

HEALTHCARE **DISRUPTED**

Next Generation Business Models
and Strategies



JEFF ELTON and ANNE O'RIORDAN

WILEY

Praise for *Healthcare Disrupted*

“A confluence of scientific, economic, social, and technological forces is compelling changes throughout the healthcare industry. *Healthcare Disrupted* offers an in-depth examination of the current state of this industry and of strategies that will emerge to maximize value for providers, payers, industry, and—most importantly—patients. I particularly appreciated the descriptions of the four business models likely to emerge: Lean Innovators, Around-the-Patient Innovators, Value Innovators, and New Health Digitals. *Healthcare Disrupted* is an inspirational call-to-action for everyone associated with healthcare, especially the innovators who will develop the next generation of therapeutics, diagnostics, and devices.”

—Bob Horvitz, Ph.D., David H. Koch Professor of Biology, MIT;
Nobel Prize in Physiology or Medicine

“During a time of tremendous change and uncertainty, *Healthcare Disrupted* gives executives a framework and language to determine how they will evolve their products, services, and strategies to flourish in an increasingly value-based healthcare system. Using a powerful mix of real world examples and unanswered questions, Elton and O’Riordan lead you to see that ‘no action’ is not an option—and push you to answer the most important question: ‘What is your role in this digitally driven change and how can your firm can gain competitive advantage and lead?’”

—David Epstein, Division Head, Novartis Pharmaceuticals

“In the rough and tumble shakeout of the healthcare industry, the search for new business models and an understanding of emerging models is critical for patient outcomes to catch up with scientific progress. Elton and O’Riordan in their new book bring some great new insights into this arena that have broad implications for thinking about healthcare globally.”

—Trevor Mundel, M.D. and Ph.D., President of Global Health
at the Bill & Melinda Gates Foundation

“In a time of dizzying change across all fronts: from biology, to delivery, to the use of big data, *Health Disrupted* captures the impact of these forces and thoughtfully develops new approaches to value creation in the healthcare industry. A must-read for those who strive to capitalize on change and reinvent the industry.”

—Deborah Dunsire, M.D., President and CEO,
FORUM Pharmaceuticals

“While no one can definitively say how healthcare will look 10 years from now, Elton and O’Riordan go a long way to provide insights into the changes underway and the likely innovations that will characterize the future of healthcare. A good read for anyone worried about tomorrow’s healthcare and what can be done now to prepare for that future.”

—Cuong Do, Executive Vice President,
Global Strategy, Samsung

This book comes at a perfect time, as science and technology have never been so rich to address the disrupted healthcare environment. Anyone active in healthcare, any patient, and any future patient (that means all of us!) should read this book and reflect on how they contribute to build a system aligned on delivering superior value to patients by innovation, incentives, systems, and communications.

—Roch Doliveux, Honorary CEO, UCB

“*Healthcare Disrupted* reveals how seismic shifts in healthcare delivery will significantly improve patient and economic outcomes. It gives companies options for how to adapt and stay relevant in the new age of digital medicine and outlines four new business models that can drive growth and performance. This is a ground-breaking book.”

—Clive A. Meanwell, M.D. and Ph.D., CEO, The Medicines Company

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Contents

Preface ix

Acknowledgments xiii

Introduction xvii

Then, Now, and Potential xviii

Emerging Models xxi

Disrupting and Reshaping Responsibly xxii

PART I THE TSUNAMI OF CHANGE 1

Chapter 1 Why and How the Healthcare Industry Is Changing So Rapidly 3

Opportunities 5

The Signs of Change 6

A Closer Look at Healthcare Reform 7

Real Reform: Why This Time Will Be Different 9

From Reactive to Proactive 19

Chapter 2	Strategic Choices No Healthcare Company Can Avoid	23
	Market Positioning: “What Market Will My Organization Seek to Shape and What Will It Take to Influence That Marketplace?”	24
	Differentiating Capabilities: “What Internal and External Capabilities Does My Organization Need in Order to Gain and Maintain a Leading Market Position?”	31
	Performance Anatomy: Pivoting the Operating Structures to Patients and Ensuring Differentiating Capabilities	37
	A Responsibility for Your Company’s Future	40

