The future of growth and the life sciences industry:
Aligning patient value and shareholder value

SPRING 2017
Contents

Introduction 4
Technology and public policy provide answers — and more questions 5
  Mobilizing the power of technology and data
  The opportunity cost of technology
  Tapping into political and regulatory support
Creating the life sciences company of the future, today 7
  Improve and innovate internal processes
  Create new and improved products and services
  Expand nonorganically
  Crossing borders
Conclusion 10
Introduction

We’re living in an era of defining change where possibilities appear almost endless. But they can sway in divergent directions. What will the future of the life sciences industry look like? Value-based care appears to be the predominant scenario.

The U.S. health care system has long rewarded volume — more services, more pills, more tests. Value-based care looks for better outcomes — lower costs, improved patient experiences, greater societal benefit from the health care investment.

Research comparing the U.S. and other countries on a cost-per-patient outcome and health spending certainly suggests that value-based care is the desired option. In the U.S., the cost-per-patient outcome is $107.8, which is nearly double the level in Germany ($55.3) and France ($53.8). Health care spending in the U.S. dwarfs the amount spent in any developed nation, and health care’s share of gross domestic product is set to grow from 17.5% in 2015 to 20.1% by 2025. Despite that level of spending, the U.S. compares unfavorably with most developed nations on measures of patient outcomes.

Lowering costs while helping patients grapple with the prevention or management of diseases is a noble idea and a societal good. But how can the life sciences industry shift a business model based on increasing volumes and products to one that is based on increasing value to patients?

The companies that will be future industry leaders will be those that can demonstrate and deliver the larger societal value of effective treatments, and monetize that value for shareholders.
Technology and public policy provide answers — and more questions

Mobilizing the power of technology and data

The FDA sees the “convergence of people, information, technology and connectivity” as powerful drivers to improve health care outcomes.1 Across the health delivery spectrum, the winners will be life sciences companies that can not only identify opportunities quickly, but can also zoom in on the best ones and act on them.

In these circumstances, the future holds many opportunities for life sciences companies. Technology and data management are revolutionizing insight into patients’ behaviors and needs. For instance, key tools enabled by technology are mobile health, telehealth, and wearable devices, which help reduce inefficiencies and costs, improve access, increase quality, and personalize medicine. Moreover, advanced predictive and prescriptive analytics are increasingly generating powerful insights about patients. Yet, amid all this technological advancement, there is also the people factor, relating, for instance, to data privacy and ownership, personalized care, or health equity.

Future health/care/equity?

Futurist and Organizational Strategist Eric Meade of Whole Mind Strategy Group LLC points out that there is a dynamic tension in the health care system:

“There is a tension between two current directions of the health care system: toward standardization (e.g., evidence-based) and toward health equity, for which I adopt the definition of equity as treating each person differently.

How can the system move toward equity given greater standardization of medical protocols? And to the extent that care is personalized, does the data reflect all ethnic or racial groups? As we use data to figure best practices and common protocols, there are populations with distinct needs, whose needs would not be met by a standard. Is the data set broadly collected and is there transparency around the collection? Whose data is collected? Who owns the data? Is the data collected equitably? What are the biases of the people that develop the research algorithms? These are important questions the health care system will need to wrestle with.

This debate will continue until the U.S. is willing to have a broader discussion as to what we want out of our health care system. Do we focus on the individual good or the collective good? We are not there yet. Life sciences can collectively agree to compete vigorously on factors like innovation and pricing. But on clear, transparent norms of data collection, they can lead by establishing industrywide governance on the privacy and open ownership of data critical to expanding care.”

---

The future of growth and the life sciences industry

The opportunity cost of technology
With technological leaps, vulnerabilities also increase. Early this year, the FDA revealed vulnerabilities in St. Jude Medical’s implantable cardiac devices — pacemakers, defibrillators and resynchronization devices that regulate heart rhythms — and a linked Merlin@home transmitter.²

The threat is also worryingly present in hospitals where insulin pumps, heart monitors and X-ray communications systems have been held hostage to malware and ransomware attacks.³ Unauthorized interventions on medical devices could have extremely harmful repercussions for patients and the wider industry.

Tapping into political and regulatory support
Life sciences innovation needs favorable public policy to give it flight. One of the rare bipartisan efforts in the past few years was the 21st Century Cures Act, passed in late 2016. The $6.8 billion act received widespread bipartisan support to combat opioid abuse, improve mental health services, and effect changes for the FDA and the National Institutes of Health.⁴ Commitment to the 21st Century Cures Act is a rare example of Congress investing in a holistic view of health care and moving toward a value-driven model.

