

The Business of Healthcare Innovation

The tech sectors are the least understood portion of the healthcare system, but the ones that supply most of the innovation in healthcare services and generate the most revenue. Fully updated for this third edition, *The Business of Healthcare Innovation* is a wide-ranging analysis of business models and trends in the tech sectors of the healthcare industry. It provides a thorough overview of and introduction to the innovative sectors that fuel improvements in healthcare: pharmaceuticals, biotechnology, life science startups, medical devices, and information technology. For each sector, the book examines the trends in scientific innovation, the science behind that innovation, the business and revenue models pursued to commercialize that innovation, the regulatory constraints within which each sector must operate, and the growing issues posed by activist payers and consumers. From a combination of academic and industry perspectives, the authors show why healthcare sectors are such an important source of growth in any nation's economy.

Lawton Robert Burns, Ph.D., is The James Joo-Jin Kim Professor of Health Care Management, Director of the Wharton Center for Health Management & Economics, and the Co-Director of the Vagelos Program in Life Sciences and Management at the Wharton School, University of Pennsylvania. He has conducted research on the tech sectors in healthcare for the past two decades, covering pharmaceuticals, biotechnology, medical devices, medical-surgical supplies, and information technology. He teaches executives and is a regular expert witness in litigation involving these sectors.

“Understanding the dynamics of the medical device industry has been extremely important to me. Perhaps more than in any other sector, future medical devices, and the promises they hold for real solutions, represent the true intersection of high technology and healthcare. The information in this book provides a great understanding of this complex industry – the challenges of creating, improving, distributing, and competing in this space. The materials included in this book provide an excellent foundation for anyone looking to solve healthcare problems with the incredible technology available today. I highly recommend it.”

Kevin R. Sayer, President and CEO, Dexcom, Inc.

“Anyone interested in the healthcare field absolutely needs to read this book. The perspective across all aspects of our industry gives the reader a unique understanding of how it all fits together. As I read the book, I felt like I was reliving my over forty years in the industry. A must-read for all of us in a company, building a company, or investing who are committed to making a difference for patients.”

Mark Levin, Co-founder and Partner, Third Rock Ventures

“We are in the midst of a revolution that is transforming the pharma and biotech sectors, their strategies, business models, and revenue models. This revolution is breaking down the barriers between these two sectors, relabeling them both as ‘life sciences,’ and calling for new models of discovery and commercialization. This new edition, written by industry experts, chronicles these changes to provide unique insights and learnings, and identifies the skill sets needed to help lead these sectors through revolutionary times.”

John Maraganore, Ph.D., CEO, Alnylam Pharmaceuticals

“This is an important and opportune time to study and understand the medical technology sector of the healthcare market. As our US and global healthcare systems and industries transform and in many areas consolidate, med-tech approaches an important crossroads. At the same time, the definition of med-tech is changing with new entrants from big tech and traditional med-tech companies re-defining and re-inventing their businesses. Strong forces are reshaping the way the vital med-tech industry interacts with patients, clinicians, regulators, payers and hospitals, creating a dynamic med-tech business model.

This book does an excellent job of simplifying this complicated subject into its unique elements, analyzing each in a clear, direct style that illuminates the key issues facing this rapidly changing industry. The discussion of the sources of, impediments to, and changing attitude toward device innovation and regulation is particularly welcome. I recommend this astute analysis to healthcare executives, policymakers, investors, innovators, and anyone else who wants to understand the critical importance and future direction of the medical technology industry and its innovation for patients around the world.”

Michael Mussallem, Chairman and CEO, Edwards Life Sciences

Praise for Previous Editions

“Since the first edition of *The Business of Healthcare Innovation*, the workings of the industry have become even more complex, intertwined, and tricky to navigate. The industry’s evolution is effectively captured in this successor edition which includes important updates relevant to traditional and newer, ‘maverick’ innovators who will find the insights and frameworks described to be invaluable.”

Peter A. Tollman, Ph.D., Senior Partner and Managing Director,
The Boston Consulting Group

“Burns has produced an exceptional successor to *The Business of Healthcare Innovation* with this new edition. The original made an important contribution to those of us who work and invest in the life sciences. The updated and expanded chapters on challenges and possibilities for the pharmaceutical and biotechnology industries, the new insights into the potential of digital health, and the overall theme of convergence of technologies into an innovative model of modern medicine, make it a timely and valuable volume.”