PART II FROM STRATEGY TO VALUE WITH NEW BUSINESS MODELS 43

Chapter 3	Old Models and New	45
	A Profile of the Old Way (The Starting Point for Many Organizations)	47
	Fundamental Shifts in the Operating Environment	47
	The New Models Array Themselves on Value and Payment Dimensions	51
	The Emerging Business Models	52
	Hybrids and Other Novel Solutions	60
Chapter 4	Lean Innovators	63
	The Generic Chassis and How It Evolved	64
	Shifting Opportunities and Rising Pressures	66
	Enter the Lean Innovator Model	68
	Early Challenges to the Lean Innovator Model	74
	The Techniques of a Lean Innovator	76
	The “Lean” Operating Model Position: Execution, Execution, Execution	79
	Lean Innovators: Spoilers or Value Vanguard?	83
Chapter 5	Around-the-Patient Innovators	85
	Identifying Unmet Needs	88
	Innovating to Meet Needs, Fill Gaps	94
	Examples of Emerging Around-the-Patient Innovators	100
	The Questions That Around-the-Patient Innovators Ask and Why They Ask Them	104
	The Around-the-Patient Operating Model: Innovating the Therapy and Patient Care	108

Around-the-Patient: New Commercial Model or Value Vanguard? 113

- Chapter 6** Value Innovators 115
- A Mindset Shift (“Health” as Opposed to “Disease”) 116
 - Value Innovators: The “Living” Service Providers 121
 - Better Operators: Examples of Emerging Value Innovators 125
 - How to Succeed as a Value Innovator 127
 - Suites of Solutions 129
 - The Value Innovator Operating Model Is Integrated, Digital, and Services- and Outcomes-Centric 129
 - The Value Innovator: Value Partner and Services Provider 135

- Chapter 7** The New Health Digitals 137
- Digital Gone Healthcare 139
 - Healthcare Gone Digital 142
 - Start-Up Digitals 145
 - Digital Economics in Healthcare 146
 - Implications Now, Soon, Later On 147
 - Working with the New Health Digitals 149
 - Health Digitals Positioning, Capabilities, and Anatomy 150
 - The Health Digitals: Disruptions and New Foundations 156

PART III BUILDING NEW ORGANIZATIONS 157

- Chapter 8** Toward a New Model of Collaboration and Competition 159
- Critical Innovations from “Without” 161
 - Value Innovating with Your Customers 162
 - Driving Convergence: At the Intersection of Therapeutics, Devices, and Process 166
 - Mapping Big Digital: Where Digital Consumer and Digital Healthcare Meet 170
 - Competition: Protecting the Business 174
 - Change Catalyzing Collaboration Catalyzing Change 176

- Chapter 9** Talent Strategy for the New Healthcare Ecosystem 179
- Transforming through Talent 180

Recruiting 183
Onboarding 186
Skills to Create Value 188

**PART IV LOOKING BACK—LOOKING
FORWARD 191**

**Chapter 10 A New Age of Healthcare—Placing Patient and
Value at the Center 193**

New Future 195
New Language 198
New Economics 199
Your Starting Point, Your Strategies 200

Glossary 203

Notes 219

About the Authors 253

Index 255

Preface

There are more than 7 billion people in the world, and the population is aging in almost every major region. Healthcare costs in most countries are rising faster than gross domestic product (GDP). Prevailing approaches to healthcare reward volume (of sales, of procedures, of patients treated) over positive outcomes or positive changes to health system performance. At the same time, awareness of the importance of health to national economic productivity and long-run performance around the world has never been so acute. Governments, institutions, companies, and individuals are feeling pressure to redress the balance of health, responsibility, and outcomes and to ensure that all constituents play a productive part.

And we have a tremendously exciting opportunity.

