

Life Sciences

Product Launch Excellence: Perspective from Industry Leaders

For biotechnology and emerging pharmaceutical companies, the transition from research and development to commercialization represents an organization's most disruptive event.

To shed light on the complexity involved for a company to bring its first product to market, five industry experts participated in a panel to provide guidance on launch best practices: Dan Brennan, chief commercial officer for Catalyst Pharmaceuticals; Thomas Gibbs, SVP and Chief Commercial Officer for Sunovion; Eduardo Schur, Life Sciences practice lead for Guidehouse; Riley Smith, former J&J Global Strategy and Business Transformation Leader; and, Justin Zamirowski, Launch Excellence Practice lead for Life Sciences at Guidehouse.

In this forum, the panelists discussed a range of topics, digging deep into the "critical success factors" for achieving launch objectives, how to best prepare for launch as a company moves from a development to a commercial orientation, and the organizational intricacies involved in navigating this important inflection point for biotechs and emerging pharmas. Panelists included lessons learned from past launches, and shared results from a Guidehouse analysis of the market fates of products launched between 2011-2018.

Approximately 30% of approved products exceeded forecasted expectations, but 60% underperformed to some degree in their initial years post-launch, according to Guidehouse analysis of 104 U.S. Launch Products from 2011-2015. Retail products fared worse than specialty and hospital ones. Of these, a majority of the therapies that achieved similarly to or exceeded expectations were in oncology, whereas a large portion of the underperformers were in cardiovascular or immunology.

"Historically, analyst reports and forecasts did not prove to be the best predictor of a successful launch," **Zamirowski** said. "However, the findings of the two-year data appear to indicate the increased level of sophistication in data and analysis is helping companies create more accurate forecasts and more clearly communicate expectations. In fact, nowadays, some products are becoming blockbusters in their second or third year on market."

The products that performed better than expected shared several attributes, including:

1. Addressed a clear, unmet need
2. Entered a less-crowded spaces
3. Fit into existing reimbursement and payment models
4. Were clearly differentiated from existing standards of care
5. Had previous experience in the therapeutic area



"It is important to understand the market landscape before product launch in order to maximize product positioning to address true unmet needs at launch and thereafter," **Schur** said. "Failure to do so could result in a significant setback for product success, especially in crowded marketplaces against standards of care." **Brennan** added: "You need to understand the dynamics of the market you are trying to enter. What you are trying to do depends on the market. So, you need to take the time to think about what will move the needle. You need to find something that actually matters."

In addition, the companies behind these products generally had completed market development shaping activities prior to market entry, leveraged a specialty care setting, and established a commercial track record in a therapeutic area. "Identifying a few key areas for investment could be the make or break strategy for launch success," **Zamirowski** said. "In some cases, this also may mean that being second to market is an advantage, because whichever company was first has already helped prime the market."

Based on the analysis results and their own practical business experiences, panelists agreed companies should begin conditioning markets early in order to build awareness of and interest in new therapies among payers, health care professionals and patients.

Areas of effort shared by the panelists included:

- Medical affairs to ensure the therapeutic addresses clinical and patient needs;
- Market access to help align and expedite the treatment option to improve access, coverage and reimbursement; and
- Patient support services to streamline and facilitate the patient's journey onto and remain on therapy.

Another critical factor is setting expectations internally with a clear view of the realizable product potential. For example, "conducting an objective, strategic market assessment based on comprehensive research, real world evidence and analysis helps companies identify, assess, and reduce market risk, as well as uncover opportunities, and shift gears in response to new market dynamics," said **Schur**.

Going through this process often also helps provide alignment across organizational stakeholders on a product's value proposition and appropriate go-to-market strategies, including investment scenarios.

Market dynamics dictate different emphases be placed within different market types to overcome access barriers and spur adoption. For example, specialty markets tend to benefit most from precise segmentation, while orphan markets tend to require a greater emphasis on patient and physician services. "Investing early on and in important areas is key to avoiding post-launch issues," **Smith** said. "Setting up the right trajectory is imperative, because it is difficult to bend the uptake curve."

Gibbs said: "Conduct analytics to segment your patient pool, so you are targeting those who would benefit most from the therapy and who are most likely to be compelled to use it. If you have entrenched competitors, you likely need to have a huge sales force or a leapfrog strategy. In addition, analyze the market to understand where the soft spot is, and aim for that."

Added **Schur**: "You have to understand the right data to look at and how your KPIs change depending on the market issues, including standards of care and care settings. Those dynamics adjust the issues you'll need to encounter and address. You also need to put mechanisms in place to gain insights over time, so you can adjust accordingly, because the market changes quickly."

Getting to the commercial launch wasn't the final destination of launch for any of the panelists. They said companies should collect and analyze data to evaluate the product's journey once on market. This will help measure success against expectations, as well as inform future plans, including how to manage capital constraints and build capabilities over time.

Preparing for launch is an evolution in the company's operating model and culture. Doing so in a pragmatic and iterative approach has helped companies succeed in meeting their objectives. "Most of us need to take a risk-based approach toward investing," **Gibbs** explained. "So, it's helpful to leverage certain skillsets at appropriate times from outside the company to augment your company's capabilities, especially as you work toward reaching key de-risking milestones on the road to launch success."



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