

Over the next five years, global spending on medicines is expected to increase by 29 to 32%, reaching \$1.4 trillion in 2020. During the same time frame, global drug use is expected to increase by 24%. Developed markets will drive spending growth, with higher prices per unit and access to newer and more innovative medicines, while pharmerging markets\* will drive expanded usage.<sup>1</sup>

While increased healthcare spend will likely lead to higher revenues for manufacturers, life sciences companies will focus heavily on addressing regulatory requirements, industry and consumer influences, pricing, and demonstrating comprehensive therapeutic value. Many organizations will adopt or invest in data-driven technologies to monitor and improve treatment efficacy and long-term patient outcomes. Furthermore, some may integrate new business units, or implement new, or more agile, processes, which will deliver both organizational efficiency and profitability. Companies that successfully leverage technological advances, partnerships with industry organizations and academia, and internal resources will see a definite impact throughout the value chain.

\*Pharmerging countries: China (Tier 1), Brazil, India, Russia (Tier 2), Algeria, Argentina, Bangladesh, Chile, Colombia, Egypt, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, South Africa, Saudi Arabia, Turkey & Vietnam (Tier 3)





# State of the Industry

## **Regulatory Scrutiny and the Push for Global Standards**

Over the past several years, global regulatory agencies have introduced or expanded upon regulations and guidance for life sciences companies. Whether specifically addressing supply chain, quality, information technology (IT) or marketing elements, the ultimate intent is to protect and empower consumers.

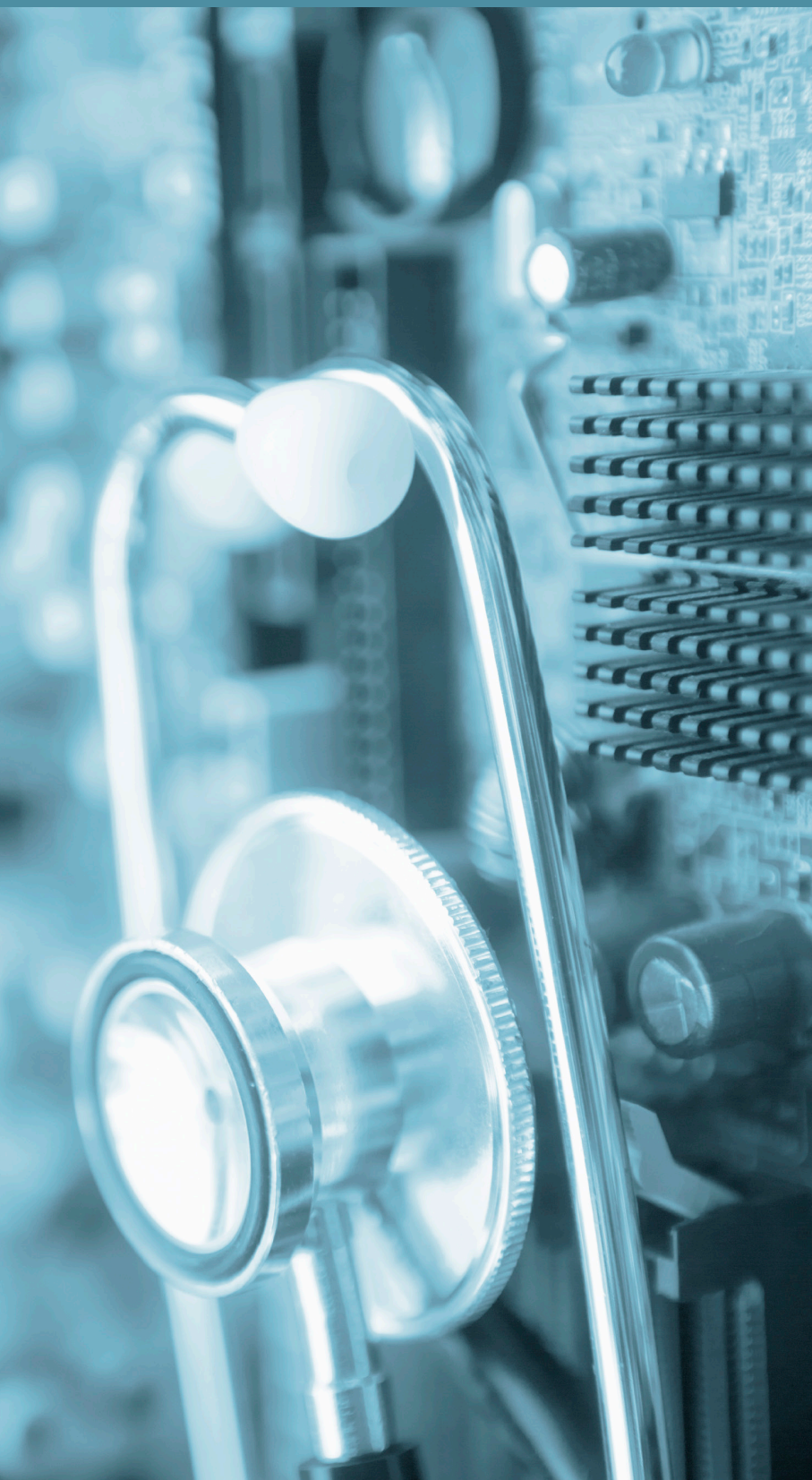
Multinationals are perhaps most impacted by the regulations (and lack thereof), particularly considering the infrastructure and resources available in certain markets and fluctuations within the global economy. Companies operating in China and India have repeatedly been in the media for allegations of corruption or bribery, or for failing to meet product quality or data integrity standards. To mitigate the latter, and to maintain product safety and efficacy throughout the global supply chain, the World Health Organization has been working with regulatory bodies to harmonize Good Distribution Practices (GDP) across nations.