In the coming 3, 5, or 10 years, we can dramatically improve patient care around the world. Through profound commitments to collaboration and disruption along nontraditional lines, we can improve the standard of care on a global scale. New targeted therapeutics, smart diagnostics, advanced informatics, and digital technologies promise to redefine

healthcare as less reactive and dependent on traditional facilities and acute interventions, and rather as proactive management of health. Rapidly developing economies and countries will meet critical healthcare needs more efficiently and effectively. More people will stay healthy for longer periods of time, avoiding hospital stays and readmissions at a much greater rate. Well-developed healthcare systems will definitively move toward the practice of precision medicine, where the focus is truly on the patient, and where a variety of forms of information and evidence are brought to bear in real time to tailor treatment approaches. These systems will also raise expectations—and standards—around the world of what healthcare can and should be.

Seismic shifts in the healthcare industry have already begun. For the first time, we are seeing large-scale collaboration across industry boundaries. Providers, pharmaceutical companies, medical device organizations, payers, nurses, caregivers, health care personnel (HCP), patients, citizens, wellness companies, and technology disrupters are joining forces in new and innovative ways—all centered around driving the health and wellness outcomes that are critical for long-term economic sustainability. And positive catalysts abound, including advances in science, the evolution and availability of genomic, health, and lifestyle data, and the abundance of technology solutions coming to the market every day to help us monitor, measure, and adjust our habits to improve our health and the outcomes of treatment.

In fact, a confluence of forces—economic, social, and technological—are compelling changes to everyone’s “job” in healthcare in the years to come: individuals, health providers, health insurers, policy makers, regulators, therapeutics innovators, app developers, digital infrastructure providers, and more, with no exceptions.

The question is: What “whole” will we make of all of these changes? Right now, we are seeing the outlines of new, very performance- and value-focused business and operating models form. These emerging models are more than promising; healthcare with higher value and impact is at stake—healthcare that can better contribute to the quality of patients’ lives, and the productivity of companies and countries. But their success—analogueous to thriving and leading through the digital disruptions that have reshaped far-flung industries such as media, entertainment, financial services, insurance, photography, telecommunications, transportation, and lodging—isn’t guaranteed.

To harness their potential, executives, boards, and industry leaders will need to understand the implied redefinitions of markets, the evolution of services-centric approaches, and the parameters of new outcomes- and value-centric performance models, as well as the fundamental impacts of these models on their organizations.

We wrote this book to recognize and acknowledge this catalytic moment, and to predict and discuss the potential business models that can and should evolve. We realize that no models have yet been carved in stone—and for many, the delineation lines drawn in the new business models will not be as clear and succinct as those we lay out in the coming chapters. But with a more comprehensive grasp of the fast-changing context in which they work, and the capabilities they need to excel, we believe that readers will be able to develop strong, forward-thinking, and flexible strategies for their organizations that will enable them to transform (or invent) themselves effectively. We believe they will be able to become leaders of a new era in healthcare, and vastly improve an ecosystem that is only just beginning to take shape. In doing so, they will set the new foundations of healthcare; as these foundations solidify, they will become the vanguard on which all other aspects of the industry will build.

Our primary focus throughout this book is the evolution necessary in the pharmaceutical, biopharmaceutical, device, and diagnostics fields and the new digital healthcare disruptors that are propelling change and paving the way for entirely new operating models. We recognize that all other players—providers, payers, HCPs, and other healthcare-related institutions throughout the world—also need to change. Through the lens of the organizations featured in this book, other stakeholders in the world of healthcare will also be able to see their own roles and choices more clearly.

In other words, we purposefully include a broad view: In the first part of the book, Chapters 1 and 2, we describe the tsunami of change going on in the sector as a whole and outline the most important strategic questions facing all types of participants in the sector. In Part II, we describe four distinct business models that are coming into focus in the pharmaceutical, biopharmaceutical, medical device, and digital health technologies fields—the result of legacy companies' transformative efforts, start-up ventures, and also the expansion of established, successful businesses from other fields that now see healthcare as a very attractive new market. In the final chapters, we provide a new framework for industry partnerships and

collaboration, the new requirements of value-centric solutions, and how to build the talent and performance systems for these new outcomes and value-focused organizations. We close with a view to the future, reconsidering the basis for how valuations have shifted from disruption in other industries and summarizing the fundamental questions any leadership team, board, or analyst of markets needs to be asking.

