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REGULATION

Growth and Disruption: Big Pharma's Response to Medical Marijuana

by Deb Ossi

The pharmaceutical industry faces disruption with the rise of medical marijuana. The way firms responsded to a similar shift with the advent of biotechnology could indicate future trends for Big Pharma.

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The Food and Drug Administration's recent announcement of the approval of Epidiolex sent shockwaves through the pharmaceutical industry. The drug, approved for certain rare forms of epilepsy, is the first one "comprised of an active ingredient derived from marijuana" to be approved by the administration. The announcement signals a historic

shift from another federal entity, the Drug Enforcement Administration, which is expected to reclassify cannabidiol (CBD) for medical use. Both developments will impact the pharmaceutical industry and the medical marijuana industry for years to come.

In their article published by CMR, "**Responding to a Potentially-Disruptive Technology: How Big Pharma Embraced Biotechnology**," Julian Birkinshaw, Ivanka Visnjic, and Simon Best describe the responses of firms in the pharmaceutical industry to the similarly game-changing advent of biotechnology. The authors studied the response profiles of twelve firms over 25 years as they faced the opportunity/threat presented by biologics. Variances in the firms' timing and focus in their engagement with biotechnology proved to be determinative of their profitability, with early movers and those with a more "open" response faring better over time. Firms such as Roche and Johnson & Johnson benefited from early investment and from incorporating this new science into their core strategies.

The authors developed a three-step process to frame the firms' approaches to disruptive technology. By sensing, responding, and scaling to opportunities/threats, firms established themselves as winners or losers in an evolving market. The phenomena observed in the study share many overlapping traits with the advent of medical marijuana acceptance and legalization and the new approval and reclassification of CBD for use in pharmaceuticals.

Budding Possibilities

Big Pharma's reaction to biologics proves especially relevant to the case of marijuana-derived drugs because the progress of that new technology was slow moving. The authors characterize biotechnology as "potentially" disruptive because early movers had no way to predict how the story would ultimately unfold. A similar circumstance exists for pharmaceutical firms today with respect to the marijuana industry. Their response to marijuana is complicated by factors within the industry and outside pressures from the general public, government bodies, and a new breed of competitors.

Unlike the rise of biologics, new offerings of marijuana-derived drugs have faced the scrutiny of the DEA, which categorizes these substances in the same class with cocaine. U.S. companies could not execute clinical trials for approval by the FDA because only one

facility (at the Ole Miss School of Pharmacy) was allowed to “legally cultivate marijuana for research purposes.” Challenged in courts with only limited degrees of success, this circumstance created a total vacuum of traditional pharmaceutical offerings that could clear regulatory hurdles. But that did not stop the marijuana industry from rapid growth in light of continuing legalization for medical use in many states. Drugs of this type are available for purchase, and legal (to varying degrees) for an increasing number of Americans, but they lack FDA testing and oversight.

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Levels of Awareness

Since awareness and response are crucial steps in the process of addressing disruptive technologies, the long road to legalization has produced many complex layers of these types of engagements. The relationships between the rising medical marijuana industry and pharmaceutical firms are fractured, entangled, and sometimes dysfunctional.

For instance, pharmaceutical giant Insys successfully backed a campaign to stop Arizona’s recreational marijuana ballot measure, then received approval from the DEA to create Syndros, a synthetic cannabinoid, a mere five months later. Defensive strategies to suppress the emergence of marijuana-derived drugs have long been a feature of the Big Pharma playbook, but increasing legalization and the option of FDA-approved synthetic cannabinoids have allowed firms to take a hybrid offensive-defensive approach, like the one used by Insys.

Other firms, such as Johnson & Johnson, are striking a more cooperative stance. Through their JLabs venture, Johnson & Johnson has brought Avicanna and Vapium Medical into its ecosystem. According to the Birkinshaw, Visnjic, Best model, this early commitment could be key to their profits and market dominance in the future.

The pathways between established pharmaceutical firms and the marijuana industry are numerous, and they often work both ways. Following instances of state-level legalization, medical marijuana companies founded by former pharmaceutical insiders have multiplied. Many of them implement innovative technologies from their past Big Pharma work to refine cannabinoid product offerings. For instance, Colorado-based Stratos and New-York-based PharmaCannis use pharmaceutical techniques in their formulation and research of medical marijuana that has roots in their stakeholders' industry pasts. Only time will demonstrate how such developments play out.

Scaling the Wall

According to Birkinshaw, Visnjic, and Best, the final stage of engaging potentially disruptive technology is to scale, or build commitment. This step proved to be crucial for firms facing the biotechnology revolution. It is perhaps the most difficult problem to solve when examining the potential for convergence in the pharmaceutical and medical marijuana industries.

Because of "baked in" unfairness in the system, numerous state laws, and political influences, firms in the medical marijuana industry face many hurdles. When combined with strict federal laws that are often circular and arcane, these challenges present more deterministic roadblocks to success. Thus, the international landscape has offered a greener pasture. Israel has surpassed many countries, and their early commitment will likely have future impact on U.S. businesses.

CW Pharmaceuticals, the manufacturer of Epidiolex, is based in the U.K. They were, controversially, allowed to execute the clinical trials on American soil that led to their FDA approval when U.S. companies would have been barred from such testing. How firms ultimately scale within this burgeoning industry depends on the number of walls they can scale within the U.S. court of public opinion and the ways they might navigate the legal barriers around research and sales. Change is imminent. The many parties involved in the legalization and commercialization of cannabinoids in the pharmaceutical space will determine the future of the industry through their responses to this disruption.

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