of the Stanford Public Interest Law Foundation and an online editor of the *Stanford Law Review*. She received a B.A. with distinction and Phi Beta Kappa from Stanford University in 2010.

CHERYL SATIN is a partner in the Business Law Group at Blake, Cassels & Graydon LLP. Ms. Satin's practice focuses on mergers and acquisitions, divestitures, private equity investments, and corporate reorganizations. She has substantial experience in negotiating and advising in connection with acquisitions and divestitures for both public and private companies, with a particular focus in the life sciences industry. She also routinely acts for manufacturers and distributors of pharmaceutical products and medical devices in connection with their product licensing, marketing, distribution, and supply arrangements.

MEGAN SHAW is an associate in the Business Law Group at Blake, Cassels & Graydon LLP. Ms. Shaw's practice encompasses a wide range of corporate and commercial matters, including mergers and acquisitions, franchising and distribution arrangements, pension fund investments, and divestitures. She provides legal services to a broad range

of clients, from large multinational pharmaceutical and medical device companies, to retailers, entrepreneurs, and franchisors.

W. GREGG SLAGER was the founder of EY LLP's Health Care Sector in the Americas Transaction Advisory Services practice. He now serves as the EY Global Health TAS leader. He focuses on financial and accounting due diligence on behalf of strategic and private equity entities in merger and acquisition, joint venture, and alliance transactions with health care payors, providers, and services companies. Mr. Slager received a B.B.A. in accounting from Western Michigan University and is a certified public accountant in New York, Michigan, and Illinois.

LENA E. SMITH is a corporate associate and a member of Debevoise & Plimpton LLP's Tax Group. Ms. Smith received a J.D. from Brooklyn Law School summa cum laude in 2015. She was the Managing Editor of the *Brooklyn Law Review* and a fellow in the Dennis J. Block Center for the Study of International Business Law. She received a B.A. magna cum laude from Boston University in 2011.

ANNE D. SPIGGLE is of counsel in the FDA practice at Polsinelli PC, where she advises clients on a wide range of regulatory, public policy, and enforcement matters involving the Food and Drug Administration, the Federal Trade Commission, the Consumer Product Safety Commission, and other federal and state health and safety regulatory agencies. Ms. Spiggle counsels clients on compliance with federal and state regulatory requirements relating to the development, promotion, and sale of foods, dietary supplements, drugs, cosmetics, and medical devices. Ms. Spiggle received a B.A. in Government magna cum laude from Cornell University and a J.D. cum laude from Georgetown University Law Center.

JACOB W. STAHL is counsel in the Litigation Department of Debevoise & Plimpton LLP. His practice focuses on representing clients on health care-related issues, including commercial litigation, administrative disputes and compliance and regulatory advice. He also represents clients in the areas of mass tort, products liability, general commercial litigation, and white collar criminal defense. Mr. Stahl is also a member of the New York City Bar Health Law Committee.

Mr. Stahl received a J.D. from Harvard Law School cum laude in 2005. He received a B.A. from the University of Pennsylvania summa cum laude and Phi Beta Kappa in 2001.

DANIEL E. STROIK is an associate in the Corporate Department of Debevoise & Plimpton LLP. He received his B.A. summa cum laude from the College of New Jersey (TCN) with honors in 2008, where he was elected to Phi Beta Kappa. He received his J.D. from the University of Chicago Law School in 2011.

STEPHEN TAINSH is a partner of Blake Morgan LLP and a member of the firm's Health and Social Care Group. Mr. Tainsh also leads the firm's Medical Equipment Manufacturers Group. Mr. Tainsh advises on corporate transactions, infrastructure projects, and public private partnerships in the health care sector. Mr. Tainsh's clients include public sector NHS hospital bodies, private sector hospital providers and operators, equipment manufacturers, and investors and banks. Mr. Tainsh advised the administrator and the UK's health care regulator on the first ever dissolution of a NHS Foundation Trust in England. Mr. Tainsh is recognized in *The Legal 500* as having "notable transactional expertise." Mr. Tainsh speaks at health care conferences, particularly those focusing on the supply of medical equipment to the NHS under new contractual models. He authored "Rethinking the PPP," in the *Health Service Journal* (2014). Mr. Tainsh joined Morgan Cole, a predecessor firm of Blake Morgan, in 2013 as a partner. He studied at Keble College, Oxford and received an M.A. in Modern History from the University of Oxford.

DMITRIY A. TARTAKOVSKIY, formerly counsel at Debevoise & Plimpton LLP, is a shareholder at Greenberg Traurig, LLP. His practice focuses on mergers and acquisitions. Mr. Tartakovskiy received a J.D. magna cum laude from Brooklyn Law School in 2001 and a law degree from Moscow Academy of Law in 1991.

CHANTAL TORTOROLI, formerly a corporate associate of Debevoise & Plimpton LLP, is currently at Hess Corporation. She received a J.D. degree from St. John's University School of Law in 2010, where she was a staff member of the *St. John's Law Review*. She received a B.A. cum laude from McGill University (Canada) in 2005.

MICHI TSUDA is a senior associate in the Global Healthcare Practice Group at Squire Patton Boggs (US) LLP, where he regularly advises hospitals, pharmacies, physician groups, health maintenance organizations, private equity funds, sovereign governments, and health-related joint ventures in operational, regulatory, transactional, and litigation matters. Mr. Tsuda has represented clients in connection with a broad range of corporate governance, reimbursement, fraud and abuse, and other regulatory compliance matters. His representations include sole community hospitals with Medicaid supplemental payments and financing issues, providers under investigation for allegations of fraud and abuse, group medical practices in the acquisition of ambulatory surgery centers, private equity funds in the acquisition of acute care hospitals, freestanding emergency centers, and senior care communities, and investors in the funding, development, and operation of acute care hospitals and outpatient facilities in Qatar and the United Arab Emirates. Mr. Tsuda received a B.A. in Economics and Spanish, magna cum laude, from Amherst College and a J.D. and M.B.A. from the University of Colorado. In 2012, Mr. Tsuda was one of two attorneys recognized by *Colorado Super Lawyers* as a Rising Star in the practice of health care law. Mr. Tsuda was also named to the *Denver Business Journal's* 2016 "Forty under 40" list, which honors Denver's up-and-coming business leaders.

CHARLES E. WACHSSTOCK is counsel in the Executive Compensation & Employee Benefits Group of Debevoise & Plimpton LLP. His practice focuses on compensatory and employment arrangements for directors, executives, and employees and includes advising clients on SEC, ERISA, and federal income tax matters as well as compensation and employee benefit matters relating to corporate transactions and the establishment of private equity funds. Prior to joining the firm in 1999, Mr. Wachsstock served in the Office of the Associate Chief Counsel at the Internal Revenue Service, Department of the Treasury, in Washington, D.C. He received a J.D. from Boston University School of Law in 1997, an LL.M. in Taxation from Georgetown University's Law School in 1998, and a B.A., summa cum laude, in International Relations and Human History from Boston University in 1993.

PETER WAND is a partner in the Frankfurt office of Baker & McKenzie and a member of the firm's M&A Practice Group. He focuses his practice on private and public M&A transactions for private equity and corporate clients. Dr. Wand has more than fifteen years of experience in cross-border transactions and longstanding experience in the health care industries. In August 2016, the German business magazine *Wirtschaftswoche* listed him as one of the top thirty M&A lawyers in Germany. In *Chambers Global* (2017), where he is ranked for Corporate/M&A work in both Germany and the U.S., a client noted that he is "a highly adaptive and highly thoughtful legal consultant." *Chambers Europe* (2015) recommends him for his outstanding knowledge of the subject matter and client service. Dr. Wand has published numerous articles relating to corporate law/M&A issues and is a frequent speaker at seminars. He graduated from Ludwig Maximilians University Munich and received his LL.M. from Columbia University School of Law. Dr. Wand worked as a research fellow at the Max Planck Institute of Intellectual Property in Munich.

BRITTANY WILLIAMS was formerly a corporate associate of Debevoise & Plimpton LLP and a member of the firm's Finance Group. She received a J.D. from Howard University School of Law cum laude in 2015, where she served as Senior Notes & Comments Editor of the *Howard Law Journal*. Ms. Williams received a B.B.A. from Baylor University in 2009.

Table of Chapters

PART I STRUCTURING HEALTH CARE M&A TRANSACTIONS

- Chapter 1 Basic Transaction Structures in Health Care M&A
- Chapter 2 Contingent Payments
- Chapter 3 Purchase Price Adjustments
- Chapter 4 License-and-Collaboration Agreements
- Chapter 5 Joint Ventures and Strategic Alliances
- Chapter 6 Transfer of Regulatory Approvals, Licenses, and Clearances
- Chapter 7 Regulatory Issues in Acquisitions of Health Insurers
- Chapter 8 Not-for-Profit Issues
- Chapter 9 Antitrust Considerations
- Chapter 10 Valuation Issues
- Chapter 11 Financing Drug Development
- Chapter 12 Financing of Health Care M&A Transactions
- Chapter 13 Tax Considerations
- Chapter 14 Accounting Considerations

PART II DUE DILIGENCE

- Chapter 15 Introduction to Due Diligence in Health Care M&A Transactions
- Chapter 16 Product Development and Marketing
- Chapter 17 Patent Extensions and Market Exclusivities
- Chapter 18 Manufacturing and Distribution Requirements
- Chapter 19 FDA Investigations and Enforcement

- Chapter 20 Promotion and Advertising
- Chapter 21 Compliance with Import and Export Requirements
- Chapter 22 Miscellaneous Communications with FDA
- Chapter 23 Compliance with DEA Controlled Substance Requirements
- Chapter 24 Compliance with Federal and State Health Care Fraud and Abuse Laws
- Chapter 25 Regulatory Issues in Acquisitions of Health Care Facilities and Physician Practices
- Chapter 26 Compliance with HIPAA and Other Privacy and Security Laws
- Chapter 27 Litigation
- Chapter 28 Intellectual Property
- Chapter 29 Material Contracts
- Chapter 30 Environmental Considerations
- Chapter 31 Employee Benefits
- Chapter 32 Foreign Corrupt Practices Act
- Chapter 33 Real Property

PART III

TRANSACTION DOCUMENTATION

- Chapter 34 Elements of Acquisition Agreements
- Chapter 35 Representations and Warranties
- Chapter 36 Covenants and Deal Protection
- Chapter 37 Closing Conditions
- Chapter 38 Documentation for Indemnification
- Chapter 39 Documentation for License-and-Collaboration Agreements
- Chapter 40 Documentation for Joint Ventures

PART IV
SPECIAL TOPICS

- Chapter 41 Acquisitions of U.S. Companies by Non-U.S. Buyers
- Chapter 42 Health Care M&A Transactions in France
- Chapter 43 Health Care M&A Transactions in Germany
- Chapter 44 Health Care M&A Transactions in Russia
- Chapter 45 Health Care M&A Transactions in England
- Chapter 46 Health Care M&A Transactions in Canada
- Chapter 47 Health Care M&A Transactions in Japan

Table of Contents

About the Editors	vii
About the Contributors	xi
Table of Chapters	xxxiii
Table of Contents	xxxvii
About This Book	cix
Acknowledgments	cxi
Glossary and Abbreviations	cxiii
Current Trends in Health Care M&A	cxlv
Today's Health Care Legal and Regulatory Environment and Its Impact on the Health Care Marketplace	clix

PART I

STRUCTURING HEALTH CARE M&A TRANSACTIONS

Chapter 1 Basic Transaction Structures in Health Care M&A

Andrew L. Bab & Dmitriy A. Tartakovskiy

Acquisition of the Whole Business	1-2
Q 1.1 What is a whole business acquisition?	1-2
Q 1.1.1 What is a stock purchase?	1-3
Q 1.1.2 What is a merger?	1-4
Q 1.1.3 What is a tender offer?	1-5
Q 1.1.4 What is an asset purchase?	1-9
Product and Portfolio Acquisitions	1-10
Q 1.2 What is a product or portfolio acquisition?	1-10
Option Transactions	1-11
Q 1.3 What are typical M&A structures in the pharmaceutical and biotechnology industries?	1-11

Q 1.4	What are the key terms of an option transaction?.....	1-11
Q 1.4.1	What is the purpose of the up-front payment?.....	1-12
Q 1.4.2	What determines the duration of the option?	1-14
Q 1.4.3	How is the option transaction documented?	1-16
Other Structuring Considerations	1-17
Q 1.5	What other factors may affect the structuring decision in health care M&A transactions?	1-17
Q 1.6	When should the transaction be structured as a stock purchase as opposed to an asset purchase?	1-18
Q 1.6.1	What are assumed vs. excluded assets and liabilities?.....	1-18
Q 1.6.2	What are the tax implications of structuring the transaction as a stock or asset deal?.....	1-20
Q 1.6.3	How does the transaction structure affect the need to obtain regulatory approvals and third-party consents?.....	1-23
Q 1.6.4	What are relevant documentary considerations?.....	1-25

Chapter 2 Contingent Payments

Andrew L. Bab

Contingent Value Rights	2-2
Q 2.1	What are contingent value rights?	2-2
Q 2.1.1	What are stock-based CVRs and when are they used?.....	2-2
Q 2.1.2	What are event-driven CVRs?	2-3
Q 2.2	What events can trigger payments under event-driven CVRs?	2-4
Q 2.3	Are event-driven CVRs equity, debt, or something else entirely?	2-5
Q 2.4	When is an event-driven CVR treated as a security and not a contract right?	2-5
Q 2.5	How are CVRs treated from an accounting perspective?.....	2-6
Q 2.6	Must issuers of CVRs exert a certain level of effort to bring about the agreed milestones?.....	2-7
Q 2.6.1	What efforts obligations may courts imply?.....	2-7
Q 2.6.2	What efforts obligations do health care issuers typically include in their CVR agreements?.....	2-8
Q 2.7	What special issues confront private equity sponsors who buy health care companies and who wish to use CVRs?	2-12

Table of Contents

Earnouts Compared to CVRs	2-13
Q 2.8 What is an earnout?	2-13
Q 2.9 What triggers are used in earnouts?	2-13
Q 2.10 Can earnouts pay the buyer rather than the seller, if the target performs poorly?	2-13
Q 2.11 Do earnouts last as long as CVRs?	2-14
Q 2.12 Are earnouts more likely than CVRs to be enforced?	2-14
Q 2.13 What are the income tax consequences of earnouts?	2-15

Chapter 3 Purchase Price Adjustments

*Andrew L. Bab, Dmitriy A. Tartakovskiy &
Jonathan L. Lubin*

Functions of Purchase Price Adjustments	3-2
Q 3.1 What are the functions of a purchase price adjustment?	3-2
Balance Sheet Adjustments	3-4
Q 3.2 What is the most common type of purchase price adjustment used in health care M&A transactions?	3-4
Q 3.3 What is a working capital adjustment?	3-4
Q 3.3.1 How should working capital be defined in the agreement?	3-6
Q 3.3.2 What is the appropriate baseline for a working capital adjustment?	3-9
Q 3.3.3 What accounting principles should be used in calculating the working capital adjustment?	3-11
Q 3.3.4 What are the mechanics of a working capital adjustment?	3-12
Q 3.4 What other types of balance sheet adjustments are used in health care acquisitions?	3-14
Other Types of Purchase Price Adjustments	3-15
Q 3.5 What other types of purchase price adjustments are used in health care M&A transactions?	3-15
Q 3.5.1 What are event-driven purchase price adjustments?	3-16
Q 3.5.2 What are liability-driven purchase price adjustments?	3-17

Purchase Price Adjustments Versus Indemnification	3-18
Q 3.6 What is the difference between a purchase price adjustment and indemnification?	3-18
Q 3.7 What is the interaction between a working capital adjustment and indemnification provisions?	3-19
Dispute Resolution	3-20
Q 3.8 How are disputes about purchase price adjustments typically resolved?	3-20

Chapter 4 License-and-Collaboration Agreements

Kevin A. Rinker & Henry Lebowitz

Scope of the License	4-2
Q 4.1 What are the principal terms of a license grant for a pharmaceutical product?	4-2
Q 4.1.1 Should a license be exclusive or nonexclusive?.....	4-3
Q 4.1.2 Should the license cover one or more fields of use or should the field of use be unlimited?.....	4-3
Q 4.1.3 Should the license cover one or more jurisdictions or be worldwide?.....	4-4
Payments	4-5
Q 4.2 What are the typical economic arrangements in a license?	4-5
Q 4.2.1 What are up-front payments?	4-5
Q 4.2.2 What are milestone payments?	4-5
Q 4.2.3 What are royalties?	4-6
Q 4.3 Are there other types of payments?.....	4-7
Assigning the Responsibilities of the Parties	4-8
Q 4.4 Which party is typically responsible for development of the product?.....	4-8
Q 4.5 Which party is typically responsible for filing and maintaining New Drug Applications and conducting related studies?.....	4-8
Q 4.6 Which party is responsible for prosecution of trademarks and patents?.....	4-9
Q 4.7 When should the parties consider a co-promotion arrangement?	4-9
Q 4.8 Should the licensee seek a right of first negotiation, first offer, or first refusal?	4-10

Table of Contents

Q 4.9 Should the license-and-collaboration agreement include a noncompetition covenant?4-10

Q 4.10 Which party is typically responsible for manufacturing?4-11

 Q 4.10.1 Should the licensee have manufacturing transfer assistance from the licensor?4-11

Q 4.11 Under what circumstances may each party terminate the agreement?4-12

Chapter 5 Joint Ventures and Strategic Alliances

Sarah A.W. Fitts

Objectives5-2

Q 5.1 Why create a joint venture or strategic alliance in the health care industry?5-2

 Q 5.1.1 Is capital the only reason to consider a joint venture or strategic alliance?5-3

Q 5.2 What additional motivations might health care service providers have for creating joint ventures and strategic alliances?5-5

Q 5.3 What additional motivations might pharmaceutical and biotechnology companies have for creating joint ventures and strategic alliances?5-6

Health Care Providers5-7

Q 5.4 What are common strategic alliances involving health care service providers?5-7

Q 5.5 When might a joint venture be appropriate for a hospital or other health care service provider?5-9

Q 5.6 What else should health care providers keep in mind in determining whether to form a joint venture?5-11

Pharmaceutical and Biotech Companies5-12

Q 5.7 What are common joint ventures and strategic alliances involving pharmaceutical and biotechnology companies?5-12

Q 5.8 What factors influence the structure of the pharmaceutical or biotechnology joint venture or strategic alliance?5-14

 Q 5.8.1 What concerns may influence the allocation of control in pharmaceutical and biotechnology joint ventures and strategic alliances?5-15

Q 5.9 How should the parties deal with the possibility of termination of the joint venture?5-17

Examples	5-18
Q 5.10 What are some recent examples of joint ventures in health care services?	5-18
Q 5.11 What are some recent examples of strategic alliances in health care services?	5-20
Q 5.12 What are some recent examples of joint ventures in pharmaceuticals and biotechnology?.....	5-22
Q 5.13 What are some recent examples of strategic alliances in pharmaceuticals and biotechnology?.....	5-24

Chapter 6 Transfer of Regulatory Approvals, Licenses, and Clearances

Carey B. Nuttall

Drugs and Biologics	6-2
Q 6.1 Is it possible to transfer ownership of a New Drug Application or Abbreviated New Drug Application?.....	6-2
Q 6.2 Is it possible to transfer ownership of a Biologics License Application?.....	6-3
Devices	6-4
Q 6.3 Is it possible to transfer ownership of a Premarket Approval?	6-4
Q 6.4 Is it possible to transfer ownership of a 510(k)?.....	6-5

Chapter 7 Regulatory Issues in Acquisitions of Health Insurers

Nicholas F. Potter & Sean P. Neenan

General Considerations	7-2
Q 7.1 When does a change of control occur?	7-2
Q 7.2 What are the basic regulatory approvals required in order to effect the acquisition of control of a health insurer?.....	7-2
Q 7.3 If the health insurer is a health maintenance organization, are any additional regulatory approvals required?	7-3
Q 7.4 As a practical matter, what is the best way to manage and coordinate all the jurisdictions where filings are required?	7-4

Table of Contents

Form A	7-5
Q 7.5 What information is required to complete the Form A change-of-control filing?	7-5
Q 7.6 Is information submitted with a Form A confidential?	7-6
Q 7.7 In addition to the insurer's domiciliary regulator, do any other states' insurance regulators have to approve a change of control?	7-7
Form E	7-8
Q 7.8 When is a Form E required?	7-8
Approval Process	7-9
Q 7.9 Once the filings are made, how long will it take to receive an approval?.....	7-9
Additional Approvals and Filings	7-9
Q 7.10 What if the insurer being acquired is a third-party administrator or utilization review agency?	7-9
Q 7.11 If the health insurer being acquired has entered into Medicare or Medicaid contracts, will additional approvals be required?	7-10
Q 7.12 Do federal premerger notification rules apply?.....	7-10
Q 7.13 Are there additional filings that may be required?	7-10
Chapter 8 Not-for-Profit Issues	
<i>Michael Bolotin & Lena E. Smith</i>	
Public Interest	8-2
Q 8.1 What are the key differences between not-for-profit and for-profit organizations that can affect acquisitions and joint ventures?.....	8-2
Federal Tax-Exempt Status	8-3
Q 8.2 What are the benefits of tax-exempt status?.....	8-3
Q 8.2.1 If an organization has tax-exempt status, is all of its income exempt from federal tax?.....	8-4
Q 8.3 What are the requirements for tax-exempt status?.....	8-4

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 8.4	What makes a health care provider’s activities “charitable” within the meaning of section 501(c)(3)?.....	8-5
Q 8.4.1	Are additional requirements imposed by the health care reform law?.....	8-6
Q 8.5	Can a health insurance provider be tax-exempt?.....	8-9
Q 8.6	Can an HMO be tax-exempt?.....	8-11
Q 8.7	Can a tax-exempt, not-for-profit health care provider engage in transactions involving for-profit investors without jeopardizing its exempt status or incurring federal or state sanctions?.....	8-11
Joint Ventures		8-12
Q 8.8	Why are joint ventures between nonprofit and for-profit entities useful in the health care industry?.....	8-12
Q 8.9	For the nonprofit to maintain its tax-exempt status, how must the joint venture be structured?.....	8-13
Q 8.9.1	What sort of control of the joint venture must the nonprofit maintain?.....	8-13
Q 8.9.2	What other factors are relevant?.....	8-14
State Law Requirements for Asset Sales		8-15
Q 8.10	What are typical state law requirements for approving a sale of assets by a nonprofit health care organization?.....	8-15
Q 8.10.1	What are the California requirements?.....	8-15
Q 8.10.2	What are the Massachusetts requirements?.....	8-17
Q 8.10.3	What are the New York requirements?.....	8-18
State Approval of For-Profit’s Acquisition of Not-for-Profit Facilities		8-20
Q 8.11	What special conditions can a state impose before granting approval of the acquisition of a nonprofit health care provider’s facilities?.....	8-20
Excess-Benefits Transactions		8-23
Q 8.12	What sanctions can the Internal Revenue Service impose on individuals who receive “excess” benefits in a deal between a nonprofit and a for-profit entity?.....	8-23
Q 8.13	How does a charitable organization establish the rebuttable presumption that a transaction is not an excess-benefit transaction?.....	8-24
Q 8.13.1	What is approval by an authorized body?.....	8-25
Q 8.13.2	What is reliance on comparable data?.....	8-26
Q 8.13.3	What is the proper-documentation requirement?.....	8-27

Chapter 9 Antitrust Considerations

Daniel M. Abuhoff & Terriane M. Patnode

Premerger Notification	9-2
Q 9.1 What is the Hart-Scott-Rodino Act?	9-2
Q 9.2 What types of transactions are covered by the HSR Act?.....	9-2
Q 9.2.1 Are licensing transactions covered by the HSR Act?.....	9-3
Q 9.3 What information is required in the HSR filing?	9-4
Q 9.4 What happens after the HSR filing?.....	9-5
Q 9.5 What additional information is typically sought by the Assigned Agency during the initial waiting period?	9-5
Q 9.6 What happens after the initial waiting period?	9-5
Q 9.6.1 What information is sought by the formal request for additional information (or second request)?	9-6
Q 9.6.2 Once a second request has been issued, is there any possibility of the Agencies granting clearance without substantial compliance?	9-6
Q 9.6.3 How burdensome is compliance with a second request?	9-7
Q 9.7 Once the parties submit the information called for by the second request, how does the Assigned Agency proceed?	9-7
Merger Analysis	9-8
Q 9.8 What is merger analysis?.....	9-8
Q 9.9 What types of transactions are subject to merger analysis?	9-8
Q 9.10 How is the relevant product market defined?	9-9
Q 9.10.1 How is the relevant product market defined for hospital mergers?	9-9
Q 9.10.2 How is the relevant product market defined for pharmaceutical mergers?.....	9-11
Q 9.10.3 How is the relevant product market defined for licensing arrangements?.....	9-13
Q 9.11 How is the relevant geographic market determined?.....	9-16
Q 9.11.1 How is the relevant geographic market determined for hospital mergers?.....	9-16
Q 9.11.2 How is the relevant geographic market determined for pharmaceutical mergers?.....	9-19
Q 9.12 What market conditions are considered in assessing market power?	9-20
Q 9.12.1 How might a merger impair competition in the relevant market?.....	9-21
Q 9.12.2 What types of procompetitive effects might outweigh any potential impairment of competition?	9-22

Q 9.13	What other “defenses” might be argued in the face of a post-merger market with competitive impairment?	9-25
Q 9.13.1	What is the “failing firm” defense?	9-25
Q 9.13.2	What is the “ease of entry” defense?	9-27
Protections for Certain Health Care Mergers		9-28
Q 9.14	Does the nonprofit status of a hospital affect the analysis of a merger involving the hospital?	9-28
Q 9.15	What transactions are protected under the state action immunity doctrine?	9-31
Q 9.16	What guidance is available from the antitrust authorities on health care merger analysis?	9-33
Antitrust Considerations Applicable to Patent Pools		9-34
Q 9.17	What are patent pools?	9-34
Q 9.18	What is the Agencies’ approach to reviewing patent pools?	9-34
Q 9.19	What guidance is available from the Agencies on the treatment of patent pools?	9-36

Chapter 10 Valuation Issues

G. Christopher Louis

The Appraisal Process		10-3
Q 10.1	What is an appraisal?	10-3
Q 10.2	Are appraisers and the appraisal process subject to professional standards?	10-3
Q 10.2.1	How do regulatory requirements in the health care industry relate to appraisal standards?	10-3
Q 10.2.2	What is the scope-of-work rule?	10-4
Q 10.2.3	What are the different types of valuation reports?	10-4
Q 10.3	When is a valuation necessary?	10-5
Q 10.4	What is the appropriate standard of value in a given case?	10-6
Q 10.4.1	What is the typical standard of value used in health care transactions?	10-7
Q 10.4.2	What is the typical standard of value used in the pharmaceutical and biotech industry?	10-8
Q 10.5	What are the primary approaches to value?	10-8