## ***Pharmaceuticals: Serialization & Partner Integration***

Specifically within the United States, the Drug Supply Chain Security Act (DSCSA) requires that manufacturers, repackagers, wholesalers and third party logistics providers (3PLs) implement means to transmit product and transaction information and determine the validity of product over a 10-year period (2013 to 2023). By November 27, 2017, all manufacturers must ensure that each drug package and homogenous case carries a product identifier, including a unique standard numerical identifier (SNI). Manufacturers will also be required to provide transaction details in electronic form, verify suspect product at the package level, and maintain product identifier records for six years or more, by the deadline.

Many companies have begun implementing serialization solutions and are working towards integration with contract manufacturing organizations (CMOs), 3PLs and trading partners. As companies' respective deadlines approach, these efforts will drive investment in integrated supply chain and IT solutions, though many are struggling with which entity or departments will carry the costs.





### ***Medical Devices: UDI, Security & Vulnerability***

In a similar push to track and protect medical devices, the FDA established guidelines for a unique device identification system in 2013, for which the next deadline is September 24, 2016. On that date: required class III devices must bear a unique device identifier (UDI); class II device labels and packages must have UDIs and accompanying data must be submitted to the GUDID database; and noted devices must also meet certain formatting and software requirements.

While UDI implementations will require consistent transfer and tracking of device information, industry experts are also evaluating the vulnerability of medical devices and the security of associated data. In 2015, the Department of Homeland Security was investigating potential cases of device exploitation, which prompted the Institute of Electrical and Electronics Engineers (IEEE) to develop guidelines for medical device manufacturers.<sup>2</sup> While these are not mandatory standards, cybersecurity and device vulnerability will continue to be an eminent concern for life sciences executives, as noted by the passing of the Cybersecurity Information Sharing Act of 2015 this past October,<sup>3</sup> and the FDA's draft guidance (January 2016) addressing how companies monitor and manage postmarket cybersecurity of medical devices.<sup>4</sup>

Though concern was expressed primarily over drug infusion pumps, insulin pumps and defibrillators (among other devices), few have questioned patient safety from low-risk devices—like wearables. Guidance<sup>5</sup> was issued in January 2015, basically noting that such devices won't be "vigorously regulated" as long as they are non-invasive and do not pose a risk to users (and generally promote a healthy lifestyle). Samsung and industry organizations, like the Telecommunications Industry Association and Consumer Electronics Association, are pushing for specific device examples, particularly clarification surrounding those that track and store consumer data.<sup>6</sup> As companies look for partners to leverage and integrate this type of data, security is a primary concern; a recent report estimated that one out of every three healthcare records may be compromised in 2016.<sup>7</sup>

In addition to security concerns, industry organizations have been collaborating with lawmakers and the FDA to improve the premarket review process<sup>8</sup> and the safe and timely approval of devices.<sup>9</sup> Along with the two-year suspension of the medical device tax, Internet of Things (IoT) advances, and increasing investments due to continuing debates around pharmaceutical pricing, the outlook for 2016 is optimistic for device companies.