We can achieve a best-case scenario for healthcare in the future. But only if all of the healthcare industry's stakeholders—including patients—understand the forces that are driving healthcare's changing ecosystem, and the strategic challenges, opportunities, and business models that are emerging as a result.

And only if we are able to work together proactively to create the future.

Acknowledgments

Discussing the topic of healthcare disruption in any meaningful, purposeful way requires significant input from a multiplicity of sources—on the industry, on the structure and organization of companies, and on the scale and influence of change, from the macroeconomic through the social, scientific, and technological, to the core of how a patient reacts, interacts, and operates with the entire system. It is a task that cannot be addressed without a significant wealth of experience and help. Our research and work have hugely benefited from a global network of colleagues dedicated to the healthcare industry. It has been challenged, informed, and enriched by our clients, by our experienced research team, and by industry thought leaders, and further shaped by our own interactions with the healthcare system as patients, parents, and caretakers.

We are privileged to have such an incredible global network of people, experiences, and capabilities to draw upon to complete this work. There

are also some key people without whom this book would not have been possible.

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In any topic as broad and technical as "Healthcare Disrupted," it is always a challenge to communicate the key concepts successfully to a diverse audience. Here we thank Regina Maruca and Jens Schadendorf. They brought experience and knowledge of the process of writing and publishing a book that was exceptional and deeply valued.

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—Jeff Elton, Ph.D., *Boston, MA, USA*
Anne O’Riordan, *Hong Kong, PRC*

Introduction

There have been only a few times over the past 100 years when leading companies delivering fundamental products and services have been challenged just to survive. The challenges they've faced have usually involved one or a combination of major technological shifts, government or other regulatory changes, new economic models, and disruptive competition. Some have made it; some haven't. Only a few have managed to hold on to their leadership status.

Think of Kodak and Polaroid in photography and imaging, Digital Equipment and Data General in computing, Nokia and BlackBerry in mobile phones, and Blockbuster video stores for home entertainment, to name a few of the most visible. The one-two punch of digital photography and smartphones with advanced cameras turned wet-chemistry photography into a niche field. Personal computers that could access greater power through the combination of advanced graphical interfaces and Internet connectivity sidelined mid-range and mainframe computer companies. Google's Android and Apple's iOS mobile operating systems,

integrated app stores, plus content partners' own ecosystems upended the order of things in mobile handsets. Deregulation, competition from cable infrastructure operators, and the rise in popularity of mobile devices and the Internet as a means of communication forced the transformation of local landline and long-distance services. And Netflix developed an Internet delivery model that, together with other types of delivery systems, hit video stores where it hurt; then streaming did most of them in.

Importantly, during these times, we also saw a personal computer company with modest market share, Apple, and an Internet search engine company, Google (now Alphabet), become the highest value enterprises in the world in terms of market capitalization. These companies took the throw-weight of all the aforementioned disruptions and collapsed distinctions between communications, entertainment, work, and commerce, providing ranges of solutions and convenience others did not foresee. Together they transformed the medium, mechanisms, and economics of personal relationships, where we worked, how we consumed entertainment, and the music industry. We welcomed the changes, and they emerged as winners.

Healthcare is on the brink of a similarly monumental change. “Brink” might not even be a strong enough word; the disruptions are already underway. We wrote this book after two years of research to capture this point in time and give executives across pharmaceutical, biopharmaceutical, medical device, medical diagnostics, and health services companies an opportunity to step back and see the big picture. We wrote it to help them understand the changes that are coming and position their companies to use those changes as building blocks for new and successful strategies. To that end, we frame key trends and offer options for new business models that can drive growth and performance. Ultimately, our goal is to advance a productive discussion about how all stakeholders in healthcare (the aforementioned types of companies, plus regulators, insurers, healthcare providers, and individuals) can take on new roles to drive better health for patients and add value to the healthcare system overall.