G. Steven Burrill, CEO of Burrill & Company

“This book is the authoritative text on the medical device industry. The authors combine extensive research with intimate insights to distill a complex topic to its essential ingredients.”

Dan Starks, Chairman & CEO, St. Jude Medical

“After decades of anxiety, concerns with healthcare quality, costs, and safety have become alarm. Several significant efforts by government and the private sector are under way to transform healthcare. These efforts center on diverse performance-based reimbursement mechanisms that bind those who provide care with those who purchase care.

As Burns astutely notes, these efforts appear to view those organizations that provide products and services to the industry as incidental to the transformation of care. This view is a mistake.

Companies that deliver innovative advances in the life sciences, medical devices, and health information technology can be and are significant contributors to our collective efforts to improve care. Vaccines, medical imaging, pacemakers, and electronic health records are examples of these contributions.

The Business of Healthcare Innovation does an exceptional job of describing the nature, challenges, and contributions of the companies that produce these products and services. This understanding is essential – effective care transformation requires the efforts of all stakeholders and that each stakeholder understand the nature of the others and how best to form and manage partnerships. Without this understanding, care transformation will deliver less than we deserve.”

John Glaser, Ph.D., CEO, Siemens Health Services

“Innovation is the answer to the cost and quality challenges in healthcare today. Despite its importance, few scholars have offered a comprehensive assessment of innovation in medicine – what it is, how it arises in specific sectors, and what are the barriers to achieving transformation of healthcare. This ambitious work makes a substantial contribution to our understanding of this key concept in healthcare.”

Kevin A. Schulman, MD, MBA, Professor of Medicine and Gregory Mario and
Jeremy Mario, Professor of Business
Administration, Duke University

“Healthcare looms as the central issue for the swarm of baby boomers seeking the goal of wellness in this decade. This primer by Burns and his colleagues nicely summarizes the challenges of developing new technologies that will be relevant and affordable. How will healthcare reform influence the healthcare industry to innovate and invest in new technologies? What will new regulatory approaches do to early-stage investment in new therapies? How will the United States remain a net exporter of medical devices and pharmaceuticals that is the envy of the rest of the world? Can uncommon profitability in the device sector be perpetuated? How are the processes of research and development, collaboration, mergers, and acquisitions different in the pharmaceutical, biotechnology, and medical device industries? The answers can be found in this articulate and well-referenced text.”

Stephen Oesterle, MD, Senior Vice-President, Medtronic

“Burns provides an excellent overview of the competitive dynamics of the medical technology sector, which has had increasingly significant effects on health service costs and outcomes. Understanding the dynamics of this sector is important for all future healthcare leaders, and this comprehensive and accessible book provides first-rate coverage of the subject.”

Regina Herzlinger, Ph.D., Professor, Harvard Business School

“The healthcare sector of the developed world’s economies has become one of the most significant in terms of both cost and human benefits created. The authors have done an excellent job of providing a clear understanding of the basic industry platforms that create both the product innovation and their associated benefits and costs. This book offers valuable insights in to how the diverse segments converge to create a rapidly changing healthcare experience impacting both patients and payors.”

James Vincent, Chairman and CEO (ret.), Biogen

“All sectors of the healthcare products industry are not the same. *The Business of Healthcare Innovation* provides an interesting primer on the various product categories, while framing key questions regarding the future evolution of this fascinating industry.”

Arthur D. Collins, Jr., Chairman and CEO, Medtronic, Inc.

“This book presents a concise analysis of the factors influencing innovation in the health supplier sector. It is highly recommended for programs in health services management and will also be of interest to healthcare executives seeking to obtain a deeper understanding of the supplier side of the industry.”

Stephen M. Shortell, Ph.D., Blue Cross of California Professor of Health Policy and Management, Dean, School of Public Health, University of California–Berkeley

“This book is an up-to-date and authoritative description of innovation in the healthcare industry. While there is substantial change in how healthcare services are delivered and reimbursed, the focus here is on innovation in products. This is appropriate as new pharmaceuticals and devices generate the greatest new benefit to patients and value to our economy. In addition to related subject matter, the book provides a comprehensive discussion about the biotechnology industry, in particular those companies devoted to the healthcare sector: their innovations, financing, development, evolution, and how they are regulated on a global basis. The profound impact biopharmaceuticals are having on serious diseases is effectively illustrated by cogent examples of breakthrough medicines and the companies that developed them. This book presents compelling evidence that the pharmaceutical industry, with its productivity gap, has become ever more dependent on the biotechnology industry as its engine of innovation for new products.”

