TRIANGLE INSIGHTS GROUP
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Insights and Perspectives Series

October 2018

Launch Planning:
Lessons Learned from Experienced Pharmaceutical Executives

- Get Started Early
- Bring in the Right Team...at the Right Time
- Really Know Thy Market
- Consider an Inverse Approach to Positioning and Messaging
- Have a Core Brand Strategy Around Which Everyone is Aligned – But Recognize Uncertainties
- Getting Access Right Will Likely Be Your Biggest Challenge
- Launch Planning Doesn't End at Launch

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Introduction

Within the world of pharmaceutical launches, there are countless success stories over the past decade – instances in which drugs were approved by regulatory agencies despite long odds, examples of product launches for which sales surpassed Wall Street analysts' highest expectations, stories of brilliant strategic thinking and flawless commercial execution.

There are also, of course, examples of when things didn't go as well.

Maybe the product's value proposition did not address a key market need – or perhaps it simply wasn't properly articulated. Critical path launch timelines were missed. Bad hires were made.

Notable Pharmaceutical Launch Failures

Product	Company	Therapeutic Condition	Launch Year	Potential Rationale for Not Meeting Expectations
Benlysta	Human Genome / GSK	Lupus	2011	Product label did not specify appropriate treatment candidates within the very heterogenous condition of lupus. For more mild lupus patients, the price point was too high. For more severe patients, there was little trial data to support use.
Enbrel	Immunex / Amgen	Rheumatoid Arthritis	2000	Marketing team under-forecasted early demand for the drug Outsourced manufacturing facility was unable to keep up, resulting in a product shortage A two-year shortage resulted in an estimated >$1B lost revenue potential
Krystexxa	Savient	Refractory Chronic Gout	2010	Savient had insufficient resources at launch, with only 35 reps in the field after major commercial cutbacks. Krystexxa had a much higher price point than competitor Uloric.
Provenge	Dendreon	Prostate Cancer	2010	Reimbursement uncertainty around an expensive buy-and-bill drug deterred physicians from prescribing it. Logistical hurdles associated with Provenge use proved to be prohibitive for prescribers.
Quillivant	NextWave / Tris	ADD/ADHD	2013	From a formulary access perspective, daily liquid formulation was not a strong enough value proposition to command the premium price that NextWave sought.
Treximet	Pozen / GSK	Migraines	2008	Approval delay hurt the opportunity to transition patients from branded Imitrex before generic sumatriptan was on the horizon.
Zaltrap	Sanofi	Metastatic colon cancer	2012	Product was priced high for the marginal benefit the drug offered (it extended median survival by only 42 days).

An introspective examination of launch failures – and what can be learned from those failures - can help future launch teams avoid repeating the same mistakes. To better understand where things can go wrong with the launch of new drugs, Triangle Insights interviewed ten experienced pharmaceutical launch executives to gain insights on the past mistakes they've observed with launch teams. These individuals were involved in more than a hundred product launches and had experience ranging from small, one-product pharmaceutical companies to the largest pharmaceutical companies in the world. Here are the key "lessons learned" from these experienced launch veterans.

1 Get Started Early

Interviewed pharmaceutical veterans highlighted that launch planning should start as early as three or four years prior to anticipated launch. While a regular cadence of cross-discipline launch meetings may not start that early, collectively determining a brand vision and strategic imperatives for the brand early on is critical as these will serve as the roadmap for future pre-launch activities.

Respondents also indicated that specific timing for the start of launch planning may of course depend on the product and market being entered. Companies that are launching a product for the first time, creating a new therapeutic category, or blazing new ground on access (as with the case of something like gene therapy) will have to start earlier than companies launching a fourth-in-class competitor within an established market.

> *"You must recognize quickly what you know and don't know - and that has to start early. That's especially the case for a company launching a product for the first time."*

2 Bring in the Right Team…at the Right Time

For a company launching a product for the first time, the timing for building out a commercial infrastructure is important. Companies need commercial input early enough to influence the ultimate positioning of the brand, but often also will want to mitigate some of the clinical risks before making significant resource investments. Below are ranges for when several critical commercial hires should be made, according to interviewed executives.