THEN, NOW, AND POTENTIAL

Consider some of the newfound abilities and possibilities that are changing our expectations—as policy makers, as executives, as individuals, and

as populations—of what “care” can and should be, and how it should be financed.

We used to think of “evidence” of effectiveness as meaning the results of clinical trials and post-approval studies that took years to progress.¹ *Now, through digitally gathered real-world data, we can gain that evidence at population scale in hours, days, or weeks at most.*^{2,3}

Pharmaceutical and device (life sciences) companies used to put their products out on the market and wonder why results in the actual clinical settings were different from what they expected. *Now, with the ability to track activities and outcomes in almost real time, they can identify the factors in people’s lives that influence the effectiveness of treatment approaches and therapeutic products. They can see the extent to which extenuating circumstances (such as gaps in treatment, non-adherence to dietary and activity modifications) influence outcomes. As a result, they can contemplate new strategies that might include filling those gaps for patients.*

Providers used to see patients in offices or facilities designed for the purpose, and after an examination or a procedure, tell patients what to do, and then, barring emergency, wait until the next scheduled check-in to learn how their treatment plans were working out. *Now they can extend their involvement with patients beyond the office, hospital, or clinic, track progress in real time, and adjust treatments as necessary along the way.*⁴

From Inputs to Outcomes

Now, in other words, we’re seeing an emerging rationale for moving from an input-based approach (inputs being patients seen, or drugs and devices sold) to an output-based approach (outputs being patients’ best possible health outcomes) to healthcare. In the literature of economics, there is a strong distinction between payment that is based on input and payment based on output.⁵ When payment is based on inputs, there is a built-in adverse incentive to “shirk,” that is, to do as little as possible and receive the same compensation. When payment is based on outputs, the incentive is to optimize productivity and maximize “system” benefits.

In Europe, for example, we’re seeing a move toward “value-based reimbursement,” where the health authorities and providers are being

asked to balance the needs of the system as a whole with the treatment they are providing to the individual. The idea is to assess the healthcare industry on its ability to provide the greatest possible benefit to a population against a set of resource constraints. Variants of that approach are going into place in the United States as part of the Affordable Care Act (ACA) and supporting legislation.

Meanwhile, in the same spirit, we're seeing payers moving into the direct provision of care, technology companies spinning out of provider systems, technology companies connecting remote clinical monitoring technologies together as a service, and medical device companies providing direct patient care management services. We're seeing health providers manage financial risk, make tradeoffs among the services they offer, and pursue payment through "alternative" or outcomes-based approaches. Each of these entities is working together with other partners to create, advance, or deliver their services. The relationships are extending back from early drug discovery, right through clinical development, to commercialization and patient end-use.

Power to the Patient

Unsurprisingly, the patient's power as a consumer is also evolving. One hundred years ago, healthcare was largely inaccessible to most people even in the wealthiest economies. Sixty years ago, we created mandates and public institutions that ensured some measure of access to the majority of people in the United States and Europe. Over the course of the past 50 to 60 years, healthcare unions, private employers, states, and countries have ensured increasing access. Regulations and programs for reimbursement, professional credentialing and guidelines, institutional licensure, and product approvals have focused on institutions and health professionals—ensuring access to a safe and efficacious service for citizens and employees as a "benefit." Now, we're entering a time when the priorities of the individual patient with a specific disease or health condition can drive a real determination of value in therapies (drugs and combinations thereof), interventions, and services. The patient is taking on more direct responsibility for outcomes, viewing them from a new vantage point as beneficiary *and* active customer. Healthcare is pivoting to the patient.

EMERGING MODELS

Is it any wonder that new business models with fundamentally different economics are forming and solidifying, setting precedents and standards for others to follow and try to surpass? Already we see this happening beyond isolated use cases. We are seeing a bifurcation of strategies and business models between those catering to the needs of the mass market and those focused on serving niche groups/disease areas. In addition we see disruptors—those companies leveraging new technologies and new science to cut across traditional industry processes to make a step change in how healthcare is delivered and patient outcomes are affected.

