

Entrepreneurship in Regulated Markets: Burden or Boon?

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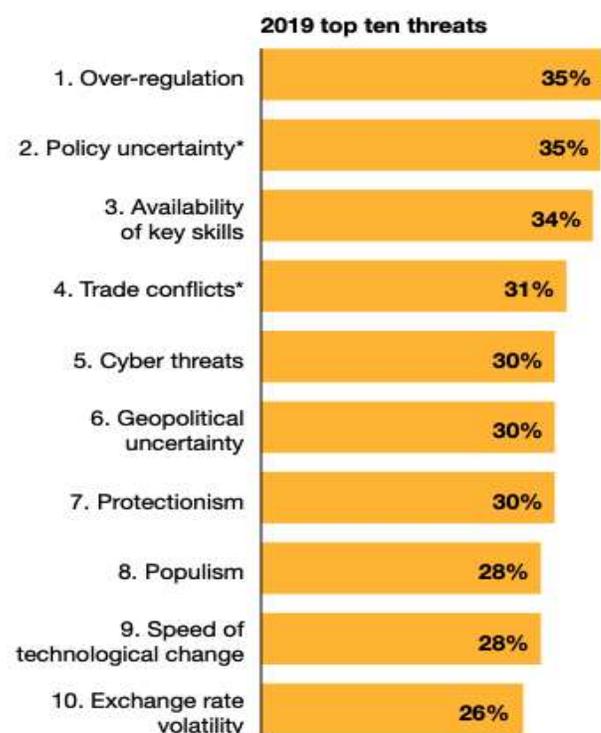
Executive Summary

- Regulation can stifle markets and limit innovation—but regulation can also result in breakthrough business models facing less competition.
- Investors invested record levels of funding in regulated markets in 2019, most notably in the fintech, medtech, biotech, and edtech markets.
- Entrepreneurs are developing new ways to navigate regulatory complexity to create and capture value through business model innovation.
- Entrepreneurship in regulated markets requires deep knowledge of the context and an ability to walk a fine line between conforming to the environment and pushing institutional boundaries.

Challenges of regulated markets

Regulated markets feature government intervention as to what companies sell, how much they charge and what protections they provide individuals, communities and the environment. Examples of regulated markets that are attracting large investments include financial services, education, healthcare, energy and defense. In these and other regulated markets, regulation can distort dynamics between buyers and sellers and limit innovation. While the aim of regulators is to promote societal welfare, business leaders often express frustration with the limitations that come with governmental oversight. For more than a decade, the annual PwC global survey of CEOs has listed “over-regulation” as executives’ primary concern (PwC, 2019).

At the 2020 Frontiers of Entrepreneurship Conference, Susan Cates of Leeds Equity Partners described the “stroke of the pen” risks and opportunities that can emerge without warning when regulators intervene in markets. For example, in recent years, regulators halted the rapid growth of some for-profit online colleges, causing some to declare bankruptcy. On the other hand, the introduction of the No Child Left Behind Act resulted in \$6 billion in grants for literacy efforts that resulted in the formation of successful businesses. Recent research on the ridesharing market also demonstrates the power of regulators to create value for businesses while also holding power to curb growth (Paik, Kang, and Seamans, 2018). The cost of doing business in a regulated market adds a level of uncertainty. Companies can fail and others can be created with a single signature, making regulated markets high-risk, high-reward environments.



Source: PwC, 22nd Annual Global CEO Survey (2019)

Opportunities for entrepreneurs to innovate

Despite the challenges inherent in regulated markets, investors are betting big on new entrants. In 2018, venture capitalists invested \$14 billion in biotech, \$10 billion in fintech, \$8 billion in medtech, and nearly \$2 billion in edtech (Wall Street Journal, 2019; Tech Crunch, 2019). Entrepreneurs in these regulated markets are developing novel business models that limit exposure to regulatory uncertainty and take advantage of protected positions. Finding novel business models for regulated markets sometimes requires persistence and sometimes a pivot. Alliances with strong partners can provide stability.

Regardless of the specific strategy, entrepreneurs need to understand in depth the contexts of regulated markets. Perhaps more than in other settings, entrepreneurs in regulated markets must make sizeable commitments before starting a business. Steve Blank, a serial entrepreneur and investor, argues that entrepreneurs approaching regulated markets must understand the laws and regulations at the national and local levels, agree with board members about the sizeable costs and risks, and decide whether to ask for permission or forgiveness when pursuing novel solutions (2018). Research on regulated markets demonstrates that entrepreneurs succeed when they anticipate, react to and shape regulations through a strategy of "co-creation" with governments.