Table of Contents

Cost Approach	10-9
Q 10.6 What is the cost approach?	10-9
Q 10.7 When is the cost approach most appropriate?	10-9
Q 10.8 What are the strengths and weaknesses of the cost approach/asset-based approach?	10-10
Q 10.9 How are intangible assets identified and categorized?	10-10
Q 10.9.1 What are market-related intangible assets?.....	10-11
Q 10.9.2 What are consumer-related intangible assets?.....	10-11
Q 10.9.3 What are contract-based intangible assets?.....	10-12
Q 10.9.4 What are technology-based intangible assets?	10-12
Market Approach	10-12
Q 10.10 What is the market approach?.....	10-12
Q 10.10.1 What is the guideline publicly traded company method?.....	10-13
Q 10.10.2 What is the guideline merged and acquired company method?.....	10-14
Q 10.10.3 What is the direct sales comparison method?	10-15
Q 10.11 When is the market approach most appropriate?	10-15
Income Approach	10-17
Q 10.12 What is the income approach?	10-17
Q 10.13 What is the discounted cash flow analysis?	10-18
Q 10.13.1 What are the main components of a DCF analysis?	10-18
Q 10.13.2 How are revenues estimated?.....	10-19
Q 10.13.3 How are expenses determined?.....	10-19
Q 10.13.4 What is the economic measure generated from the DCF?.....	10-19
Q 10.13.5 What is the reversion?.....	10-20
Q 10.13.6 What are the special considerations in applying the DCF analysis in health care transactions?	10-21
Q 10.14 What are the decision tree method and real options analysis?	10-21
Reconciliation	10-22
Q 10.15 What is the reconciliation?	10-22
Other Functions for Valuation Opinions	10-23
Q 10.16 What is the role of valuation in complying with acquisition accounting rules?	10-23

Q 10.17	How can a valuation be used to facilitate compliance with fraud and abuse laws?	10-24
Q 10.18	How can a valuation opinion be used to ensure compliance with the IRS regulations relating to “excess-benefit transactions”?	10-25

Chapter 11 Financing Drug Development

Robert Masella & Ilir Mujalovic

Background	11-3	
Q 11.1	How have companies addressed recent developments in the biopharmaceutical industry?	11-3
Financing from Seed Capital to Initial Public Offering	11-4	
Q 11.2	How has the industry financed drug development historically?.....	11-4
Q 11.3	What is the current role of angel investors?	11-4
Q 11.4	What is the current role of venture capital?	11-5
Q 11.5	What is the current role of initial public offerings?	11-5
Post-IPO Financing for Public Biotech Companies	11-6	
Q 11.6	What financing needs exist after the initial public offering?.....	11-6
Q 11.6.1	What is a follow-on offering?.....	11-7
Q 11.6.2	What is a registered direct offering?.....	11-7
Q 11.6.3	What are private investments in public equity?	11-8
Q 11.6.4	What are at-the-market offerings?.....	11-8
Q 11.6.5	What are committed equity financing facilities?	11-8
Q 11.6.6	What other forms of equity financings are used to raise capital?	11-9
Licensing and Other Collaborations Between Pharmaceutical and Biotech Companies	11-9	
Q 11.7	Why is licensing becoming more attractive to big pharma?	11-9
Q 11.8	What can big pharma and biotech companies each contribute in a collaboration?	11-10
Q 11.9	At what stage of drug development does a collaboration take place?.....	11-10
Q 11.10	What terms can be expected in a licensing transaction?.....	11-10
Q 11.11	When are contingent value rights used?	11-11

Table of Contents

More Financing Alternatives	11-11
Q 11.12 What are some alternatives to dilutive equity financing of drug development?	11-11
Q 11.12.1 What is venture lending?.....	11-12
Q 11.12.2 What are royalty-based financings?.....	11-12
Q 11.12.3 What are financings linked to clinical research organizations?.....	11-12
Q 11.12.4 What are structured drug development financings?	11-13

Chapter 12 Financing of Health Care M&A Transactions

Jeffrey E. Ross, Daniel E. Stroik & Brittany Williams

Acquisition Financing Generally	12-2
Q 12.1 What are the different types of acquisition financing?.....	12-2
Q 12.1.1 What is cash-flow financing and how is it used in acquisition financing?.....	12-3
Q 12.1.2 What is asset-based financing and how is it used in acquisition financing?	12-4
Acquisition Financing in the Health Care Industry	12-5
Q 12.2 What are typical financing concerns when financing the acquisition of a target in the health care industry?.....	12-5
Q 12.3 Why is the “corporate practice of medicine” doctrine relevant to acquisition financing?	12-6
Q 12.4 How does HIPAA affect the due diligence process, inspection rights, enforcement rights, and control mechanisms of a lender?.....	12-7
Q 12.4.1 Is it possible to avoid having HIPAA apply to a financing?	12-9
Q 12.5 What are typical asset-based financing issues in the health care industry?	12-9
Q 12.5.1 What is a borrowing base?	12-9
Q 12.5.2 What is the typical payor mix in the borrowing base of a borrower in the health care industry?.....	12-10
Q 12.5.3 What are Medicare and Medicaid?.....	12-11
Q 12.5.4 How does the payor mix affect collectability of accounts receivable and, in turn, the borrowing base?	12-11

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 12.5.5	Why do gross and net health care receivable amounts differ substantially?	12-13
Q 12.5.6	What protections are built into the borrowing base against deterioration of the health care business?.....	12-14
Q 12.5.7	What issues are associated with lending against inventory in the health care industry?.....	12-15
Q 12.6	How predictable is the cash flow of a health care business and how is it relevant for financing?.....	12-15
Q 12.6.1	What are setoff rights?.....	12-16
Q 12.6.2	What is the true-up process?.....	12-17
Q 12.7	How does a lender perfect a security interest in government receivables such as Medicare and Medicaid receivables?.....	12-18
Q 12.7.1	What is Article 9 of the Uniform Commercial Code?	12-18
Q 12.7.2	How does Article 9 apply to government receivables?.....	12-18
Q 12.7.3	What are Medicare and Medicaid anti-assignment laws?.....	12-19
Q 12.7.4	How do anti-assignment laws affect acquisition financing in the health care industry?.....	12-20
Q 12.7.5	What is a double lockbox structure?.....	12-22
Q 12.7.6	Does the double lockbox structure provide complete control to the lender?	12-22
Q 12.8	What other enforcement risks do lenders face?	12-23

Chapter 13 Tax Considerations

Gary M. Friedman

Tax Reform	13-2	
Q 13.1	What are the key provisions of the recent tax reform that will affect the pharma industry?	13-2
Q 13.2	How does TCJA affect the U.S. federal income tax rate?.....	13-2
Q 13.3	How does TCJA affect U.S. pharma companies with undistributed offshore earnings as of December 31, 2017?.....	13-2
Q 13.4	How does TCJA affect the U.S. regime governing the deferral of foreign income?	13-3
Q 13.5	How does TCJA affect U.S. pharma companies that make deductible payments to foreign affiliates?	13-4

Table of Contents

Tax Consequences of Acquiring Publicly Traded Target Shares for Cash and CVRs	13-6
<i>Open Transactions</i>	13-6
Q 13.6 What is the open transaction doctrine?.....	13-6
Q 13.7 Is open transaction reporting available in connection with the issuance of CVRs in a corporate acquisition?.....	13-6
Q 13.8 What is the tax treatment of shareholders who receive CVRs in an open transaction?.....	13-7
Q 13.9 Is the open transaction doctrine always favorable to the taxpayer?	13-7
<i>Closed Transactions</i>	13-8
Q 13.10 What is the closed transaction doctrine?	13-8
Q 13.11 What is the tax treatment of shareholders who receive CVRs in a closed transaction?	13-8
Q 13.12 Can the installment sale method of reporting be used in connection with the receipt of a CVR?	13-9
<i>Other Issues</i>	13-10
Q 13.13 What special tax issues may arise when CVRs are issued to non-U.S. persons?	13-10
Q 13.14 Can a CVR that only pays in shares of the issuer be received free of tax in a corporate reorganization?	13-10

Chapter 14 Accounting Considerations

*W. Gregg Slager, John M. (Chip) Clark III,
John L. Babitt & Peter Hornecker*

EBITDA	14-3
Q 14.1 What is EBITDA and how does it impact valuation?.....	14-3
Q 14.1.1 What are common derivatives of EBITDA?	14-4
Q 14.1.2 What is Management EBITDA?	14-6
Q 14.2 What considerations are unique to the health care industry and result in financial statement risk?.....	14-6
Revenue Recognition	14-8
Q 14.3 What are the primary considerations with respect to proper revenue recognition?	14-8

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 14.4	What are the gross-to-net revenue reconciling items impacting revenue recognition in health care services companies?.....	14-11
Q 14.5	What are the gross-to-net-revenue adjustments impacting revenue recognition in life sciences companies?.....	14-12
Q 14.5.1	How are product returns handled?.....	14-13
Q 14.5.2	How are chargebacks handled?.....	14-13
Q 14.6	What is the potential impact of the new revenue recognition standard on life sciences transactions?	14-14
Q 14.6.1	What is the potential impact on collaboration arrangements?	14-15
Q 14.6.2	What is the potential impact on estimating variable consideration?	14-16
Q 14.6.3	What is the potential impact on reseller and distributor arrangements?	14-17
Q 14.6.4	What is the potential impact on licenses of intellectual property?	14-18
Q 14.7	What are the general revenue recognition considerations related to research and development arrangements between life sciences entities?	14-19
Q 14.8	How can one determine the substance of a R&D arrangement?	14-21
Q 14.9	What are the accounting considerations for R&D arrangements from the point of view of the entities involved?	14-24
Q 14.10	How are collaborations or arrangements to perform R&D services that are not financing arrangements accounted for?	14-27
Q 14.11	How should up-front fees be recognized for R&D activity?	14-29
Q 14.12	What are multiple-element contracts?.....	14-30
Q 14.13	What are important revenue recognition issues related to intellectual property licensing?	14-31
Balance Sheet Considerations		14-32
Q 14.14	What balance sheet considerations are particularly important during due diligence?	14-32
Q 14.15	What is unique about patient receivables in a health care services setting?	14-32
Q 14.16	What are third-party settlements?	14-33
Q 14.17	What are medical claims liabilities?.....	14-33

Table of Contents

Q 14.18	What risks arise in analyzing medical malpractice, workers' compensation, and other self-insured claims?	14-34
Q 14.19	What are key considerations with respect to product warranties with life sciences companies?	14-35
Q 14.20	How should research and development costs be treated in target financial statements?	14-36
Q 14.21	What other liabilities should be considered in conducting due diligence of health care entities?	14-37
Q 14.22	What are restructuring reserves and expenses?	14-38
Commitments and Contingencies		14-39
Q 14.23	What are commitments and contingencies?	14-39
Q 14.23.1	How are commitments and contingencies quantified?	14-39
Q 14.24	What types of commitments and contingencies are common in health care services entities?	14-40
Q 14.24.1	What risks relate to managed care agreements with employers or subcontract agreements with payors?	14-41
Q 14.24.2	What risks relate to physician guarantees?	14-41
Change in Control		14-41
Q 14.25	What change-in-control considerations are there with respect to share-based compensation?	14-41
Q 14.26	What change-in-control considerations are there with respect to employment contracts?	14-43
Q 14.27	What change-in-control considerations are raised by debt and financing agreements?	14-43
Q 14.28	What change-in-control considerations are specific to joint ventures and alliances?	14-43
Q 14.29	What change-in-control considerations are raised by licenses and service contracts?	14-44
Risk-Based Capital		14-44
Q 14.30	What is risk-based capital?	14-44
Q 14.31	What is statutory net worth?	14-44
Q 14.32	How does SAP accounting impact statutory net worth?	14-45
Q 14.33	What calculations are typically used to assess the adequacy of an insurer's statutory net worth?	14-45
Q 14.33.1	What measure do most advisors use to assess an insurer's statutory net worth?	14-46

Q 14.34	How are the insurer's RBC ratio and authorized control level calculated?	14-46
Q 14.35	Why are RBC and statutory net worth relevant in health care M&A?	14-47
Financial Statements Needed to Finance and Complete an Acquisition.....		14-47
Q 14.36	What are the SEC reporting requirements for public companies in connection with acquisitions?.....	14-47
Q 14.37	What tests are used to determine whether an acquisition is considered to be a significant subsidiary?.....	14-49
Q 14.38	What are the timing requirements for filing?	14-50
Q 14.39	What are the requirements with respect to foreign acquisitions?	14-51
Q 14.40	What is pro forma financial information as required by the SEC?.....	14-52
Q 14.41	For what period is pro forma financial information required?	14-52
Q 14.42	What are pro forma adjustments?.....	14-53
Q 14.42.1	When are pro forma adjustments factually supportable?	14-55
Q 14.42.2	How are purchase price allocations handled?	14-56
Q 14.42.3	What new arrangements should be presented as pro forma adjustments?	14-58
Q 14.42.4	What adjustments are inappropriate in pro forma financial statements?	14-58
Q 14.43	What financial statements do banks require in connection with an acquisition?	14-59
Other Bank Requirements.....		14-59
Q 14.44	What should I consider in negotiating bank covenants?	14-59
Q 14.45	What are reasonable financial reporting requirements?.....	14-61
Q 14.46	What is minimum working capital?.....	14-61
Acquisition Method.....		14-62
Q 14.47	Under what circumstances does the acquisition method of accounting apply?.....	14-62
Q 14.48	How does the acquirer determine whether or not a transaction is considered a business combination?.....	14-63
Q 14.49	What are the accounting considerations in assessing the valuation of the balance sheet?	14-64
Q 14.50	What is pushdown accounting?.....	14-65

Table of Contents

Q 14.51	When can pushdown accounting be applied?	14-65
Q 14.52	What are the most important measurement and recognition concepts and what are the exceptions?	14-66
Q 14.53	How does the acquisition method of accounting impact inventory?	14-67
Q 14.54	What are considerations in a business combination when an acquirer has a preexisting relationship with the target?	14-68
Q 14.55	How does the acquisition method of accounting impact leases?	14-68
Q 14.56	How does the acquisition method of accounting impact research and development assets?	14-69
Q 14.57	What is the subsequent accounting for IPR&D acquired in a business combination?	14-69
Q 14.58	What should an acquirer consider in evaluating a target company's deferred revenue?	14-70
Earnouts	14-71
Q 14.59	When are earnouts used in acquisitions and what are the accounting implications?	14-71

PART II DUE DILIGENCE

Chapter 15 Introduction to Due Diligence in Health Care M&A Transactions

*Andrew L. Bab, Dmitriy A. Tartakovskiy &
Jonathan L. Lubin*

Due Diligence Generally	15-3
Q 15.1	Why is due diligence important?	15-3
Q 15.2	When is due diligence conducted?	15-4
Due Diligence in Health Care Deals	15-5
Q 15.3	What is the proper scope of health care M&A due diligence?	15-5
Q 15.4	What are the key areas of health care M&A due diligence?	15-7
Q 15.5	Who are the key parties and how are due diligence responsibilities typically allocated?	15-7

Chapter 16 Product Development and Marketing

Paul D. Rubin, Melissa B. Runsten & Carey B. Nuttall

Definitions	16-2
Q 16.1 What is a “drug” under the Federal Food, Drug, and Cosmetic Act?	16-2
Q 16.2 What is a “new drug”?	16-3
Q 16.3 What is a “biologic”?	16-3
Q 16.4 What is a “medical device”?	16-4
Q 16.4.1 Is software considered a medical device?	16-4
Q 16.5 What categories of medical devices are regulated by FDA?	16-6
Q 16.5.1 What is a Class I medical device?	16-9
Q 16.5.2 What is a Class II medical device?	16-10
Q 16.5.3 What is a Class III medical device?	16-10
Preclinical Testing	16-10
Q 16.6 What is preclinical testing and why is it conducted?	16-10
Q 16.7 What types of preclinical tests must be completed before engaging in clinical testing in humans?	16-11
Q 16.8 What are good laboratory practices for preclinical testing?	16-12
Clinical Studies: The IND and IDE Processes	16-13
Q 16.9 What are clinical studies?	16-13
Q 16.10 What are the clinical trial registry requirements?	16-14
Q 16.11 What is the Investigational New Drug process?	16-15
Q 16.11.1 What is a “sponsor” of an IND?	16-16
Q 16.11.2 What are an IND sponsor’s responsibilities?	16-16
Q 16.12 What is an Investigational Device Exemption?	16-18
Q 16.13 What device studies do not require an IDE?	16-19
Q 16.14 What device studies require an IDE?	16-19
Q 16.14.1 What is the procedure for investigational devices that present nonsignificant risks?	16-20
Q 16.14.2 What is the procedure for investigational devices that present significant risks?	16-20
Q 16.15 What phases of clinical studies are conducted during the IND process?	16-21
Q 16.16 What is an institutional review board (IRB)?	16-22

Table of Contents

Clinical Studies: Good Clinical Practice Requirements	16-23
Q 16.17 What are FDA's good clinical practice (GCP) requirements?.....	16-23
Q 16.18 What are the requirements for obtaining informed consent from study subjects?.....	16-25
Q 16.18.1 What information must be provided to subjects?	16-25
Q 16.18.2 Are there exceptions to the informed consent requirements?.....	16-26
Q 16.19 What financial disclosures must be made by clinical investigators?.....	16-28
Q 16.19.1 What must be included in FDA Form 3455?	16-28
Q 16.19.2 What must be included in FDA Form 3454?	16-29
Q 16.19.3 What can FDA do if it has concerns about an investigator's financial bias?.....	16-29
Other FDA Powers	16-30
Q 16.20 With regard to clinical studies, what inspection rights does FDA have?.....	16-30
Q 16.21 What is an FDA clinical hold?	16-30
Applications to FDA	16-31
Q 16.22 What is a New Drug Application?	16-31
Q 16.23 What is an Abbreviated New Drug Application?	16-31
Q 16.24 What is a 505(b)(2) NDA?	16-32
Q 16.25 What is a biologics license application (BLA)?	16-33
Q 16.26 Is there an approval process for generic or "follow-on" biologics?.....	16-34
Q 16.27 What is a device premarket approval application?.....	16-34
Q 16.28 What is a device 510(k) clearance?	16-35
Q 16.28.1 What is an abbreviated 510(k)?	16-35
Q 16.28.2 What is a special 510(k)?.....	16-36
Q 16.29 Can any medical devices be marketed without prior FDA review or approval?.....	16-37
Application Fees	16-37
Q 16.30 What diligence is needed regarding payment of application fees to FDA?.....	16-37
Q 16.31 What are drug user fee laws?	16-38
Q 16.31.1 Can companies obtain a waiver of PDUFA user fees?	16-39
Q 16.31.2 Can "small" companies obtain a waiver of PDUFA user fees?.....	16-39

Q 16.32	What is the Medical Device User Fee and Modernization Act?	16-40
Q 16.32.1	Can companies obtain a waiver of MDUFMA user fees?.....	16-41
Assessing the Target’s Regulatory Basis for Marketing Regulated Products		16-41
Q 16.33	What are basic diligence issues regarding the target’s marketing of drug, biologic, and medical device products?.....	16-41
Q 16.34	What is FDA’s over-the-counter drug review process?	16-43
Q 16.35	What if the target produces homeopathic drugs?	16-45
Q 16.36	What issues are raised by unapproved drugs?	16-47
Q 16.37	What issues are raised by 510(k) clearances?	16-49
Q 16.38	What issues are raised by medical devices marketed without prior FDA review or approval?	16-50
Q 16.39	What issues are raised by modifications to a drug, device, or biologic that has been approved or cleared by FDA?.....	16-51
Q 16.40	What issues are raised by promotion of drugs limited to certain indications?.....	16-52
Q 16.41	What issues are raised by drug approval limited to specific patient populations?.....	16-52
Q 16.42	What other limitations may be placed on a product by the terms of its approval or clearance?.....	16-53
Postapproval Requirements		16-54
Q 16.43	What are postapproval requirements for approved or cleared products?.....	16-54
Q 16.44	What types of postapproval requirements can FDA impose on drug products?	16-54
Q 16.44.1	What NDA and ANDA supplements may be required?	16-55
Q 16.44.2	What annual reports may be required?.....	16-56
Q 16.44.3	What postmarket studies may be required?.....	16-56
Q 16.45	What types of postapproval requirements can FDA impose on medical devices?	16-57
Q 16.45.1	What PMA supplements may be required?.....	16-57
Q 16.45.2	What annual reports may be required?.....	16-58
Q 16.45.3	What postmarket studies may be required?.....	16-58
Q 16.45.4	What general postapproval requirements may be imposed?	16-59

Chapter 17 Patent Extensions and Market Exclusivities

Paul D. Rubin, Melissa B. Runsten & Carey B. Nuttall

Summary of Incentives	17-2
Q 17.1 What are the chief ways in which the law creates incentives for drug development and competition?.....	17-2
Extensions of Patent Term	17-5
Q 17.2 What are the available statutory patent term extensions?.....	17-5
Exclusivities	17-6
Q 17.3 What is five-year “new chemical entity” exclusivity under the Hatch-Waxman Act?.....	17-6
Q 17.4 What is three-year exclusivity under the Hatch-Waxman Act?.....	17-6
Q 17.5 What is seven-year orphan drug exclusivity?.....	17-7
Q 17.6 What is six-month pediatric exclusivity?	17-7
Q 17.7 What is five-year Qualified Infectious Disease Product (QIDP) exclusivity?.....	17-8
Q 17.8 What is innovator product exclusivity for biologic products?.....	17-9
Q 17.9 What are 180-day generic drug exclusivity, follow-on biologic exclusivity, and the thirty-month stay of generic drug approval?.....	17-9

Chapter 18 Manufacturing and Distribution Requirements

Paul D. Rubin, Adriana D. Kohler & Anne D. Spiggle

Good Manufacturing Practices	18-2
Q 18.1 What are FDA’s good manufacturing practice requirements for drugs?	18-2
Q 18.2 What are FDA’s quality system regulations?	18-3
Q 18.3 Can FDA inspect the premises of drug, biologic, and device manufacturers?.....	18-3
Q 18.4 What due diligence is appropriate regarding current good manufacturing practices?.....	18-4
Standard Operating Procedures	18-5
Q 18.5 What are “standard operating procedures” for drug, device, and biologic operations?.....	18-5

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 18.6	What types of operations should be supported by written SOPs?	18-5
Q 18.7	What are the benefits of maintaining standard operating procedures?.....	18-6
Q 18.8	What due diligence should be conducted regarding the target’s standard operating procedures?	18-6
Systems for Handling Reports of Failures or Malfunctions		18-7
Q 18.9	What systems should a company have for responding to product failures or malfunctions?	18-7
Q 18.10	What are “corrective and preventive action” requirements generally?	18-7
Q 18.11	What are the CAPA requirements for medical devices?	18-8
Q 18.12	What are the CAPA requirements for drugs and biologics?.....	18-9
Q 18.13	What due diligence should be conducted regarding the target’s CAPA systems?.....	18-9
Contract Manufacturers		18-11
Q 18.14	What role do contract manufacturers play in the industry?	18-11
Q 18.15	What are the respective responsibilities of contract manufacturers and entities holding FDA approvals or clearances?.....	18-11
Q 18.16	What due diligence should be conducted regarding the target’s use of contract manufacturers?.....	18-12
Establishment Registration, Product Listing, and Requirements for Bulk Active Pharmaceutical Ingredients		18-12
Q 18.17	What are FDA registration requirements for drug and device establishments?	18-12
Q 18.18	What due diligence should be conducted regarding registration issues?	18-13
Q 18.19	What are FDA listing requirements for drugs and devices?.....	18-14
Q 18.20	What due diligence should be conducted regarding listing issues?	18-14
Q 18.21	What are the requirements for bulk active pharmaceutical ingredients?.....	18-15
Q 18.22	What due diligence should be conducted regarding bulk active pharmaceutical ingredients?	18-15

Table of Contents

Distribution of Prescription Drugs	18-16
Q 18.23 What is the closed drug distribution system?.....	18-16
Q 18.24 What is the Prescription Drug Marketing Act?.....	18-16
Q 18.25 What are licensed drug distributors?.....	18-16
State Licensing Requirements	18-17
Q 18.26 Do the states require licenses to manufacture, repackage, or distribute drugs, biologics, or medical devices?.....	18-17
Q 18.27 What due diligence should be conducted regarding the target's state law licensing?.....	18-17

Chapter 19 FDA Investigations and Enforcement

*Paul D. Rubin, Anne D. Spiggle &
Alexandra S. Marzelli*

Inspections	19-2
Q 19.1 What is an FDA inspection?.....	19-2
Q 19.2 What is FDA Form 483?.....	19-2
Q 19.2.1 Must a company respond to a Form 483?.....	19-3
Q 19.2.2 What is the significance of Form 483 for due diligence?.....	19-3
Q 19.3 How does FDA classify inspection results?.....	19-4
Q 19.4 What is an establishment inspection report?.....	19-4
Q 19.5 Where can official information about past inspections be found?.....	19-5
Q 19.6 What other inspection-related communications with FDA are relevant to due diligence?.....	19-5
Enforcement Mechanisms	19-6
Q 19.7 What is FDA's general enforcement authority?.....	19-6
Q 19.8 What is a warning letter?.....	19-6
Q 19.9 What is an untitled letter?.....	19-7
Q 19.10 What is a seizure?.....	19-8
Q 19.11 What is an injunction?.....	19-8
Q 19.12 What is an FDA consent decree?.....	19-9
Q 19.13 What criminal penalties are available under the FFDCA?.....	19-9
Q 19.14 What civil monetary penalties are available under the FFDCA?.....	19-10

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 19.15	What are disqualification and debarment?	19-10
Q 19.16	What are due diligence considerations regarding corrective actions in response to FDA enforcement?.....	19-11
Product Recalls and Market Withdrawals		19-11
Q 19.17	What are product recalls?	19-11
Q 19.18	How does FDA classify recalls?	19-11
Q 19.19	What are “voluntary” recalls?.....	19-12
Q 19.19.1	What are FDA-requested recalls?	19-13
Q 19.19.2	What information must be provided to FDA if a company initiates a recall?	19-13
Q 19.20	When can FDA recall medical devices?	19-14
Q 19.21	When can FDA recall biological products?	19-15
Q 19.22	What is a market withdrawal?	19-15
Q 19.23	What is a stock recovery?	19-15
Reporting Adverse Events		19-15
Q 19.24	What is an adverse drug event?	19-15
Q 19.25	How does a company find out about adverse events involving its drugs?	19-16
Q 19.26	What is an adverse event report?	19-16
Q 19.27	Is adverse event reporting required for nonprescription, over-the-counter drugs?	19-17
Q 19.28	Is adverse event reporting required for medical devices?.....	19-18
Q 19.28.1	What MDR event reports must be made by user facilities?.....	19-18
Q 19.28.2	What MDR event reports must be made by manufacturers?.....	19-18
Q 19.29	What systems should a company have for responding to and reporting adverse drug events?	19-19
Q 19.30	What systems should a company have for responding to and reporting adverse medical device events?	19-20

Chapter 20 Promotion and Advertising

Carey B. Nuttall

General Principles		20-2
Q 20.1	What are the fundamental requirements for drug promotion and advertising?	20-2
Q 20.2	How do FDA and FTC share regulation of drug advertising?.....	20-2

Table of Contents

FDA Regulation of Drug Promotion and Advertising	20-3
Q 20.3 What are advertising and promotional labeling?	20-3
Q 20.4 What is “off-label” promotion?.....	20-3
Q 20.5 What is risk information and how is it to be disclosed?	20-4
Q 20.6 What else can cause drug promotion to be considered misleading?.....	20-6
Q 20.7 What are the rules for direct-to-consumer advertising?	20-7
Q 20.8 What is drug preapproval promotion?	20-7
Q 20.9 Must promotional materials be submitted to or approved by FDA?	20-8
Q 20.10 What is the Office of Prescription Drug Promotion?	20-8
FDA Regulation of Device Marketing and Advertising	20-9
Q 20.11 How does FDA regulate device marketing and advertising?.....	20-9
FTC Advertising Requirements	20-10
Q 20.12 How do the FTC and FDA work together to regulate drug and device promotion?.....	20-10
Q 20.13 What are the basic principles of FTC advertising regulation?.....	20-10