### **Mergers, Acquisitions & Divestitures**

Over the past few years, the industry has seen a surge in mergers and acquisitions, not only among Big Pharma, but also technology, medical device and bioinformatics companies. Whether to reduce costs or improve or complement current capabilities, the cumulative value of healthcare sector deals in 2015 was approximately \$600 billion—with the Pfizer and Allergan deal noted as the largest ever in the sector.

As these deals continue in 2016, life sciences companies should continue to expect increasing levels of scrutiny from regulators, and focus on untraditional methods of partnering—and engaging consumers. In addition, effectively integrating new business units is perhaps most pivotal to a profitable deal. Acquired companies often have a range of legacy systems, data sources and processes that will need to be evaluated and understood in order to develop an appropriate integration or standardization plan. This, along with the organizational benefits associated, will need to be considered in the planning and execution of deals; otherwise, the advantages of integration may not be realized in the desired timeframe.

### **High Value Biologics, Specialty & Orphan Drugs**

Between 2016 and 2020, drug patents for small molecules will expire at a higher rate than in the past five years. Competition from generics and biologics will strengthen, and companies will continue to incorporate more innovative and high-value treatments into their pipelines. Industry analysts estimate that there will be approximately 470 drugs available to treat orphan diseases by 2020, addressing 7,000 diseases with minimal or nonexistent therapeutic options. In addition, the number of orphan and breakthrough designation applications is increasing, with steady approval rates predicted through 2018.

By 2020, 36% of spending in developed markets will be on specialty medicines—the majority focusing on oncology, anti-infectives and anti-virals, and central nervous system disorders. Particularly in the US, invoice price growth will reach historic rates, driven in part by innovation and patent expiries, but pricing will remain a pertinent issue. As the effects of the Affordable Care Act expand through 2020, and medicines are progressively paid for by government organizations and programs, the focus on health outcomes, with correlated pricing, will be even more critical.<sup>10</sup>



# Looking Ahead



## Focus Shifts from Drug to Patient

Along with the larger gradual shift to value-based healthcare, life sciences companies are no longer relying solely on the approval and efficacy of a therapy. Instead, companies are expanding their understanding of the complete disease state, which includes side effects, patient adherence, and verbal and data-driven feedback. This not only requires a shift in how research and development operates, but may drive larger organizational transformations that involve incorporating, analyzing and effectively translating patient feedback into product and service improvements.

In the past, companies only integrated analytics capabilities into functions that directly touched consumers (i.e., sales and marketing). Now, many are realizing that the type of data they collect and employ should be driven by value to the business—and the consumer. Some organizations are creating patient advocacy groups, and disease communities and forums, which allow them to directly engage consumers and gather real-time insights for clinical trials, product development, or marketing messaging.<sup>11, 12</sup> With direct-to-consumer advertising attracting disdain from the American Medical Association, and drug pricing attracting scrutiny from the government, industry and consumer groups,<sup>13</sup> these efforts will help companies not only articulate, but also demonstrate, their true value.

As the focus on patient-centricity amplifies, consumer engagement—and monitoring and tracking this engagement—will be critical.





## Digital Drives Transformation

In order to effectively engage consumers, collaborate with partners, ensure compliance—and maintain competitiveness—life sciences companies must adopt, and adapt to, digital business practices. Advances in technology and analytics capabilities have already introduced the potential of bioinformatics and device interconnectivity to truly enrich the quality and depth of patient care. Many companies are leveraging genomics data and biomarkers to better understand patients' therapeutic responses. Verily's (formerly Google Life Sciences) Baseline Study is creating patient profiles that include data from before, during, and after treatment to gauge the efficacy and toxicity of treatments. This breadth and depth of data could dramatically improve health outcomes, and create alignment among life sciences companies, payers, and providers regarding the definition of health benefits and quality of life metrics.

While this information will inevitably lend itself to more personalized, more effective therapies—and overall quality of life—for patients, this data will likely continue to overwhelm organizations. Industry analysts estimate that, by 2017, 60% of existing research and development data models will be obsolete due to new, complex datasets. Without a strategy, or systems and processes in place to

collect, store and interpret such large amounts of data meaningfully, companies will lag behind competitors, and other industries. Unfortunately, and perhaps most remarkably, 80% of life sciences companies will establish digital business strategies by 2017, but only 20% will define actionable tactics and procedures.<sup>14</sup>

This lack of direction could in part be driven by resources or the slow pace of FDA and regulatory guidance regarding technological advances, patient engagement, and data security and integration. For example, though wearables, 3D printing and sensors are attracting business and consumer investment, most companies won't effectively, and profitably, integrate them into their business model by 2017, if at all.<sup>15</sup> Further, though social media is a mockingly useful channel for patient engagement, analysts estimate that 70% of pharmaceutical companies are limiting or suspending their use due to the potential liability risk—even though 50% of life sciences companies will likely use social media analytics for business growth. Companies will need to evaluate their digital integration tactics and capabilities, whether transmitting data to or from connected devices, among divisions and partners, or between patients and physicians or providers and payers.





