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PHARMACEUTICALS AND THE ENGAGED CONSUMER THE OPPORTUNITY VIA PATIENT-GENERATED DATA

By Kenneth Beers, Giles Thurston and Julien Gagnon

Driven by the increasing cost burden they bear and enabled by the wide array of information available to them from today's digital infrastructure, patients are more engaged than ever in deciding their own care. Patientgenerated data captured within this digital infrastructure are opening new avenues for pharmaceutical companies to engage directly with patients, as consumers and as partners in care.

"Voice of the patient" input is increasingly influential in global market access decisions.

> Pharmaceutical companies should focus on digital investments that will uniquely position themselves to add value by linking solutions to products. While digital engagements like these offer new opportunities to augment the value of its products, entering this space is not without challenges. Between reimbursement barriers and the threat their digital offerings pose to activities traditionally conducted by providers, pharmacies and payers, the rationale and return on investment of digital solutions remains unclear and under question.

Creating a welcoming environment among payers, providers and patients, and developing successful solutions can occur if these organizations narrow their focus to one that supports concerted investments and stakeholder engagement.

Establish Efficacy and Real-World Effectiveness

Patient-generated data are useful to establish therapeutic effectiveness, in trials or real-world populations. These data may be patient selfreported responses captured by smartphone apps or other digital devices, or they may be passively generated from wearables or web-enabled devices. Where patient-generated data are internally useful to pharmaceutical companies, investment return does not need to depend on reimbursement or gaining of incremental share.

Patient-generated data can expand the picture of disease burden and effect of treatment beyond the few "hard" endpoints in trial protocols. Patient-reported outcomes (PROs) capture the unfiltered patient experience and perceived value in therapies, and can be cited in labels if captured in real time to avoid recall bias and linked to therapeutic effect. Here, entry of patient reports by always-on, always-carried digital devices aid consistent realtime capture and support broad post-approval demonstration of real world effectiveness. Such "voice of the patient" input is increasingly influential in global market access decisions.

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Patient-generated data can also provide "hard" endpoints in trials, when they directly measure symptoms or intended therapeutic benefit. Parkinson Disease patients often develop levodopa-induced dyskinesia, cycling between "off" and "on" periods of undertreatment and overtreatment. Wrist devices can capture the time-dependent arm motion and physical activity associated with dyskinesia, profiling intraday variability that is difficult for clinicians to observe directly.

Improve Patient Self-Management

Patient-generated data may help patients use therapies more effectively or otherwise manage their disease. For patients with diabetes, continuous glucose monitoring provides glucose readings every five minutes, as opposed to three to four times per day with finger sticks. This helps patients better control glucose variability and can lower HbA1c by nearly a percentage point even without a direct linkage to insulin delivery. This technology is agnostic to the insulin used and has been commercialized not by pharmaceutical companies but by device manufacturers.

Without a unique tie to a therapeutic brand, pharmaceutical companies have been challenged to define a digital role where they provide value that device manufacturers or healthcare providers cannot. Here, the split coverage of pharmacy and medical benefit in the U.S. often precludes reimbursement unless the digital solution is closely and uniquely integrated to the drug or its delivery device. Their digital solutions are often low-cost, patient-education websites or hub services for specialty products that are often not reimbursed but are expected of specialty-priced therapies.

Respiratory agents often require multi-step administration and a defined breathing cadence. Many patients diverge from the protocol which lowers the drug's effectiveness. A coupled digital solution where branded inhalers provide real-time instruction or feedback (through the device or by an app) could improve effectiveness. Development would clearly fall to pharmaceutical companies, though demonstrating added benefit and being rewarded by payers for it is still challenging.

Coordinate Care and Trigger Interventions

Digital solutions provide further benefit when they engage patients, caregivers and healthcare providers to improve care coordination and continuity, but again the challenge for pharmaceutical companies is to identify situations where it can provide unique value that another service provider cannot. Making delivery devices web enabled or otherwise reporting adherence is of little use unless a healthcare provider (HCP) makes an intervention or clinical decision based on this data, which overworked HCPs inundated with data often struggle to do.

This calls for outsourced support services, such as messages to nonadherent patients and their caregivers or HCPs. These make little sense for pharmaceutical companies to provide on a stand-alone basis unless it has a dominant product or portfolio in a disease, or they can integrate various solutions together, otherwise they will be an unwanted complication to HCPs. Even then, pharmaceutical companies' offerings should not duplicate HCP activities or specialty pharmacy services. This requires close integration of pharmaceutical company offerings into clinical practice, suggesting partnerships with major providers to codevelop a comprehensive solution that can be replicated for broader adoption.

Often, the optimal path for pharmaceutical companies is to collaborate with an external service provider supporting multiple products in a disease area. An example is Propeller Health's disease management program for asthma and chronic obstructive pulmonary disease (COPD). In partnership with GlaskoSmithKline, Boehringer Ingelheim and Novartis it created a way to use a common digital device to link to multiple inhalers and spirometers. Such collaborations

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spread out the investment and simplify use by HCPs and patients through a common platform. While pharmaceutical companies cede the opportunity to differentiate via a digital solution, reimbursement is often lacking and incremental share is hard to secure, so the upside may be small. Meanwhile the collective value provided by branded therapies is enhanced (with possible access benefits), patients' outcomes are improved and increased adherence may result in incremental sales.

Learnings for Pharmaceutical Companies

While pharmaceutical companies have a variety of digital solutions they could develop, internal investment is best focused where the solution uniquely ties to their products. This is easiest to achieve when the solution generates effectiveness data that supports the manufacturers' own regulatory or access objectives. Where the solution aims to improve patient self-care or trigger HCP intervention, it is often not optimal for a pharmaceutical company to provide a solution on a stand-alone basis. Here, partnerships with provider networks or service providers are preferred, especially to achieve simplification for HCPs and shared-investment benefits of a common platform across products.

Key Takeaways

To be successful in the evolving healthcare market, organizations must:

Think differently.

Pharmaceutical companies are the right providers of digital solutions when the solution closely and uniquely integrates with its therapy.

Plan differently.

Prioritize digital investments on solutions that are a unique coupling to a product and do not dilute the marketplace with offerings that other service providers could offer just as well, or better.

Act differently.

Pursue partnerships with providers and service vendors to ensure offerings are well integrated into clinical practice and deliver patient impact from shared investments.

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