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The Future of Healthcare from the Viewpoint of Regulators

(Source: An article by Michael Gibney for PharmaVoice)

As technology improves and gaps in healthcare come to light, players throughout the drugmaking industry have made efforts to streamline the path to approval. Rather than cutting corners on safety, this approach has focused on ensuring that truly innovative products encounter minimal roadblocks along the way.

Less than 15% of drugs arrive successfully to market, according to the FDA. Regulators are working with the industry to make sure the evolution reflects both the newest digital capabilities and the need to save time and money on products moving through the trial process.

For a more streamlined process, both regulators and industry need to more quickly weed out products that will not make it to the finish line.

"So-called fast-failure is very important to avoid exposing patients to the risk of clinical trials or ineffective treatments, and preventing the raising of false hopes," according to FDA Commissioner Robert Califf, when speaking to attendees at the Drug Information Association annual meeting in Chicago in June. "Both successes and failures can be critical to guiding developers to the best and most efficient pathway, and help them save time and money, prevent wasted or duplicative efforts, and ensure speedy development of the best and most effective products."

At the same time, continued monitoring of products after they have been driven to the market is crucial to solving the problem of waning life expectancy in the U.S., which now trails other high-income countries by a full five years, Califf said.

"Proposed legislative changes and increased recognition of the complexity of assigning value to a medical product will push us to continue evidence generation throughout the lifecycle of a product – not only for safety, but also for proof of efficacy, effectiveness and eventually comparative effectiveness," Califf explained. "We need to draw much better evidence for when medical products provide a true benefit."

Data is the key behind advances in the medical industry that improve patient outcomes and do so in a way that benefits people across the board, not just those with certain socioeconomic

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In Brief...

- **Walgreens Boots Alliance** (WBA) announced third quarter 2022 financial results with sales of US$32.6 billion down 2.8% on a constant currency basis, including a 720 basis point impact from **Alliance Rx Walgreens**, as anticipated. Q3 operating income from continuing operations was US$1.0 billion, down 33.5% on a constant currency basis, and operating income for the first nine months of fiscal 2022 increased 54.3% to US$2.2 billion, compared with US$1.4 billion for the same period a year ago. Separately, upon completion of its strategic review, the decision was made to retain ownership of the **Boots** and **No7 Beauty Company** businesses. This marks the conclusion of the review that began in January in line with the company's strategic priorities.
- **GSK** has completed the acquisition of all outstanding shares of US-based **Sierra Oncology** in an all cash deal totalling US$1.9 billion. The conclusion of the deal comes after Sierra shareholders approved the takeover. Sierra develops targeted treatments for rare forms of cancer. Separately, GSK announced an investment of £1 billion (US$1.19 billion) over ten years to accelerate research and development dedicated to infectious diseases that disproportionately impact lower-income countries. This research will focus on new and disruptive vaccines and medicines to prevent and treat malaria, tuberculosis, HIV (through **Viiv Healthcare**), neglected tropical diseases, and

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Challenging Pharma Manufacturers to Improve Access to Global Medicines Through Digitalization

(Source: An article by Raman Bhatnagar for MedCity News)

In recent years, technology advancements have been instrumental in improving access to practitioners, even in rural and underserved areas in lower income countries. Patients are now often able to communicate with medical professionals through telemedicine, a previously unheard-of resource. While this improves access to medical professionals, without a way to make actual medications more available, significant obstacles are still a formidable challenge. According to the World Bank and World Health Organization, half of the world lacks access to essential health services.

Global pharmaceutical companies are rising to these challenges by embedding access to medicine into their business practices. For instance, Pfizer just announced it will sell its patented drugs at non-profit prices to low-income countries. Likewise, according to the Access to Medicine Foundation's 2021 Access to Medicine Index, progress is being made – other leaders like GSK and Novartis have mature approaches in place to improve access - but there is more to be done, and pharmaceutical companies have a responsibility to take positive

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The Future (cont.)...

standing.

During the same meeting, Ken Getz, deputy director and research professor at Tufts Center for the Study of Drug Development, said "It's a future where therapeutic innovation and healthcare delivery are highly customized, informed by patient needs, and rich health and medical data, enabling more accurate diagnoses, early prediction and detection of disease, individual tailored treatment planning, more timely administration of interventions to maximize individual response and more targeted, effective and safe therapies."

The industry is moving in that direction rapidly. Nearly all drugs in development for cancer and nearly 60% of drugs for other diseases rely on genetic information. Likewise, almost 40% of all drug approval are part of the class of personalized medicines, up from 9% in 2013.