L. Patrick Gage, Ph.D., Venture Partner, Flagship Ventures

“This timely and well-written volume provides a much needed analysis of the healthcare sector that delivers technological innovation. I am particularly impressed with both the breadth and depth of coverage that Lawton Burns and his colleagues achieve here, given the expansive topic.”

Edward J. Zajac, Ph.D., James F. Beresford
Distinguished Professor of Management and Organizations,
Kellogg School of Management

Other Cambridge Volumes

Edited by

Lawton Robert Burns

Managing Discovery: Harnessing Creativity to Drive Biomedical Innovation (2018)

China's Healthcare System and Reform (2017)

India's Healthcare Industry: Innovation in Delivery, Financing, and Manufacturing (2014)

The Business of Healthcare Innovation

Third Edition

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To Alex and Brendan
and to the coming Kingdom

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Justin Klein, MD, JD, is a cofounder and managing partner at Vensana Capital, a venture capital and growth equity investment firm dedicated to partnering with entrepreneurs who seek to transform healthcare with breakthrough innovations in medical technology. Justin was previously a partner at New Enterprise Associates, one of the largest and most active venture capital firms in the world. Justin also worked at the Duke University Health System, where his experience included roles in strategy, finance, and operations as Duke built one of the nation's first integrated healthcare delivery systems. Justin currently or previously served on the board of directors of Cartiva (acquired), ChromaCode, CV Ingenuity (acquired), Epix Therapeutics (acquired), FIRE1, Intact Vascular, Metavention, Personal Genome Diagnostics, PhaseBio Pharmaceuticals (IPO), Relevant MedSystems, Senseonics (IPO), Topera (acquired), Ulthera (acquired), VertiFlex (acquired), Vesper Medical, and VytronUS. Justin graduated with an AB in economics, a BS in biological anthropology and anatomy, and a minor in chemistry from Duke University. He also concurrently earned his MD from the Duke University School of Medicine and his JD from Harvard Law School.

Kurt H. Kruger was recently the CFO of Emmaus Life Sciences, a biopharmaceuticals company focused on sickle cell disease. Previously, he led the life sciences banking effort at WR Hambrecht+Co. For nearly two decades he followed the medical device industry as a Wall Street analyst for Bank of America Securities, Montgomery, and Hambrecht & Quist. Before that he spent over five years working in the medical products industry, first as a biomedical engineer developing devices used in open heart surgery for Sarns, now Terumo, and then as a marketing manager for pacemaker/defibrillator maker Guidant/Boston Scientific. Kruger holds an MS in business from the Massachusetts Institute of Technology, an MS in bioengineering from the University of Michigan, and a ScB in biomedical engineering from Brown University. He also did the postbaccalaureate premed program at Columbia University.

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Cary G. Pfeffer, MD, MBA, is a partner at Third Rock Ventures and has more than twenty-five years of business development and transaction experience, along with a broad array of biotech product development and executive management experience. He drives the firm's overall interface strategy with pharmaceutical and large biotech companies as he leads Third Rock's partner development efforts, including building and maintaining strong relationships with large biotech and pharmaceutical companies, and supporting portfolio company business development efforts. He has played an instrumental role in a number of innovative alliances and collaborative company-building efforts across Third Rock's portfolio, including an industry-leading global strategic collaboration between Agios and Celgene in the field of cancer metabolism. In addition to supporting business development efforts across Third Rock's portfolio, Cary plays a major role in new company-building efforts, is a director of multiple portfolio public and private companies, and has also assumed active executive leadership roles in several portfolio companies, functioning as Chief Executive Officer (CEO) and Chief Business Officer through the first twelve to eighteen months after launch. Before joining Third Rock, Cary founded the Pfeffer Group, a boutique consulting firm that provided business development and strategy advisory services, completing multiple transactions for leading biotechnology and life sciences companies. Prior to that, Cary spent more than a decade at Biogen, where he held a variety of senior and executive level US and global management roles focused on business and market development, product development, and international and domestic commercial operations. Earlier in his career, he spent several

years in corporate finance in the Health Care Investment Banking Group of Lehman Brothers. Cary earned his MD from the University of Pennsylvania and his MBA from the Wharton School of the University of Pennsylvania. He holds a BA in biochemistry from Columbia University.

