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Strategy resets to patient outcomes

The state of life sciences

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Lee Taurman, Grant Thornton LLP's Life Sciences practice advisory leader

The life sciences industry is resetting its strategy to focus on providing value to the patient, the payor and society. Each subsector within the industry — including brand name and generic pharma, medical device manufacturers, drug wholesalers and diagnostics — plays a role. The industry is focused on proving value, as concerns about drug pricing, overall health care costs, budgetary limits, inefficient spending and the relative efficacy of expensive treatments grow. In the new competitive environment, life sciences companies that succeed will be those that can prove their products save not only lives, but also money.

The days of the increasingly elusive blockbuster may not be over, but the focus has shifted to improving patient outcomes. "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 LLP's Life Sciences practice advisory leader. "Expensive and effective are 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 innovation of tomorrow."

Resetting strategy is taking several forms. Companies are consolidating to build scale. Larger firms have paid a premium to buy smaller competitors with promising drugs and devices in their pipelines. At the same time, companies are responding to patient and payor demand for more personalized medicine, which promises that genetic analysis, data analytics and predictive technologies can help to determine whether patients will benefit from a specific clinical treatment.

These changes contribute to rich opportunities. Companies that thrive will be agile and embrace the kind of transformations and technologies necessary to demonstrate value.

State of play

The vibrant life sciences field, comprising its major subsectors, accounted for more than 1.66 million U.S. jobs at 77,000 companies in 2014, up from 1.62 million jobs at 73,000 companies in 2012, according to a recent industry report.[1] Notwithstanding, it is tougher for companies to grow. As a result, many companies have turned to a combination of strategic acquisitions, corporate consolidation and divestitures. As an example, due to consolidations over the past five years, the four largest branded pharma players account for roughly 42% of industry revenue. The top 10 make up 77% of revenue.

Although garnering less attention than large deals in the branded pharma sector, the generics sector and retail channels have experienced significant consolidation, too. The Big Three wholesalers have entered into agreements with large retail chains, changing the way generic drugs are purchased. CVS Health's acquisition of Target's pharmacies contributes to how generic manufacturers price, supply and contract for their products.

These changes are combining purchasing power to lower prices of drugs, particularly generics. However, industry consolidation also creates supply chain risk: When large purchasers require large-scale suppliers to meet their needs, it triggers further consolidation among manufacturers. We are beginning to see longer-term price and supply arrangements between these new entities and manufacturers to create stability in supply and pricing.

[1] The Coalition of State Bioscience Institutes. "2016 Life Science Workforce Trends Report," June 9, 2016.

The Affordable Care Act is giving hospitals and other providers more than a nudge to gain scale quickly. There were more deals in 2015 than there had been since 1999, as hospitals sought to grow amid the pressures of the health care law.[2] The consolidation among providers — and when regulators agree, payors — has empowered these key players to set value-driven goals for life sciences players.

Enter value-based pricing. In November 2015, biopharmaceutical firm Amgen struck an outcomes-based deal with Harvard Pilgrim Health Systems regarding its cholesterol inhibitor drug Repatha.[3] According to the terms of the deal, if patients on the drug do not hit certain cholesterol goals, Harvard Pilgrim receives a rebate. If dosages of the drug exceed an agreed-upon threshold, the rebate increases. This type of arrangement could create models for future agreements because it ties improved patient outcomes to future payments and demonstrates value.

Given that we are already seeing value-based approaches and manufacturers are actively working with payors to define or pilot these models, the question is no longer, "will this happen" but "when will this model become more widespread and how will the industry change to overcome the challenges to making value-based pricing a profitable model?"

In "The winds of change: Pricing in the pharmaceutical industry," Lee Taurman discusses a path forward on value pricing.

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.

[2] Mathews, Anna. "Health-Care Providers, Insurers Supersize," *The Wall Street Journal,* Sept. 21, 2015.
[3] Herman, Bob. "Harvard Pilgrim Cements Risk-Based Contract for Pricey Cholesterol Drug Repatha," *Modern Healthcare*, Nov. 9, 2015.

Technology provides the measures

There will be more demand for creative approaches like value-based pricing. Life sciences companies are complementing treatments with wraparound services — adding the kind of monitoring, measurement and follow-up that gives doctors and their patients far more information and insights than they can get anywhere else. "We've seen an explosion in information-driven tools to anticipate, measure and treat disease," says Lisa Walkush, Grant Thornton's national leader of Life Sciences. "Medicine is getting smarter, and life sciences companies are seeing themselves as health care businesses instead of product manufacturers."

Technologies that can affect how drugs and devices function and are measured have been introduced from the molecular level all the way to wearables. They have opened a clearer and wider window into how the body works and responds to various treatments, thereby improving efficacy. What companies are learning can reshape how they market, develop and price drugs, devices and other key products, and where their future growth will come from. When asked what's driving treatment and the drug discovery process, life sciences firms rate improving efficacy as their top pressure point.

This new pressure point has emerged from the kind of information that is only now available. For example, now that clinicians can measure specific outcomes in certain disease categories — tumor size and the existence of biomarkers — companies can better demonstrate efficacy, and payors can better measure outcomes. If life sciences firms expect to charge a premium for their products, these kinds of data will support a higher price. Companion diagnostics can provide insights into how a corresponding drug benefits a patient, but their pace of development is slow because of reimbursement and other challenges that must be overcome to truly capture the value of their potential.

The key is not only to develop a better product but also to demonstrate that it's worth the price. This is something that isn't necessarily factored into decisions by drug safety regulators and has only recently become a focus for life sciences firms.

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Tracking for value

The prevalence of condition-monitoring devices demonstrates how life sciences companies are becoming technology companies in their own right. They are developing apps to help patients manage health care-related activities, such as drug adherence and exercise. This is essential information if you're trying to track whether patients are complying with a broad range of doctor's instructions. Such information can quickly yield insights about the value of a particular drug or device, given a broader set of patient behaviors and indicators.

While this kind of information can help support growth and maintain pricing power, it's not just about the bottom line. Life sciences companies have to demonstrate they're focused on treating complex illnesses while also improving the lives of patients and serving society more holistically. Health economics and outcomes research is becoming increasingly important in understanding the benefits of various treatments. Telling the world you have an expensive product to manage chronic disease isn't enough. You have to show that you'll help patients become healthier over time and that health care costs will decline as a result. We see this issue as a topic to be grappled with in the coming years — how can the industry and society reconcile the high cost for effective treatments of acute and chronic diseases with the need to respect the economic restraints of payors and patients?

Prescription for progress

Life sciences firms have an increasingly clear view of their evolving role in the health care ecosystem, but while the view may be clearer, the path forward isn't. Firms should focus on transforming their business so that they are part of health care decisions and outcomes even after their product is prescribed. As they hit the reset button, the industry can move forward in innovative and practical ways to meet the changing needs of patients, payors and society.

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Lisa Walkush, Grant Thornton's national leader of Life Sciences

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