Innovating around regulatory requirements

Despite the challenges of operating in a regulated market, entrepreneurs can find success as long as they are ready to embrace the complexities of the governing institutions. For example, FDA approval in the medical device market can sometimes take longer than a decade. Such was the case for approval of the TAVR heart valve replacement device, which took 17 years and \$2 billion in funding.

One strategy for ventures is to minimize the number of approvals required to bring a product to market. William Starling, CEO of Synecor, invested in iRhythm, which focused on delivering an affordable way to detect heart conditions. The company used a simple, bandage-like device that collected data about the heart but avoided regulatory scrutiny. Even then, the product required \$100 million to complete clinical trials. By decreasing the time and funding needed to launch, iRhythm focused on determining its product-market fit relatively quickly. The venture was then in a position to help patients and generate returns to investors. Starling's experience demonstrates that regulated markets, such as medtech, are difficult to enter but offer high rewards for innovation.

“Success in regulated markets often requires nontraditional thinking inside traditional institutions.”

Susan Cates, Leeds Equity Partners

Similarly, Chris Elmore of AvidXchange built businesses within the regulated fintech market by focusing on services outside of regulated activities. When founding AvidXchange, Elmore identified unmet needs for accounts payable processes and built products to fill those needs. In this way, Elmore's businesses operated within the regulated environment, but

focused on unregulated services. When Elmore expanded to services that fell under regulation, he partnered with companies that had already achieved regulatory approval. In this way, entrepreneurs can fall under the umbrella of a larger firm while delivering unique value-added activities to a larger product. Such an approach is an example of nontraditional thinking inside traditional institutions.

Regulation in the Technology Sector

Eric Ghysels, professor at UNC Kenan-Flagler Business School, believes the technology sector is likely the next major industry to experience strong regulation. As use of social media and artificial intelligence rise, these technologies face intense scrutiny from lawmakers around the globe. Technology entrepreneurs must be ready to work within a new regulatory environment. For example, the “right to be forgotten” flies in the face of blockchain technology, which is designed to be permanent. Ambiguity around regulation for artificial

intelligence is creating opportunities for entrepreneurs, but also generating negative externalities to society as a whole. Gysels argues that entrepreneurs in leading-edge technologies must be ready to adopt new levels of ethical responsibility and creativity. Recent research demonstrates that nascent markets with ambiguous regulation result in “cat and mouse” games between entrepreneurs and governments (Ozcan and Gurses, 2016). For new technologies like blockchain and AI, entrepreneurs and regulators are poised to co-develop the market through action and reaction in a high-speed, high-stakes contest.

Summary

Are regulated markets a burden or a boon? Entrepreneurs certainly face immense opportunities and challenges in regulated markets. Regulation can both shut down businesses and create protected positions. Entrepreneurs need to be ready for unexpected events in a regulated market. At the same time, regulated markets can provide valuable opportunities to address unmet needs while finding protected positions. One strategy for business leaders is to focus on unregulated opportunities within regulated markets. Another strategy is to form partnerships with businesses that have already received regulatory approval. Success in a regulated market requires intimate knowledge of both business and regulatory activities. Entrepreneurs who are familiar with the regulatory details of their market's landscape are best equipped to handle the opportunities and challenges.

Takeaways for entrepreneurs, investors, and researchers

- For entrepreneurs, regulated markets offer increasingly attractive opportunities because of increasing demand and the possibility of protected positions. Entrepreneurs are best positioned to succeed when they have a deep understanding of the complexities of the market.
- For investors, the frictions in regulated markets create both barriers and opportunities. Investors and entrepreneurs must reach an agreement that they are entering highly complex and risky environments. Together, they need to pursue opportunities with patience and anticipate unexpected changes in the rules of the game.
- For researchers, the setting of regulated markets presents a rich opportunity to explore how entrepreneurship frameworks developed in purely commercial markets apply in highly regulated settings.

List of panelists and affiliations from the Kenan Institute Frontiers of Entrepreneurship conference

Susan Cates, Partner, Leeds Equity Partners LLC, susan.cates@leedsequity.com

Chris Elmore, Community Evangelist, AvidXchange, celmore@avidxchange.com

Eric Ghysels, Faculty Director, Rethinc. Labs; Edward Bernstein Distinguished Professor of Economics, UNC-Chapel Hill; Professor of Finance, UNC Kenan-Flagler Business School, Eric_Ghysels@kenan-flagler.unc.edu

William Starling, CEO, Synecor, wstarling@synecor.com

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Paik, Y., Kang, S., & Seamans, R. (2018). [Entrepreneurship, innovation, and political competition: How the public sector helps the sharing economy create value.](#) Strategic Management Journal, Vol. 40, 503-532.

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