Chapter 21 Compliance with Import and Export Requirements

Paul D. Rubin, Melissa B. Runsten & Eric T. Rasmussen

FDA Import Regulation	21-2
Q 21.1 What is FDA’s general authority over imports?	21-2
Q 21.2 How is responsibility for imports shared by FDA and Customs and Border Protection?	21-2
Q 21.3 How does FDA become aware of an import subject to its authority?	21-2
Q 21.4 What initial steps does FDA take to determine if an imported article violates the law?.....	21-3
Q 21.5 What is the procedure when no violation is found?	21-3
Q 21.6 What is the procedure when a violation is found?.....	21-3
Q 21.7 What if the imported article is intended for export from the United States?.....	21-5
Q 21.8 What is FDA’s authority to refuse imports under the “appears-to-be-violative” standard?.....	21-5

Q 21.9	What are FDA import alerts?.....	21-6
Q 21.10	How does FDA regulate the importing of active pharmaceutical ingredients?	21-7
FDA Export Regulation		21-7
Q 21.11	What are FDA requirements to export a product produced in compliance with the FDCA?	21-7
Q 21.12	Can adulterated or misbranded products be exported?.....	21-8
Q 21.12.1	How can a company establish that a product meets the specifications of a foreign purchaser?	21-8
Q 21.12.2	How can a company establish that a product does not conflict with the laws of the importing country?	21-9
Q 21.12.3	How can a company satisfy the labeling requirement?.....	21-10
Q 21.12.4	How can a company show that the product is not sold or offered for sale in the United States?.....	21-10
Q 21.13	Can unapproved drugs, biological products, and devices be exported?	21-11
Q 21.13.1	What are the basic export requirements for unapproved drugs, biological products, and devices?.....	21-12
Q 21.13.2	What are the additional requirements to export unapproved drugs, biological products, and devices to a listed country?	21-13
Q 21.13.3	What are the additional requirements to export unapproved new drugs, biological products, and devices, to an unlisted country?	21-15

Chapter 22 Miscellaneous Communications with FDA

Paul D. Rubin & Anne D. Spiggle

Comments and Petitions		22-2
Q 22.1	When does FDA solicit comments regarding rulemakings, guidance documents, or other topics?.....	22-2
Q 22.2	What is a Citizen Petition to FDA?.....	22-2
Other Communications		22-3
Q 22.3	What other formal or informal communications with FDA should be investigated?.....	22-3

Chapter 23 Compliance with DEA Controlled Substance Requirements

Paul D. Rubin, Melissa B. Runsten & Eric T. Rasmussen

Scheduled Drugs	23-2
Q 23.1 What are the general consequences of scheduling a drug as a controlled substance?.....	23-2
Q 23.2 What are the five schedules of controlled substances?	23-3
Q 23.3 What is the process by which drug substances are scheduled?	23-3
Registration	23-4
Q 23.4 Who must register with the DEA?	23-4
Quotas	23-5
Q 23.5 What are DEA's manufacturing and procurement quotas for controlled substances?.....	23-5
Q 23.6 Has the DEA adjusted quotas in light of the ongoing opioid crisis?.....	23-5
Security	23-6
Q 23.7 What are the general requirements for security in storing and handling controlled substances?.....	23-6
Q 23.8 What factors does DEA consider in evaluating whether a company has good security regarding controlled substances?.....	23-6
Q 23.9 What are the storage requirements for controlled substances?.....	23-7
Q 23.10 How are manufacturing processes regulated?.....	23-8
Q 23.11 What are the security requirements for distribution and shipping?	23-8
Recordkeeping and Reporting	23-9
Q 23.12 What records must be kept by those working with controlled substances?.....	23-9
Q 23.13 What reporting obligations do registrants have?.....	23-9
Inspections and Enforcement Actions	23-10
Q 23.14 What are DEA's inspection powers?.....	23-10
Q 23.15 When does DEA need a warrant to make an inspection?.....	23-11

Q 23.16	How often do inspections occur?.....	23-11
Q 23.17	What administrative enforcement actions can the DEA pursue?.....	23-12
Q 23.18	Can the DEA seek monetary penalties?.....	23-12
Q 23.19	Can the DEA seek criminal penalties?.....	23-13
Q 23.20	Has the DEA pursued enforcement actions targeted at the ongoing opioid crisis?.....	23-13

Chapter 24 Compliance with Federal and State Health Care Fraud and Abuse Laws

John S. (Jay) Darden

The Anti-Kickback Statute	24-3	
Q 24.1	What is the Anti-Kickback Statute?.....	24-3
Q 24.2	What kinds of payment are prohibited?.....	24-3
Q 24.3	What level of knowledge and intent is required?.....	24-5
Q 24.4	To whom does the Anti-Kickback Statute apply?.....	24-5
Q 24.5	To what types of goods and services does the Anti-Kickback Statute apply?.....	24-5
Q 24.6	What is a “federal health care program”?.....	24-6
Q 24.7	Are there any statutory safe harbors?.....	24-6
Q 24.8	Are there any regulatory safe harbors?.....	24-7
Q 24.9	What criteria must be satisfied for a payment to fall within a safe harbor?.....	24-9
Q 24.10	What are the potential direct consequences of an anti-kickback violation?.....	24-10
Q 24.11	What are the potential collateral consequences of an anti-kickback violation?.....	24-10
Q 24.12	What due diligence is appropriate regarding anti-kickback issues?.....	24-11
The Stark Law	24-13	
Q 24.13	What is the Stark law?.....	24-13
Q 24.14	What intent is required for a violation of the Stark law?.....	24-14
Q 24.15	What are the differences between the Stark law and the Anti-Kickback Statute?.....	24-15
Q 24.16	To what services does the Stark law apply?.....	24-16
Q 24.17	What is a “referral” for purposes of the Stark law?.....	24-17

Table of Contents

Q 24.18	Are there any exceptions to the Stark law?.....	24-17
Q 24.18.1	What is the hospital-ownership exception?.....	24-18
Q 24.18.2	What is the personal-services exception?	24-18
Q 24.19	What are the potential direct consequences of a Stark law violation?	24-19
Q 24.20	What are the potential collateral consequences of a Stark law violation?	24-20
Q 24.21	What due diligence is appropriate regarding Stark law issues?.....	24-20
The False Claims Act		24-21
Q 24.22	What is the False Claims Act?	24-21
Q 24.23	What is a “claim”?.....	24-22
Q 24.24	What are “false or fraudulent” claims?	24-22
Q 24.25	What level of knowledge or intent is required?	24-22
Q 24.26	Who is liable for the submission of false or fraudulent claims?	24-23
Q 24.27	What are the potential consequences of a False Claims Act violation?	24-23
Q 24.28	What are the qui tam provisions?	24-24
Q 24.28.1	What is the relator’s share?	24-24
Q 24.29	What changes to the False Claims Act were made by PPACA?.....	24-25
Q 24.30	Are there state false claims statutes?	24-25
Q 24.31	What due diligence is appropriate regarding False Claims Act issues?	24-25
Criminal Offenses		24-27
Q 24.32	What is criminal “health care fraud”?.....	24-27
Q 24.33	To what services does the health care fraud statute apply?.....	24-27
Q 24.34	What is a “health care benefit program”?	24-27
Q 24.35	How does the fraud statute differ from the Anti-Kickback Statute and Stark law?.....	24-28
Q 24.36	To whom does the health care fraud statute apply?	24-28
Q 24.37	What is a criminal conspiracy, and why might conspiracy charges be useful to prosecutors in health care fraud cases?.....	24-29
Q 24.38	What level of knowledge and intent is required for a violation of the health care fraud statute?.....	24-29
Q 24.39	Is the fraud victim’s lack of care a defense?	24-30

Q 24.40	What are the potential direct consequences of a health care fraud violation?	24-30
Q 24.41	What are the potential collateral consequences of a health care fraud violation?	24-31
Q 24.42	What due diligence is appropriate regarding criminal health care fraud issues?.....	24-32
State Criminal Health Care Fraud and Abuse Statutes		24-32
Q 24.43	Are there state criminal health care fraud and abuse statutes?	24-32
Q 24.44	What are state “corporate practice of medicine” laws?	24-32
Q 24.45	What are the potential consequences for a violation of corporate practice of medicine laws?	24-33
Compliance Programs		24-34
Q 24.46	What is a compliance program and why is it important?	24-34
Q 24.47	What are the duties of a chief compliance officer?.....	24-34
Q 24.48	What should you expect to see in a compliance program?	24-35
Q 24.49	How should a compliance program be structured?.....	24-35
Q 24.50	What is the relevance of the U.S. Sentencing Guidelines to compliance programs?.....	24-36
Q 24.51	What other guidance is available from the government?	24-37
Q 24.52	What is a corporate integrity agreement?.....	24-37
Q 24.53	What due diligence is appropriate for the target’s compliance program?	24-38

Chapter 25 Regulatory Issues in Acquisitions of Health Care Facilities and Physician Practices

Stephen P. Nash & Michi Tsuda

Acquisitions of Licensed Health Care Facilities		25-2
Q 25.1	What are the principal health care regulatory issues likely to be implicated in the acquisition of a hospital or other type of licensed health care facility?.....	25-2
Q 25.2	What state health care regulations may impact the acquisition of a licensed health care facility?	25-4

Table of Contents

Transfer of the License	25-5
Q 25.3 What is a health care facility license?.....	25-5
Q 25.4 How may the benefit of a health care facility license be “transferred” from seller to buyer?	25-5
Q 25.5 Does a “change in control” of a licensed health care facility require prior notice and also approval?	25-7
Q 25.6 Are there similar requirements for the Medicare and Medicaid programs?.....	25-8
Transfer of the Certificate of Need	25-10
Q 25.7 What is a certificate of need program?.....	25-10
Q 25.8 How is the benefit of a certificate of need “transferred” from seller to buyer?.....	25-10
Q 25.9 Is prior notice or approval required?	25-11
Other Permits and Approvals	25-12
Q 25.10 What other health care–related permits may require attention?.....	25-12
Q 25.11 When might the host state’s attorney general become involved?	25-13
Medicare and Other Federal Law Issues	25-14
Q 25.12 What are the sources of federal health care regulation that may impact the acquisition of a licensed health care facility?	25-14
Q 25.13 What Medicare regulations and rules may be implicated in an acquisition?	25-15
Q 25.14 What are Provider Transaction Access Numbers and National Provider Identification numbers?	25-15
Q 25.15 What are Medicare “conditions of participation” and “conditions for coverage”?.....	25-16
Q 25.16 What approvals are required for a licensed health care facility to provide and bill for services to Medicare beneficiaries?	25-17
Q 25.17 How does the buyer secure the right for the acquired facility to continue to provide and bill for services to Medicare beneficiaries?	25-18
Q 25.18 What is a Medicare CHOW?.....	25-19
Q 25.19 How may the buyer handle regulatory risks arising from the seller’s pre-acquisition operation of the health care facility?	25-22

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Other Federal Approvals	25-23
Q 25.20 What approvals are required for a clinical laboratory?	25-23
Q 25.21 What approvals are required for a pharmacy?	25-24
Q 25.22 What are the requirements for accreditation and why do they matter?	25-25
Acquisitions of Physician Practices	25-26
Q 25.23 What areas of state health care regulation may impact the acquisition of a physician practice?	25-26
Corporate Practice of Medicine	25-27
Q 25.24 What is the corporate practice of medicine?	25-27
Q 25.25 What is the underlying public policy?	25-27
Q 25.26 Are there exceptions to CPOM prohibitions?	25-27
Q 25.27 How do CPOM considerations affect the transaction structure?	25-28
Fee-Splitting	25-28
Q 25.28 What is fee-splitting?	25-28
Q 25.29 What is the public policy underlying the prohibitions?	25-29
Q 25.30 Are there exceptions to fee-splitting prohibitions?	25-29
Q 25.31 How do fee-splitting considerations affect the transaction structure?	25-30
Covenants Not to Compete	25-31
Q 25.32 What is a covenant not to compete?	25-31
Q 25.33 What is the public policy underlying the limitations?	25-32
Q 25.34 In what situations is a covenant not to compete most likely to be enforceable?	25-32
Q 25.35 How do limitations on the use of covenants not to compete affect the transaction structure?	25-32
Patient Records	25-33
Q 25.36 What limitations arise in connection with the transfer and maintenance of patient medical records?	25-33
Medicare and Other Federal Law Issues	25-34
Q 25.37 What are the primary sources of federal health care regulation that may impact the acquisition of a physician practice?	25-34

Table of Contents

Q 25.38	What Medicare regulations may be implicated?	25-35
Q 25.39	What are Provider Transaction Access Numbers and National Provider Identification Numbers?	25-36
Q 25.40	What approvals are required in order for physicians (or their employers) to provide, and bill for, services to Medicare beneficiaries prior to closing?	25-37
Q 25.41	How does the buyer acquire the right for the acquired facility or practice group to continue to provide and bill for physician and NPP services to Medicare beneficiaries?	25-37

Chapter 26 Compliance with HIPAA and Other Privacy and Security Laws

Kathleen J. Lester & Melodi (Mel) M. Gates

Sanctions	26-3	
Q 26.1	What sanctions enforce compliance with HIPAA?.....	26-3
Overview of HIPAA Coverage	26-4	
Q 26.2	What activities does HIPAA cover?	26-4
Q 26.3	What is a “covered entity”?	26-4
Q 26.4	What is a “hybrid entity”?	26-6
Q 26.5	What is a “business associate”?	26-6
HIPAA Compliance	26-8	
Q 26.6	What are the core components of HIPAA compliance?	26-8
Q 26.7	Who has responsibility for determining HIPAA compliance?	26-9
Q 26.8	What is an internal HIPAA assessment or audit?.....	26-10
Q 26.9	What documents should a covered entity or business associate establish and maintain?	26-10
Q 26.10	What workforce training programs are required?.....	26-12
Q 26.11	How should the use and disclosure of PHI and ePHI be monitored and tracked?	26-13
Q 26.12	What is the “minimum necessary” standard?.....	26-14
Q 26.13	How should an entity respond to requests from individuals to exercise their rights under HIPAA?.....	26-14
Q 26.14	What administrative, technical, and physical safeguards are required?	26-15
Q 26.15	How should internal and external complaints be handled?	26-16

Impact of the HITECH Act on HIPAA Compliance	26-17
Q 26.16 How does the HITECH Act modify compliance with HIPAA?	26-17
Q 26.17 What are the expanded requirements for business associates?	26-17
Q 26.18 What are the HITECH Act’s changes to the HIPAA limitations on marketing and fundraising communications?	26-18
Q 26.19 What are the changes to the HIPAA “use and disclosure” regulations?	26-19
Q 26.20 What are the breach notification requirements?	26-19
Q 26.21 How will enforcement authority granted to state attorneys general affect HIPAA compliance?	26-21
Q 26.22 What is the impact of the new audit requirements?	26-22
State Privacy and Security Laws	26-22
Q 26.23 How do state privacy and security laws interact with federal law?	26-22
Evolving Law	26-24
Q 26.24 How does the evolving nature of privacy law affect a due diligence review?	26-24

Chapter 27 Litigation

Mark P. Goodman & Kristin D. Kiehn

Purposes of Litigation Due Diligence	27-2
Q 27.1 What is litigation due diligence?	27-2
Q 27.2 What is the purpose of litigation due diligence?.....	27-2
Q 27.3 What are the potential consequences of failing to conduct adequate litigation due diligence?	27-3
Basics of Civil Litigation	27-4
Q 27.4 What is civil litigation?	27-4
Q 27.5 What is a class action?.....	27-5
Q 27.6 What is a mass tort action?.....	27-5
Q 27.7 What are the potential consequences of liability in civil litigation?	27-5
Q 27.8 What are compensatory damages?	27-6
Q 27.9 What is injunctive relief?	27-6

Table of Contents

Q 27.10	What are punitive damages?	27-6
Q 27.11	What are treble damages?	27-6
Q 27.12	What is an award of attorneys' fees?	27-6
Common Lawsuits Against Health Care Companies		27-7
Q 27.13	What is patent litigation?	27-7
Q 27.14	What is product liability litigation?	27-7
Q 27.15	What is consumer fraud litigation?	27-8
Q 27.16	What is securities litigation?	27-8
Q 27.17	What is antitrust litigation?	27-9
Q 27.18	What is trademark litigation?	27-9
Q 27.19	What is employment litigation?	27-10
Q 27.20	What types of contract disputes do health care companies face?	27-10
Q 27.21	What is insurance carrier litigation?	27-10
Regulators and Regulatory Enforcement Actions		27-11
Q 27.22	What is a regulatory enforcement action?	27-11
Q 27.23	What is a criminal enforcement action?	27-11
Q 27.24	What is a civil enforcement action?	27-12
Q 27.25	What are the potential consequences of a regulatory enforcement action?	27-12
Q 27.26	What is the role of the Food and Drug Administration?	27-13
Q 27.27	What is the role of the Department of Justice and U.S. Attorneys' Offices?	27-14
Q 27.28	What is the role of the U.S. Securities and Exchange Commission?	27-15
Q 27.29	What is the role of the Federal Trade Commission?	27-15
Q 27.30	What is the role of the Patent and Trademark Office?	27-15
Q 27.31	What is the role of state attorneys general in enforcing laws against health care companies?	27-15
Q 27.32	What is the role of licensing authorities and accreditation bodies?	27-16
Relevant Statutes		27-17
Q 27.33	What is the Federal Food, Drug, and Cosmetic Act?	27-17
Q 27.34	What is the Prescription Drug Marketing Act?	27-19
Q 27.35	What are securities laws?	27-20
Q 27.36	What are antitrust laws?	27-20
Q 27.37	What is medical malpractice litigation?	27-22

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 27.38	What is the Stark Law?.....	27-22
Q 27.39	What are the Foreign Corrupt Practices Act and the UK Bribery Act?	27-23
Q 27.40	What are international trade laws?	27-24
Health Care Fraud	27-24
Q 27.41	What is health care fraud?	27-24
Q 27.42	What are federal health care programs?	27-24
Q 27.43	What is the role of the Office of Inspector General of the U.S. Department of Health and Human Services?.....	27-25
Q 27.44	What is the Anti-Kickback Statute?	27-26
Q 27.45	What is the False Claims Act?	27-26
Q 27.46	What does it mean to be excluded from federal health care programs?.....	27-29
Q 27.47	What is a corporate integrity agreement?.....	27-29
Q 27.48	What is a corporate monitor?	27-30
Q 27.49	What is the Civil Monetary Penalties Law?	27-30
Q 27.50	What is the Health Care Fraud Statute?.....	27-30
Materiality	27-31
Q 27.51	How is the materiality of a litigation matter assessed?.....	27-31
Q 27.52	Should certain litigation matters be considered presumptively material, regardless of projected financial exposure?.....	27-32
Q 27.53	What is an indemnitor?.....	27-32
Q 27.54	What is successor liability?.....	27-33
Due Diligence Inquiries, Analysis, and Reporting	27-33
Q 27.55	What types of information should be requested?.....	27-33
Q 27.56	Which employees of the target should be interviewed?.....	27-36
Q 27.57	What basic questions should be asked?	27-37
Q 27.58	What is a litigation reserve?.....	27-38
Q 27.59	What is the attorney-client privilege?.....	27-38
Q 27.60	How does the attorney-client privilege become relevant during litigation due diligence?	27-39
Q 27.61	How should the acquiring company respond when a target raises concerns about attorney-client privilege?	27-39
Q 27.62	Is it ever appropriate to demand that privileged materials be turned over?	27-39

Table of Contents

Q 27.63	How is the value of a potentially material litigation matter assessed?	27-40
Q 27.64	Once the diligence review is complete, how are findings communicated?	27-41
Q 27.65	What is post-closing due diligence?.....	27-42

Chapter 28 Intellectual Property

Scott A. Chambers & Lacy L. Kolo

Due Diligence Overview	28-2	
Q 28.1	What are the key intellectual property due diligence issues in health care M&A transactions?	28-2
Patents and Patent Applications	28-3	
Q 28.2	What are patents?.....	28-3
Q 28.3	What are the parts of a patent?	28-4
Q 28.4	Do patents have cross-border effects?	28-4
Q 28.5	How can one determine which patents, patent applications, and inventions are included in the deal?	28-5
Q 28.6	How is ownership or rights in patents or applications acquired?	28-6
Q 28.7	What does it mean if the list of inventors is not accurate?	28-7
Q 28.8	What is a shop right?	28-8
Q 28.9	How can one confirm that the patent-holding company has full rights to the patents and applications?	28-8
Q 28.10	How can one confirm that the key patents are valid?	28-9
Q 28.11	How can one determine whether the key patents cover the technology?	28-12
Q 28.12	How can one determine if the technology infringes another's patent?.....	28-13
Q 28.13	How can one determine if patents remain in force?	28-14
Q 28.14	How does FDA exclusivity supplement patent protection for drugs?	28-15
Q 28.15	What is the significance of a listing in the Orange Book?	28-16
Q 28.16	What are continuation, divisional, and continuation-in-part patent applications?.....	28-17
Q 28.17	How can companies maximize patent terms to extend the life of their product lines?	28-17

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 28.18	What procedure should a company follow regarding its records of inventions?	28-20
Q 28.19	What is a patent term extension?.....	28-20
Trademarks		28-21
Q 28.20	What are trademarks?.....	28-21
Q 28.21	How can a company protect its trademarks and service marks?	28-22
Q 28.22	Why are names important to branded pharmaceuticals?.....	28-23
Q 28.23	What if the target company has unregistered trademarks?.....	28-24
Copyrights and Software		28-24
Q 28.24	What are copyrights?.....	28-24
Q 28.25	What rights permit one to update, improve, or modify any software or copyrighted materials?.....	28-25
Q 28.26	How should a company protect its copyrights and software?	28-25
Q 28.27	What are the dangers of using open-source software?.....	28-26
Q 28.28	How does one investigate the protection of software and copyright-eligible intellectual property?.....	28-27
Trade Secrets and Know-How		28-27
Q 28.29	What are trade secrets?.....	28-27
Q 28.30	How do trade secrets complement patents in protecting a company's technology?	28-28
Q 28.31	Can nontechnical matters be protected as trade secrets?	28-28
Q 28.32	What due diligence issues arise if the target has licensed trade secrets?.....	28-28
Q 28.33	How should trade secrets and know-how be protected from general distribution?.....	28-29
Other Due Diligence Considerations		28-29
Q 28.34	What if someone has a valid security lien against the acquired intellectual property?	28-29
Q 28.35	How should a company's employment agreements and employee manuals protect intellectual property rights?.....	28-31
Q 28.36	What due diligence issues may arise with respect to intellectual property litigation?.....	28-31
Q 28.37	What due diligence issues may arise with respect to proceedings before the Patent and Trademark Office?.....	28-32
Q 28.38	What are "march-in" rights?.....	28-32

Table of Contents

Q 28.39	Is indemnification typically available for intellectual property infringement?.....	28-33
Q 28.40	How can due diligence review of freedom-to-operate, clearance, and invalidity opinions be addressed without waiving privilege?.....	28-34
Q 28.41	What other IP or IP-related issues should be considered during due diligence?.....	28-34

Chapter 29 Material Contracts

Andrew L. Bab & Dmitriy A. Tartakovskiy

Principal Types of Material Contracts in Health Care Transactions	29-2	
Q 29.1	What are the principal types of material contracts that a health care target is likely to have?	29-2
Q 29.1.1	What are the principal types of material contracts that hospitals and other health care service providers are likely to have?.....	29-3
Q 29.1.2	What are the principal types of material contracts that a pharmaceutical or biotechnology company is likely to have?	29-4
Change of Control Provisions	29-5	
Q 29.2	What due diligence should be conducted to determine whether the proposed transaction triggers a change-of-control or anti-assignment provision in any of the target's contracts?.....	29-5
Agreements with Third-Party Payors, Health Care Professionals, and Patient Referral Sources	29-6	
Q 29.3	What are the key issues in due diligence review of agreements with third-party payors?	29-6
Q 29.4	What are the key issues in due diligence review of agreements with health care professionals?.....	29-7
Q 29.5	What are the key issues in due diligence review of agreements with patient referral sources?	29-7
Commercial Contracts and Debts	29-8	
Q 29.6	How should the target's commercial contracts be evaluated with respect to their economic terms?	29-8

Q 29.7	What other issues may arise in the target’s commercial contracts?.....	29-9
Q 29.8	What issues may arise with respect to the target’s outstanding indebtedness?	29-10
Agreements Relating to Prior Mergers and Acquisitions		29-10
Q 29.9	What issues may arise with respect to the target’s acquisition and disposition agreements?.....	29-10
Joint Venture Agreements		29-11
Q 29.10	What are the key issues when performing due diligence review on joint venture agreements?.....	29-11
Licenses and Other Contracts Involving Intellectual Property		29-13
Q 29.11	What types of agreements relating to intellectual property might a target company have?.....	29-13
Q 29.12	What are the key issues in due diligence review of license-and-collaboration agreements?.....	29-14
Q 29.13	What risks are associated with in-licensing of technology rights?	29-15
Q 29.14	What should be the focus when reviewing the target’s outbound technology licenses?.....	29-17
Q 29.15	What due diligence concerns arise where the target’s research and development agreements address intellectual property ownership and protection?.....	29-17
Q 29.16	What is a material transfer agreement?.....	29-18

Chapter 30 Environmental Considerations

Stuart Hammer

Principal Risks		30-2
Q 30.1	Why should parties assess environmental risks in health care transactions?	30-2
Q 30.2	What is contamination?.....	30-3
Q 30.3	To what types of environmental claims can a health care company be subject?	30-4
Q 30.4	What types of compliance issues arise in health care transactions?.....	30-5

Table of Contents

Principal Environmental Laws Affecting the Health Care Industry	30-5
Q 30.5 What is the Resource Conservation and Recovery Act?.....	30-5
Q 30.6 What laws regulate medical waste?	30-6
Q 30.7 What is the Clean Air Act?.....	30-7
Q 30.8 What is the Toxic Substances Control Act?	30-7
Q 30.9 What requirements are imposed on storage tanks?	30-8
Q 30.10 What requirements are imposed on dental practices?.....	30-8
Q 30.11 What other environmental statutes may be relevant?	30-8
How Purchasers Can Assess Risk	30-9
Q 30.12 How can prospective purchasers assess environmental risks?	30-9
Q 30.12.1 What documents should the purchaser review?	30-9
Q 30.12.2 Should a purchaser interview the target's personnel?	30-10
Q 30.12.3 Should the purchaser commission a Phase I environmental site assessment?	30-10
Contract Provisions	30-12
Q 30.13 What environmental representations and warranties are typically included in purchase agreements in the health care industry?.....	30-12
Q 30.13.1 What purpose do such representations and warranties serve?	30-12
Q 30.14 Are indemnities used?	30-13

Chapter 31 Employee Benefits

Jonathan F. Lewis & Charles E. Wachsstock

Diligence Overview	31-2
Q 31.1 What are the major elements of diligence relating to executive compensation and employee benefits?	31-2
Q 31.2 What benefits information is typically available with respect to a public target?.....	31-3
Q 31.3 Why do single-employer defined benefit pension plans present significant diligence issues?.....	31-5
Q 31.4 Why do retiree medical benefits present significant diligence issues?.....	31-6

Issues Involving Senior Management	31-7
Q 31.5 Why do arrangements with senior management present significant diligence issues?.....	31-7
Q 31.6 What are “single-trigger” versus “double-trigger” compensation arrangements?	31-8
Q 31.7 What special rules apply to “golden parachutes”?.....	31-9
Issues Involving Unions	31-10
Q 31.8 What diligence issues are raised by collective bargaining agreements?.....	31-10
Q 31.9 What are “multiemployer” pension plans?	31-11
Q 31.10 For multiemployer plans, what is “withdrawal liability”?	31-12
Impact of Health Care Reform	31-13
Q 31.11 Is health care reform significant for due diligence regarding employee benefits?.....	31-13
Q 31.12 What is the significance of section 162(m)(6) of the Internal Revenue Code?	31-14
Carve-out Issues	31-14
Q 31.13 What special considerations apply to carve-out transactions?.....	31-14
Q 31.14 What arrangements may be made for transitional handling of employment benefits?	31-16
Q 31.15 What alternatives are available for tax-qualified retirement plans?.....	31-16
Q 31.16 What is “controlled group” liability?.....	31-17
Q 31.17 Under what circumstances might the Pension Benefit Guaranty Corporation intervene in an M&A transaction?	31-18
Downsizing	31-19
Q 31.18 What is the Worker Adjustment and Retraining Notification Act?	31-19
Q 31.19 What antidiscrimination laws may apply in a downsizing?	31-20
Q 31.20 Will terminated employees have a right to continued benefits?.....	31-20
Other Notice Requirements	31-21
Q 31.21 What other employment-related SEC filings might be required?.....	31-21
Q 31.22 What other PBGC filings might be required?	31-21