The use of vast amounts of data is driving these changes. In 2005, the average number of data points per pivotal trial was 494,000 and in 2010, that average increased to 929,000. In 2020, the number of data points skyrocketed to 3,453,000.

The pandemic also drove the compression of drug development timelines by shortening phase transitions and necessitating speed and efficiency in the face of a crisis-level threat. Conversely, it also exposed many shortcomings in the healthcare system, but the response showcased the ability of the system to adjust when it counted most.

"Lessons from our pandemic experience affirm much of what we have long known, and so much more," Getz said. "They magnify and demonstrate a path forward realizing a future where each study volunteer participates in the right trial, and where each individual patient receives the right treatment in the right dose at the right time."

Challenging Pharma (cont.)...

and progressive action. According to the Index, "Pharmaceutical companies have a unique role to play here, as they have the capacity to develop urgently needed health products and to improve products' availability across socioeconomic divides."

In parallel, pharmaceutical companies are embracing digital transformation, the FDA's Advanced Manufacturing Initiative and the International Society of Pharmaceutical Engineers' (ISPE) Pharma 4.0 framework seek to improve efficiencies and faster drug manufacturing. In fact, according to a 2021 research study, Culture Reimagined: How Pharmaceutical Firms Can Use Data and AI with Confidence, companies that have a more advanced digital culture use data effectively across all aspects of drug manufacturing. Eighty percent of such "digital culture leaders" in the research say their vaccine manufacturing capacity will be significantly impacted by digital technologies going forward.

Digitalization is allowing pharmaceutical companies to experience efficiencies that were simply not possible 10 years ago. Digital technologies are having a ripple effect on everything from product quality and yield to on-time delivery. Digital transformation is optimizing outcomes across the entire pharma value chain and evolving traditional supply chains to be more resilient. Take electronic batch records as just one example of digital transformation. Electronic batch records, coupled with automated product release, contain the logic and rules that enforce manufacturing workflows, improve data integrity, minimize opportunities for error, and limit held inventory waiting to be released. In another example, predictive and prescriptive maintenance give pharma companies sufficient warning that a piece of equipment is degrading, allowing action to be taken before a costly breakdown occurs.

The more efficiencies that are gained, the quicker and more cost-effectively a drug can be commercialized. Then production is leaner, there are fewer faulty batches, quicker time to market and overall reduced production cost. This can have a trickle-down effect on pharma's ability to make medicine more available and less expensive with sacrificing margins.

For pharmaceutical companies that endeavor to improve their access strategies, they could consider starting early in the pipeline with small batches of new drugs. The incurred business risk is smaller when access is considered at the onset of small batch drug design and distribution, and efficiencies are already embedded into the manufacturing process with the help of digital solutions. Then, with a successful initiative under its belt, the organization has a proven framework to scale going forward as it builds and improves upon its access strategy.

As the population grows, so will the demand for medicine and the pressure on the pharmaceutical industry to rise to meet the challenge of a more sustainable world. Operational efficiency and visibility brought on by digital transformation can help improve how pharmaceutical manufacturers do their critical part in improving equitable access and availability of medicine around the world.

In Brief (cont.)...

antimicrobial resistance.

- **McKesson** and **HCA** announced the formation of a JV combining their respective oncology research and clinical trial organizations to create what is expected to be a powerful oncology-centric contract research organization (CRO) offering for manufacturers. McKesson will own 51% and have operating control of the JV and will separately acquire the Genospace personalized medicine and clinical trial matching platform from HCA.
- **Cardinal Health** announced that it has acquired **Bendcare Group** purchasing organization (CPO-GPO) entity and made a minority investment in the Bendcare management service organization. Following the acquisition of the CPO-GPO, current Bendcare-affiliated CPO-GPO members will transition to Cardinal Health's Cornerstone Rheumatology GPO and Cardinal Health will be the exclusive distributor for those practices. This demonstrates Cardinal's strategy of prioritizing investment in strategic growth areas and expands distribution opportunities and technology solutions offerings
- **Pfizer** and **BioNTech** announced a new vaccine supply agreement with the U.S. government to support the continued fight against COVID-19. Under the new agreement valued at US$3.2 billion, the US government will receive 105 million doses, and has the option to purchase up to 195 million additional doses and may include adult Omicron-adapted COVID-19 vaccines, pending authorization from the U.S. FDA. The doses are planned for delivery as soon as late summer 2022 and continue into the 4th quarter for of this year. The companies also announced positive data evaluating the safety, tolerability and immunogenicity of two Omicron-adapted COVID-19 vaccines, both showing robust immune response across two investigational doses.

(Sources: Company Press Releases, Drug Store News, Fierce Pharma, Nephron Research and World Pharma News)