Entrepreneurship in regulated markets: Burden or boon?

Chair: **Vickie Gibbs**, Executive Director, Entrepreneurship Center, UNC Kenan-Flagler Business School

Panelists:

- **Susan Cates**, Partner, Leeds Equity Partners, LLC
- **Chris Elmore**, Community Evangelist, AvidXchange
- **Eric Ghysels**, Faculty Director, Rethinc. Labs; Edward Bernstein Distinguished Professor of Economics, UNC-Chapel Hill; Professor of Finance, UNC Kenan-Flagler Business School
- **Bill Starling**, CEO, Synecor

Regulatory barriers to entry can distort markets and limit innovation, but also result in breakthrough business models facing less competition. Examples include fintech, medtech and edtech. This session examined the challenges specific to entrepreneurship and innovation in regulated industries.

Bill Starling started the session by describing the regulatory complexities of the medtech market. Food and Drug Administration (FDA) approval for medical device products can sometimes take more than a decade. For example, approval for the TAVR heart valve replacement device 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. For example, iRhythm focused on the unmet customer need for an affordable way to detect heart conditions. The company created a simple, bandage-like device that collected data about the heart, which allowed them to avoid regulatory scrutiny. Even so, the product required $100 million to complete the clinical trials. Starling closed by noting that regulated markets are difficult to enter, but once a venture successfully enters the market, it can do very well and find protected positions.

Susan Cates provided perspective as both a business operator and as an investor within education. Cates believes that success in regulated markets often requires “nontraditional thinking inside traditional institutions.” Cates described the “stroke of the pen” risks and tailwinds that can occur when policymakers pass new laws or provide regulatory guidance. For example, regulators slowed the rapid growth of some for-profit online colleges and sent their profits tumbling. On the other hand, the introduction of the No Child Left Behind Act resulted in $6 billion of grants for literacy efforts. The cost of doing business in a regulated market adds a level of uncertainty, said Cates. Operating in such a market sometimes requires persistence and sometimes a pivot, and sometimes alliances with strong partners help to provide stability. Despite the challenges of a regulated market, Cates suggested that entrepreneurs can find success, as long as they are ready to embrace its complexities.

Eric Ghysels offered a perspective on regulated markets based on rigorous research across numerous settings. Ghysels pointed out that following the U.S. Civil War, the banking sector decided it could self-regulate. Eventually, the banking system failed and required regulation. A similar industry pattern happened prior to the Great Depression, and banking regulation once again followed to protect consumers and markets. In the last 20 years, the Sarbanes-Oxley Act (2002) and the Dodd-Frank Act (2010) responded to additional financial crises. Ghysels argued that the technology sector is likely the next major industry to experience strong regulation. Social media and artificial intelligence will face increased scrutiny from lawmakers. 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 that is designed to be permanent. Entrepreneurs face both technology and regulatory ambiguity and must be ready to adopt new levels of ethical responsibility and creativity.

Chris Elmore shared his own experiences working within financially regulated markets. Elmore built businesses within the regulated fintech market, but focused on services outside of regulated activities. For example, he found that businesses had 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. As another strategy for entrepreneurs in regulated markets, Elmore recommended partnering with companies that have already achieved regulatory approval. In this way, the entrepreneur can fall under the umbrella of the larger firm, while delivering unique value-added activities to the larger product.

Are regulated markets a burden or a boom? Collectively, the panelists agreed that entrepreneurs face immense opportunities and challenges in regulated markets. Regulation can both shut down businesses and create opportunities. Entrepreneurs need to be ready for unexpected events in a regulated market. One strategy for business leaders is to focus on unregulated opportunities within the regulated markets. Another strategy is to form partnerships with businesses that have already received regulatory approval. Starling, Cates, Ghysels and Elmore demonstrated that success in a regulated market requires intimate attention to detail of both business activities and regulatory activities. Entrepreneurs who are familiar with the regulatory details of their market's landscape will be best equipped to handle the opportunities and challenges they face.