	Phase 2	Phase 3	NDA Review
Chief Commercial Officer	*In time to influence pivotal protocol*		
Medical Science Liaisons	*Initial hiring to prep for pivotal trial sites*		*Additional MSL hiring for pre-launch campaign*
Head of Commercial Ops / Planning	*Before building out broader team*		
Head of Marketing		*Usual hire is 1.5-2 years before launch*	
Head of Managed Markets / Access		*After positive top-line pivotal data*	
Head of Trade / Distribution		*After positive top-line pivotal data*	
National Sales Director		*After positive pivotal data*	
Sales Representatives			*3 months prior to launch*

While the timing of hires is critical, equally as important is hiring the right people. According to interviewed executives, the talent profile needs to match the needs of the organization. One specific example cited by an interviewed executive highlights this acutely. The trade group for a small company preparing for its first pharmaceutical launch had arrived at the company with significant big pharma experience. Because they had always been able to rely on legacy infrastructure in big pharma, the trade group wasn't aware of the requirement to obtain state pharmacy licenses before selling directly to major distributors such as Cardinal and McKesson. The small manufacturer discovered this omission too late to be able to complete the timely state-by-state application process before launch and was thus forced to use a middleman at a cost of 4% of sales. The skills required to be successful in big pharma may be very different than the skills necessary at a small biotech about to launch its first product.

3 Really Know Thy Market

Interviewed commercial pharmaceutical executives repeatedly reinforced the importance of thoroughly understanding the product and the market into which a launched product is entering. In fact, not having rich customer insights was cited most frequently by respondents as the single biggest mistake they observe with launch teams.

Successful launch teams will develop a mastery of the disease state into which they're entering, a firm awareness of both the current and future competitive environment, and a clear understanding of how the product being launched will address unmet needs in the space. A cursory understanding is not enough.

> *"Spend more time than you think necessary on understanding your customers and your market. Even before you get to target product profile testing, identify your customers, what drives their decisions – that's the foundation for everything else."*

> *"Look at your customer first. What do they need versus what do I have? If there is an unmet need out there, how do I address it?"*

Stakeholder research is often the key to extracting these insights. Interviewed respondents agreed that the investment in market research – even early in product development – is critical.

> *"The ROI for market research is there. The cost is really marginal relative to the impact that it can have on properly understanding your market and ultimately optimizing your product's profile and positioning."*

One respondent provided a pointed example of what happens when market insights are lacking. He cited the story of a product for which millions of dollars had been spent in trials for a product to treat a complication often associated with interferon used in the treatment of hepatitis C. Hindsight now of course makes it very clear that the latest-generation treatments such as Sovaldi quickly made demand for any interferon-related product in that space obsolete. But at the time, the launch team's lack of forward vision for how a broad market development could impact its product launch severely impacted its future success.

4 Consider an Inverse Approach to Positioning and Messaging

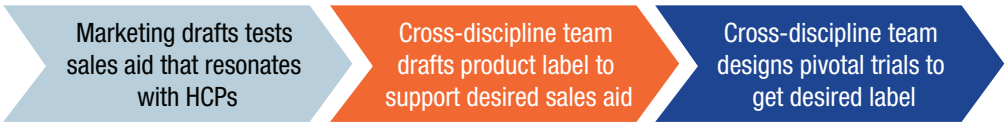
According to interviewed executives, the classic sequence to developing drug positioning and messaging is often for the clinical team to run a pivotal trial, the regulatory team to draft a product label to submit to the FDA, and then for the commercial team to develop a detail aid based on what the manufacturer is able to claim in that product label. The goal of the clinical trials is often based solely on one goal: getting the product approved.

Traditional Approach to Product Positioning

A couple of interviewed executives strongly encouraged "outside-in" approaches to developing product positioning. After developing a good sense for the needs of the market, and with a general understanding of the product being developed, they develop an HCP sales aid early – even as early as during phase two trials. The sales aid is a rough draft – of course – and a bit aspirational, but it allows at an early stage for the pharmaceutical manufacturer to identify, articulate, and test the positioning and messaging that will ultimately resonate with eventual target prescribers.

Having formulated a sales aid that the manufacturer ultimately wants to take to market, they go about the task of drafting a product label that will support the claims of that early sales aid. With a draft product label in hand, the commercial, clinical, and regulatory teams collaboratively develop a phase three protocol that supports that label – and ultimately the desired sales aid.

