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Will Pharma Take the Lead the Way in the Field of Medical AI?

(Source: An article by David Klein for STAT News)

Artificial intelligence (AI) is quickly infiltrating and impacting all facets of today's world and becoming a game changer in the areas of healthcare, including in the research and development (R&D) of many pharmaceuticals, as well as patient care.

Five years from now, it is likely patients will walk into a doctor's office presenting with almost any condition you can envision and will be prescribed both pharmaceutical-based medication and a prescription for a *digital therapeutic*. Accessible through the patient's smartphone, the digital therapeutic will deliver personalized, evidence-based interventions to treat their condition, completed through daily lessons and game-like interfaces, all guided by sophisticated algorithms that will work together to deliver the best possible outcomes for the patient. This approach will have been well-established through extensive evidence and recommended by practice outcomes.

This scenario isn't just likely; it is inevitable. The only questions are when will digital therapies become the standard of care and who will lead the movement forward?

Prescription digital therapeutics deliver broad access to the latest in behavioral, cognitive, and skills-based intervention, democratizing care traditionally restricted to patients with access to specialists and academic centers. The more advanced applications also provide neuro-modulatory mechanisms of action that safely target specific neural pathways inaccessible to biopharmaceuticals. Their consistent use retrains the brain to make new connections for lasting results, providing therapeutic benefits with minimal side effects.

Pharma has the necessary capabilities to launch these new therapies effectively and at scale in a way that best fits the needs of patients. Prescription digital therapeutics are the essential ingredient in the AI-enablement of pharma's future.

A requirement for the shift to prescription digital therapeutics will be the involvement of players who are committed to putting evidence first, and who have strong commercial and regulatory arms in place. They will also need to have a deep expertise in shifting the standard of care to embrace new therapies. The pharma industry checks every box in ways that the technology industry cannot. As has happened with biologics in the 1980s, immunotherapy and CAR-T in the past decade, or gene therapy today, pharma has the ability to enlist policymakers and prescribers to move digital therapeutics forward in a meaningful and substantive way.

Using AI to enable more effective and efficient operations is underway everywhere. We see companies working to bring AI and machine learning to bear in drug discovery, manufacturing operations, commercial launch campaigns, and clinical trials. But those efforts are about efficiencies not products – the difference

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In Brief...

- **BridgeBio Pharma** reported positive results from its Phase 3 study of its investigational drug *acoramidis* in the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM). The company announced that the results showed a statistically significant improvement in the primary endpoint, achieving an 81% survival rate in the treatment group compared with a 74% survival rate in the placebo group. ATTR-CM is a rare but potentially fatal disease of the heart muscle, according to the **American Heart Association**.
- **GSK** and **Pfizer** have raised their price ranges based on longer-term efficacy data for their RSV vaccines, but Pfizer may choose to undercut on price in order to win market share against GSK's more favorable data. GSK's *Arexvy* and Pfizer's *Abrysvo* are the first two respiratory syncytial virus (RSV) vaccines for older patients. Neither company has provided a definitive price for their respective vaccine to the **CDC's Advisory Committee on Immunization Practices (ACIP)**. However, both companies raised their price ranges – GSK increasing its to a US$200-US$295 range and Pfizer to US$180-US$270.
- **Systech**, part of **Markem-Imajie and Dover**, a leading provider of digital identification and traceability software solutions, announced a series of services designed to assist customers in the pharmaceutical supply chain meet the *U.S. Drug Supply Chain Security Act (DSCSA)* interoperability requirements by the November 27, 2023 deadline. Systech now offers three new service packages in conjunction with its software to help manufacturers understand how to meet the *Enhanced Drug Security Requirements: Readiness Gap Review*, compliance testing and master organizational validation.

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As Obesity Market Gains Strength, Access to Drugs Continues to be a Challenge

(Source: An article by Mandy Jackson for Scrip Citeline Commercial)

At the recent American Diabetes Association (ADA) annual meeting, GLP-1 agonists presented their compelling evidence of double-digit percentage weight reductions in clinical trials, and how significant weight loss can improve or prevent cardiometabolic comorbidities needed to improve payer coverage.

Given the numbers of patients eligible for treatment and the costs of new medicines, there are growing concerns that many who could benefit from obesity drugs will be unable to access them. Novo Nordisk's drug, *Wegovy (semaglutide)* has been very successful, but demand for the drug has left it in very short supply. Novo Nordisk could have an oral version of *semaglutide* by 2024, pending US and EU filings expected later

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Will Pharma Lead (cont.)...

being that products are the bet that will drive future growth.

So, what will digital therapeutics do for the industry that will be key to success? First, prescription digital therapeutics will deliver AI-driven outcomes to patients which will be highly adaptable and personalized, thus putting the patient at the center of care. By securely collecting data, prescription digital therapeutics use AI and machine learning not only to engage patients, but also to modify and individualize their treatment.