Adam C. Powell, PhD, is President of Payer+Provider Syndicate, a management advisory and operational consulting firm focused on the managed care and health-care delivery industries. His research has focused on improving healthcare quality in mHealth (mobile health) and in high-cost areas of medicine. He has taught courses on health informatics, health economics, hospital finance, and epidemiology both in the United States and in India. Adam received his PhD from the Wharton School of the University of Pennsylvania.

Jason Rhodes, MBA, is a partner with Atlas Venture, a leading biotech venture capital firm, where he focuses on creating and building novel therapeutics companies. He is the chairman of Generation Bio, where he was founding CEO; a founder, the chairman, and acting CEO of Disarm Therapeutics; and a founder and the executive chairman of Dyne Therapeutics. He is also on the boards of Replimune (NASDAQ: REPL), Gemini Therapeutics, Accent Therapeutics, and Bicycle Therapeutics. He is a member of the advisory board of the Harvard Institute for RNA Medicine, the Blavatnik Fund at Yale University, and the Berklee College of Music Presidential Advisory Council. Jason received his BA from Yale University and his MBA from the Wharton School of the University of Pennsylvania.

Preface

This is the third edition of *The Business of Healthcare Innovation*. The first edition was prepared to help train the first-year MBA students at the Wharton School majoring in healthcare management on the companies manufacturing pharmaceutical, biotechnology, medical device, and information technology products. Our MBA student cohorts are filled with former and future employees from these companies, and our classrooms are continually filled with their executives, who visit Wharton to teach and recruit students. Increasingly, our course offerings in the Department of Health Care Management have necessarily encompassed these sectors of the healthcare industry, and our faculty's academic agenda has adopted them as research topics.

In 2002, I published a four-year investigation of the flow of products, information, and money between the manufacturers of healthcare products, the distributors and organized buyers of these products, and the hospital and physician customers that purchased them. That investigation, published as *The Health Care Value Chain* (2002), examined the trading relationships between (a) the providers of healthcare services, such as physicians and hospitals (a traditional focus of scholarly inquiry), and (b) their upstream suppliers (a nontraditional focus for scholars). The book was the first formal analysis of supply chain relationships in the healthcare industry. It included separate chapters on three sets of manufacturers (or “producers”) of healthcare products: pharmaceuticals, medical devices, and medical-surgical supplies. In writing it, I realized there was no central source of information about the “producer” side of the healthcare industry. Most textbooks on the industry either ignored producers or focused just on the regulatory side of this portion of the industry (e.g., the Food and Drug Administration).

This volume seeks to fill this gap in our understanding. The book is intended for two different audiences. First, it is designed to teach students (and their faculties) in graduate programs of health administration about a major portion of the healthcare industry that gets neglected. It provides a detailed overview of the pharmaceutical, biotechnology, medical device, and information technology sectors. In addition, because these are for-profit

sectors, the book also examines the business models and corporate strategies of firms in these sectors. Finally, to take account of the incredible entrepreneurship in life science, this volume includes two new chapters on start-ups in the biotechnology and medical device sectors. As a result, the book may be more at home in health administration programs located in business schools but may still be useful for programs in schools of public health and public administration.

Second, the book is intended for practitioners in each of the sectors covered – not so much to educate them about their own sphere of activity, but rather to educate them about the other sectors that are increasingly interdependent with their own. For example, there is a clear trend for the pharmaceutical and biotechnology sectors to align with each other in drug discovery, development, and commercialization efforts. That explains why these two sectors are now commonly and collectively referred to as “biopharma” or “life sciences.” There are also trends for pharmaceutical firms to partner with medical device and information technology firms in order to facilitate drug development and deliver new patient care therapies. Finally, all of these sectors are now confronted by a common set of pressures from downstream customers for “value.”