### **Era of Agility**

As the pace of innovation, industry consolidation, governmental influence and industry scrutiny steadily increase, agility will be essential for companies operating on a global scale. Today, many life sciences companies over-invest in certain areas or technologies, or focus on cost-cutting instead of concentrating their efforts on building a more agile business model. Others improve flexibility and reduce overhead by partnering with contract organizations, or third or fourth party logistics providers. Regardless of the current tactics, many companies are tasked with managing and integrating progressively more complex supply chains, enterprise systems and data streams under the direction of multiplying decision-makers.

Currently, 72% of companies report a lack of end-to-end supply chain visibility.<sup>16</sup> H. D. Smith, however, leveraged their recent SAP ERP system implementation to then employ a cloud solution that traces pharmaceutical product through the pipeline; this solution allows them to not only track gross margin, volume and demand, but also customer service metrics. This highlights the criticality of real-time monitoring and integration for improving visibility, ensuring data security and regulatory compliance, and addressing challenges such as demand planning, cost management and customer engagement. Developing an agile business model will require reevaluating current structures, technologies and processes—and potentially investing in new ones—but life sciences companies that do so will gain efficiency, transparency and value in the long-term.





## Proving Value

Pricing debates from 2015 will likely continue into the coming years, particularly with the presidential election in 2016, and the global spotlight on the US healthcare system. Political, industry and media entities are fueling discussion and action, with consumers and providers sharing similar opinions. A recent study found that 76% of US consumers believe that brand name drug prices are unreasonably high, with a majority (53%) attributing higher prices to better pharmaceutical profits.<sup>17</sup> This issue is also exacerbated by research that depicts US drug spend and pricing as substantially higher than other nations,<sup>18</sup> which has prompted a call for reference pricing or other solutions from some advocates.<sup>19</sup>

The issue denotes the importance of proving value—whether to partners, payers, providers, or consumers. Considering the trends and advances impacting the life sciences industry, perhaps the most critical for doing so is: collaboration. Whether with bioinformatics companies, research institutes, or payer or provider programs, life sciences companies that initiate and drive complementary partnerships to improve patient outcomes will be more profitable, and reputable, in the long-term. Baxter Healthcare (Asia), for instance, partners with Changi General Hospital in Singapore to leverage medical and

technological innovations that will extend care beyond the hospital.<sup>20</sup> While this type of initiative may not be feasible, companies should also consider risk-sharing deals, pilot programs, restricted geographic areas, or other innovative options when designing offers.

In addition, companies need to manage research and development pipelines and clinical trial with value in mind; this not only means trials to ensure effectiveness, but programs to monitor longer-term effects and adherence, which will improve targeting. In November 2015, the Department of Health and Human Services hosted a meeting with government, industry, and academia to discuss “drug spending, development and innovative approaches that are being tried to control costs and improve access,” and ultimately payment “based on research evidence of their effectiveness.”<sup>21</sup> Though cost has consistently been a concern for patients, personalization, efficacy and engagement will increasingly gain importance. Furthermore, as consumers become more educated and informed, gathering, integrating and employing patient data to refine therapies and engagement tactics will be vital—though data access, relevance and security will remain primary concerns.



## About the Author



Janel Firestein leads Clarkston Consulting's life sciences practice and has been helping senior executives in pharmaceutical, medical device, and biotechnology firms address

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## Additional Insights

- Analytics in Life Sciences (*Blog Series*)
- Developing Data Strategies for the Future
- Healthcare Focus Shifting to Performance, Not Just Pricing
- Leading Global Serialization Programs (*Interactive Report*)
- Machine Learning and the Future of Medical Devices
- Strategies for Global Serialization and Track & Trace Implementations
- United States Drug Supply Chain Security Act (DSCSA)

*For detailed information about how we work with life sciences companies, please visit our website [www.clarkstonconsulting.com](http://www.clarkstonconsulting.com).*



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