Alternative Approach to Product Positioning



Not aligning your label (and sales aid) to the strategic imperatives set by your market and product can have disastrous effects. Two examples were cited by interviewed executives that illustrate the damage that can occur when this happens.

Product	*Restasis*	*Xartemis XR*
FDA Approval	2002	2014
Market Insight	Chronic dry eye	Acute pain
Labeling Mismatch	• The Restasis pivotal trial was designed to show increase in tear production but did not measure improvement stinging or blurred vision. • This omission has enabled a new competitor (Xiidra) to differentiate based on improvement in symptoms.	• Because of the way the trial was designed, the FDA did not grant abuse deterrence language in the Xartemis label. • Other competitors (Oxycontin, Embeda, Hysingla) were able to get abuse-deterrent language in their labels, offering them a key advantage over Xartemis XR.

5 Have a Core Brand Strategy Around Which Everyone is Aligned – But Recognize Uncertainties

This one seems intuitive, but according to surveyed executives, is often ignored. Too frequently, various functional teams focus too much on only the activities that fall within their discipline, without incorporating input from other functional teams or understanding how their activities can have a cross-functional effect.

Respondents reinforced that it was imperative for launch teams to agree on a basic strategy for the brand, and then ensure that all teams are operating in accordance with that strategy. A regular cadence of cross-functional launch meetings will promote necessary communication, where functional leads can discuss tactical execution of strategy and understand how the activities of one team can affect the planning/tactics of another.

The notion of aligning to a core strategy should extend beyond brand strategy and into the allocation of organizational resources. Interviewed executives reported that when there is less cross-functional communication and collaboration, teams naturally work independently and may build out plans that are disproportionate to their relative importance within the organization. Across functional areas, work (and budgets) must be calibrated to avoid misappropriation of resources – investing too heavily in areas that are less important as value drivers for the product being launched.

> *"Having a core central strategy drives everything. Being too tactical or reactive is where mistakes are made and what prevents opportunities from being maximized."*

While the development of a core strategy for a product launch is important, launch teams must also recognize that curve balls will come. Brand strategy and launch teams must be flexible, and pivot based on the outcome of anticipated and unanticipated events. Various clinical, regulatory, trade, and commercial scenarios must be considered – and teams must plan for all possible contingencies.

6 Getting Access Right Will Likely Be Your Biggest Challenge

Perhaps not surprisingly, pricing and reimbursement was a frequently mentioned topic when it came to lessons learned from previous pharmaceutical launches, especially when entering into highly competitive markets. We'll highlight several key lessons here:

Carefully balance speed and access at launch

Interviewed executives indicated that it is certainly possible to quickly ramp up access immediately after launch – but that this may not be the best strategy because of the high price that may be required to get that access so quickly. Contracting cycles can be fairly long for payers – especially for CMS. Bidding for Medicare formulary access may require a 12-18-month forward vision. In many cases, if a pharmaceutical manufacturer requests immediate access after launch, they'll be asking the payer to break an existing contract. In turn, the payer will likely require a very high rebate – a rebate, of course, that is unlikely to ever decrease over the course of that drug's life once the bar is set. To weigh this decision, the manufacturer should consider how quickly they can drive demand. If they can't drive HCPs to prescribe the drug at high volumes right at launch, it is likely not worth the high rebate for immediate access. If, on the other hand, the drug being launched has a short period of exclusivity and the manufacturer is geared up to invest heavily in promotion right out of the gates to drive demand, it may be worth paying the higher rebate to get on formularies immediately.

> *"Once you pay down to convince a payer to break contracts, you're stuck. You never go down on a 50% rebate – it only goes up from there."*

Set appropriate expectations for access with HCPs

The access game is not necessarily about the absolute access that a new product is able to achieve. More important may be the perceived access of the drug in the eyes of prescribing HCPs. It is not uncommon for a physician to believe a product has poor access when in fact coverage is in fact fairly robust. This may be attributed to something as simple as one or two poor experiences the HCP had in getting coverage early in a product's life – it only takes a small number of those poor access experiences to forever tarnish a product's reputation.

Executives interviewed for this paper stressed the importance of setting HCP expectations for access up front. Be clear in what HCPs will and won't be able to do from a reimbursement perspective. Remind them that copay assistance can be used only for commercial patients. Let them know if there are major plans within their practice geography that do not cover the drug being launched – or that do so only with severe restrictions. A lot of companies now are employing formulary information tools – sometimes married to network EMR system – to equip prescribing physicians with better intelligence around access.