Some of the chapters in this volume are quite long by necessity. The sectors covered in each chapter are research-intensive and technologically complex. They are also dynamic competitively, despite their very different market structures (e.g., some are fragmented markets, others are oligopolistic). The authors of the respective chapters have done an excellent job of distilling all of this complexity (for the first time in one volume) into as few pages as they have, without sacrificing scope or relevant detail. As the editor, I beg the reader’s indulgence in confronting the detailed analyses of these fascinating sectors of healthcare. They comprise the only truly global portion of the healthcare industry.

Acknowledgments

I have taught an introductory MBA-level course on the healthcare system since 1984. Originally, my view of the healthcare system was shaped by my PhD and MBA training, which emphasized the *providers* of healthcare services (e.g., physicians and hospitals) and the *payors* for these services (e.g., governments, employers, insurance companies, managed care organizations). It was not until my arrival at the Wharton School in 1994 that I began to be heavily exposed to an entirely new portion of the industry: *the producers* of healthcare products such as pharmaceuticals, biologicals, medical devices, and information technology (IT).

At Wharton, I assumed responsibility for the core introductory course, Healthcare Management (HCMG) 841, “The Health Services System.” This particular course, more than any other course I have taught, has challenged me to broaden my view of what the healthcare industry really consists of. A large percentage of the first-year MBA students taking the class come from the producer side of the industry or from investment and consulting firms dealing with the producer side of the industry. They come to Wharton seeking deeper knowledge of these firms, along with the financial and strategic tools to manage them. In response to their interest, HCMG 841 adopts a tripartite course structure that covers “payers, providers, and producers.”

I thus owe a great deal of gratitude to the students of this class, who I have had the privilege to teach and learn from over the past two decades. Their desire to know more about the producer side of the healthcare industry has pushed me to learn it myself. I am certainly no expert yet, but after three editions I am getting there. Moreover, I have had the opportunity to write extended analyses of the healthcare systems in two other countries (*India’s Healthcare Industry*, 2014; *China’s Healthcare System and Reform*, 2017), both published by Cambridge University Press, which include deep coverage of their pharmaceutical, biotechnology, and medical device sectors. The producer sectors in these emerging economies seek to emulate the success of their US counterparts.

During the years I have taught HCMG 841, I have relied on industry experts to teach much of the course content on producers. I have been fortunate to draw on the expertise of several Wharton School graduates

who have worked in the pharmaceutical, biotechnology, medical device, and IT sectors and possess a far deeper understanding of them than I. These individuals have graciously agreed to return to Wharton each fall semester to teach the incoming MBA class about their particular sector. Over time, they have honed their presentations, several of which form the basis for the chapters contained herein. I thank Cary Pfeffer (of Third Rock Ventures, formerly with Biogen) and Jason Rhodes (of Atlas Venture) for broadening the students' understanding of the biotechnology sectors. They have contributed Chapters 3 and 4, respectively.

For other producer sectors, I have called on longtime friends and colleagues to teach the course content. Richard Evans has taught my class on the pharmaceutical sector for the past several years. Kurt Kruger, formerly a top medical devices analyst with Hambrecht & Quist, Montgomery, and Banc of America Securities, has been a close friend for nearly three decades and taught in my class many years. John Glaser has taught my class on the information technology sector for decades. Richard, Kurt, and John helped to contribute to Chapters 2, 6, and 7, respectively. Richard Evans is joined by Scott Hinds; John Glaser is joined by Adam Powell, my former doctoral student here at Wharton. Finally, Justin Klein joins our masthead by contributing a new chapter on entrepreneurship among small start-ups in the medical device sector.

Several people have enabled me to produce this volume. I wish to thank three authors who contributed to earlier editions of this book and helped to get this volume off the ground: Jon Northrup (formerly of Eli Lilly), Sean Nicholson (faculty member at Cornell University), and Steve Sammut (adjunct faculty member at Wharton). I also wish to thank my administrative assistant, Tina Horowitz, who has been invaluable in helping me get this book edited and forwarded to Cambridge University Press. Tina is the academic's dream hire. Lastly, I wish to thank my wife Alexandra and our son Brendan for their continuing love and support, and for having helped me to reorient my priorities in life.

Finally, let me reiterate: this book represents a major slice of the Wharton core MBA curriculum on the healthcare industry. It represents a fascinating portion of the industry, which is research intensive, technologically complex, and heavily focused on innovation. My hope is that we have done justice to the enormous complexity here. I trust readers will find the volume as useful to read as we found in assembling it.