Chapter 32 Foreign Corrupt Practices Act

Sean Hecker, Andrew M. Levine & Erich O. Grosz

Scope of the Statute	32-2
Q 32.1 What is the FCPA?.....	32-2
Q 32.2 Who is subject to the FCPA?	32-2
Q 32.3 Who enforces the FCPA?.....	32-3
Q 32.4 What are the potential consequences of violating the FCPA?.....	32-3
Q 32.5 Do other countries have laws similar to the FCPA?.....	32-4
Q 32.6 Why is the health care industry particularly susceptible to FCPA risks?.....	32-6
The Antibribery Provisions	32-7
Q 32.7 What types of payments are prohibited by the FCPA's antibribery provisions?	32-7
Q 32.8 Who qualifies as a "foreign official" under the FCPA?.....	32-7
Q 32.9 What makes a payment "corrupt" for purposes of "obtaining or retaining" business in violation of the FCPA?	32-8
Q 32.10 What type of "knowledge" of a subsidiary's or other affiliate's conduct is required for liability under the antibribery provisions?	32-8
Q 32.11 Can a company be liable for payments made by third parties, such as sales agents, consultants, and distributors?.....	32-9
Q 32.12 What exceptions are available under the antibribery provisions?	32-9
Q 32.13 What affirmative defenses are available under the antibribery provisions?	32-10
Exposure of Acquiring Companies	32-11
Q 32.14 Is an acquiring company exposed to FCPA liability for the target's violations?	32-11
Q 32.15 What is an acquiring company's potential exposure to liability for the target's antibribery violations?.....	32-11
Q 32.16 What is an acquiring company's potential exposure to liability for the target's pre-acquisition violations of the accounting provisions?.....	32-12
Diligence Strategies	32-12
Q 32.17 What are some of the benefits of pre-acquisition FCPA diligence?.....	32-12

Q 32.18	What steps should a company take as part of pre-acquisition FCPA diligence?	32-13
Q 32.19	What information should be sought during the due diligence process?	32-14
Q 32.20	What types of questions should be asked regarding potential FCPA liability?	32-15
Q 32.21	Can a company ever conduct too much FCPA diligence prior to an acquisition?	32-16
Q 32.22	What if FCPA diligence cannot be completed pre-acquisition?	32-17
Q 32.23	What post-acquisition steps are advisable where comprehensive FCPA diligence cannot be completed prior to closing?	32-17
Q 32.24	Is requesting a DOJ opinion a viable option?	32-18
Compliance Programs		32-19
Q 32.25	What factors should be considered in assessing whether a target company has a robust FCPA compliance program?	32-19
Q 32.26	What potential FCPA risks should be considered with respect to clinical trials?	32-20
Q 32.27	What potential FCPA risks should be considered with respect to sales and marketing programs?	32-22
Q 32.28	What potential FCPA risks should be considered with respect to government product approvals, product certifications, and other licensing requirements?	32-23
Disclosing Violations to the Government		32-23
Q 32.29	In the M&A context, when is it advisable to disclose an FCPA violation to the government?	32-23
Q 32.30	What considerations weigh in favor of a voluntary disclosure?	32-24
Q 32.31	What considerations militate against a voluntary disclosure?	32-25

Chapter 33 Real Property

Peter J. Irwin

Separate Ownership of Real Estate		33-2
Q 33.1	Are there advantages to having real property held by an entity distinct from the entity conducting health care operations?	33-2

Table of Contents

Due Diligence Considerations	33-3
Q 33.2 What kind of real estate diligence is needed as part of a health care M&A transaction?	33-3
Q 33.2.1 What diligence is typically needed for a target’s owned properties?	33-3
Q 33.2.2 What diligence is typically needed regarding leased properties?	33-4
Q 33.2.3 What if the property is the subject of a sale-leaseback arrangement?	33-5
Q 33.3 What other issues may arise in real estate diligence?.....	33-6
Q 33.3.1 How does a prospective acquirer review zoning?	33-6
Q 33.3.2 When should a prospective acquirer review underlying land use issues?	33-6

**PART III
TRANSACTION DOCUMENTATION**

Chapter 34 Elements of Acquisition Agreements

Andrew L. Bab & Dmitriy A. Tartakovskiy

Principal Elements	34-2
Q 34.1 What are the principal elements of a health care acquisition agreement?.....	34-2
Variations	34-3
Q 34.2 What provisions do parties typically focus on in health care M&A transactions?	34-3

Chapter 35 Representations and Warranties

*Andrew L. Bab, Dmitriy A. Tartakovskiy &
Jonathan L. Lubin*

Purposes and Effects	35-2
Q 35.1 What is the difference between a representation and a warranty?.....	35-2
Q 35.2 How can representations and warranties in acquisition agreements be categorized?	35-3

Q 35.3	What purposes do representations and warranties serve in health care acquisition agreements?	35-4
Typical Provisions in Health Care Deals.....		35-5
Q 35.4	What industry-specific representations and warranties are typically included in health care acquisition agreements?.....	35-5
Q 35.5	What industry-specific representations and warranties are typically included in acquisition agreements involving pharmaceutical or biotechnology companies or medical device manufacturers?	35-6
Q 35.5.1	What representations and warranties relating to legal and regulatory compliance are typical?.....	35-6
Q 35.5.2	What representations and warranties relating to intellectual property are typical?.....	35-9
Q 35.5.3	What representations and warranties relating to material contracts are typical?.....	35-9
Q 35.5.4	What representations and warranties relating to litigation and product liability matters are typical?	35-10
Q 35.6	What additional representations and warranties may be included in purchase agreements relating to product or portfolio acquisitions?.....	35-11
Q 35.7	What industry-specific representations and warranties are typically included in acquisition agreements involving health care providers?.....	35-13
Q 35.7.1	What representations and warranties relating to legal and regulatory compliance are typical?.....	35-14
Q 35.7.2	What representations and warranties relating to the target's participation in Medicare, Medicaid, CHAMPUS, TRICARE, and other federal, state, or local government reimbursement programs are typical?	35-16
Q 35.7.3	What representations and warranties relating to the target's accounts receivable and billing practices are typical?.....	35-17
Q 35.7.4	What representations and warranties relating to the target's material contracts are typical?.....	35-18
Q 35.7.5	What representations and warranties relating to the target's licensed personnel and medical staff matters are typical?	35-18
Q 35.7.6	What representations and warranties relating to the target's environmental matters are typical?	35-19

Table of Contents

Limiting the Scope of Representations and Warranties35-21

- Q 35.8 How can parties limit the scope of their representations and warranties in health care acquisition agreements?.....35-21
 - Q 35.8.1 What is the role of materiality qualifiers?35-21
 - Q 35.8.2 What is the role of knowledge qualifiers?35-22

Chapter 36 Covenants and Deal Protection

Dmitriy A. Tartakovskiy, Uri Herzberg & Christopher Anthony

Pre-Closing Covenants36-3

- Q 36.1 What types of pre-closing covenants related to the transaction process are typically included in health care M&A agreements?.....36-3
- Q 36.2 What is the interim-conduct-of-business covenant?.....36-4
- Q 36.3 What is “gun jumping”?36-7
- Q 36.4 What covenants relating to regulatory approvals and third-party consents may be included in health care acquisition agreements?36-7
- Q 36.5 What is a buyer financing covenant?36-9
- Q 36.6 What is a financing cooperation covenant?.....36-9
- Q 36.7 What industry-specific covenants are sometimes included in agreements for the acquisition of pharmaceutical, biotechnology, or medical device companies?.....36-10
- Q 36.8 What industry-specific covenants are sometimes included in agreements for the acquisition of a health care service provider?.....36-14
- Q 36.9 What are the legal consequences of breaching a pre-closing covenant?36-14

Post-Closing Covenants36-15

- Q 36.10 What types of post-closing covenants are typically included in health care M&A agreements?.....36-15
- Q 36.11 What is a covenant for further assurances?36-16
- Q 36.12 What is a covenant not to compete?36-17
- Q 36.13 What are the remedies for a breach of a post-closing covenant?36-19

Deal Protection	36-20
Q 36.14 What are deal protection provisions?.....	36-20
Q 36.15 What is a “no-shop” provision?	36-20
Q 36.16 What is a termination fee?.....	36-22
Q 36.17 What is a reverse termination fee?.....	36-23

Chapter 37 Closing Conditions

*Andrew L. Bab, Dmitriy A. Tartakovskiy &
Chantal Tortoroli*

Mutual and Individual Conditions	37-2
Q 37.1 What types of mutual closing conditions typically appear in health care transactions?.....	37-2
Q 37.2 What closing conditions applicable to only one party may appear in health care acquisition agreements?.....	37-3
Conditions Relating to Regulatory Approvals and Third-Party Consents	37-4
Q 37.3 What types of regulatory approvals and third-party consents may be included as closing conditions in health care M&A agreements?	37-4
Q 37.4 What types of antitrust approvals typically constitute closing conditions in health care M&A agreements?.....	37-5
Q 37.5 What other types of regulatory approvals and third-party consents may be included as closing conditions in health care M&A agreements?	37-6
Q 37.6 What are typical points of negotiation with respect to closing conditions relating to regulatory approvals and third-party consents?.....	37-7
Q 37.7 How does the structure of the deal affect the choice of regulatory approvals and third-party consents as closing conditions?.....	37-8
The Bringdown Condition and Related Provisions	37-9
Q 37.8 What is the bringdown condition?.....	37-9
Q 37.9 Should the bringdown condition require that the representations and warranties be true and correct as of signing as well as of closing?	37-9
Q 37.10 Should all of the parties’ representations be reaffirmed as of the closing date?	37-10

Table of Contents

Q 37.11	What materiality standard should be used?	37-10
Q 37.12	For what representations is a materiality standard considered inappropriate?	37-11
Q 37.13	Is performance of the parties' covenants typically included as a closing condition in health care acquisition agreements?	37-12
Q 37.14	What is the purpose of an officer's certificate?	37-12
Material Adverse Effect Conditions		37-13
Q 37.15	What is a standalone material adverse effect condition?	37-13
Conditions Specific to the Business or Industry		37-15
Q 37.16	What industry-specific closing conditions may be included in health care acquisition agreements?	37-15

Chapter 38 Documentation for Indemnification

*Andrew L. Bab, Dmitriy A. Tartakovskiy &
Jonathan L. Lubin*

Purposes and Types of Indemnification Provisions in Health Care Acquisition Agreements		38-3
Q 38.1	What purposes do indemnities serve in health care acquisition agreements?	38-3
Q 38.2	What is the interaction of indemnification provisions with purchase price adjustment mechanics?	38-6
Q 38.3	What industry-specific special indemnities may be included in health care acquisition agreements?	38-7
Q 38.3.1	What industry-specific indemnities may be included in acquisition agreements involving pharmaceutical or biotechnology companies or medical device manufacturers?	38-8
Q 38.3.2	What industry-specific indemnities may be included in acquisition agreements involving health care providers?	38-9
Limitations on Indemnification Obligations in Health Care Acquisition Agreements		38-10
Q 38.4	How can parties limit the scope of their indemnification obligations in health care acquisition agreements?	38-10
Q 38.5	What is a cap?	38-10

Q 38.6	What is a basket?.....	38-11
Q 38.7	What is a materiality read-out?.....	38-12
Q 38.8	What is a minimum claim threshold?	38-12
Q 38.9	What is a survival period?.....	38-13
Q 38.10	What is the effect of buyer’s knowledge of the breach on indemnification?.....	38-14
Q 38.11	What is loss mitigation?.....	38-16
Q 38.12	Is there an obligation to seek available insurance proceeds?	38-16
Q 38.13	What is the effect of tax benefits on indemnification obligations?	38-17
Security for the Indemnifying Party’s Obligations.....		38-17
Q 38.14	What arrangements may be used to secure indemnification obligations in health care transactions?	38-17
Q 38.15	What is the difference between an escrow and a holdback?	38-18
Transaction Insurance in Health Care Acquisitions.....		38-19
Q 38.16	What is transaction insurance?	38-19
Q 38.17	Do health care transactions present special problems for this type of insurance?	38-20

Chapter 39 Documentation for License-and-Collaboration Agreements

Kevin A. Rinker & Henry Lebowitz

Licensing and Collaborative Use.....		39-2
Q 39.1	Which types of intellectual property may be licensed?	39-2
Q 39.2	In what ways may the licensee use the licensed intellectual property?	39-2
Q 39.3	May the licensee sublicense the intellectual property to affiliates or third parties?	39-3
Q 39.4	Which party owns intellectual property developed after the grant date?	39-3
Defense and Enforcement.....		39-3
Q 39.5	Which party controls the defense or prosecution of infringement claims?.....	39-3
Q 39.6	What are the potential solutions to a third-party infringement claim?.....	39-4

Table of Contents

Q 39.7	How are recoveries from an enforcement action allocated between the licensor and the licensee?	39-4
Representations, Warranties, and Indemnities		39-5
Q 39.8	How do intellectual property representations and warranties in a license-and-collaboration agreement compare to those in an outright acquisition?	39-5
Q 39.9	What are the key indemnities?	39-5
Confidentiality, Duration, and Wind-Down		39-6
Q 39.10	Should confidentiality obligations be included?	39-6
Q 39.11	What is the typical duration of a license-and-collaboration agreement?	39-7
Q 39.12	What are the typical wind-down arrangements after termination or expiration of the license-and-collaboration agreement?	39-7

Chapter 40 Documentation for Joint Ventures

Sarah A.W. Fitts

Organization of the Joint Venture		40-2
Q 40.1	What legal entities may be used for an equity joint venture?	40-2
Q 40.2	What sorts of contributions do the participants make to an equity joint venture?.....	40-5
Q 40.3	What are the key terms of a joint venture agreement?.....	40-5
Objectives		40-6
Q 40.4	Should the objectives of the joint venture be addressed in the joint venture agreement?.....	40-6
Management and Governance		40-8
Q 40.5	How should management and governance be addressed in the joint venture agreement?.....	40-8
Q 40.6	Should the joint venture have a board of directors?	40-9
Q 40.7	What is the role of officers?	40-9
Q 40.8	What issues arise with respect to decision making by the joint venture participants?.....	40-9
Q 40.9	What if the decision makers do not agree on a course of action?	40-11

Indemnification	40-12
Q 40.10 What kinds of losses can be indemnified?	40-12
Allocation of Income	40-13
Q 40.11 How is income allocated among participants?.....	40-13
Transfer of Interests	40-14
Q 40.12 Should there be restrictions on transfers of joint venture interests?	40-14
Q 40.12.1 What is a right of first offer?	40-15
Q 40.12.2 What is a right of first refusal?.....	40-15
Q 40.12.3 What is a tag-along right?	40-16
Q 40.12.4 What are drag-along rights?.....	40-16
Q 40.12.5 What are put and call rights?.....	40-17
Q 40.12.6 What are registration rights?	40-17
Q 40.13 What transfer issues arise if a participant's interests are held by a special-purpose company?	40-17
Termination	40-18
Q 40.14 What are typical circumstances for termination of the joint venture, or the exit of partners?.....	40-18
Q 40.15 What are some important termination issues that should be addressed in the agreement?.....	40-19

**PART IV
SPECIAL TOPICS**

Chapter 41 Acquisitions of U.S. Companies by Non-U.S. Buyers

Jeffrey P. Cunard

Statutory Basis	41-2
Q 41.1 What is the source of the U.S. government's authority to review foreign acquisitions of U.S. businesses?	41-2
Filing a Notice	41-3
Q 41.2 Is filing a Notice required?.....	41-3
Q 41.3 What are the benefits of filing a Notice?.....	41-3

Table of Contents

Q 41.4	What transactions might be subject to CFIUS review and a Notice?	41-3
Q 41.4.1	What constitutes national security?	41-4
Q 41.4.2	What health care–related transactions might raise national security concerns?	41-5
Q 41.4.3	What types of corporate transactions are covered?	41-6
Q 41.4.4	What constitutes control?	41-7
Q 41.4.5	What sorts of transactions are not “covered”?	41-8
Q 41.5	When should the Notice be filed?	41-8
Q 41.6	What are the contents of the Notice?	41-9
Government Review		41-10
Q 41.7	What is the process prior to the filing of the Notice?	41-10
Q 41.8	What happens after filing of the Notice?	41-10
Q 41.9	What happens during the review and investigation periods?	41-12
Q 41.10	Are the Notice and CFIUS review process confidential?	41-12
Q 41.11	What happens at the end of the process?	41-12

Chapter 42 Health Care M&A Transactions in France

*Antoine F. Kirry, Antoine d’Ornano &
Rosanne Lariven*

Principal Considerations in Structuring Health Care M&A Transactions in France		42-5
Q 42.1	What considerations affect the choice between a stock deal and an asset deal?	42-5
Stock Deals		42-7
Q 42.2	What are the legal requirements for stock deals involving providers of medical services?	42-7
Q 42.3	What are the legal requirements for stock deals involving manufacturers of health products?	42-8
Q 42.4	What are the legal requirements for stock deals involving biomedical laboratories?	42-9
Asset Deals		42-11
Q 42.5	What are the French law requirements applicable to asset deals generally?	42-11

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 42.6	What are the legal requirements for asset deals involving health care establishments?	42-11
Q 42.7	What are the legal requirements for asset deals involving pharmaceutical establishments?.....	42-12
Q 42.8	What are the legal requirements for asset deals involving manufacturers of health products?.....	42-12
Q 42.9	What are the legal requirements for asset deals involving manufacturers of health equipment?.....	42-12
Transfers	42-13
Q 42.10	What are the legal requirements for the transfer of intellectual property rights?	42-13
Q 42.11	What are the legal requirements for the transfer of marketing authorizations?	42-13
Antitrust, Tax, and Social Security Issues	42-16
Q 42.12	What antitrust notices are required for health care transactions in France?	42-16
Q 42.13	What substantive antitrust rules are applicable?	42-17
Q 42.14	What are the tax incentives for the development of pharmaceutical or medical devices under French law?.....	42-19
Q 42.15	What pricing considerations are relevant to health care M&A transactions?	42-20
Principal Due Diligence Considerations	42-22
Q 42.16	What are the key due diligence considerations in health care M&A transactions in France?	42-22
Q 42.17	What are the key due diligence considerations in transactions involving health institutions?	42-24
Q 42.18	What are the key due diligence considerations in transactions involving developers or manufacturers of health care products?	42-25
Q 42.18.1	What considerations are relevant if the target is a pharmaceutical company?	42-25
Q 42.18.2	What considerations are relevant if the target develops medicinal products?.....	42-26
Q 42.18.3	What considerations are relevant if the target develops or manufactures medical devices?.....	42-28
Q 42.19	What are the operational constraints on health care companies under French law?	42-28

Table of Contents

Q 42.20	What are the regulatory constraints on manufacturing health care products in France?	42-30
Q 42.21	What are the regulatory constraints on the distribution and marketing of health care products in France?	42-32
Q 42.21.1	What are the registration and certification requirements?	42-32
Q 42.21.2	What testing is required?	42-33
Q 42.21.3	What are the distribution constraints?	42-34
Q 42.22	What due diligence issues arise with respect to investigations or enforcement actions by governmental agencies involving the target?	42-36
Q 42.23	What are the product liability rules applicable to health care products?	42-37
Q 42.24	What are the medical malpractice liability rules?.....	42-39
Q 42.25	What are the applicable environment law constraints?.....	42-41
Q 42.26	What are the key intellectual property issues relating to medicinal products and medical devices?	42-41
Q 42.27	What are the key personal data issues relating to the health care industry?	42-43
Q 42.28	What are the applicable labor law considerations?.....	42-44
Q 42.29	Are there any issues related to foreign anticorruption programs?.....	42-47
Transaction Documents		42-49
Q 42.30	What special issues should be addressed in drafting and negotiating transaction documents in health care M&A transactions in France?	42-49
Q 42.31	Is the opinion of the <i>Comité Social et Economique</i> (or the works council) required?	42-50
Q 42.32	How should the transfer of permits be addressed?.....	42-51
Q 42.33	Are any foreign investment approvals required?	42-51
Q 42.34	What are the special documentation requirements in stock deals?	42-51
Q 42.35	What are the special documentation requirements in asset deals?	42-52
Q 42.36	What are some typical issues to be addressed in a licensing or collaborative arrangement?	42-53

Chapter 43 Health Care M&A Transactions in Germany

Peter Wand

Regulation of Hospitals	43-7
Q 43.1 How is a hospital operated under German law?	43-7
Q 43.2 What are the requirements for patient data protection in German hospitals?.....	43-8
Q 43.3 How are German hospitals financed?	43-13
Regulation of Medicinal Products	43-16
Q 43.4 What is the regulatory regime that governs the development, manufacture, and distribution of medicinal products?.....	43-16
Q 43.5 What is a medicinal product?	43-16
Q 43.6 What are the requirements for developing medicinal products in Germany?	43-17
Q 43.7 What are the rules facilitating the development of generic medical products?.....	43-22
Q 43.8 What are the regulatory requirements for manufacturing medicinal products in Germany?	43-23
Q 43.9 What are the regulatory requirements for marketing medicinal products in Germany?	43-24
Q 43.10 What are the national authorization procedures in Germany?	43-24
Q 43.11 What are the European authorization procedures?.....	43-27
Q 43.11.1 What is the Centralized Procedure in the EU?.....	43-27
Q 43.11.2 What are the Decentralized Procedure and the Mutual Recognition Procedure in the EU?	43-28
Q 43.12 What are the pricing concerns in connection with the distribution of medicinal products in Germany?	43-29
Q 43.13 What are the basic price regulations for medicinal products in Germany?	43-31
Q 43.14 How are insured persons reimbursed for medicinal product costs?	43-32
Regulation of Medical Devices	43-34
Q 43.15 What is the regulatory regime that governs the development, manufacture, and distribution of medical devices in Germany?.....	43-34
Q 43.16 What are the requirements for developing and manufacturing medical devices in Germany?.....	43-35

Table of Contents

Q 43.17	What are the requirements for distributing medical devices in Germany?	43-36
Q 43.18	What are the pricing concerns in connection with the distribution of medical devices in Germany?	43-38
Q 43.19	What is pharmacovigilance?	43-39
Product Liability and Medical Malpractice		43-40
Q 43.20	What special product liability rules apply to medicinal products and medical devices?	43-40
Regulation of Health Care Advertising		43-44
Q 43.21	What rules govern advertising in the health care sector?	43-44
Health Care M&A Issues		43-47
Q 43.22	What are the key considerations in structuring a health care M&A transaction in Germany?	43-47
Stock Transactions		43-48
Q 43.23	What are the key legal considerations in connection with stock transactions?	43-48
Q 43.23.1	What are the considerations for partnerships?	43-48
Q 43.23.2	What are the considerations for limited liability companies?	43-49
Q 43.23.3	What are the considerations for stock corporations and partnerships limited by shares?	43-49
Q 43.24	What are the rights of the target's employees and their representatives in stock transactions?	43-51
Q 43.25	What are the tax considerations in stock transactions?	43-52
Q 43.26	What are the health care-specific issues in stock transactions?	43-53
Asset Transactions		43-55
Q 43.27	What are the key legal considerations in connection with asset transactions?	43-55
Q 43.28	What are the rules governing the transfer of assets, liabilities, and contracts?	43-55
Q 43.29	What are the rights of the target company's employees and their representatives in asset transactions?	43-58
Q 43.30	What are the tax considerations in asset transactions?	43-61

Q 43.31	What are the health care-specific issues in asset transactions?.....	43-62
Q 43.32	What are the key legal considerations in connection with a transfer of intellectual property rights?.....	43-65
Merger Control, Data Protection, and Other Restrictions		43-66
Q 43.33	What are the key merger control considerations in connection with health care M&A transactions in Germany?	43-66
Q 43.34	What are the key data protection considerations in German M&A transactions?	43-69
Q 43.35	Are there any restrictions on foreign investment?	43-70
Q 43.36	Are there applicable foreign exchange controls or reporting requirements?.....	43-71
Due Diligence		43-71
Q 43.37	What are the key due diligence considerations in health care M&A transactions in Germany?	43-71
Q 43.38	What are the key due diligence considerations in connection with the sale of a hospital business?	43-72
Q 43.38.1	What is the importance of determining the legal status of the target hospital?	43-73
Q 43.38.2	What issues arise regarding the financing arrangements of the target hospital?.....	43-73
Q 43.39	What are the key due diligence considerations in connection with the sale of a pharmaceutical or medical devices business?	43-74
Q 43.39.1	Why is it important to determine the legal status of the target's products?.....	43-75
Q 43.39.2	Why is it important to determine whether the target is in possession of necessary marketing authorizations?	43-76
Q 43.39.3	What are the potential issues relating to the prescription status and off-label use of the target company's medicinal products?.....	43-78
Q 43.39.4	What are the potential issues relating to pricing and eligibility for health insurance reimbursement?	43-79
Q 43.39.5	What are the potential pharmacovigilance and product liability issues?	43-80
Q 43.39.6	What are the potential issues relating to the protection of intellectual property rights?	43-81

Chapter 44 Health Care M&A Transactions in Russia

Alyona N. Kucher & Anna V. Maximenko

The Health Care Industry in Russia	44-2
Q 44.1 What are Russia's development goals for the health care industry?.....	44-2
Q 44.2 What recent legislation affects the health care market?.....	44-3
Q 44.3 What roles does the Russian government play in the health care industry?	44-5
Structuring Health Care M&A Transactions in Russia	44-7
Q 44.4 How are health care M&A transactions usually structured in Russia?.....	44-7
Q 44.4.1 Why are stock deals more common than asset deals?.....	44-7
Q 44.4.2 What are typical offshore transactions?	44-8
Q 44.5 What types of companies do health care M&A transactions in Russia primarily involve?.....	44-8
Q 44.6 What types of corporate reorganizations are used in M&A activity in the health care sector?.....	44-10
Q 44.7 Are there restrictions on foreign ownership of Russian companies operating in the health care market?.....	44-11
Q 44.8 What regulatory approvals are required for M&A transactions in the Russian health care market?	44-13
Q 44.8.1 What transactions require competition clearance?	44-13
Q 44.8.2 What transactions require strategic investment clearance?	44-14
Key Due Diligence Considerations	44-16
Q 44.9 What challenges do buyers face in acquisitions of Russian health care companies?.....	44-16
Q 44.10 What are the key issues in conducting due diligence of a Russian health care company?	44-18
Q 44.11 What are the potential issues relating to the seller's title to the shares or assets of the target company?	44-18
Q 44.11.1 What is a void transaction?.....	44-19
Q 44.11.2 What is a voidable transaction?	44-19
Q 44.12 What types of health care activities are subject to licensing?.....	44-20

