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Bayer Consumer Health's Evendon-Challis On The 'Huge Potential' Of OTC Digital Therapeutics, AI

by [David Ridley](#)

HBW Insight speaks to Bayer Consumer Health's head of R&D and chief scientific officer David Evendon-Challis about the opportunity presented by a new generation of OTC digital therapeutics as well as by AI-driven self-care.

There's been a "lot of talk about digital therapeutics within the consumer health industry," with the excitement around this space "growing rapidly," according to Bayer's David Evendon-Challis.

"When there's an opportunity for digital to not just be a health companion, which is useful in many instances, but actually to provide a service directly, that is really interesting. I think that there's huge potential within consumer health for these kinds of products," said Evendon-Challis, who is Bayer Consumer Health's head of R&D and chief scientific officer.

Defined by the Digital Therapeutics Alliance as "delivering evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease," the digital therapeutics sector has seen tremendous growth and investor interest during the pandemic. (Also see "['Training People To Be Healthier': Digital Therapeutics Programmed For Growth](#)" - Medtech Insight, 13 Dec, 2021.)

Digital therapeutics have been developed for a wide range of applications, such as women's health, cardiovascular conditions such as hypertension, pulmonary disease such as asthma and COPD, neurological disorders such as Alzheimer's and Parkinson's disease, and gastrointestinal disease, enabled in large part by technological advancements.

An exciting recent example is Akili Interactive's mobile video game therapy for attention deficit/hyperactivity disorder (ADHD), launched recently at the inaugural Digital Therapeutics

Alliance Summit in Washington, DC.

Based on the same technology as Akili's EndeavorRx therapy for children, EndeavorOTC is available without a prescription in the Apple App Store for adults 18 and older with ADHD. (Also see "[Akili Introduces Adult Version Of Video Game Therapy To Lessen ADHD Symptoms](#)" - Medtech Insight, 7 Jun, 2023.)

Clinical trial results show that using EndeavorOTC improved participants' ability to focus by an average of 85%, with over one-third of participants no longer exhibiting an attention deficit following treatment. Furthermore, almost three quarters of participants reported quality-of-life improvements including completing tasks on time and managing multiple tasks at once.

Depending on what it learns from the early feedback, the company says it may decide to ask the US Food and Drug Administration to clear EndeavorOTC as a prescription therapy or it may pursue over-the-counter labeling.

What It's All About

"I think this is great," Evendon-Challis enthused, asked about the product as an example of what digital therapeutics might offer consumer health. "I think sometimes we think health has to be always very serious and look like a pill in a white box. But the reality is, we're all people and if we can integrate something into our lives in a really simple way, with a fantastic product experience, that's the key."

For Evendon-Challis, EndeavorOTC represents what consumer health is really all about. "For example, we have to make sure that our Berocca effervescent immunity tablets taste great, that people enjoy using them and can incorporate them into their routine. It's the same with these digital therapeutics. If something is hard work, if it's more like homework, then people aren't going to do it. If gamification can help, we absolutely need to be part of that."

Bayer Consumer Health is taking digitalization very seriously, so much so that it recently created a business unit – Precision Health – focused entirely on identifying "digital and digital-supported consumer healthcare opportunities."

Working with start-up companies and other digital health providers while also improving Bayer's existing digital capabilities, precision health is about offering a holistic and personalized

'Faster, Better, More Efficient' – Why Bayer Is Investing In 'Precision Health'

By [David Ridley](#)

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Like other big global OTC players, Bayer Consumer Health is stepping up its investment in digital self-care. In the first part

approach to self-care that increases trust in the company's consumer health brands, Evendon-Challis explained.

AI Opportunity

Along with digital therapeutics, Bayer sees artificial intelligence as another big opportunity within this space, noted Evendon-Challis. "Sure, there's a lot of hype, but I think it's justified."

Although still in its infancy, AI technology can offer consumers a whole new world of self-care products, from automated shopping experiences to body enhancing bio-wearables to camera-based skin diagnostics. (Also see "[HBW Insight's Key Takeaways From 2021: #3 Keep Your Eye On AI](#)" - HBW Insight, 5 Apr, 2022.)

of an exclusive interview, HBW Insight catches up with the company's head of R&D and chief scientific officer David Evendon-Challis to dig deeper into the rationale for setting up a new 'precision health' business unit, including why a holistic and personalized approach to digital self-care increases trust in long-loved and science-backed brands.

[Read the full article here](#)

"But equally important is what AI can do behind the scenes" Evendon-Challis pointed out. "AI has huge potential as a foundational technology, to be applied across the whole product development lifecycle."

"As an R&D person," he continued, "when I think about the potential of AI, I think about the insights it can generate with regards to everything from product formulation and stability to creating claims and designing packing."

"AI has an amazing potential for improving productivity and unleashing creativity, I would say. So, I'm really excited about both sides of that."

Seeing Patterns

Thinking specifically about Bayer's new Precision Health business, Evendon-Challis acknowledged the power of AI in leveraging datasets generated by the use of self-care digital health products to provide personalized insights to consumers. "Finding patterns in big data requires AI, so it's a super-critical technology for us."

However, this is where the regulation gets a bit tricky. Currently, both EU and US regulators are attempting to create frameworks for AI that balance innovation with consumer protection.

In the US, the FDA is exploring a new risk-based review framework that would allow for modifications to AI algorithms based on real-world learning and adaptation while ensuring patient safety. (Also see "[Rise Of The Machines: FDA Artificial Intelligence Guidance Is Coming](#)" -

Medtech Insight, 2 Apr, 2019.)

The new pathway will look at the manufacturer, rather than the product, and will take into account a number of metrics about the manufacturer to decide whether the company is trustworthy, and whether it has processes in place to ensure post-approval reliability and safety.

In the EU, the European Commission is taking a more cautious approach. The Artificial Intelligence Act – recently endorsed by the European Parliament – proposes to up-schedule many AI-based medical devices that are currently medium-risk under the existing Medical Devices Regulation. (Also see "[EU AI Act Proposal Adopted By Parliament In Landslide Plenary Vote](#)" - Medtech Insight, 14 Jun, 2023.)

“Under the proposed rule, medical devices and software as a medical device that use AI would be considered high risk products,” clarified EU medtech regulation expert Amanda Maxwell, speaking to HBW Insight. “So, that’s serious. It’s costly and very time consuming to get a product like that onto the market.” (Also see "[Artificial Intelligence In Consumer Health: Reality, Challenge And Opportunity](#)" - HBW Insight, 5 Apr, 2022.)

Second Nature

Nevertheless, Evendon-Challis was not too concerned. “When it comes to regulation, you know, the consumer health industry is used to this. We’re a relatively new industry and having a good and consistent regulatory framework is important. We definitely aren’t there yet when it comes to regulating AI, so I think we should be having these policy conversations.”

However, he stressed that the consumer health industry needed to be part of these conversations. “It’s really important that digital health tools show value so AI isn’t just about societal and individual information security risks. It’s important that we demonstrate how digital can help meet broader policy priorities around better access to healthcare, for example.”

“I think in future it’s going to be really important to make that distinction between something that is there to provide a bit of information, or to help with ‘wellness,’ which may bring anxieties around data security and privacy, and something that is there to actually do some work to diagnose or to treat you,” he predicted.

“These are very different things, and I think they need to be treated differently,” he concluded.