For example, we're seeing players that are driving value by bringing the good science developed over the past 20 years to the market in the most efficient way possible. These *Lean Innovators*, many built on the chassis of a generics company, are arriving with extremely efficient, world-class manufacturing and supply chains. They have an eye for acquisition and aspirations of rapid growth, and they will challenge incumbents and the cost structures, productivity, and operating models of the past.

We are also seeing *Around-the-Patient Innovators*—companies (or divisions) that are bringing the latest scientific insights and a focus on the most devastating of patient diseases to bear to advance new specialty therapeutics and complementary product and service offerings.

Embracing outcomes as their strategic center, *Value Innovators*, a third model, will define and differentiate themselves on integrated, digitally enabled services that include remote sensors, devices, and centrally located clinical staff. These organizations will focus on improving patient and clinical outcomes on a broad scale; and they will be willing to tie economics of their business to their ability to achieve patient outcomes and system efficiencies in how healthcare resources are deployed.

Finally, we're seeing the fast rise of *New Health Digitals*, companies that most likely grew and evolved outside of healthcare and life sciences, that see this sector as a natural sector for their relationships, partnerships, infrastructure, performance systems, and capabilities. We are only just beginning to gain a sense of these organizations' interests, models, and influence. But it is clear that their economics—driven by global scale, vast ecosystems of devices and applications, broad developer communities, and the cloud—will provide some solutions at orders of magnitude with less cost and greater capability.

Four models are clearly emerging, but likely we will see more. Even as we put the final touches on this manuscript, technological advances continue to astound us and foreshadow breakthrough opportunities in medicines, treatment, and business models. In August 2015, for example, the U.S. Food and Drug Administration (FDA) approved the first 3D-printed drug, Spiritam, developed by the U.S.-based pharmaceuticals company Aprexia. Used in treatments for people who suffer from epilepsy, Spiritam is made by layering powdered medicine with liquid to create a pill that dissolves almost instantly when taken with just a sip of water.

The initial hope is that by making the pill easier to swallow, more patients will be inclined to stay the course with their treatment. But the implications of the technology are potentially far greater. We can envision localized manufacturing “to order” in the dosage form best suited for an individual patient. We can envision therapeutic combinations required for the management of a specific patient’s comorbidities coming together in a single dose to aid compliance and lower medication errors.^{6,7,8} It would not be inconceivable to see an “Amazon-like” entity—streamlining ordering and manufacturing processes, and delivering within hours—disrupting traditional retail pharmacies, pharmaceutical generics, therapeutics distributors, and patient adherence services. Could an enterprise that doesn’t actually own any assets be a future “Uber” of retail pharmacy and generics manufacturing? Yes, it could.

DISRUPTING AND RESHAPING RESPONSIBLY

We approached this book as professionals with a goal of supporting the healthcare industry’s evolution toward a more effective state. But healthcare is very personal. And so throughout the process of writing this book, we’ve found ourselves reflecting on and talking about the implications of these changes for our families and ourselves—and for those populations with the highest unmet needs. We have come to the conclusion that executives in healthcare, life sciences, and new health-focused technology companies will need courage to shape the healthcare environment and transition successfully—courage that will take different forms as they explore business and operating models that go far beyond their companies’ traditional products, technologies, or services.

They will need to work through questions of privacy and use of broad sources of data for the benefit of the patient—advancing a new level of

trust and operating competence. They will need to resolve all dilemmas—ethical or financial—in favor of their responsibilities to patients. They will need to take the high road, versus a defensive posture, with regulators as rightfully representing the interest of patients in the way that only health providers previously could. Collaborations founded on trust and courage may even prove to be as important as having economic fundamentals and a “winning” business model.