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 44.13	What are the principal industry-specific regulatory requirements?	44-21
Q 44.13.1	What is state registration of pharmaceuticals and medical equipment?	44-22
Q 44.13.2	What is state regulation of pricing?	44-22
Q 44.13.3	What are the key regulatory requirements for the manufacture of pharmaceuticals?	44-24
Q 44.13.4	What are the requirements for the storage of pharmaceuticals?	44-24
Q 44.13.5	What are the applicable disclosure rules with respect to side effects?	44-25
Q 44.13.6	What are the standards and procedures for the provision of medical services?	44-25
Q 44.13.7	What are the rules for accreditation of employees engaged in performing medical or pharmaceutical activities?	44-25
Q 44.13.8	What are the applicable sanitary rules?	44-26
Q 44.13.9	What are the applicable restrictions on advertising?	44-26
Q 44.13.10	What preferences exist for pharmaceuticals originating from the Eurasian Economic Union?	44-26
Q 44.14	How can intellectual property rights to pharmaceuticals and medical equipment be established and protected under Russian law?	44-28
Q 44.15	Are Russian anticorruption requirements consistent with international standards?	44-28
Q 44.16	What are the main labor safety and environmental requirements affecting the Russian health care industry?	44-29
Q 44.17	Can information relating to litigation matters and other disputes involving the target company be obtained from public sources?	44-30
Choice of Law	44-30
Q 44.18	Can the parties choose non-Russian law to govern the deal?	44-30
Arbitration	44-31
Q 44.19	What dispute resolution mechanisms are typically used in health care M&A transactions in Russia?	44-31

Chapter 45 Health Care M&A Transactions in England

Sarah Bricknell, Guy Constant & Stephen Tainsh

Background	45-2
Q 45.1 What is the role of the public sector?.....	45-2
Q 45.2 How is the role of the private sector changing?.....	45-2
Q 45.3 What is the size of the health care market?.....	45-3
Q 45.4 What factors affect the current health care M&A market?	45-3
Q 45.4.1 What sorts of entities are typically involved in deals?.....	45-4
Q 45.4.2 How does the public/private distinction affect the market?	45-4
Q 45.4.3 What are the opportunities in the social care area?.....	45-4
Q 45.4.4 What are the opportunities in the pharmaceuticals area?.....	45-5
Organization of the Public Health Care System in England	45-5
Q 45.5 What is the NHS?	45-5
Q 45.6 What is the “commissioning” of health care services?	45-6
Q 45.7 What is NHS England?.....	45-6
Q 45.8 What is Monitor or NHS Improvement?.....	45-7
Q 45.9 What is a clinical commissioning group?	45-8
Q 45.10 What is an NHS Trust?	45-8
Q 45.11 What is an NHS Foundation Trust?	45-8
Q 45.12 Can an NHS organization provide privately funded health care?.....	45-10
Q 45.13 How is the system of health care funded in England?	45-11
Q 45.14 How are prices set for public health care?	45-11
Q 45.15 How are health care services planned and purchased?.....	45-12
Q 45.16 Do elected bodies have any role in the provision of health care?.....	45-13
Q 45.17 What is the role of local authorities in the planning and provision of health care?.....	45-13
Q 45.18 How is the provision of health care regulated?.....	45-13
Q 45.18.1 What is the role of the Care Quality Commission?	45-14
Q 45.18.2 What is the role of Monitor and the NHS Trust Development Authority?	45-14
Q 45.19 How is regulatory oversight managed?.....	45-15
Q 45.20 What happens to failing regulated providers?.....	45-16
Q 45.20.1 What if a private provider fails?	45-17

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 45.21	How are health care professionals regulated?.....	45-18
Q 45.22	Are there other relevant regulatory authorities?.....	45-18
Q 45.23	How is the public engaged in the provision of health care in England?.....	45-19
Q 45.24	What is the role of the Secretary of State for Health in the provision of health care?	45-19
Q 45.25	What is Public Health England?.....	45-20
Q 45.26	What are primary, secondary, and tertiary care, and how are their practitioners organized?	45-20
Q 45.27	Can an NHS Trust (including an FT) or its assets be transferred into private ownership?	45-21
Q 45.28	How are medicines licensed for manufacture and use?	45-21
Q 45.28.1	Are there special provisions for herbal medicines?	45-22
Q 45.28.2	Can marketing authorizations be transferred?.....	45-22
Q 45.29	How are medical devices authorized?	45-23
Private Health Care Provision in England		45-23
Q 45.30	What types of activities are currently covered by private company providers?	45-23
Q 45.31	How can new private providers enter the English health care market?.....	45-24
Q 45.31.1	What is a startup?	45-24
Q 45.31.2	What is a Public Private Partnership?	45-24
Q 45.31.3	What is a joint venture?.....	45-25
Mergers and Acquisitions Involving Private Health Care Companies		45-25
Q 45.32	How are transactions typically structured?.....	45-25
Q 45.33	How is the purchase price paid?	45-25
Q 45.34	What are the advantages and disadvantages of share purchases?	45-26
Q 45.34.1	What protections are available to the buyer in a share purchase?	45-26
Q 45.34.2	What if some assets are to stay with the seller?	45-27
Q 45.35	What are the advantages and disadvantages of asset purchases?	45-27
Q 45.35.1	Are there special considerations for employment contracts?.....	45-27
Q 45.36	Are there alternatives to share and asset purchases?.....	45-28
Q 45.37	Are there restrictions on foreign ownership of companies operating in health care?.....	45-28

Table of Contents

Q 45.38	What regulatory approvals are relevant to health care M&A transactions under the Monitor license?.....	45-28
Q 45.38.1	Who is exempt from the requirement of a Monitor license?.....	45-29
Q 45.39	What competition laws should be considered?	45-29
Q 45.40	What are the tax considerations in share purchase transactions?.....	45-31
Q 45.41	What are the tax considerations in asset purchase transactions?.....	45-32
Q 45.42	Does the choice of law have any impact?	45-32
Due Diligence		45-33
Q 45.43	Are there particular due diligence issues for share purchases?	45-33
Q 45.44	Are there particular due diligence issues for asset purchases?	45-33
Q 45.45	What issues arise with respect to overtime pay for employees?.....	45-34
Q 45.46	What is the impact of the “duty of candor”?	45-34
Q 45.47	What is the impact of the “any qualified provider” concept?.....	45-34
Q 45.48	What if the seller is subject to product liability claims?.....	45-35
Q 45.48.1	What are the elements of a product liability action?.....	45-35
Q 45.48.2	Who are the potential defendants?.....	45-35
Q 45.48.3	What defenses are available?.....	45-36
Q 45.48.4	What is the limitation period?	45-36
Q 45.49	What if the seller is subject to clinical negligence claims?.....	45-36
Q 45.49.1	What are the elements of a tort action for clinical negligence?.....	45-36
Q 45.49.2	Who are the potential defendants?.....	45-37
Q 45.49.3	Can a contract action be brought?.....	45-37
Q 45.49.4	What is the limitation period?	45-37
Q 45.50	Where can a buyer find published quality or performance data about the target?.....	45-38
Q 45.51	What data protection considerations apply in health care M&A transactions?	45-38
Q 45.52	Are there particular intellectual property considerations?.....	45-39
Q 45.53	Does the Bribery Act have any implications in health care transactions?.....	45-40
Q 45.54	Are there any special requirements to be a director of a health care company?.....	45-40
Q 45.55	What impact will Brexit have on M&A transactions in the health care sector in England?	45-41

Chapter 46 Health Care M&A Transactions in Canada

Cheryl Satin & Megan Shaw

Regulatory Environment	46-3
Q 46.1 What is Health Canada?	46-3
Q 46.2 What role do the provinces play?	46-4
Q 46.3 What is the role of the Patent Medicine Prices Review Board?.....	46-5
Q 46.4 How is the advertising of health care products regulated?	46-5
Q 46.5 Is there self-regulation in the industry?.....	46-6
Q 46.6 What legislation governs pharmaceutical products, medical devices, and natural health products in Canada?	46-7
Q 46.6.1 What is the scope of the Food and Drugs Act?.....	46-7
Q 46.6.2 What criminal laws are applicable?	46-7
Q 46.6.3 Are there applicable provincial laws as well?.....	46-7
Q 46.6.4 What is the effect of the Patent Act?	46-8
Q 46.6.5 What competition laws apply?	46-8
Structuring the Transaction and Obtaining Regulatory Approvals	46-8
Q 46.7 What considerations affect the choice of a share purchase versus an asset purchase?	46-8
Q 46.8 What is the general process for transferring licenses and approvals for pharmaceutical and medical device products?	46-9
Q 46.9 What notices and approvals do health regulatory authorities require in connection with transactions involving pharmaceutical products?	46-10
Q 46.10 What notices and approvals do health regulatory authorities require in connection with transactions involving medical device products?	46-12
Competition Law	46-14
Q 46.11 What mergers are subject to Canadian competition laws?.....	46-14
Q 46.12 What are the thresholds that trigger a duty to give notice of a merger?.....	46-14
Q 46.12.1 What is the effect of the Canadian thresholds as compared to the lower U.S. thresholds?	46-15
Q 46.13 What substantive test is applied to mergers under Canadian competition/antitrust laws?.....	46-16
Q 46.14 What is the current enforcement policy regarding the health care industry?	46-17

Table of Contents

Q 46.15	In what ways does the Canadian Competition Bureau cooperate with agencies in other countries?	46-18
Q 46.16	What are some examples of transactions that have raised competition concerns?	46-19
Investment Canada Act		46-21
Q 46.17	Are there any restrictions on foreign investment in the health care industry in Canada?	46-21
Bulk Sales		46-22
Q 46.18	Is compliance with bulk sales legislation required?	46-22
Some Due Diligence Considerations		46-22
Q 46.19	What are the legal requirements for transferring material contracts?	46-22
Q 46.19.1	Should notice be given to the counterparty in any case?	46-23
Q 46.20	What issues should be considered relating to third-party distribution arrangements?	46-24
Q 46.21	What are the anticorruption risk considerations?	46-25
Privilege		46-26
Q 46.22	What privileges are recognized in Canadian law?	46-26
Q 46.22.1	What is solicitor-client privilege?	46-26
Q 46.22.2	What is litigation privilege?	46-26
Q 46.22.3	What is settlement privilege?	46-27
Q 46.22.4	What is common interest privilege?	46-27
Q 46.23	When documents need to be disclosed, what should be done to preserve a potential claim for common interest privilege?	46-28
Anti-Spam Laws		46-28
Q 46.24	What restrictions apply to sending commercial electronic messages?	46-28
Q 46.25	What are the penalties for violations?	46-29
Q 46.26	What due diligence is appropriate?	46-29
Transaction Documents		46-30
Q 46.27	What documentation is typically required in a share purchase?	46-30

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 46.28	What documentation is typically required in an asset purchase?	46-31
Q 46.28.1	What is the value of a separate transfer agreement relating to Canadian assets?	46-31
Q 46.29	What is a transition services agreement?	46-32
Product Liability		46-32
Q 46.30	Are class actions used in product liability cases?	46-32
Q 46.31	Are individual actions used in product liability cases?.....	46-33
Q 46.32	What is the basis for a product liability claim?	46-33
Q 46.33	Who is potentially liable?	46-34
Q 46.34	What damages may be available?	46-34
Q 46.35	Where can one find public information about claims against the target?	46-35
Anticorruption Laws		46-35
Q 46.36	What are the main Canadian anticorruption statutes?	46-35
Q 46.37	How does the CFPOA address corruption?.....	46-36
Q 46.37.1	Could “foreign public officials” include non-Canadian health care professionals?	46-36
Q 46.37.2	What payments are permitted as exceptions?	46-37
Q 46.37.3	What are the penalties for violations?.....	46-37
Q 46.38	How does the Criminal Code address corruption?	46-37
Q 46.38.1	When is a health care professional a “government official”?	46-38
Q 46.38.2	Do the Criminal Code provisions reach private sector activity?	46-39
Q 46.38.3	What are the penalties for violation of the anticorruption offenses?	46-39
Q 46.39	How does Canadian anticorruption law compare to that of the United States?.....	46-39
Q 46.40	How does Canadian anticorruption law compare to that of the United Kingdom?	46-40
Q 46.41	Can an acquiring company be liable for the target’s anticorruption violations?.....	46-40
Procurement System		46-41
Q 46.42	What is the legal framework applicable to the procurement of health care goods and services in Canada?	46-41
Q 46.43	What information does a purchaser need to know about a target’s eligibility to participate in the Canadian public procurement process?	46-43

Table of Contents

Q 46.44	If a target has a bid pending in a binding competitive government procurement, is there anything a purchaser should consider?	46-46
---------	---	-------

Chapter 47 Health Care M&A Transactions in Japan

Taisuke Igaki & Yoko Kasai

Overview of the Health Care Industry in Japan.....	47-5
---	-------------

Q 47.1	What is the structure of the health care insurance system in Japan?	47-5
Q 47.2	How are the market prices of drugs determined?.....	47-6
Q 47.3	How are the market prices of medical devices determined?.....	47-6

Structuring Health Care M&A Transactions in Japan.....	47-7
---	-------------

Q 47.4	How are transactions typically structured?.....	47-7
Q 47.5	What are the primary differences among the structures?	47-7
Q 47.6	What are the differences from a tax perspective?.....	47-9
Q 47.6.1	What is the tax treatment of a stock transfer?	47-9
Q 47.6.2	What is the tax treatment of a business transfer?	47-9
Q 47.6.3	What is the tax treatment of a company split?.....	47-10
Q 47.7	Are there cases where a buyer takes over the tax liabilities of the target?	47-11

Corporate Procedures Required for Each Structure.....	47-12
--	--------------

Q 47.8	What are the required procedures for stock transfers?	47-12
Q 47.9	What are the required procedures for business transfers?.....	47-13
Q 47.10	What are the required procedures for company splits?	47-15
Q 47.10.1	What procedures are required under the Companies Act?	47-16
Q 47.10.2	What is a simplified company split?	47-16
Q 47.10.3	How are employee relationships handled in a company split?.....	47-17

Regulatory Framework and Compliance in the Health Care Industry	47-18
--	--------------

<i>Pharmaceuticals and Medical Devices.....</i>	<i>47-18</i>
---	--------------

Q 47.11	What is the primary law governing the health care industry in Japan?	47-18
Q 47.12	What is a “drug” under the Pharmaceuticals and Medical Devices Act?	47-19

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q 47.13	What is a “medical device” under the Pharmaceuticals and Medical Devices Act?.....	47-19
	<i>Regulatory Pathways; Licenses and Approvals</i>	47-20
Q 47.14	What are the regulatory pathways for the development of drugs and medical devices?.....	47-20
Q 47.15	What are the marketing authorizations for drugs?.....	47-20
Q 47.15.1	What is a marketing authorization holder?	47-21
Q 47.15.2	What is the role of the drug master file system?.....	47-21
Q 47.16	What business licenses are required for manufacturing drugs?	47-21
Q 47.17	What business licenses are required for marketing drugs?.....	47-22
Q 47.18	What are the required regulatory approvals for the marketing of medical devices and in vitro diagnostic drugs?.....	47-22
Q 47.19	What business licenses are required for manufacturing medical devices and in vitro diagnostic drugs?	47-23
Q 47.20	What business licenses are required for marketing medical devices and in vitro diagnostic drugs?.....	47-23
Q 47.21	What are the regulatory approvals and business licenses for marketing, manufacturing, and distributing regenerative medicine products?.....	47-24
Q 47.21.1	What marketing authorization is needed for regenerative medicine products?.....	47-24
Q 47.21.2	What marketing business license is needed for regenerative medicine products?.....	47-25
Q 47.21.3	What manufacturing business license is needed for regenerative medicine products?.....	47-25
Q 47.22	What are the procedures for transferring marketing authorizations for drugs and medical devices in connection with health care M&A?.....	47-25
Q 47.22.1	What are the procedures where a stock transfer is involved?	47-25
Q 47.22.2	What are the procedures where the transaction is a merger, company split, or business transfer?	47-26
Q 47.23	What regulations govern preclinical studies and clinical trials?.....	47-27
Q 47.24	What post-market safety monitoring is in place for medicinal products?.....	47-28
Q 47.25	What is the relief system for adverse drug reactions in Japan?	47-28
Q 47.26	What are the restrictions on advertising medicinal products?.....	47-29

Table of Contents

Q 47.27	What are the restrictions on improper promotional activities for drugs or medical devices?.....	47-29
Q 47.27.1	What is the Fair Competition Code?	47-29
Q 47.27.2	Is resale price maintenance prohibited?	47-30
Q 47.28	What are the major regulatory compliance issues in the health care industry in Japan?.....	47-30
Other Key Due Diligence Considerations		47-31
Q 47.29	How can intellectual property rights in drugs be protected under Japanese patent law?.....	47-31
Q 47.29.1	What is the term of patent protection?	47-31
Q 47.29.2	Can generic versions of drugs be approved during the patent term?	47-32
Q 47.30	Is there any “data exclusivity” or “market exclusivity” for drugs in Japan?	47-32
Q 47.31	What are the key issues in contract review for health care M&A due diligence?	47-33
Q 47.32	What are the merger control regulations in Japan?	47-33
Q 47.33	Are there any restrictions on foreign investment?	47-34
Index		I-1

About This Book

This book is designed to offer our readers easy access—through its question-and-answer format—to reliable guidance on an array of legal and practical issues arising in health care merger and acquisition (M&A) transactions. We wrote this book for those who find the health care sector or M&A generally mystifying or fascinating. We wrote it for those who regularly work at or for health care companies and are suddenly asked to advise on or manage an acquisition or sale. We wrote it for M&A practitioners who need to understand the intersection of their specialty with the pharmaceutical or biotech industries. We wrote it for the general counsels and other corporate lawyers who are expected to understand the health care M&A process and advise their directors and management on the legal issues arising at the various stages of a health care acquisition. And we wrote it for outside counsel, private equity deal professionals, industry executives and business development professionals, accountants, investment bankers, and anyone else interested in a detailed overview of the legal aspects of health care M&A transactions.

While the book touches on a number of general M&A topics and concepts, this is not a book about how to do M&A. Instead, we focused on the ways in which these general concepts apply to M&A transactions in the health care sector and sought to provide our readers with practical advice on how to address the various industry-specific issues arising in health care acquisitions, including structuring, regulatory, financing, and tax considerations, due diligence topics, and special issues arising in drafting and negotiating transaction documents. To this end, the book analyzes examples from recent health care transactions and provides practice tips on what to look out for and how to avoid the various pitfalls that our readers may encounter while working on health care transactions.

We endeavored in this book to cover a broad spectrum of health care M&A transactions, but we do not purport to have addressed every issue in every sub-sector of the health care industry: the book is long enough! The book does, however, cover deal-making involving pharmaceutical and biotech companies, hospitals, health insurers, private equity firms investing in health care, and other participants

of the health care sector. In addition to transactions involving outright acquisitions of health care companies, we also sought to review alternative structures used in health care M&A transactions, such as joint ventures, strategic alliances, product and portfolio acquisitions, option transactions, and licensing and collaboration agreements.

Part I: Structuring Health Care M&A Transactions focuses on the various considerations that can have an impact on the structure of a health care M&A transaction. These include provisions relating to purchase price (including earnouts and contingent value rights) and purchase price adjustments, as well as regulatory, antitrust, financing, tax, and accounting considerations. The covered topics also include special issues arising in transactions involving not-for-profit health care facilities and valuation techniques used in health care acquisitions.

Part II: Due Diligence explores the various industry-specific issues on which a buyer should focus in conducting its due diligence investigation of a health care target. It discusses, among others, such topics as the regulatory and compliance issues arising in health care transactions (including compliance with the federal and state health care fraud and abuse laws, Medicare and Medicaid rules, HIPAA, and other health care regulations), intellectual property rights, material contracts, and product liability and medical malpractice claims.

Part III: Transaction Documentation discusses the principal elements of a purchase agreement for a health care transaction. It covers, among others, industry specific representations and warranties, pre- and post-closing covenants, closing conditions, and indemnification provisions typically found in health care acquisition agreements.

Part IV: Special Topics covers several topics that we thought might be of interest to our readers. These include special issues arising in acquisitions of U.S. companies by non-U.S. buyers, as well as an overview of health care M&A transactions in France, Germany, Russia, England, Canada, and Japan.

A health care M&A transaction is a complex process fraught with pitfalls at every stage. The main purpose of this book is to share the authors' substantial practical experience with the various types of transactions discussed in the book. We hope you find these insights useful.

Acknowledgments

First and foremost, we want to thank all of our contributing authors, both our colleagues here at Debevoise and outside the firm, who have worked incredibly hard, often under intense time pressure, to make sure every chapter in this book is professional, accurate, accessible, and, we hope, terribly informative.

We could never have made this happen without the tireless efforts of the many folks at Debevoise—past and present—who contributed over the years to the effort and who have been so instrumental in making this project come together. On the top of the list are Michelle Maupin and former Debevoise counsel Dmitry A. Tartakovskiy, former Debevoise associate Jonathan L. Lubin, and Debevoise associate Michael G. Stern. We are so appreciative of their incredible dedication to the project. And finally, we could never have gotten this done without our fabulous assistants, Darlene Ivan and Claudia Creason Moran.

On a more personal note, Andrew would like to dedicate this book to the memory of his father, Donald S. Bab, who passed away during its writing and who has been an inspiration to him.

Glossary and Abbreviations

340B Drug Pricing Program	A federal program established under section 340B of the Public Health Service Act (1992) that requires drug manufacturers to provide outpatient drugs to eligible nonprofit health care organizations at reduced prices
501(c)(3)	The provision of the Internal Revenue Code under which most not-for-profit health care providers are exempt from federal income tax
505(b)(2)	See New Drug Application
510(k)	See Premarket Notification
Abbreviated New Drug Application (ANDA)	The application submitted to the FDA for approval of a “generic drug product.” A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. The ANDA submissions are governed by 21 C.F.R. Part 314, Subpart C.
ACA	See Patient Protection and Affordable Care Act
Accountable care organization (ACO)	A group of doctors, hospitals, and other health care providers intended to give coordinated, high-quality care to patients
ACO	See Accountable care organization
Adverse event report	A report submitted by an NDA holder to the FDA containing information about an adverse event associated with its drug
<i>Agence Nationale de Sécurité des Médicaments et des Produits de Santé</i> (ANSM)	The French governmental agency responsible for the safety of health products

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

AIA	America Invents Act of 2011
ALJ	Administrative law judge
ANDA	See Abbreviated New Drug Application
ANSM	See <i>Agence Nationale de Sécurité des Médicaments et des Produits de Santé</i>
Anti-Kickback Statute	A federal criminal statute, 42 U.S.C. 1320a-7b(b), that prohibits offering, giving, soliciting, or receiving anything of value in order to induce or reward the referral of business under a federal health care program
API	See Bulk active pharmaceutical ingredients
ASC	Ambulatory surgical center
AST	Aboveground storage tanks
ATM	See At the market
At the market (ATM)	A registered offering of listed securities sold directly into the public markets through a broker-dealer over a period of time. Usually involves a small number of shares being sold at the issuer's discretion on any given day at prevailing market prices.
Bayh-Dole Act	A federal statute that allows nonprofit organizations such as universities to elect to take title to federal agency funded inventions in return for the grant to the U.S. government of a royalty-free, nonexclusive license to the invention
Biologic (biological product)	Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man, 21 C.F.R. § 600.3(h); typically created through a biological process rather than chemically synthesized
Biologics license application (BLA)	A request for authorization, or license, to introduce a biologic product into interstate commerce in the United States. 21 C.F.R. § 601.2. The content of a BLA and rules for biologics licensing are governed by 21 C.F.R. Part 601.

Glossary and Abbreviations

Biologics Price Competition and Innovation Act (BPCIA)	A federal statute that establishes an approval pathway for manufacturers of follow-on biologic products or “biosimilars” to obtain a biologic product license for a product that is biosimilar to a reference product without having to duplicate the innovator product manufacturer’s safety and efficacy data. The BPCIA also provides a period of exclusivity to innovator biologic products.
Biosimilar	A biological product that is “highly similar” to an already-approved biological product, including in safety and efficacy, and thus receives approval for use based on these similarities
BLA	See Biologics license application
BPCIA	See Biologics Price Competition and Innovation Act
Bringdown condition	Condition to closing of an acquisition agreement that a party’s representations and warranties be true and correct as of the closing date
Bulk active pharmaceutical ingredients (API)	Any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. See 21 C.F.R. § 207.3. APIs are regulated as drugs pursuant to the FFDCA.
CAA	Clean Air Act
CAH	Critical access hospital
CAPA	See Corrective and preventive action
CBER	Center for Biologics Evaluation and Research, a unit of the FDA
CBP	Customs and Border Protection
CCN	See CMS Certification Number
CCSQ	Center of Clinical Standards and Quality, a unit of the Centers for Medicare and Medicaid Services (CMS)

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research, a unit of the FDA
CDRH	Center for Devices and Radiological Health, a unit of the FDA
Center for Medicare and Medicaid Innovation	A unit of the Centers for Medicare and Medicaid Services charged with providing funding to support demonstration initiatives that test innovative ways to improve the delivery of health care and advance effective models for broader adoption, with a focus on high-cost populations, individuals dually eligible for Medicare and Medicaid, and individuals with chronic health conditions
CEPS	See <i>Comité Economique pour les Produits de Santé</i>
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act, also known as “Superfund”
Certificate of need (CON)	Administrative approval of the construction, acquisition, or expansion of a hospital or other health care facility required in certain states
CfC	See Conditions for coverage
cGMP	See Current good manufacturing practice
CHAMPUS	See TRICARE
Children’s Health Insurance Program (CHIP)	State-administered program intended to provide health coverage to children in families with incomes too high to qualify for Medicaid
CHIP	See Children’s Health Insurance Program
CHOW	See Medicare Change of Ownership
CIA	See Corporate integrity agreement

Glossary and Abbreviations

Citizen petition	A formal submission to the FDA, in which a member of the public (including a company or industry group) may request FDA action. The specific format is dictated by regulation. See 21 C.F.R. § 10.30.
Civil Monetary Penalties (CMP) Law	A provision of the Social Security Act authorizing the government to assess money fines for a variety of conduct relating to health care fraud, including submitting false claims for payment to the government and violations of the Anti-Kickback Statute and the Stark law
Class I Medical Device	A medical device subject only to general controls because (1) such general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or (2) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish “special controls” to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury. See 21 C.F.R. § 860.3(c)(1); General controls.
Class II Medical Device	A medical device subject to “special controls” because general controls alone are insufficient to provide reasonable assurances of its safety and effectiveness and there is sufficient information to establish special controls to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the special controls must be determined to provide adequate assurance of safety and effectiveness. See 21 C.F.R. § 860.3(c)(2); General controls.