But the promise of coordinated policy may be at risk. While the 21st Century Cures Act seeks to move regulatory oversight into the 21st century, it requires funding from a new administration that so far has looked to cut budgets for domestic programs. And while the Trump administration has promised to deregulate the FDA to speed up drug approvals and create a more competitive corporate tax rate, President Trump has also supported popular calls that criticize drug pricing as being too high.⁵

The U.S., with the highest corporate tax rate in the industrialized world, has seen a range of so-called inversions — where a large U.S.-based firm buys a relatively smaller overseas firm and domiciles itself in the new overseas market, thereby capturing a lower tax rate. Life sciences companies have pursued inversions, although U.S. policymakers and lawmakers are working to curtail the practice.

A hopeful scenario for the future will shift the direction of investment back to the U.S., in large part through thoughtful policy and regulations that encourage innovation. In this scenario, the future presents an opportunity for life sciences leaders to play a mainstage role by advocating for smart policy, by highlighting the importance of a vibrant life sciences sector to the overall U.S. economy and by demonstrating their vital role in improved patient outcomes.

Blockchain
One of the most ground-breaking advancements is blockchain technology. A shared digital ledger, blockchain technology can be leveraged for a variety of solutions across the life sciences value chain. Clinical trials, supply chain transactions, medication usage, clinical and post-marketing surveillance, efficacy and other treatment considerations are just some of the opportunities that could be captured as a secure transaction. While still in the early stages of development, blockchain holds significant promise for life sciences companies, which can use it to understand the value of their treatments, while verifying and validating a more decentralized approach to intellectual property distribution, supply chain, and licensing. Blockchain also has the potential to be an anti-counterfeiting solution by managing secured transactions within a separate cloud-based ledger.

---

² FDA. Cybersecurity Vulnerabilities Identified in St. Jude Medical’s Implantable Cardiac Devices and Merlin@home Transmitter, Jan. 9, 2017.
³ Higgins, Kelly Jackson. “Hospital Medical Devices Used as Weapons in Cyberattacks,” DarkReading.net, June 8, 2015.
Creating the life sciences company of the future, today

As life sciences look toward the future, they will have to walk carefully on a tightrope that, on the one hand, offers opportunity and, on the other, presents a chasm of risk.

Seeking and embracing innovation has become imperative for life sciences companies, but they also need to manage their business models effectively and balance growth strategies in an environment of policy disruption.

Life sciences companies are preparing for their future by reinventing the entire enterprise to focus on value for the patient, from core processes like supply chain management and R&D to the way products are sold and marketed. In this scenario, innovation is centered on the patient, from exploring new business models and sales channels to developing new products.

One example is the way life sciences products are sold now in contrast to how they used to be. A new model focuses on encouraging doctor practices that empower patients to take a more active role in managing their diseases. For instance, the Physician Payments Sunshine Act, passed in 2010 as part of the Patient Protection and Affordable Care Act, triggered greater transparency relating to sales practices. Previously, doctors were motivated to prescribe certain medications to increase sales volume. Now they have shifted to a model where they encourage patients to take a more active role in managing their diseases to improve value. In addition, to support them, companies have developed devices that monitor efficacy and encourage patient discipline, which doctors can also use as part of the new model of care they are promoting.

But the shift from volume to value is not an easy move to make. There will be a great deal of experimentation in the industry to get this model right. How are sales incentives structured? What is the governance regarding acceptable sales practices? There is plenty of room for innovation in the future.
Create new and improved products and services

Life sciences companies need to adapt to bring products to market faster and more efficiently, while maintaining high standards to deliver value to patients and stakeholders. This acceleration will lead to the usual successes and failures, but the innovation pressure that they are under will also mean that, in the future, they will need to fail fast and succeed even faster.

One way for life sciences companies to move in this direction is to look at process improvement through technologies that focus on innovation while increasing efficiency in their development processes and clinical trials. As part of this trend, immunoassay instruments, for example, are used for measurement of molecules and pathogens in areas such as pharmaceutical analysis, disease diagnosis and therapeutic drug monitoring. The immunoassay instruments market totaled $16.9 billion in 2016 and is forecast to grow to $24.2 billion by 2021. This investment will help life sciences companies increase efficiency in their development processes and clinical trials.\(^6\)

Value pricing to tie payments to outcomes

In The winds of change: Pricing in the pharmaceutical industry, Lee Taurman discusses steps to a path forward on value pricing.\(^7\)

1. Stay engaged with payors and providers on value-based approaches. Engagement with value-based programs serves as a defense mechanism in the event that price controls do come.

2. Focus near-term efforts on therapeutic categories and specialty-driven products where measurement is already realistic. Measurable endpoints, such as tumor size and the existence of biomarkers or companion diagnostics, make pricing based on outcomes more realistic.

3. In therapeutic categories such as chronic diseases where co-morbidities are common and adherence is challenging, a broader partnership with entities like accountable care organizations is recommended.