Executives, managers, team leaders, and associates at all levels will also need courage to break down organizational barriers within their organizations and to act as integrators. They won’t necessarily be shipping products, but rather they will be integral to producing product and service packages of value, and interacting directly with patients, health providers, and others. They will need courage to help patients connect the dots and resolve the gaps and deficiencies that limit outcomes. Managers, and those with expertise in one or another area, will have to think differently, broadening their horizons in order to work well with people and organizations that have never before been partners, with new immediate priorities.

There is a real opportunity here to shape the future, rather than be shaped by it. In order to take advantage of this opportunity, though, more than a few people will have to move fast and far out of their comfort zones. Building a strong foundation for a healthcare system that works as well as we can imagine will take more than safe strategies and test-the-water approaches.

This isn’t about responding to a shifting environment by making incremental strategic changes. It isn’t even about reacting to growth, cost pressures, and/or a significant change in competitive dynamics. This is about determining the role their organizations will play in a broadly defined industry that is rethinking how it creates and rewards value, and even what “value” means. It is about planting a flag and taking a stand when the stakes are high and the ground beneath your feet is moving so rapidly it seems out of focus.



PART

I

THE TSUNAMI OF CHANGE

Chapter 1

Why and How the Healthcare Industry Is Changing So Rapidly

The collective throw-weight of socio-economic and policy changes, technological advances, and structural shifts has primed the healthcare industry for upheaval and disruption—and presented an incredible opportunity to advance the standard of care worldwide.

Over the past several decades, as the healthcare industry (including providers, payers, life science companies, health services companies, and other ancillary businesses) has grown in size and complexity, choices regarding patient care have often become entangled in a myriad of objectives and controls. To survive and thrive, healthcare-related companies and organizations have focused increasingly on individual objectives—the products companies on product sales, the healthcare delivery organizations on providing services at the right price point, the payers on actuarial modeling. And somewhere in the mix, the common goal of achieving the best outcomes for the patient and overall value for the healthcare system was diminished.

But that's all changing. There have been periods throughout economic history where a confluence of policy, technological, and industry structural changes has created a foundation for upheaval and disruption—times where

4 The Tsunami of Change

opportunistic strategies have offered handsome near-term rewards, where new entrants have had the potential to be the better operators, and where consolidations and integrated approaches have created unprecedented opportunities. Healthcare is in one of those periods now. And in 10 to 15 years, it will function fundamentally differently than it currently does. Value, defined anew, will increasingly be the metric that matters as healthcare pivots back to the patient in extraordinarily new and different ways.

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The world changed, and healthcare—broadly speaking—did not. Like all good catalytic circumstances, this one offers to healthcare the opportunity to leapfrog and make fundamental and sweeping changes that will sustain for years to come. As a result, many of us who work in, with, and around the industry now find ourselves simultaneously playing catch-up and looking forward with a new sense of responsibility to ensure that those without care can access it, to build strength into our national health systems, and to see that healthcare truly re-emerges as patient-responsive, responsible, and centric. We're directly confronting the companies and business models we've built or built upon, and we're defining what worked, what did not work, and what will work in the future. We are also comparing where healthcare stands relative to other industries that have transformed themselves in recent years.

But we're doing all of this under increasing pressure.

The global population is expected to increase by 1 billion by 2025. By then, more than 500 million people will be over the age of 50. Projections from a variety of sources (including the United Nations and the World Health Organization) report that by that same year, 70 percent of all illnesses will be chronic diseases. Overall we are living longer, living with an increasing amount of chronic and comorbid illnesses, and doing so regardless of what country or region of the world we are living in.

We're also spending more money. In developed countries such as the United States and Germany, where the aging workforce is a key driver of rising healthcare costs, spending on healthcare ranges from 11 to 18 percent of gross domestic product (GDP). In recently developed countries such as China and Brazil, it is between 5 and 10 percent. Overall healthcare spending will be doubling from an aggregate \$8.4 trillion in 2015 to \$18.3 trillion in 2030 with an estimated lost productivity from chronic diseases alone of \$47 trillion over the same period. As Figure 1.1 shows, all of the world's major healthcare systems face enormous cost pressures and potential productivity losses.