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Class III Medical Device	A medical device (1) as to which insufficient information exists to determine that general controls and the additional “special controls” applicable to Class II Medical Devices are sufficient to provide reasonable assurance of its safety and effectiveness and (2) which is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. See 21 C.F.R. § 860.3(c)(3); Premarket Approval; General controls.
Clinical Laboratory Improvement Amendments (CLIA)	Program for certification of laboratories (other than research laboratories), implemented by the Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ) of the Centers for Medicare and Medicaid Services (CMS)
Clinical research organization (CRO)	An entity created in the biopharmaceutical industry to further the development of and manage clinical trials
CMHC	Community mental health center
CMMI	See Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare and Medicaid Services
CMS Certification Number (CCN)	A number unique to each Medicare service provider that identifies survey and certification reports performed by a state agency and is tied to that provider’s Medicare participation agreement; also called a Provider Transaction Access Number (PTAN)
CNIL	See Commission Nationale de l’Informatique et des Libertés
COBRA	Consolidated Omnibus Budget Reconciliation Act
<i>Code de la Santé Publique</i> (CSP)	The French Public Health Code

Glossary and Abbreviations

<i>Comité Economique pour les Produits de Santé</i> (CEPS)	A committee established by the French Ministry of Health, Ministry of Economy, and Ministry of Social Security that determines which products can be reimbursed by the French social security system, and to what extent
<i>Commission Nationale de l'Informatique et des Libertés</i> (CNIL)	The French data protection agency
Committed equity financial facility (CEFF)	Sale of a specific dollar amount of equity securities to an investor over a period of time. The issuer may determine in its discretion the timing, dollar amount, and floor price for any draw under the facility based upon a contractual formula tied to a volume-weighted average price of the common stock.
CON	See Certificate of need
Conditions for coverage (CfC)	Health and safety standards established by CMS that providers of health care services must meet in order to begin and continue participating in Medicare Part B (medically necessary services and preventive services) and Medicaid
Conditions of participation (CoP)	Health and safety standards established by CMS that providers of health care services must meet in order to begin and continue participating in Medicare Part A (hospital, nursing home, hospice) and Medicaid
Contingent value rights (CVRs)	Rights issued to stockholders of an acquired company that will pay out depending upon the acquiring company's achievement of specified financial milestones

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Contract research organization (CRO)	A person that assumes, as an independent contractor with the sponsor of a clinical investigation, one or more of the obligations of a sponsor, for example, design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA. 21 C.F.R. § 312.3.
Controlled premises	Registered establishments (including factories, warehouses, and other establishments) where regulated persons may lawfully hold, manufacture, and distribute controlled substances or where records relating to those activities are maintained
Controlled substance	A drug classified into one of five schedules based on its medical value, potential for abuse, and capacity for producing physical or psychological dependence
CoP	See Conditions of participation
Copyright	An exclusive right to reproduce, distribute copies, make derivative works, publicly perform, and publicly display an author's original expression that is fixed in a tangible media, such as printed or written on paper, audio or visually recorded, or saved on a computer media
CORF	Comprehensive outpatient rehabilitation facility
Corporate integrity agreement (CIA)	A contract between a company and the U.S. government in which the company agrees to undertake a set of defined obligations designed to promote compliance with federal law
Corporate practice of medicine (CPOM)	The practice of medicine by a business corporation or employment of a physician by a business corporation to provide professional medical services. Such practices are prohibited by law in certain states.

Glossary and Abbreviations

Corrective and preventive action (CAPA)	Systems adopted by medical device manufacturers (pursuant to QSRs) and drug and biologic manufacturers (under cGMPs) to monitor their processes, investigate complaints, identify and correct product nonconformities or quality problems, and prevent recurrence of such problems
CPG	Compliance policy guide
CPOM	See Corporate practice of medicine
CRO	See Clinical research organization; Contract research organization
CSA	Controlled Substances Act
CSP	See Code de la Santé Publique
Current good manufacturing practices (cGMPs)	Manufacturing practices required by FDA regulations, 21 C.F.R. Parts 210 and 211, that contain the “minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess,” 21 C.F.R. § 210.1(a)
CVR	See Contingent value rights
DDC	Drug development company
DEA	Drug Enforcement Agency

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Debarment	Statutory authority that permits the FDA to prohibit researchers from conducting clinical testing of new drugs and devices where a clinical investigator has repeatedly or deliberately submitted false information to the agency or the study sponsor in a required report; or it determines that the researcher has repeatedly or deliberately failed to follow the rules intended to protect study subjects and ensure data integrity. FDA also has authority to debar individuals and firms that have been convicted of certain felonies or misdemeanors related to generic drug products.
Derivation proceeding	A proceeding in which a patent may be awarded to an original inventor who shows that another inventor derived his, her, or its invention from the original inventor
DMF	See Drug Master File
DPA	Deferred prosecution agreement
DOJ	Department of Justice
Drug Master File (DMF)	Discretionary submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more drugs
DTC	Direct-to-consumer
Earnout	A contractual provision by which the seller of a company or asset can receive additional compensation in the future if the acquired company or asset achieves financial goals or product milestones agreed upon in advance by the parties
EBITDA	Earnings before interest, income taxes, depreciation, and amortization

Glossary and Abbreviations

EBITDAR	Earnings before interest, income taxes, depreciation, amortization, and rent
EBITDARM	Earnings before interest, income taxes, depreciation, amortization, rent, and management fees
EEOC	Equal Employment Opportunity Commission
EIR	See Establishment Inspection Report
EPA	Environmental Protection Agency
ePHI	Electronic protected health information
ERISA	Employee Retirement Income Security Act of 1974
ESOP	Employee stock ownership plan
ESRD	End-stage renal disease
Establishment Inspection Report (EIR)	A final report on inspection of a manufacturing, processing, or storage facility by the FDA that contains the FDA's final judgment regarding regulatory violations and other observations
False Claims Act	A federal statute, 31 U.S.C. § 3729 <i>et seq.</i> , that imposes civil liability in the form of penalties and damages against those who knowingly present or cause to be presented a false or fraudulent claim to the federal government, as well as against those who knowingly make or use or cause to be made or used a false record or statement material to a false or fraudulent claim
FAS	Federal Antimonopoly Service of the Russian Federation
FASB	Financial Accounting Standards Board
FCPA	Foreign Corrupt Practices Act
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act
FEHBP	Federal Employees Health Benefits Program
FFDCA	Federal Food, Drug, and Cosmetic Act

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOIA	Freedom of Information Act
Form 483	FDA form used to notify drug and device manufacturers of initial findings of violations of cGMP/QSR or other regulatory requirements identified in an FDA inspection
Form A	Statement Regarding the Acquisition of Control of or Merger with a Domestic Insurer, generally required to be filed with a state insurance regulatory authority to obtain approval of a change of control of an insurance company domiciled in the state
Form E	Statement filed with state insurance regulatory authorities in connection with a proposed business combination between insurers summarizing the competitive impact of the combination of the market share of the insurers
FQHC	Federally qualified health center
FTC	Federal Trade Commission
GCPs	See Good clinical practices
General controls	The controls applicable to the manufacture, sale, and marketing of medical devices in the United States under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the FDCA
GINA	Genetic Information Nondiscrimination Act of 2008
GLPs	See Good laboratory practices
GMPs	See Current good manufacturing practices
Good clinical practices (GCPs)	FDA guidances, regulations, and requirements that apply to clinical trials or studies of drugs, biologics, and medical devices

Glossary and Abbreviations

Good laboratory practices (GLPs)	Practices prescribed by FDA regulations that apply to preclinical testing and development of drugs, biologics, and medical devices. See 21 C.F.R. Part 58.
GRAS/E	Generally recognized as safe and effective
HAS	See <i>Haute Autorité de Santé</i>
Hatch-Waxman Act	The Drug Price Competition and Patent Term Restoration Act of 1984, a federal statute that established the regulatory framework applicable to the approval of generic pharmaceuticals. The Hatch-Waxman Act framework includes various structures and incentives to protect the interests of both generic and innovator pharmaceutical manufacturers, such as the opportunity for streamlined approval of generic drugs, the possibility of obtaining certain periods of market exclusivity, a patent dispute resolution framework, and potential patent term extensions to account for the period of FDA regulatory review.
<i>Haute Autorité de Santé</i> (HAS)	The French National Authority for Health
HCERA	Health Care and Education Reconciliation Act
Health Care Fraud Prevention and Enforcement Action Team (HEAT)	A multiagency team of federal, state, and local investigators that investigates health care program fraud in various regions of the United States
Health Care Fraud Statute	A federal criminal statute, 18 U.S.C. § 1347, that prohibits fraud in connection with a submission to obtain health care benefits
Health Information Technology for Economic and Clinical Health Act (HITECH Act)	Act that provides incentives for the adoption of electronic health records, modifies HIPAA requirements, and imposes new obligations related to inappropriate disclosures of protected health information (PHI); passed as part of the American Recovery and Reinvestment Act of 2009

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Health Insurance Portability and Accountability Act of 1996 (HIPAA)	Act that authorizes the Department of Health and Human Services (HHS) to promulgate regulations regarding standard electronic transactions and privacy and security for patient information. These rules establish the federal standards for protecting “protected health information” (PHI).
Health maintenance organization (HMO)	A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO
Health Resources and Services Administration (HRSA)	A unit of the U.S. Department of Health and Human Services responsible for increasing access to health care services
HEAT	See Health Care Fraud Prevention and Enforcement Action Team
Herfindahl-Hirschman Index (HHI)	A measurement of market concentration commonly used in merger analysis
HHA	Home health agency
HHI	See Herfindahl-Hirschman Index
HHS	Department of Health and Human Services
HHS OIG	Office of Inspector General of the Department of Health and Human Services
HIPAA	See Health Insurance Portability and Accountability Act of 1996

Glossary and Abbreviations

HIPAA Privacy Rule	Regulations promulgated by the HHS Office for Civil Rights (OCR) under Title II of HIPAA, which establishes the federal requirements for the use and disclosure of individually identifiable health information by “covered entities,” including health care clearinghouses, certain public and private health plans (that is, payors), and certain health care providers. The regulations also apply to certain contractors (called “business associates”) that create, receive, transmit, or maintain protected health information on behalf of covered entities.
HITECH Act	See Health Information Technology for Economic and Clinical Health Act
HMO	See Health maintenance organization
Homeopathic drug	A category of drug products developed pursuant to the principles of homeopathy that generally do not require formal FDA approval, nor are they required to comply with an OTC monograph. Homeopathic medicines treat the symptoms and conditions of disease with drugs derived from substances that have produced similar symptoms in healthy subjects.
Homeopathic Drug CPG	Compliance policy guide published by the FDA that sets forth enforcement policies for manufacture and distribution of homeopathic drugs
Homeopathic Pharmacopeia of the United States (HPUS)	A compendium of homeopathic drugs, identified in the FFDCAs as an “official” compendium
HPUS	See Homeopathic Pharmacopeia of the United States
HRSA	See Health Resources and Services Administration
HSR Act	Hart-Scott-Rodino Antitrust Improvements Act of 1976

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

IASB	International Accounting Standards Board
ICF/MR	Intermediate care facility for persons with mental retardation
IDE application	See Investigational Device Exemption application
Import alert	An FDA product-specific or categorical warning that generally prohibits the importation of specified articles
Import detention	An FDA administrative act requiring that imported articles that appear to violate FDA-administered laws be held intact
Import hold	An FDA administrative act requiring that an imported item be held pending further information from sampling or examination
IND	See Investigational New Drug Application
Independent Payment Advisory Board (IPAB)	An advisory body created by the PPACA that is charged with making recommendations for reducing Medicare costs
Institutional review board (IRB)	A board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. 21 C.F.R. § 50.3(i).
Investigational Device Exemption (IDE) application	Application by the sponsor of an investigational medical device for exemption from the prohibition against transport, distribution, or marketing of medical devices across state lines without first obtaining FDA approval or clearance. The IDE application is governed by 21 C.F.R. Part 812, Subpart B.
Investigational New Drug (IND) application	Application by the sponsor of an investigational drug for exemption from the legal requirement that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. The IND application is governed by 21 C.F.R. Part 312, Subpart B.

Glossary and Abbreviations

IPAB	See Independent Payment Advisory Board
IPR&D	In-process research and development
IRB	See Institutional review board
Joint Commission	A not-for-profit organization that accredits and certifies health care organizations and programs in the United States. A hospital accredited by the Joint Commission is deemed to have met applicable Conditions of Participation (CoPs) and other applicable regulatory requirements in some states. Formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
Joint venture	An arrangement between parties for a limited and specific purpose; especially an equity arrangement whereby two or more parties form a new entity or buy into an existing entity to carry out an enterprise together
JSC Law	The Russian federal law on joint stock companies
Lanham Act	A federal statute, 15 U.S.C. §§ 1051–1141n, that prohibits trademark infringement and dilution, false advertising, and cyberpiracy, among other things. It permits a private plaintiff to bring a claim based on false or misleading promotion, or based on a trademark or trade dress (product packaging or design) that is likely to cause consumer confusion as to the source or sponsorship of goods or services.
LTC	Long-term care
MAC	Medicare administrative contractor
MACPAC	See Medicaid and CHIP Payment and Access Commission
Managed care organization (MCO)	An organization, such as an HMO or PPO, that provides care using techniques intended to reduce costs

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

March-in right	Right of the federal agency that funds an invention to require the contractor or inventor electing to retain title to an invention under the Bayh-Dole Act to grant licenses to agency-elected applicants on reasonable terms or for the agency to grant sublicenses itself
Market withdrawal	Removal or correction of a distributed product that has a minor violation that would not be subject to FDA legal action or that involves no violation. 21 C.F.R. § 7.3(j).
Mass tort	A class of civil actions in which multiple plaintiffs are injured in a similar fashion, typically by the same defective or allegedly defective product. Mass tort litigation usually cannot be brought as a class action because of the different circumstances surrounding each individual plaintiff's use of the product and the unique factors relevant to each plaintiff's alleged damages.
Material transfer agreement (MTA)	A legal contract defining how materials may be transferred among parties as well as how they can be used
MCO	See Managed care organization
MD&A	Management discussion and analysis
MDR	See Medical device reporting
MDUFMA	See Medical Device User Fee and Modernization Act
Medicaid and CHIP Payment and Access Commission (MACPAC)	An advisory body directed to analyze Medicaid and CHIP services, payment policies, and costs and to make annual recommendations to Congress on ways to strengthen these programs

Glossary and Abbreviations

Medicaid rebate agreement	Agreement between a drug manufacturer and HHS under which the manufacturer is required to pay rebates directly to each state Medicaid agency using a statutorily defined formula that is based, in part, on the company's "best price," which is the lowest price at which the company sells its drug to certain categories of customers. 42 U.S.C. § 1396r-8.
Medical device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h).
Medical device reporting (MDR)	FDA requirements applicable to medical device user facilities, manufacturers, importers, and distributors that require reporting of an event in which a device has or may have caused or contributed to death or serious injury. 21 C.F.R. § 803.1(a).
Medical Device User Fee and Modernization Act (MDUFMA)	A federal statute enacted in 2002 and reauthorized in 2007 that permits the FDA to collect certain types of user fees in connection with the FDA's review of medical device applications and certain annual establishment registration fees

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Medicare Advantage	A type of Medicare health plan offered by a private company that contracts with Medicare to provide Part A (hospital, nursing home, hospice) and Part B (medically necessary services and preventive services)
Medicare Change of Ownership (CHOW)	A change in the legal entity previously assigned a CCN and a UPIN, such that the CCN and UPIN are associated with a new federal taxpayer identification number, resulting in assignment of the seller's Medicare provider agreement
MPFS	Medicare Physician Fee Schedule
MTA	See Material transfer agreement
NAIC	National Association of Insurance Commissioners
National Provider Identifier (NPI)	A health care provider's Medicare billing number, used by CMS (and its fiscal intermediaries) for claims processing and frequently used by other payors, including commercial health insurers; formerly the Unique Provider Identification Number (UPIN)
NCE	See New chemical entity
NDA	See New Drug Application
Negative monograph	Publication by the FDA that lists therapeutic categories in which no OTC drugs can be marketed without approval
New chemical entity (NCE)	A drug in which no active ingredient has been previously approved in any other new drug application. Such a drug is eligible for five-year marketing exclusivity under the Hatch-Waxman Act.

Glossary and Abbreviations

New Drug Application (NDA)	The application submitted to the FDA for approval of the sale and marketing of a new drug in the United States. The standard form, based on a sponsor's own data, is referred to as a 505(b)(1) NDA (named for the relevant section of the FDCA). An alternative form, used when a sponsor is submitting the application based on data it does not own or control, is referred to as a 505(b)(2) NDA. The NDA is governed by 21 C.F.R. Part 314, Subpart B.
NIH	National Institutes of Health
Notice of detention and hearing	A notice issued by the FDA following examination or sampling of an article offered for import indicating that the article appears to be in violation of the FDCA or another act or regulation enforced by the FDA and may be detained
Notice of sampling	A notice issued by the FDA requesting an examination or sample of imported articles subject to FDA oversight and examination
NPA	Nonprosecution agreement
NPI	See National Provider Identifier
NPP	Nonphysician practitioner
OCR	Office for Civil Rights of the U.S. Department of Health and Human Services
OECD	Organization for Economic Cooperation and Development
Off-label	The use of a drug for indications for which the FDA has not reviewed safety or efficacy data as part of a new drug application or OTC drug review. Off-label drug promotion is the promotion of a drug product for uses that are outside the scope of the uses that are contained in an approved drug application or final OTC drug monograph.

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Office of Prescription Drug Promotion (OPDP)	A unit of the FDA's Center for Drug Evaluation and Research (CDER) with responsibility for regulating drug advertising and promotion (formerly the Division of Drug Marketing, Advertising, and Communications (DDMAC))
ONC	Office of the National Coordinator for Health Information Technology
OPDP	See Office of Prescription Drug Promotion
OPO	Organ procurement organization
OPPS	Outpatient Prospective Payment System of Medicare
ORA	Office of Regulatory Affairs, a unit of the FDA
Orange Book	<i>Approved Drug Products with Therapeutic Equivalence Evaluations</i> , an FDA publication that identifies drug products approved on the basis of safety and effectiveness by the FDA, including the patents covered by such products
Orphan Drug Act	A federal statute that provides various incentives, including tax incentives and grant funding for clinical trials, and awards seven years of market exclusivity for a drug designated as an "orphan drug"—a drug for the treatment of a rare disease or condition
Order to show cause (OTSC)	May be issued by the DEA as a formal action to deny or revoke a DEA registration as a result of significant violations by a registrant involving failure to maintain effective controls against diversion of controlled substances or a pattern of violations occurring over a prolonged period of time
OTC	Over-the-counter
OTSC	See Order to show cause
PACE	Programs for All-Inclusive Care for the Elderly

Glossary and Abbreviations

PAPS	Promotion and Advertising Policy Staff of the FDA's Center for Devices and Radiological Health (CDRH)
<i>Park doctrine</i>	Doctrine established by the Supreme Court in <i>United States v. Park</i> , 421 U.S. 658 (1975), holding that executives and managers can be convicted of a criminal misdemeanor under the FFDCA based on the acts or omissions of their subordinates if, by virtue of the executive's or manager's position in the company, they had the responsibility and authority to prevent or correct a violation but failed to do so
Patent	A property right granted to the inventor of a novel, nonobvious, and useful invention, which gives the patent owner the exclusive right to make and sell the invention for a specified period of time
Patient Protection and Affordable Care Act (PPACA)	The U.S. health care reform statute enacted in 2010, P.L. 111-148, sometimes referred to as "Obamacare"
PBGC	Pension Benefit and Guaranty Corporation
PDMA	See Prescription Drug Marketing Act
PDUFA	See Prescription Drug User Fee Act
PECOS	See Provider Enrollment, Chain, and Ownership System
Phase 1	<p>(1) Drugs: The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. 21 C.F.R. § 312.21(a).</p> <p>(2) Environment: An initial environmental site assessment.</p>

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Phase 2	<p>(1) Drugs: The controlled clinical studies conducted to evaluate the effectiveness of an investigational new drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. 21 C.F.R. § 312.21(b).</p> <p>(2) Environment: A more intrusive environmental site assessment, typically including soil or groundwater testing.</p>
Phase 3	Expanded human trials of an investigational new drug performed after preliminary evidence suggesting effectiveness of the drug has been obtained. Intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. 21 C.F.R. § 312.21(c).
PHI	See Protected health information
PIM	Program Integrity Manual of the Centers for Medicare and Medicaid Services (CMS)
PIPEs	See Private investments in public equity
PMA	See Premarket Approval
PNO	Premerger Notification Office of the FTC
Potentially responsible person (PRP)	A person upon whom liability for cleanup costs is imposed under CERCLA, including the current owner or operator of a site at which there has been a release of a hazardous substance, and the former owner or operator of the site if such person owned or operated the site at the time the release of hazardous substances occurred
PPACA	See Patient Protection and Affordable Care Act
PPM	Physician practice management

Glossary and Abbreviations

PPO	Preferred provider organization
Premarket Approval (PMA)	FDA process of scientific and regulatory review to evaluate the safety and effectiveness of a Class III medical device, other than a Class III device that is “substantially equivalent” to a device legally marketed prior to May 28, 1976. An application for approval of such devices by the FDA is required under section 515 of the FFDCa. Such devices may not be marketed until approval is granted.
Premarket Notification	Notification provided by a medical device manufacturer to the FDA pursuant to section 510(k) of the FFDCa, informing FDA of the device manufacturer’s intention to market a medical device for which there is a lawfully marketed, substantially equivalent, predicate device. When required, such notification must be submitted at least ninety days in advance of sale.
Prescription Drug Marketing Act (PDMA)	A federal statute that, among other things, prohibits the reimportation into the United States of a U.S.-made prescription drug by anyone other than the drug’s original manufacturer
Prescription Drug User Fee Act (PDUFA)	A federal statute, reauthorized by Congress every five years since its original enactment in 1992, that authorizes FDA to collect fees from companies that produce certain human drug and biological products
Privacy Rule	See HIPAA Privacy Rule
Private investments in public equity (PIPEs)	An offering of equity securities to institutional investors. Can be implemented more quickly and less expensively than underwritten offerings.

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Protected health information (PHI)	Information that is subject to privacy and security regulation under HIPAA. It includes “individually identifiable health information” held or transmitted by a “covered entity” or its “business associate,” in any form. For this purpose, “individually identifiable health information” is information that relates to an individual’s past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual.
Provider Enrollment, Chain, and Ownership System (PECOS)	Internet-based system by which a licensed health care facility may enroll in the Medicare program in order to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries
Provider Transaction Access Number (PTAN)	See CMS Certification Number
PRP	See Potentially responsible person
PTAN	See CMS Certification Number
PTO	Patent and Trademark Office
Quality System Regulations (QSR)	FDA regulations (21 C.F.R. § 820 <i>et seq.</i>) that require medical device manufacturers to establish and maintain quality systems to help ensure that their products consistently meet applicable requirements and specifications
Qui tam	A lawsuit brought by a private plaintiff on behalf of a government. The plaintiff may be entitled to a portion of the government’s recovery in the suit. Qui tam suits are authorized under the False Claims Act.
QSR	See Quality System Regulations
R&D	Research and development
RBC	Risk-based capital

Glossary and Abbreviations

RCO	Responsible corporate officer
RCRA	Resource Conservation and Recovery Act
RDO	See Registered direct offering
REC	See Recognized environmental condition
Recognized environmental condition (REC)	Condition defined under applicable engineering rules as “the presence or likely presence of any hazardous substances or petroleum products on a property under conditions that indicate an existing release, a past release, or a material threat of a release of any hazardous substances or petroleum products into structures on the property or into the ground, ground water, or surface water of the property”
Registered direct offering (RDO)	A public offering of equity securities marketed by a placement agent on an agency basis to a limited number of institutional investors
Right of first offer	Obligation of a party to a joint venture or other multilateral arrangement to offer to sell the interests to the other joint venture participants and keep such offer open for a specified period of time
Rospatent	The Russian Federal Service on Intellectual Property
RPM	Regulatory project manager
SA	See Survey agency
Schedule I	Controlled substance classification applicable to drugs with a high potential for abuse and no currently accepted medical use; Schedule I controlled substances are not legally available to the public
Schedule II	Controlled substance classification applicable to drugs with a high potential for abuse and dependence but also a currently accepted medical use (for example, opioids such as morphine and oxycodone)

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Schedule III	Controlled substance classification applicable to drugs with a moderate potential for abuse and an accepted medical use
Schedules IV and V	Controlled substance classification applicable to drugs with medical uses and successively lower potentials for abuse and dependence
<i>Schéma Régional d'Organisation des Soins</i> (SROS)	A regional plan for the provision of health care services developed by a French regional health agency
SCHIP	State Children's Health Insurance Program
SEC	Securities and Exchange Commission
Second request	A formal request by the DOJ or FTC for additional information concerning a proposed business combination
SOP	See Standard operating procedure
SPARC	Special purpose accelerated research company
SPCC	See Spill Prevention, Control, and Countermeasure
Spill Prevention, Control, and Countermeasure (SPCC)	EPA requirements applicable to both aboveground and underground storage of petroleum and other oils. 49 U.S.C. § 5103(a).
SROS	See <i>Schéma Régional d'Organisation des Soins</i>
Standard operating procedure (SOP)	A written document that formalizes specific operational processes
Stark law	A federal law that prohibits a physician from making a referral to an entity with which the physician, or an immediate family member of the physician, has a financial relationship, for the furnishing of designated health services for which payment is made by the federal government under the Medicare or Medicaid programs, and prohibits the entity from presenting or causing to be presented a claim to the federal government for such services. 42 U.S.C. § 1395nn.

Glossary and Abbreviations

Stock recovery	Removal or correction by a company of a product that has not been marketed or distributed, or has not left the direct control of the company
Strategic Investments Law	The Russian federal Law on Foreign Investments in Entities of Strategic Importance for National Defense and National Security
Survey agency (SA)	An office or division of a state's department of health tasked with determining whether an institutional health care provider meets the requirements for participation in the Medicare program
SWORD	Stock and warrant off-balance sheet research and development
Tentative Final Monograph (TFM)	A publication by the FDA in connection with the second phase of OTC drug review process that sets forth the findings of the relevant advisory review panel with respect to safety and effectiveness, labeling, strength, dosage form, and route of administration of the proposed drug. Following a comment period, the FDA publishes final regulations in the form of a final monograph.
TFM	See Tentative Final Monograph
TPA	Third-party administrator
Trade secret	Valuable information that is not generally known, not readily ascertainable by others, and subject to secrecy
Trademark	Any word, name, symbol, or device, or any combination thereof, that identifies or distinguishes one's goods from those manufactured or sold by others and indicates the source of the goods

HEALTH CARE MERGERS & ACQUISITIONS AB 2018

TRICARE	U.S. Department of Defense health care program that provides civilian health benefits for military personnel, military retirees, and their dependents; formerly known as Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)
TSCA	Toxic Substances Control Act
UBTI	See Unrelated business taxable income
UCC	Uniform Commercial Code
UKBA	United Kingdom Bribery Act 2010
Uniform Standards of Professional Appraisal Practice (USPAP)	A code of ethics and standards developed by the Appraisal Foundation; adopted by most major appraisal organizations in North America and recognized as the generally accepted standards of appraisal practice
Unrelated business taxable income (UBTI)	Income to a tax-exempt organization that is taxable because it is deemed not to be substantially related to the fulfillment of the organization's exempt purposes
Untitled letter	A letter issued by the FDA indicating that it has identified an alleged violations of a statutory or regulatory requirement that does not reach a level of regulatory significance sufficient to result in a warning letter
UPIN	See National Provider Identifier
URA	See Utilization Review Agency
U.S. Preventive Services Task Force (USPSTF)	A government-appointed expert panel in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services
USPAP	See Uniform Standards of Professional Appraisal Practice
USPSTF	See U.S. Preventive Services Task Force

Glossary and Abbreviations

UST	Underground storage tank
Utilization Review Agency (URA)	An entity that conducts prospective, concurrent, or retrospective review of the medical necessity and appropriateness of health care services provided or proposed to be provided to a covered individual
VA	Department of Veterans Affairs
Valid Marketing Authorization	An affirmative decision by the appropriate public health authority in a foreign country to permit a drug, biological product, or device to be sold in that country, even where the item is unapproved by the FDA
VIE	Variable interest entity
WARN	Worker Adjustment and Retraining Notification Act of 1988
Warning letter	A formal advisory letter issued by the FDA indicating its belief that an individual or a company has committed a significant violation of a statutory or regulatory requirement

Current Trends in Health Care M&A

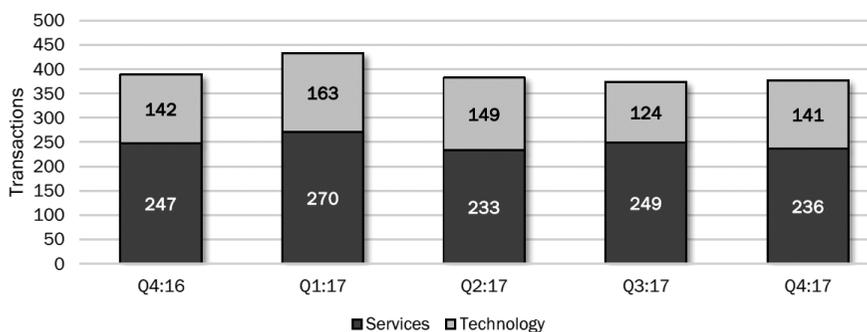
Andrew L. Bab, Jennifer L. Chu & Samantha L. Berkovits

By one key metric, global M&A activity in 2017 remained relatively consistent with 2016. Total deal value in 2017 was \$3.6 trillion, on par with total deal value of \$3.7 trillion in 2016. However, total deal volume increased by 3%; 49,448 deals were announced in 2017, an increase from the 46,055 deals announced in 2016 and the most deals ever recorded in a single year. This increase can be in part explained by a 7% increase in the number of deals valued at less than \$1 billion.¹

Health care was the third most active sector, measured by deal volume, in global M&A in 2017.² 1,566 health care sector deals were announced in 2017, a slight decrease from the 1,593 health care sector deals reported for 2016.³ Deal value in the health care sector in 2017 increased to \$315.3 billion from \$256.7 billion in 2016,⁴ although this number still did not approach 2015 levels, when health care sector deal value was \$563 billion.⁵ Health care deal activity was most pronounced during the first quarter of 2017, when it spiked from the fourth quarter of 2016, but thereafter activity levels fell and remained relatively constant for the remainder of the year.⁶

Quarterly health care transaction volumes for 2017, broken down by deals involving health care “services” (including behavioral health, home health, hospitals, long-term care, managed care, physician medical groups, and rehabilitation services) and those involving health care “technology” (including biotech, medical devices, and pharmaceuticals) are shown in Table 1.