Secondly, AI-powered digital biomarkers, captured by prescription digital therapeutics via sophisticated sensors on a patient's smartphone, will deliver insights that can be used to quantify a drug or treatment's effect. This enables clinicians to more deeply and fully understand a patient's disease experience. This allows for more personalized support that will allow developers to use the information and predictive power they provide to transform how care is delivered.

Finally, prescription digital therapeutics drive the long-term, high-quality data collection essential for AI to benefit pharma companies. By leveraging prescription digital therapeutics to gain real world data insights, drug companies inform their portfolio planning and enable development of more effective treatments.

Tech companies are already looking for ways to use prescription digital therapeutics. Apple announced that their iPhone iOS 17 update will include new mental health and vision companion apps. Likewise, Google and Amazon are also making inroads into this space. Amazon has made significant acquisitions such as RxPass, PillPack and One Medical, while Google has extended its Vertex AI tool suite into healthcare, including its recently announced partnership with the Mayo Clinic. Big Tech's growing interest in AI-based healthcare solutions signals that the software ecosystem that will define healthcare's future is already being shaped.

In that future, patients lose out on the clinical expertise pharma brings to the table. The pharma industry also suffers, and will have difficulty thriving if it continues to wait for "the next blockbuster". This market strategy will become unsustainable as payments shift to value-based and outcomes-driven approaches.

Pharma companies that wait for other companies to drive the first commercial success in this space will likely be left playing catch-up. While tech companies are ready and willing to step in, this could lead to proliferation of digital solutions that will lack the clinical rigor of medicines that are critical to the success of the patient journey.

Obesity Market (cont.)...

this year, but the timing of its launch may depend on whether the company's manufacturing for the injectable version can catch up with US demand.

Cardiovascular outcomes data may be crucial to justifying the cost of chronic treatment with obesity therapies in a large patient population that has mostly gone without pharmaceutical options. SELECT cardiovascular outcomes trial (CVOT) of *Wegovy* are expected within the next several months. The data from CVOT may provide the needed evidence for why weight loss induced by a GLP-1 agonist is worth widespread use.

Nevertheless, given the predictions for a mega-blockbuster for the obesity drug market – despite manufacturing, pricing and other access challenges – many players are competing to bring new weight loss therapies forward for the largely untapped market. Recent statistics on obesity from the National Institute of Diabetes and Digestive and Kidney Diseases show that as of 2018, 42.4% of US adults are obese and 30.7% are overweight. It is predicted that by 2030, more than 1 billion people globally will be obese.

Among the contenders is Eli Lilly's new injectable GLP-1 drug due to hit the US market in late 2023. It is a dual agonist of GLP-1 and GIP, *Mounjaro (tirzepatide)* which was approved for use in the treatment of diabetes in 2022. Lilly also has an oral GLP-1 agonist, *orforglipron*, that is currently in Phase III trials and has shown impressive results announced at the ADA meeting.

Wegovy, Mounjaro, oral *semaglutide* and *orforglipron* all may face competition from another formidable competitor in the GLP-1 agonist class from Lilly's *incretin* agonist portfolio, a "trip G" or GGG agonist targeting GLP-1, GIP and glucagon. This new drug, *retatrutide*, delivered up to 24.2% weight loss at 48 weeks at its highest dose and was the greatest weight loss ever observed in a trial of less than one year duration.

But there remains concerns about how health care systems around the world would be able to deliver medicines impacting not only weight but blood glucose levels and markers of cardiovascular health to all of the patients who need them.

In Brief (cont.)

These services will address endpoint data connection, product registrations, authorized trading partner verifications and record keeping requirements.

- In a court filing, **Merck** has asked a federal court for a decision without a trial in its battle against the drug price negotiation provision in the *U.S. Inflation Reduction Act (IRA)*. In its request for summary judgment against the **U.S. Department of Health & Human Services** and the **Centers for Medicare and Medicaid Services**, Merck reiterated its claim that the drug price negotiation violates the First and Fifth Amendments of the Constitution, calling the system "extortion". The system violates the First Amendment by forcing companies to say that the prices are fair. Merck claims that prices of its drugs would be affected by the measure – including mega-blockbuster *Keytruda* in 2028 – due to the government setting the price of drugs rather than prices being negotiated with drug manufacturers.
- **Novartis** has acquired **DTx Pharma**, a preclinical stage biotechnology company addressing the delivery challenges of oligonucleotide therapeutics with its *Fatty Acid Ligand Conjugated Oligo Nucleotide (FALCON)* platform, for US$500 million upfront and additional payments of up to US$500 million based on pre-specified milestones. The FALCON platform enables the delivery and activity of small interfering RNA (siRNA) therapeutics to tissues beyond the liver, enhancing biodistribution and cellular uptake. DTx Pharma's lead program is currently in preclinical development, with FDA Orphan Drug Designation in the treatment of Carcot-Marie-Tooth Disease Type 1A.

(Sources: Contract Pharma, Dow Jones NewsWire, FiercePharma, Scrip Intelligence, and World Pharma News