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Who's missing in the C-Suite is costing you millions

Hettie Stroebel, Founder & CEO

Pharmaceutical Executive chatted with Hettie Stroebel, Founder and CEO of Launch Excellence Partners, a strategic marketing planning and commercialization advisory firm to the Life Sciences industry, optimizing launch and commercial success to meet both internal and external expectations. Clients include early-stage pharmaceutical, cell-and-gene, and medical device companies. Hettie is a former Merck & Co., Inc executive with 25+years' experience in Life Sciences. Her focus is on global strategic marketing and commercialization creating value for clients, patients, providers, and payers.

Pharm Exec: "Who missing in the C-suite is costing you millions?" An intriguing title - tell us a little bit about the challenge at hand.

Hettie Stroebel: Bringing a drug to market is a costly and time-consuming endeavor as noted in the most current study available in the Journal of the American Medical Association. The authors estimate the cost of developing a drug ranged from $314 million on the low end to as much as $2.8 billion on the high end. Only around 14% of phase 1 drugs reach FDA approval, and the commercialization success rate compared to internal and external expectations are low.

All the above results in patients having to wait longer for new drugs: or, in some cases these new drugs do not become available at all.

We, as an industry, must get beyond short-term thinking. We often only focus on the current stage of the development process and do not direct our attention with the long-term goal in mind. While that may be challenging with staff turnover and

quarterly financial results, we must develop a plan with the long-term goal in mind. Appointing a Chief Planning Officer is one key step in this process in the effort to reduce the time from laboratory to patient, decrease R&D investment, and achieve commercial launch excellence.

When should I start the process of building a commercialization plan?

Successful commercialization depends on having a product with a compelling and meaningful value proposition. The target product profile, which is developed before IND application, is the blueprint for the development of a product with a compelling and meaningful value proposition. Building the actual commercialization plan starts at this point. It is not a full-baked plan at all at this stage. Rather a company has started to frame the product and how the product will be distinctly differentiated to address a particular unmet need in the market. A commercial plan is like building a house, the blueprint needs to be in place first before the foundation, walls and the finishing touches are completed.

How much of an investment should be made for this comprehensive commercialization plan?

Investments should be made early, as noted above. The investment, at a minimum, needs to help the company understand the unmet need, patient profile and journey, competition and market evolution. The actual dollar value depends on the opportunity assessment of the current and future market and how many players are in the space.

How do we engage the major stakeholders earlier in the clinical development process?

It starts with a deep dive into the burden of the disease; unmet need and the cost of managing or preventing the disease. Once this is done, the evidence will clearly show who are the influencers, decision makers and opinion leaders in the field. These people need to be engaged with before an IND is submitted. Remember, almost 60% of the money spent to develop a new drug happened in phase 3 of the clinical development, and understanding the market before these investments can save millions of dollars or months.

Is it possible to have a stronger focus on understanding the real patient journey before the phase 3 protocols are developed?

Absolutely. Real world data is one of the best sources to demonstrate who the patient is and the pathway to treatment (or prevention) as well as what payers are actually reimbursing for in the management of the disease. Real world data is of immense value to make strategic choices for the commercialization plan.

When and how do you determine product value proposition?

This starts, as mentioned above, with the blueprint for the product development - namely the target product profile before IND submission.

And here are four key new product planning strategies:

- Begin with the end in mind: Determine a compelling and meaningful value proposition for product across all stakeholders: patients, providers, payers, and policymakers starting with the target product profile.

- Align and unify fronts: Launches are highly complex, multidimensional, and “moments of truth”, where all the cross-functional efforts of a company to advance a product through development and commercialization come together into success or failure - as measured by market uptake versus the company’s expectations.

- Shorten the time to patient: We need to reduce phase 2 and 3 in the development process and attrition rates. To achieve that, we need to understand the real-world data and use new product planning to reduce cost and time to market.

- Master the coverage and reimbursement environment early: As an industry, we need to clearly understand what will impact outcomes and funding decisions of the health insurance players prior to conducting clinical development.

What is the job description for this missing seat in the C-Suite?

Many job descriptions are available on typical job seeking sites, but commonly found is this:

Directs the establishment of goals, major priorities, and advise in the development of strategies and resolution of major problems. Direct the implementation of transit project goals and objectives, policies, work, standards, and controls for professional staff and consultants.

What is more important, however, is to find the experienced candidate with actual launch leadership experience and a track record of launch excellence.

Companies that embrace the leadership role of new product planning at the C-suite level will demonstrate high levels of success in bringing innovation to patients.

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