Table 1
Health Care Mergers & Acquisitions
Total Transactions in 2017
by Quarter



Source: Irving Levin Associates, Inc., Health Care M&A Report (Fourth Quarter 2017)

Within the health care sector, the long-term care subsector was the most active based on deal volume, with 300 deals in 2017. The biotechnology subsector was also active, accounting for 208 deals.⁷ Deal volume by subsector for each quarter of 2017 is shown in Table 2 and Table 3.

Table 2
Health Care Mergers & Acquisitions
Deal Volume by Subsector in
Q1 and Q2 2017

	Q2:17 Deals	Q1:17 Deals	Change	Q2:16 Deals	Change
Services					
Behavioral Health Care	8	16	-50%	17	-53%
Home Health & Hospice	9	15	-40%	13	-31%
Hospitals	23	20	15%	20	15%
Labs, MRI and Dialysis	13	12	8%	13	0%
Long-Term Care	75	76	-1%	90	-17%
Managed Care	5	4	25%	5	0%
Physician Medical Groups	30	59	-49%	42	-29%
Rehabilitation	6	12	-50%	10	-40%
Other	51	53	-4%	49	4%
Services subtotal	220	267	-18%	259	-15%
Technology					
Biotechnology	54	63	-14%	34	59%
eHealth	43	48	-10%	60	-28%
Medical Devices	33	23	43%	27	22%
Pharmaceuticals	16	29	-45%	44	-64%
Technology subtotal	146	163	-10%	165	-12%
Grand Total	366	430	-15%	424	-14%

Source: Irving Levin Associates, Inc., Health Care M&A Report (Second Quarter 2017)

Table 3
Health Care Mergers & Acquisitions
Deal Volume by Subsector in Q3 and Q4 2017

	Q4:17 Deals	Q3:17 Deals	Change	Q4:16 Deals	Change
Services					
Behavioral Health Care	12	14	-14%	10	20%
Home Health & Hospice	13	12	8%	24	-46%
Hospitals	21	15	40%	23	-9%
Labs, MRI and Dialysis	16	15	7%	9	78%
Long-Term Care	70	74	-5%	93	-25%
Managed Care	10	8	25%	4	150%
Physician Medical Groups	32	43	-26%	28	14%
Rehabilitation	11	17	-35%	11	0%
Other	51	51	0%	45	13%
Services subtotal	236	249	-5%	247	-4%
Technology					
Biotechnology	49	42	17%	56	-13%
eHealth	30	42	-29%	30	0%
Medical Devices	28	23	22%	23	22%
Pharmaceuticals	34	17	100%	33	3%
Technology subtotal	141	124	14%	142	-1%
Grand Total	377	373	1%	389	-3%

Source: Irving Levin Associates, Inc., Health Care M&A Report (Fourth Quarter 2017)

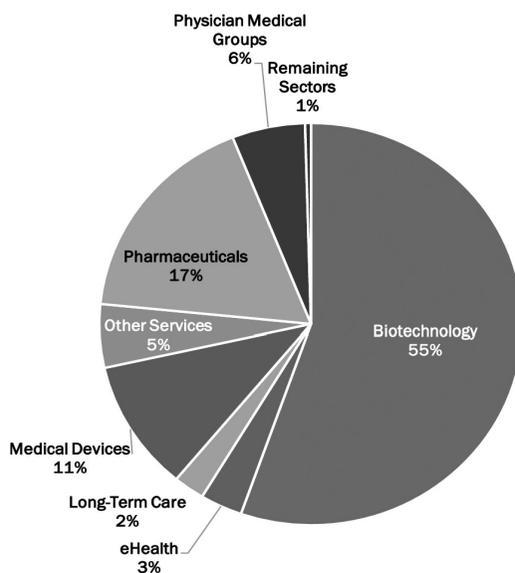
In the first and third quarters, biotechnology constituted 55% (\$32.5 billion) and 33% (\$14.1 billion) of total deal value. Johnson & Johnson's first quarter \$30.2 billion acquisition of Actelion Ltd. and Gilead Science's third quarter acquisition of Kite Pharma for \$11.9 billion accounted for the majority of those quarterly totals. Likewise, in the fourth quarter, a mega-deal in the managed care subsector, CVS Health's acquisition of Aetna for \$77.0 billion, alone accounted for 67% of the quarter's total deal value.

In the second quarter, "Other Services," a subsector which includes contract research organizations, dental practices, and institutional and specialty pharmacy companies, was the largest subsector measured

by deal value, representing 37% (\$34.0 billion) of deal value that quarter with three large transactions announced (for companies involved in pharmaceutical research and laboratory support products and services), each with a value exceeding \$5 billion. The medical devices subsector was nearly tied for total value at 35% (\$33.8 billion) and was bolstered by Becton, Dickinson & Co.'s \$24.0 billion acquisition of C.R. Bard, Inc.⁸

The percentage breakdown of total deal value by subsector in each quarter of 2017 is shown in Table 4.

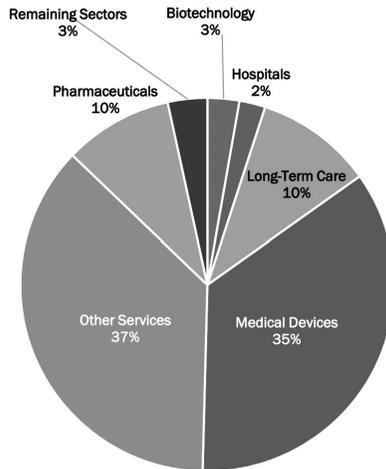
Table 4
Health Care Mergers & Acquisitions
Dollar Volume and Share by Subsector
Q1 2017



Source: Irving Levin Associates, Inc., *Health Care M&A Report (First Quarter 2017)*

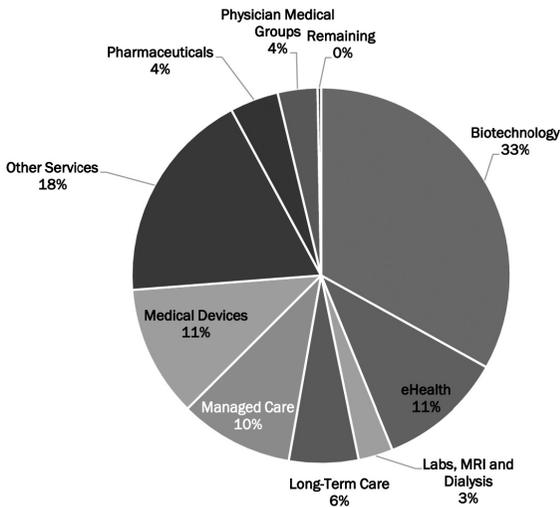
HEALTH CARE MERGERS & ACQUISITIONS AB 2018

Q2 2017



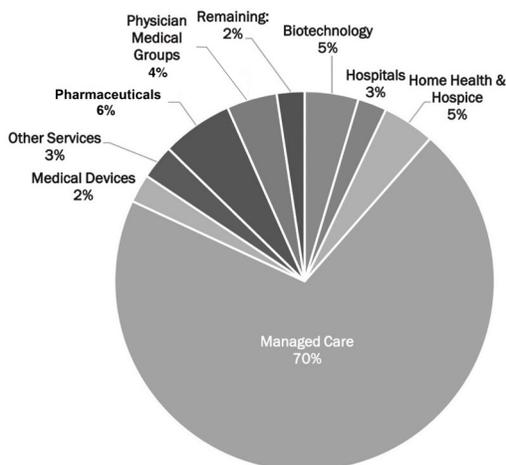
Source: Irving Levin Associates, Inc., Health Care M&A Report (Second Quarter 2017)

Q3 2017



Source: Irving Levin Associates, Inc., Health Care M&A Report (Third Quarter 2017)

Q4 2017



Source: Irving Levin Associates, Inc., *Health Care M&A Report (Fourth Quarter 2017)*

In the remainder of this report, we outline a couple of the trends and developments driving health care M&A activity today. A proactive focus on utilizing highly strategic business structures and deal structures has driven recent health care M&A activity, and we believe will continue to do so.

Vertical Integration

Vertical integration, the practice of merging businesses which operate at different levels of the same industry, is not a new concept for the health care industry. However, in recent years, as industry participants have become increasingly focused on providing cost-effective health care, these deals have become front-page news.⁹

These transactions generally involve three traditionally distinct kinds of health care industry players: insurers, health care providers, and participants in the prescription drug space, whether pharmacies or pharmacy benefit managers. By aligning the interests of parties

with historically divergent goals, buyers aim to create opportunities to develop new ways to control health care costs and models for value-based care,¹⁰ for example, by facilitating access to cost-effective primary/preventive care and decreasing the amount of unnecessary and costly hospitalizations.

In recent years, major health insurers have continued on acquisition sprees for vertical integration opportunities, even while horizontal mergers among the same insurers have been blocked by antitrust regulators. In 2016, Aetna and Texas Health Resources, a twenty-seven-hospital not-for-profit health system based in Arlington, Texas, established a joint venture to own and operate a new health plan.¹¹ During the same year, Anthem joined forces with Aurora Health Care, a fifteen-hospital system based in Milwaukee, Wisconsin, to form a new health insurance company.¹²

UnitedHealthcare Group, through its Optum health services unit, has been at the forefront of health insurers seeking to transform health care delivery. Optum has its own pharmacy benefits manager (PBM) business, as well as a data and analytics arm, and in recent years has been aggressively expanding its health care delivery offerings. In 2017, Optum announced several acquisitions of physician groups, including the acquisition of the DaVita Medical Group for \$4.9 billion.¹³ If the DaVita acquisition closes (which it has not as of the time of writing), it would provide Optum access to 280 clinics offering primary/specialist care, thirty-five urgent care centers, and six outpatient surgery centers. Earlier in the year, Optum also announced the acquisition of ambulatory surgery center and surgical hospital provider Surgical Care Affiliates for \$2.3 billion.¹⁴ The pace of growth for companies like Optum does not appear to be slowing down. During the first quarter of 2018, UnitedHealthcare Group's CEO signaled that the company would continue to be "very strong deployers of capital."¹⁵

Other competitors are following suit. In 2017, Humana, in the wake of its failed merger with Aetna, pivoted to a vertical integration opportunity in the home health sector. Humana teamed up with private equity firms TPG Capital and Welsh, Carson, Anderson & Stowe to acquire Kindred Healthcare, a publicly traded post-acute health care

provider. The transaction, which closed on July 2, 2018, separated Kindred into two businesses: a hospital business owned by the private equity consortium, and a home health, hospice and community care business, owned 40% by Humana and 60% by the private equity consortium.¹⁶ In 2018, Humana and the TPG-Welsh Carson consortium also teamed up to acquire Curo Health, a leading hospice operator, which they intend to combine with the hospice business of Kindred.¹⁷

In late 2017, CVS announced its acquisition of Aetna, a mega-merger valued at approximately \$69 billion. If completed, this deal would integrate an insurer (Aetna), a pharmacy benefits manager (CVS's Caremark unit), CVS's almost 10,000 pharmacies, and CVS's 1,000 Minute Clinics, which offer primary care.¹⁸ The aim is to continue the transformation of CVS's drugstores to one-stop shops for health care.

In the first quarter of 2018, Cigna followed suit and announced it had entered into an approximately \$52 billion agreement to purchase Express Scripts, the country's largest pharmacy benefits manager.¹⁹ The announcement of this deal was less than a year after Cigna's proposed merger with competitor Anthem was terminated. Filings made in connection with the Cigna-Express Scripts merger indicate that Cigna had considered other horizontal merger opportunities before ultimately pursuing the Express Scripts transaction and that Cigna's board discussed changes in the health care environment, including the recently announced CVS-Aetna merger.

By blurring the lines between traditionally separate spheres, the move towards vertical integration has the potential to transform the health care industry. While antitrust regulators have historically reserved their scrutiny for horizontal mergers, this recent wave of vertical integration mega-deals has also drawn their attention. Both the CVS-Aetna and the Cigna-Express Scripts mergers have been subject to DOJ review (although it was reported in July 2018 that the DOJ will not challenge the CVS-Aetna merger), and both deals have attracted congressional scrutiny as well with requests for hearings on the deals.²⁰ At the time of writing, the Optum-DaVita transaction has been similarly held up by requests from the FTC for additional information.²¹ Whether antitrust scrutiny of these deals will impact vertical M&A activity remains to be seen, but the trend towards transformative vertical activity seems likely to continue.

Alternatives to Traditional M&A

There continues to be growing interest in the health care industry in licensing, joint ventures, options, collaborations, and other alternatives to the traditional M&A deal structure. Alternative transactions allow buyers to acquire new capabilities with less up-front financial investment and potentially fewer regulatory approvals.²² Licensing and partnerships can provide smaller companies with the scale and sophistication of a larger organization while allowing the companies to maintain local control. Options allow large buyers to temper their risk while infusing necessary early capital in research and development processes. The downside is that the success of these transactions often depends on the parties being able to effectively collaborate and align their goals.²³

Option transactions—in which a buyer purchases an option to acquire another company or its product or to license another company's product at some future date—have become increasingly popular ways for big pharmaceutical and biotech companies to partner in early-stage products and technology, as well as an important source of potential financing for those early-stage companies. This strategy allows the potential buyer to wait and see how the technology progresses; for instance, the buyer can see whether the research is successful or the FDA approves the drug or device.

2017 saw a number of deals involving the exercise of existing options as well as entry into new option arrangements. For example, Astellas exercised its option to acquire 100% of the equity of Mitobridge, Inc. for total consideration of up to \$450 million—an option which it held under the parties' 2013 partnership agreements, which were focused on developing novel drugs that target mitochondrial function.²⁴ Other notable recent deals include Novartis AG's \$665 million exercising of its exclusive option to buy Selexys Pharmaceuticals Corporation and its developing sickle cell anemia drug following successful completion of its Phase 2 study (the fourth-largest biotechnology deal in 2016); Pfizer Inc.'s \$250 million option to exclusively license Oncolmmune Inc.'s ONC-392 drug; Amgen's \$35 million option to license Arrowhead's technology to reduce elevated lipoproteins; and Johnson & Johnson's option to acquire Bird Rock Bio, Inc., a biopharmaceutical company developing an antibody to treat nonalcoholic steatohepatitis.²⁵

Licensing has always been a critical tool in the health care toolkit and historically has been useful in circumstances where the asset owner is not a suitable M&A target (such as a university). However, in recent years, it is increasingly being used in much larger deals as an alternative to traditional M&A. Licensing arrangements allow for risk sharing and retention of talent at the original developer, while avoiding taking on unwanted products and liabilities. Fees and royalties in such deals can include up-front payments, an opt-in payment payable on exercise of the option, development and commercialization milestone payments, standard royalties, or combinations thereof. Depending on how developed the product is and its prospects for success, there is significant freedom for parties to negotiate how profits will be distributed. These deals tend to be extremely complex and involve all aspects of a product, portfolio of products, or business.

By utilizing licensing agreements, large pharmaceutical companies with struggling research and development pipelines are able to tap into innovative biotech while providing the biotech firm additional resources and marketing. A biotech firm may be working on innovative new formulas and solutions, but will not have the capacity to market and distribute a drug globally, while a large, established pharmaceutical company has that capacity, but may be striking out when it comes to developing a drug that addresses a specific market need.

During the fourth quarter of 2017, of the over 1,100 licensing deals reported, forty-nine were valued in excess of \$100 million, including several worth potentially over \$1 billion. For example, in late 2017, Eli Lilly announced a \$1.8 billion licensing and collaboration deal to work with CureVac on five mRNA cancer vaccines, a therapeutic area where pharmaceutical companies have had a disappointing development track record. Under the terms of the arrangement, Eli Lilly agreed to pay CureVac an up-front payment of \$50 million and to take an equity stake in CureVac valued at \$53 million. In addition, CureVac is eligible to receive up to \$1.7 billion in milestone payments plus royalties on sales if the vaccines are approved.

Also in late 2017, Bayer and Loxo Oncology announced a \$1.55 billion development and collaboration partnership to develop medicines for patients with genetically defined cancers. Under the terms of the arrangement, Bayer agreed to pay Loxo an up-front payment of \$400 million,

and Loxo is eligible to receive up to \$650 million in milestone payments upon regulatory approvals and first commercial sales in certain major markets. In addition, Bayer will pay up to \$475 million in royalties on net sales.

In February 2018, the Janssen Pharmaceutical Companies of Johnson & Johnson entered into a global collaboration and licensing agreement with Theravance Biopharma, Inc. to jointly develop TD-1473, the total consideration for which may reach approximately \$1 billion.²⁶ Johnson & Johnson agreed to pay \$100 million up front with an option to enter into an exclusive license agreement with Theravance Biopharma for an additional \$200 million following the completion of certain Phase 2 activities. Theravance Biopharma is further entitled to receive up to an additional \$700 million based on development and commercialization milestones. In this example, the licensor was granted an option to acquire an exclusive license of important intellectual property related to the compound in exchange for funding research and development activities and taking certain (joint) responsibility for development activities.

For 2018, signs seem to indicate that industry players will continue to pursue M&A to grow and to respond to what appear to be inevitable shifts in the industry driven by reimbursement models, developing technology, and increasing patient-centrism in the consumption of health care.

Notes

1. Thomson Reuters, *Mergers & Acquisitions Review* (Full Year 2016), at 1.
2. J.P.Morgan, 2018 M&A Global Outlook, at 3.
3. Irving Levin Assocs., Inc., *Health Care M&A Report* (Fourth Quarter 2017), at 6.
4. *Id.*
5. Irving Levin Assocs., Inc., *Health Care M&A Report* (Fourth Quarter 2015), at 14.
6. Irving Levin Assocs., Inc., *Health Care M&A Report* (Fourth Quarter 2017), at 7.
7. Irving Levin Assocs., Inc., *Health Care M&A Report* (Fourth Quarter 2017), at 8; Irving Levin Assocs., Inc., *Health Care M&A Report* (Second Quarter 2017), at 8.
8. Irving Levin Assocs., Inc., *Health Care M&A Report* (Fourth Quarter 2017), at 13; Irving Levin Assocs., Inc., *Health Care M&A Report* (Third Quarter 2017), at 13; Irving Levin Assocs., Inc., *Health Care M&A Report* (Second Quarter 2017), at 13; Irving Levin Assocs., Inc., *Health Care M&A Report* (First Quarter 2017), at 13.
9. Sharon Terlep, Anna Wilde Matthews & Dana Cimilluca, *CVS to Buy Aetna for \$69 Billion, Combining Major Health-Care Players*, WALL ST. J., Dec. 3, 2017, www.wsj.com/articles/cvs-to-buy-aetna-for-69-billion-1512325099.
10. Andrew Bab, Maura Kathleen Monaghan, Kevin Rinker, Paul Rubin & Jacob Stahl, *A Look at Recent Efforts to Contain Health Care Costs*, LAW360 (Jan. 5, 2018), www.law360.com/articles/998972/a-look-at-recent-efforts-to-contain-health-care-costs.
11. Bob Herman, *Aetna Strikes Another Hospital Joint Venture*, MODERN HEALTHCARE (May 31, 2016), www.modernhealthcare.com/article/20160531/NEWS/160539989.
12. Bob Herman, *Anthem Hatches Another Hospital Joint Venture, This Time in Wisconsin*, MODERN HEALTHCARE (Apr. 20, 2016), www.modernhealthcare.com/article/20160420/NEWS/160419909.
13. *UnitedHealth to Buy DaVita Primary Care Unit for \$4.9 Billion*, REUTERS (Dec. 6, 2017), www.reuters.com/article/us-davita-m-a-unitedhealth/unitedhealth-to-buy-davita-primary-care-unit-for-4-9-billion-idUSKBN1E01HJ.
14. Alicia McElhaney, *Surgical Care Affiliates Spikes on Deal with UnitedHealth*, THE STREET (Jan. 9, 2017), www.thestreet.com/story/13946591/1/surgical-care-affiliates-sees-shares-spike-on-deal-news.html.
15. Bruce Japsen, *Buying Binge for UnitedHealth's Optum Is Only Just Beginning*, FORBES (Apr. 18, 2018), www.forbes.com/sites/brucejapsen/2018/04/18/the-buying-binge-of-unitedhealths-optum-is-only-just-beginning/#5e20867a192d.

16. *Debevoise Advises TPG Capital and WCAS on Consortium's \$4.1 Billion Acquisition of Kindred Healthcare* (Dec. 19, 2017), www.debevoise.com/news/2017/12/debevoise-advises-tpg-capital-and-wcas.

17. *Humana, Private-Equity Firms to Buy Hospice Operator Curo Health for \$1.4 Billion*, REUTERS (Apr. 23, 2018), www.reuters.com/article/us-curo-m-a-humana/humana-pe-firms-to-buy-hospice-operator-curo-health-for-1-4-billion-idUSKBN1HU1GU.

18. *CVS Health to Acquire Aetna; Combination to Provide Consumers with a Better Experience, Reduced Costs and Improved Access to Health Care Experts in Homes and Communities Across the Country* (Dec. 3, 2017), <https://cvshealth.com/newsroom/press-releases/cvs-health-acquire-aetna-combination-provide-consumers-better-experience>.

19. Katie Thomas, Reed Abelson & Chad Bray, *Cigna to Buy Express Scripts in \$52 Billion Health Care Deal*, N.Y. TIMES, Mar. 8, 2018, www.nytimes.com/2018/03/08/business/dealbook/cigna-express-scripts.html.

20. Lydia Ramsey, *CVS and Aetna's Megamerger Could Get Blocked, and We'll Soon Get a Hint of What Will Happen Next*, BUS. INSIDER (Apr. 12, 2018), www.businessinsider.com/cvs-health-aetna-merger-potential-antitrust-challenges-to-the-deal-2018-4; Susannah Luthi, *Cigna-Express Scripts Deal Needs Congressional Oversight, House Democrat Says*, MODERN HEALTHCARE, www.modernhealthcare.com/article/20180314/NEWS/180319956.

21. Darcy Reddan, *FTC Seeks More Info on DaVita's \$4.9B Sale to Optum*, LAW360 (Mar. 13, 2018), www.law360.com/articles/1021622/ftc-seeks-more-info-on-davita-s-4-9b-sale-to-optum.

22. PricewaterhouseCoopers Health Res. Inst., *Top Health Industry Issues of 2017*, at 14.

23. Mary Rechteris, *How Hospitals Can Play into the ASC Joint Venture Game*, BECKER'S HOSP. REV. (Apr. 29, 2016), www.beckershospitalreview.com/hospital-transactions-and-valuation/how-hospitals-can-play-into-the-asc-joint-venture-game.html.

24. *Astellas Acquires Mitobridge in \$450-Million Deal*, BIO PHARM INT'L (Dec. 4, 2017), www.biopharminternational.com/astellas-acquires-mitobridge-450-million-deal.

25. Irving Levin Assocs., Inc., *Health Care M&A Report (Fourth Quarter 2016)*, at 19, 66; Irving Levin Assocs., Inc., *Health Care M&A Report (Third Quarter 2016)*, at 70, 74.

26. *See Janssen Enters into Worldwide Collaboration with Theravance Biopharma for Oral, Pan-Jak Inhibitor Drug Candidate for the Treatment of Inflammatory Bowel Disease* (Feb. 7, 2018), www.jnj.com/media-center/press-releases/janssen-enters-into-worldwide-collaboration-with-theravance-biopharma-for-oral-pan-jak-inhibitor-drug-candidate-for-the-treatment-of-inflammatory-bowel-disease; *Theravance Biopharma Enters Global Collaboration with Janssen for TD-1473 in Inflammatory Intestinal Diseases* (Feb. 7, 2018), <http://investor.theravance.com/news-releases/news-release-details/theravance-biopharma-enters-global-collaboration-janssen-td-1473>.

Today's Health Care Legal and Regulatory Environment and Its Impact on the Health Care Marketplace

Jacob W. Stahl

In 2016, President Trump and Congressional Republicans campaigned—and won—on pledges to “repeal and replace” the ACA. Although the Republicans’ transformative health care reform plans in Congress have collapsed, the Trump Administration, Congress, and state governments have implemented a variety of initiatives that are likely to have a significant impact on the health care industry for years to come.¹ These changes have created opportunities and risks for strategic companies and investors in the health care industry.

The ACA: What Has and Has Not Changed

The Original ACA Framework

Prior to the enactment of the ACA, people who did not receive health insurance from large employers or government programs often had difficulty obtaining private health insurance. Insurers offering plans for individuals or small groups often refused to cover preexisting conditions or would charge high premiums. The ACA drafters attempted to address these issues through provisions that were designed to ensure that insurance met three objectives, namely that it was (1) affordable, (2) accessible to those who needed it, and (3) provided adequate coverage.

With a few notable exceptions, most of these provisions remain in effect:

- *ACA exchanges*: The ACA provides that each state must have an exchange on which individuals and small groups can purchase health insurance. Insurers must treat everyone who

purchases insurance on the applicable state's exchange as being part of the same risk pool. Insurance plans are categorized into four principal tiers based on the percentage of health care costs the plans are supposed to cover (on an actuarial basis): platinum (90%), gold (80%), silver (70%), and bronze (60%). People under age 30 are also eligible to purchase catastrophic plans, which have lower premiums than bronze plans but have very high deductibles.

- *Insurance regulations to promote accessibility:* The ACA requires insurers to offer insurance to any qualified individuals who want to purchase it and precludes insurers from excluding preexisting conditions from coverage. It also precludes insurers from charging people different rates depending on their health status, although insurers are allowed to charge more (within limits) based on tobacco use and age. The ACA also provides that children can stay on their parents' insurance plan until age 26.
- *Minimum essential benefits:* Plans sold on ACA exchanges must cover ten categories of minimum essential benefits, including emergency services, hospitalization, ambulatory care, maternity care, and prescription drugs.
- *Payout caps:* The ACA prohibits insurers from capping the amount of money an insurer would pay out on an annual or lifetime basis for essential health benefits.
- *Subsidies:* The ACA provides for two forms of subsidies to facilitate the ability of lower income individuals to purchase insurance on exchange plans. The Advance Premium Tax Credit (APTC) provides subsidies on a sliding scale for people making between 100% and 400% of the federal poverty level. Additionally, the ACA originally included Cost Sharing Reductions (CSRs) for anyone making between 100 to 250% of the federal poverty level who purchased a "silver" plan on the exchanges. CSRs were meant to subsidize out-of-pocket expenditures for people with very low incomes. President Trump abolished CSRs in 2017.