Regulators are evaluating pricing policies to find ways that reward innovation, while shifting the model to value-based services that improve outcomes. What might happen? It seems unlikely that the government will engage in direct price negotiations for purchasing through Medicare Part D, given the lack of Republican support for these proposals. There does seem to be consensus, however, that greater price transparency is needed. Several large pharmaceutical companies, including Eli Lilly, Merck, and Johnson & Johnson, are getting ahead of these efforts by proactively publishing year-over-year gross and net price increases.

“How new innovative products, even at a high cost, can be a great deal for society and the health care system if they cure a chronic disease,” explained Lee Taurman, Grant Thornton Life Sciences Advisory principal. “Expensive and effective is a societal good, if overall health care costs are reduced. But when lower-cost treatments, such as generics, exist as alternatives, society should rightly challenge the more expensive options. A drug does not become less effective because it goes off patent. Society as a whole benefits from the collective innovations of yesterday and today, and we must continue to fund the innovations of tomorrow.”

---


\(^7\) Taurman, Lee. The winds of change: Pricing in the pharmaceutical industry, grantthornton.com, March 21, 2016.
Expand nonorganically

The pace of M&A in the industry was tepid in the past couple of years, as life sciences companies adopted a wait-and-see approach to the presidential election. But M&A maintains front-line priority for life sciences companies since it enhances drug pipelines; it ensures access to new technologies, such as in biologics — genetically engineered proteins derived from human genes — and it facilitates innovation through advanced manufacturing technology like 3-D printing for medical devices. In addition, M&A can advantageously prove to be an important route to tapping into international know-how and talent in the future, if U.S. immigration policy limits the movement of industry personnel going forward.

Regardless of the drivers for an M&A, the most successful life sciences companies develop and follow an M&A strategy that factors in due diligence, a post-merger integration process, updates on tax structures and a plan for change management. First, developing and following a due diligence process that effectively evaluates candidate companies is an imperative. If M&A is a key component of the company’s business strategy, the company will assign executive-level oversight and leadership for the M&A process. Second in importance comes the imperative to design and implement a post-merger integration process for onboarding the newly acquired company. Central to this integration process is prioritizing the integration of often disparate systems that silo data in order to make this valuable asset widely available and accessible. Third comes paying attention to updating tax structures, which often fail to keep pace with evolving organizational structures and supply chains. In this respect, it is advisable that companies perform an immediate evaluation of the efficiency of the current tax structure. Finally, life sciences companies benefit from factoring in change management to help employees and investors make the transition to the new organizational structure more smoothly.

Crossing borders

Life sciences companies are increasingly looking to new markets to meet their growth strategies. But whether they make the move through M&A, an alliance partner, or organic expansion, life sciences companies face new risks, regulations and challenges in getting their products to market effectively.

Disease knows no borders, but life sciences companies that enter new markets face borders related to the nuances of local health care delivery norms and each particular country’s health ecosystem. Is the health system nationalized? Are doctors employed by the government (and therefore subject to Foreign Corrupt Practices Act regulations on gifts and incentives)? Do intermediaries like non-governmental organizations play a role in health care delivery? What role do nurses, midwives and other health advocates play? Understanding these nuances will both help life sciences organizations manage their risks and create the necessary infrastructure to work effectively in the local market.

A one-size-fits-all approach does not work, but how can life sciences companies effectively modify their business models for individual markets? Data can offer at least a partial solution to this challenge. For example, if a certain market coordinates care more through other intermediaries like nurses and midwives than doctors, life sciences companies need to work carefully with those intermediaries to help make them more effective in their role. More importantly, life sciences companies need to build trust with those intermediaries so that all parties are aligned for better patient outcomes. Greater trust will also open doors to a greater willingness to embrace change and share critical data that will improve sales and marketing practices, inventory management, product labeling, and intellectual property policies.
Conclusion

As the life sciences industry makes the transition from a volume-based, supply-driven model to a patient-focused approach, it needs to dramatically reduce costs while still maintaining product integrity, consumer outcomes and stakeholder returns.

The industry has to adopt smart strategies to manage disruptive forces, such as technological innovation, data management advances and the pervasive threat of value-eroding cybercrime.

Companies need to remain diligent and responsive to policy and political change, and be prepared to reshape their strategies to adapt to the new paradigm.

Well-prepared players will fully activate various growth levers to facilitate their goals. They are reshaping their businesses and innovating from within. Many are improving existing products, and creating innovative products and services. Growth through acquisition will remain key for many larger companies. International sales expansion will also appeal to a growing number of companies.

As they consider these opportunities, life sciences companies must remain constantly vigilant against existing and emerging risks that could compromise their plans.

With an agile and responsive outlook on the challenges that the dynamic life sciences industry faces, successful companies will be prepared to make the leap to a value-based model, benefiting generations of health care consumers and industry stakeholders.
We want to hear from you
Please take this quick survey and
tell us what you thought of this content.