- *Individual mandate:* The ACA includes an “individual mandate,” which is a tax on people who do not purchase qualifying health insurance. The tax is \$695 per adult, or 2.5% of taxable income, whichever is larger. The mandate is intended to discourage people from delaying the purchase of health insurance until they become sick. The ACA would otherwise have incentivized such behavior, because the ACA does not allow insurers to charge more or exclude people with preexisting medical conditions. When healthy people decline to purchase health insurance, health insurance premiums typically rise because the risk pool becomes relatively sicker. The mandate is abolished starting in 2019.
- *Medical loss ratios (MLRs):* The ACA requires insurers who offer plans that cover individual and small group plans to have an MLR of at least 80%, meaning that they must spend at least 80% of their premiums on health care claims and quality improvement. The remainder is for administration, marketing, and profits. For insurers that offer insurance to large groups, the MLR must be at least 85%.
- *Medicaid expansion:* Before the ACA, Medicaid covered children and their parents and the low-income elderly; Medicaid did not cover “childless adults.” The ACA allows state Medicaid programs to cover childless adults who earn up to 138% of the federal poverty level. Although the Medicaid expansion was supposed to be mandatory, the Supreme Court held that each state could decide for itself whether to accept the expansion. To date, thirty-three states and Washington, D.C. have expanded Medicaid. The other states have declined to expand Medicaid, typically because of opposition from conservative governors or legislatures to expanding social welfare programs.

What Has Changed During the Trump Administration?

1. Abolition of the Individual Mandate

In December 2017, the Tax Cuts and Jobs Act abolished the individual mandate starting in 2019. The abolition of the mandate may lead some people to stop purchasing health insurance, because they no

longer will be penalized for declining to do so. There is a debate over how many people are likely to stop purchasing insurance after the mandate is abolished. While the Congressional Budget Office estimates that the abolition of the mandate will result in 13 million additional people being uninsured by 2027, others argue that this estimate is too high for several reasons: (1) the mandate has many exceptions and in any event has not actually been enforced; (2) people with lower incomes receive heavily subsidized insurance, so they have a strong incentive to purchase insurance even without the mandate; (3) premiums for many ACA-compliant health insurance plans are so high that some people have decided that it is more economical to pay the mandate tax than health insurance premiums; and (4) some healthy people purchase health insurance without regard to the individual mandate because they are risk-averse.

2. Proposed Expansion of the Availability of Association Health Plans (AHPs)

In January 2018, the Department of Labor issued a Proposed Rule to expand the availability of AHPs. AHPs are business and employer trade associations that offer health insurance to their members. Previously, AHPs were limited to organizations that had a bona fide purpose other than offering health insurance, and AHP plans were subject to the ACA's consumer protection provisions. If the Proposed Rule is finalized and survives potential legal challenges, AHPs could be established for the sole purpose of providing health insurance, provided that the members are either (1) in the same trade, industry, line of business, or profession, or (2) have a principal place of business within the same region—defined as either a state or a metropolitan area, even if it crosses state lines. The Proposed Rule would also allow AHPs to be classified as large group health insurance plans. This categorization is significant because large group plans are exempt from some of the ACA's consumer protection provisions, including the minimum essential benefits requirement. The Proposed Rule would also loosen restrictions on the rates that AHPs could charge members. While AHPs would still be subject to the ACA's prohibitions against charging insured with preexisting conditions higher rates or refusing to cover them altogether, AHPs could still alter premium levels based on age, gender, and location.

3. Proposed Expansion of Short-Term, Limited Duration Insurance (SDLI) Plans

In February 2018, the Departments of Health and Human Services, Labor, and the Treasury issued a Proposed Rule that would expand the availability of SDLI plans. This type of insurance was originally intended for people between jobs. SDLI plans typically provide only limited coverage. For example, such plans may not cover all of the ACA's minimum essential benefits; may charge more for people with preexisting conditions; and may impose caps on the amount that can be paid out over the life of the policy. SDLI plans are often profitable for insurers, because they are not subject to the ACA's MLR requirements. In 2016, the Obama Administration issued a rule which provided that a SDLI plan could have only a three-month term. The Proposed Rule would expand the maximum duration of such policies to 364 days.

Even if the Departments issue a final rule expanding access to SDLI plans, the availability of such policies will vary by state because such plans are subject to state regulation. Some states prohibit SDLI plans from being sold altogether, some states have durations on such policies that are less than a year, and others require SDLI plans to cover certain minimum benefits.

The Departments predict that between 100,000 and 200,000 people will shift from ACA-compliant plans to SDLI plans. Most of these people would not have been eligible to purchase subsidized plans on the ACA exchanges.

4. Abolition of CSRs

In August 2017, the Trump Administration ended CSRs. The Administration justified this decision on the basis of a court ruling that CSRs were unconstitutional because Congress had never appropriated funds for this program. When the Administration made this decision, some warned that it would lead to a spike in prices for “silver” plans because insurers are generally required to fund the CSRs regardless of whether they receive reimbursement from the federal government. In retrospect, the impact appears to be relatively small because the size of the APTC is directly correlated to silver plan premiums. Thus, for low-income individuals, the increase in APTC offset the premium resulting from the termination of CSRs.

What Do the Changes Over the Past Year Mean for the Health Care Industry?

Implementation of the ACA led to a significant increase in the number of people with insurance. That benefitted many health care industry subsectors. Hospitals often treat patients without regard to their ability to pay. When hospitals treat low-income, uninsured patients, the hospital often has to write off the cost of care as charity care or bad debt. Therefore, when there are fewer people who are uninsured, hospitals have lower charity care/bad debt writeoffs. Further, more people with insurance means additional purchasers of services offered by health care providers and products sold by drug and device manufacturers.

These benefits may be partially undone by the changes made over the course of the past year. During the Obama Administration, many people who did not receive health insurance from their employer or the government had essentially two options: (1) purchase ACA-compliant health insurance, or (2) pay the “individual mandate” penalty. This structure was intended to incentivize healthy people to join the exchange risk pool, which would result in healthy people subsidizing the cost of medical care for the sick. As a result of the recent changes, there will be no mandate starting in 2019 and there may be new non-ACA qualified options on the market (either through AHPs or SDLI plans) that are attractive to healthy people who want lower premiums (even at the tradeoff of limited coverage). To the extent that healthy people stop purchasing plans on the ACA exchanges, the risk pool on the ACA exchanges will become sicker. Premiums on ACA-compliant plans may increase as a result. In states which allow non-ACA plans to proliferate, the ultimate result may be that purchasers of plans sold on the ACA exchanges are largely limited to people who receive large subsidies and those that have expensive health conditions.

The cumulative impact of these changes is likely to be more people who have no health insurance at all or elect to purchase plans that offer limited coverage. These trends are likely to intersect with another development that predates the Trump Administration: To limit the rate in increase of premium growth, many health insurers

are increasing the annual deductible (that is, the amount of money consumers must spend out of pocket before insurance coverage kicks in). Thus, either because of high deductibles or “thin” insurance coverage, consumers are likely to be paying for more health care out of pocket.

The increase in the number of people with no health insurance or health insurance with limited coverage is generally bad news for the health care industry, because people paying out of pocket in many cases are unwilling or unable to pay for health care goods and services. Nonetheless, this trend may create opportunities for one subsector: retail providers of health care, including urgent care clinics and providers of primary care in facilities such as pharmacies. To the extent such providers can offer cost-effective care and transparent pricing, they may be uniquely suited to providing care to people who pay for it out of pocket.

What Does Tax Reform Mean for Health Care Companies?

The Tax Cuts and Jobs Act dramatically altered the existing corporate tax framework. The bill reduced the corporate tax rate from 35% to 21% while limiting interest deductibility. For health care companies that derive substantially all of their revenues from the United States—including hospitals, managed care organizations, and physician practices—this reduction in corporate taxes offers a significant benefit.

For multinational health care companies, including pharmaceutical and medtech companies, the impact of the statute is more complex because of the changes in taxation of overseas earnings. The bill imposed a one-time repatriation tax on deferred overseas earnings at a rate of 15.5% for earnings held in cash and 8% for earnings held in noncash assets. The repatriation tax is payable over eight years. Going forward, the United States will have a “territorial” tax system in which dividends received by U.S. companies from their foreign subsidiaries will generally be tax-free. However, there will be a minimum tax imposed on the “excess profits” (defined as the overall income in excess of a stated return on tangible depreciable property) of foreign subsidiaries of U.S. companies, whether or not repatriated. The bill

also contained anti-base erosion provisions that limit the deductibility of payments from U.S. companies to foreign related parties.

These tax reforms are likely to be beneficial to U.S. companies that desire to bring foreign cash back to the United States. These repatriated funds may result in additional research and development and mergers and acquisition activity. For U.S. companies that plan to expand overseas, the repatriation tax is likely to be viewed as a negative, because U.S. tax law previously permitted deferral of offshore earnings.

The other international changes are likely to be of particular interest to multinational health care companies. Although the territorial tax is generally positive, the current tax on excess foreign profits is likely to affect existing structures (including intellectual property holding structures) of U.S. parented groups. The broad anti-base erosion rules will significantly affect the tax planning of foreign parented groups with U.S. affiliates. Companies with significant internal cross-border transactions will be the most heavily affected.

The Tax Cuts and Jobs Act also included a provision that affects only the pharmaceutical industry: a reduction in the orphan drug tax credit. Orphan drugs are drugs that are designed to treat rare diseases that either impact (1) fewer than 200,000 people in the United States or (2) more than 200,000 people in the United States if the cost of developing the drug exceeds anticipated revenue from the drug. The Orphan Drug Act of 1983 provided a variety of incentives to develop orphan drugs. One of those incentives was a tax credit in the amount of 50% of the cost of human clinical testing. That credit has now been reduced to 25%.

While the reduction of this tax credit will hurt the bottom line of pharmaceutical companies that are developing drugs, there are still other provisions of the Orphan Drug Act that make orphan drug development lucrative. Most importantly, approved drugs have seven years of marketing exclusivity—during which time there can be no competitors in the market. Orphan drugs are also exempt from a program which requires certain drugs to be sold to government-supported hospitals and clinics at a discount.

What Changes May Be in Store for the Medicaid Program?

The Medicaid program plays a significant role in U.S. health care. In 2016, Medicaid spending was \$565 billion, which is 17% of total national health expenditures. Approximately two-thirds of Medicaid expenditures nationwide are borne by the federal government. State governments are responsible for the remainder. Medicaid expenditures constitute one of the largest budget items in most states, and the amount states are spending on Medicaid has been growing rapidly.

As part of the health care reform debates of 2017, Congressional Republicans proposed taking steps that would have limited the growth of Medicaid spending. Those efforts failed. Efforts to limit Medicaid expenditures have now shifted to the state level. The Medicaid statute allows states to file section 1115 waiver applications with the Centers for Medicare and Medicaid Services (CMS). If approved, section 1115 waivers allow states to deviate from certain Medicaid requirements. States have been exploring different ways that section 1115 could be used to limit Medicaid eligibility or otherwise restrain Medicaid spending.

Currently, ten states have submitted waiver applications to CMS seeking to impose work requirements on certain categories of adults. In January 2018, CMS approved Kentucky's waiver application. Under the application, applicable adult Medicaid beneficiaries (basically healthy nonpregnant adults ages 19 to 64) must complete eighty hours per month of "community engagement activities," which could include working, education, job skills training, or community service. Applicable beneficiaries who fail to satisfy this requirement would have their Medicaid coverage suspended. Kentucky anticipates that this program would result in 95,000 fewer Medicaid beneficiaries and save the state \$2 billion over five years. This waiver has been challenged in court by Kentucky Medicaid enrollees who have argued that the Medicaid statute does not authorize the imposition of work requirements. CMS has also approved Medicaid work requirements submitted by Indiana and Arkansas.

Arizona, Kansas and Utah have proposed lifetime limits on Medicaid coverage for healthy adults. These lifetime limits range from three to five years. CMS has never approved lifetime limits on Medicaid eligibility and has not acted on these waiver requests. It is unknown if CMS will impose these lifetime limits. If they are approved, they will almost certainly be challenged in court by Medicaid recipients arguing that the Medicaid statute does not allow for lifetime caps.

Massachusetts submitted a section 1115 waiver under which it proposes to control Medicaid spending by establishing “closed formularies” that would exclude certain prescription drugs from coverage. Under the Massachusetts plan, the Medicaid formulary would include at least one prescription drug in each therapeutic class, but not necessarily more than that. Massachusetts believes that if were allowed to adopt a closed formulary, it could negotiate volume discounts for the drugs that are included in the formulary. Massachusetts also wants permission to review, and possibly exclude, drugs that have been approved by the FDA under the accelerated approval program. This program applies to drugs that are intended to treat serious conditions for which there is no approved treatment. The FDA can approve qualified drugs on the basis of surrogate endpoints, which are clinical markers that predict clinical benefit (for example, tumor shrinkage) rather than the ultimate clinical benefit itself (prolonged life expectancy). Notwithstanding that the FDA thoroughly reviews drugs that are approved under the accelerated approval program, Massachusetts wants to be able to exclude these drugs if it believes they do not provide sufficient benefit.

CMS has not yet taken action on Massachusetts’s waiver request. If CMS approves it, the waiver would almost certainly be challenged by the pharmaceutical industry. The Pharmaceutical Research and Manufacturer of America (PhRMA) has publicly stated that it believes Massachusetts’ proposal is unlawful because the Medicaid Drug Rebate Program is not subject to section 1115 waivers and, with limited exceptions, requires coverage for all qualifying drugs.

It is too early to assess the cumulative impact of the types of waiver requests described above, because CMS has not acted on many of them. Moreover, because all of these waiver requests are controversial, they are likely to be subject to challenges in court if approved. At

the very least, these waiver applications show that states are thinking about restraining Medicaid spending either by taking steps that may reduce the number of eligible beneficiaries or by reducing the amount states spend on those beneficiaries. Since Medicaid purchases health care goods and services from the private sector, a reduction in the number of individuals covered by the Medicaid program or limitations in what Medicaid will cover is likely to directly impact the bottom line of health care companies.

What Steps Is the Government Taking to Address Drug Pricing?

In recent years, the issue of prescription drug pricing has been politically charged. During the 2016 presidential campaign, Democrats proposed implementing controls on prescription drug costs while candidate Trump proposed other measures that were intended to reduce drug prices. With the election of President Trump, the issue of price controls was taken off the table, but that has not reduced the focus on drug pricing.

In 2017, the FDA undertook initiatives that may indirectly reduce drug prices, and California enacted two high-profile drug pricing measures. During his 2018 State of the Union Speech, President Trump stated that he “directed [his] administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down. Watch.” Since that time, the President signed one bill that addresses drug pricing and his Administration has made a variety of other drug pricing proposals as well. These developments are discussed below.

FDA Initiatives to Promote Generic Drug Competition

Although drug pricing is technically outside of the FDA’s statutory mandate, the agency has implemented a number of initiatives that may encourage competition and indirectly reduce drug prices. In 2017, the FDA announced the highest annual total of generic approvals (1,027) in the agency’s history.

First, the FDA is expediting the review of ANDAs for generic drugs when there are fewer than three drugs in the marketplace. Research has confirmed that when there are three or more versions of the same

drug in the marketplace, prices drop substantially as compared with no generic or even a single generic option. Relatedly, in 2017, the FDA published a list of off-patent and off-exclusivity drugs for which there is not an approved generic and now includes patent submission dates in Orange Book listings. This enables generic companies to determine the earliest date on which they may be able to market new generics. Even though this information has always been available to interested stakeholders, the FDA is streamlining the presentation of the data in an effort to make it easier for generic companies to determine which drugs should be prioritized.

Second, the FDA is facilitating approval of generic versions of “complex drugs.” Complex drugs include drugs that act locally (for example, an eye drop that acts on the eye’s surface) or drugs that require administration through a device such as metered dose inhaler or auto-injector. These drugs possess features that may make it difficult for an ANDA sponsor to satisfy the requirement of establishing therapeutic equivalence to the branded drug. The FDA has developed guidance documents to facilitate development of such complex generic drugs. The FDA has also developed channels for enhanced communication between the FDA and the sponsors of complex generics to allow for more efficient development and regulatory review of such drugs.

Third, the FDA is continuing to target practices of innovator drug manufacturers who attempt to prolong marketing exclusivity beyond the period allowed by law. For example, the FDA is concerned about innovator drug manufacturers who, for a variety of legal reasons, are reluctant to provide a branded drug product to generic companies for bioequivalence and bioavailability studies.

California’s Drug Pricing Measures

In October 2017, California enacted two statutes designed to address drug pricing.

The first statute requires a prescription drug manufacturer to notify the California government and private payors in the state sixty days before it issues a price increase that would raise the drug’s wholesale acquisition cost by more than 16% over two years. The notification must include (among other things) an explanation as to what factors

drove an increase of a drug's price and a description of any changes or improvements in the drug.

While this statute does not formally restrict drug price increases, it will make it more challenging for drug manufacturers to increase prices by an amount that triggers the disclosure threshold. Once a disclosure is required, payors would have two months to push back against any price increases before they went into effect. PhRMA filed a lawsuit (currently ongoing) arguing that the statute is unconstitutional because it impermissibly seeks to regulate pharmaceutical manufacturers nationwide (something only Congress is entitled to do) and interferes with their First Amendment right to free speech.

The other statute prohibits innovator drug companies from offering any type of rebate that reduces out-of-pocket costs for drugs for which there is a cheaper generic available that is therapeutically equivalent to the branded drug. Proponents argue that this statute will help reduce drug costs by making it more difficult for innovator companies to maintain market share for their higher-priced products when lower-cost generic versions of therapeutically equivalent drugs are available.

Bipartisan Budget Act of 2018

The Bipartisan Budget Act, which was signed by President Trump on February 9, 2018, contains a provision that should reduce prescription drug prices for some seniors who are beneficiaries of the Medicare Part D program.

As background, Part D assists seniors in purchasing prescription drugs. It includes four phases, depending on how much money the beneficiary spends on prescription drugs:

- The deductible phase, where the beneficiary pays for all costs;
- The initial coverage phase, where the beneficiary pays 25% coinsurance up to the initial coverage limit;
- The “coverage gap” (also known as the “doughnut hole”), where the beneficiary is responsible for a significant portion of the drug costs; and

- The “catastrophic” phase, where the beneficiary is responsible for 5% coinsurance.

The ACA included a provision that gradually closed the coverage gap between 2013 and 2020 such that by 2020, the beneficiary’s cost-sharing requirement would be 25% (the same as the initial coverage limit). The Bipartisan Budget Act accelerated the closure of the coverage gap from 2020 to 2019. It also reallocates responsibility for payment of drug costs for patients in the coverage gap. Going forward, pharmaceutical manufacturers will be required to discount the cost of prescription drugs by 70% (instead of the current 50%), and the Part D insurer will be responsible for paying 5% of the drug cost (instead of the current 25%). This means that the beneficiary’s coinsurance obligation would become 25% (the same percentages as in the initial coverage phase). This provision is likely to cost the pharmaceutical industry billions of dollars and may offer a significant benefit to insurance companies that sponsor Part D plans. The pharmaceutical industry was caught off guard by the insertion of this provision into the budget bill and is seeking to repeal it.

The White House Blueprint

On May 11, 2018, the White House released the President’s “Blueprint to Lower Drug Prices.” The Blueprint focuses in large part on promoting competition and altering misaligned incentives. In the aftermath of the announcement, the stock price of many drug companies and other health care companies such as pharmacy benefit managers (PBMs) rose. Key elements of the Blueprint are discussed below.

1. FDA-Related Proposals

The Federal Food, Drug, and Cosmetic Act (FFDCA) does not grant the FDA direct regulatory authority over drug pricing. The Blueprint, however, includes several initiatives that the FDA is already implementing with the aim of promoting competition and thereby indirectly reducing drug prices. These measures include:

- *Facilitating development of biosimilars:* Scientific advances have resulted in the increased development and marketing prominence of biologics. Biologics are chemically complex, long-chain molecules, and are therefore more challenging to

produce than most small-chain synthetic drugs. After the applicable patent and exclusivity periods expire, pursuant to the Biologics Price Competition and Innovation Act of 2009, biologics may be subject to competition from lower-cost “generic” versions (known as “biosimilars”). The FDA is working on facilitating the development of biosimilars and educating providers, consumers, and payors regarding applicable regulatory pathways and their overall availability.

- *Facilitating approval of Abbreviated New Drug Applications (ANDAs):* The FDA has expressed concern about innovators allegedly misusing the Risk Evaluation and Management Strategies (REMS) process to prevent generic drug companies from obtaining necessary drug samples for testing purposes. Pursuant to the REMS process, safety and mitigation strategies are implemented for drugs that potentially present serious risks. The REMS process sometimes will involve limitations on how a drug can be prescribed or distributed. As a result of such restrictions, generic manufacturers may be unable to obtain drug samples in certain situations. Without such samples, generic manufacturers cannot conduct the bioequivalence testing that is required to file ANDAs. The Blueprint does not specify how the FDA plans to address this issue. On May 17, 2018, the FDA publicly released a list of approximately fifty innovator drugs for which the agency received complaints that the manufacturer was allegedly prohibiting access to drug samples (thereby purportedly impeding competition from generic drug companies). The FDA stated that this unprecedented step was taken “because we believe greater transparency will help reduce unnecessary hurdles to generic drug development and approval.” Critics contend that public shaming in the guise of “transparency” may not have the effect the FDA is intending.
- *Accelerating development of over-the-counter (OTC) drugs:* Many drugs that do not require a prescription are sold pursuant to OTC drug monographs developed as part of the OTC Drug Review. OTC drug monographs specify the ingredients, claims, warnings, and other aspects of an OTC drug that, if implemented,

authorize the drug for marketing in the absence of a new drug application. In other words, an OTC drug monograph is the equivalent of a “recipe book” for specific OTC drugs.

The OTC monograph process, however, has not been appreciably updated since the 1970s, and the FDA believes many aspects of the process are antiquated. The FDA and industry players are working with Congress on new monograph legislation. In one of its most recent iterations, this proposed legislation would, among other things, (1) impose user fees on manufacturers of OTC drugs (these fees would fund the FDA’s review of applications to approve new monographs or change existing ones); (2) accelerate the process for changing OTC drug labeling; and (3) provide a period of exclusivity to companies that, among other things, receive FDA approval to add a new active ingredient to an OTC monograph.

- *Communications between drug companies and payors:* As a general rule, federal law prohibits drug manufacturers from promoting drugs for uses other than those on FDA-approved labeling. The Blueprint alludes to a proposal by Commissioner Gottlieb indicating that it may be appropriate for pharmaceutical manufacturers to provide information to payors about potential off-label uses for their drugs if those off-label uses can result in cost savings. The FDA has not yet issued a guidance document addressing this subject.
- *Direct-to-consumer (DTC) drug advertising:* The Blueprint also includes a new proposal: an FDA review of the potential mandatory inclusion of drug prices in direct-to-consumer (DTC) drug advertising. Alex Azar, Secretary of the Department of Health and Human Services, recently argued that, from a perspective of “fair balance” in DTC advertising, consumers should be told how much drugs will cost them. The Blueprint, however, does not provide any further details regarding this proposal. In particular, it does not address the challenging question of determining what is meant by a drug’s price. Consumers typically do not pay the drug’s list price. Unlike OTC drugs, the price paid by consumers for prescription drugs is dependent on a variety of factors, including (1) whether the consumer

has a high-deductible insurance policy and/or a prescription drug deductible; (2) which tier of the formulary the drug is placed on; and (3) the size of the co-pay for the applicable drug. Price may also vary because of other factors including geographic region and pharmacy. Thus, there is no standard price that is paid by consumers.

The Blueprint's proposal to include prescription drug prices in DTC advertising also fails to address the impact of such a policy on price flexibility and the potential unintended consequences that may result if drug companies were precluded from lowering prices during the course of an advertising campaign. In addition, the Blueprint does not address contentious legal issues that may emerge, including issues implicating the First Amendment and the FDA's authority to require price disclosures under the FFCA. Finally, this proposal would have no relevance to many of the highest-priced orphan drugs, which are aimed at a very small population and therefore are often not widely advertised.

2. CMS-Related proposals

- *Medicare Part D:* The Blueprint includes several proposals that would facilitate the ability of Part D plans to manage prescription drug costs. For example, the Blueprint raises the concern that Part D plans are not currently able to negotiate prices for drugs in the six “protected classes.” Part D formularies must cover all drugs in these classes because they are vital to treating certain conditions. The Blueprint proposes giving Part D plans “full flexibility” to manage the cost for such drugs, but it does not state how the administration plans to accomplish that objective.
- *Medicare Part B:* Part B covers drugs that are administered in outpatient clinical settings. Part B covers many high-cost specialty drugs that treat conditions such as cancer, blood disease, and eye disorders. Part B drugs are reimbursed based on a formula dictated by law. That is different than Part D, where PBMs generally can decide which drugs are included

on formularies (outside of the protected classes) and drug manufacturers may have to offer rebates to be included on the formularies. The Blueprint suggests that some unspecified prescription drugs might be shifted from the Part B to the Part D program.

- *Value-based pricing*: The last decade has seen increased interest in tying the level of health care reimbursement to the value of the health care services or drugs provided. The Blueprint proposes that CMS develop value-based pricing models for prescription drugs—but it does not identify the types of criteria that could be used as the basis for value-based pricing. There are multiple value-based pricing models that could be implemented, and it remains to be seen whether it becomes commonplace, for example, for drug and health care companies to make reimbursement contingent on satisfying a performance metric in individual patients (or cohorts of patients).

3. PBMs

The Blueprint reflects the view that PBMs have contributed to rising drug prices. PBMs often condition the placement of a drug on their formularies on the manufacturer’s willingness to offer a sizeable rebate off the drug’s list price. PBMs often keep a portion of the rebate as compensation. This practice could be seen as encouraging high list prices and large rebates, although PBMs cite procompetitive benefits associated with their services.

The Blueprint raises the prospect of imposing a fiduciary obligation on PBMs to act in the interest of patients. Separately, Commissioner Gottlieb raised the possibility that the government could consider eliminating the “safe harbor” under the Anti-Kickback Statute for drug rebates. Were that to happen, it might become impossible for drug companies to continue offering rebates for drugs whose purchase was subsidized by the federal government.

The health care marketplace, however, is in flux and may already be in the process of addressing the market impact of PBMs. In recent years, private insurers have been merging with PBMs, including (1) UnitedHealth’s purchase of Catamaran in 2015; (2) the 2017 agreement by CVS (which owns Caremark PBM) to purchase Aetna; and

(3) the 2018 agreement by Cigna to purchase Express Scripts. Moreover, UnitedHealth recently announced that, starting in 2019, it would have rebates passed on to consumers enrolled in fully insured commercial group plans. To the extent there is increased integration between PBMs and health insurance companies, the combined entities may have a greater interest in controlling drug prices.

What Do These Drug Pricing Developments Mean for the Pharmaceutical Industry?

In this challenging political environment, the pharmaceutical industry to date has emerged relatively unscathed. The initiatives described above may diminish the profitability of some drugs, but none of them are likely to significantly change how drug prices are set. That said, there are likely to be more initiatives at all levels of government aimed at reducing or controlling drug prices. The pharmaceutical industry will therefore have to remain vigilant against the possibility of future harmful measures.

Note

1. This section addresses the legal and regulatory environment as of March 2018.