"You need to really carefully craft your access message to providers. What really matters is the early experience those providers have when trying to get a drug covered."

Consider the perspective of payers when determining price

For an alternate perspective on pricing, Triangle interviewed a pharmacy director at a leading managed care organization. The managed care perspective on pricing can of course be in stark contrast to perspectives from industry, but understanding this perspective is critical as the power dynamic continues to shift to payers.

Payer Perspective: Drug companies often think their product has more value than it actually does. We don't come to the table without doing our own homework.

"A lot of companies think their product is the best thing since sliced bread and price their drug commensurately. We have a lot of information (internally-generated and third-party) that we can leverage to determine fair, value-based pricing. We have a plethora of organizations like Kaiser and ICER that we often use to determine appropriate pricing."

Payer Perspective: Manufacturers often don't consider how future competitors may impact the price and access we'll offer.

"Companies launching a new drug often drink their own Kool-Aid and are oblivious to what their competition might do. They don't understand their competition and how they're going to respond. In a recent case we saw, a large pharma company launched a biosimilar with a solid price – and they thought that was it. In the background, the innovator came back to us and negotiated price and the innovator won."

Payer Perspective: Manufacturers should have a long-term approach to pricing – and remember the future implications of their actions today.

"We often see companies approach pricing from the perspective of 'what will the market bear'? The product may be a reformulation of a 50-year old drug, but now it has an orphan indication and so the manufacturer charges an astronomical price. We note it. We'll remember what happened when the manufacturer comes back with a new product in the future. Managed care has a memory."

7 Launch Planning Doesn't End at Launch

Finally, for all the work that goes into a successful drug launch, interviewed executives emphasized that planning should not stop at launch. One interviewed executive holds a formal post-launch assessment (3 to 6 months after launch) to determine what is working and what is not. Intelligence can be gained by conducting primary research with key brand prescribers (or, conversely, from high-volume market prescribers who have not yet adopted your brand). Manufacturers can also get a lot of input from their field force: hosting an internal ad board with effective and influential sales reps or sales managers can bring practical, feet-on-the-ground intel on a brand's performance in the early months. If a brand is not meeting its KPIs, the commercial team must be willing to adjust.

"You yourself might think your product positioning is great, but the only thing that matters is how your customers perceive the product. So you have to continuously get that feedback and adjust accordingly. You can't be too wed to your original ideas – you must adapt."

"Early successes right after launch may come easy. You're grabbing the low-hanging fruit at that point, so you may meet expectations. But how do you continue driving growth? It's not just about getting out of the gate – it's critical to position yourself for sustainable growth. You often see a flattening of uptake not too far after launch, and you need to prepare for that. Plan for what happens after you take the low-hanging fruit."

Conclusions

Interviews with pharmaceutical executives conducted by Triangle Insights highlighted several "lessons learned" from previous launches in the industry. While many of the cited stories and examples were specific to a particular product, indication, or therapeutic class, several central themes arose and can be applied broadly across future commercial launches:

- ✓ Set a core brand strategy – but also anticipate alternative scenarios and plan appropriate contingencies
- ✓ Develop deep insights early with a focus on understanding critical needs of the customer / prescriber – with a lens toward how your product can address those needs
- ✓ Anticipate different plausible launch scenarios – across clinical, regulatory, and commercial dimensions – and prepare an action plan for each
- ✓ Think from a macro perspective – taking into account your competitive situation and the perspectives of other stakeholders
- ✓ Expect the unexpected and be willing to adapt as the market and customer needs evolve

A keen awareness of past stumbles committed during previous launches can help leaders of future pharmaceutical launches avoid making those same mistakes.

About Triangle Insights Group

Headquartered in Research Triangle Park, Triangle Insights Group, LLC is a strategy consulting firm providing guidance on the most critical business issues to leaders in life sciences organizations. The firm's approach combines deep knowledge of the industry across therapeutic areas and functional groups, with a dedication to creativity and disciplined critical thinking. Recommendations from Triangle Insights Group are original, relevant to the industry environment, and supported by rigorous analytics. Clients of Triangle Insights Group include large pharmaceutical companies, emerging biotechnology firms, diagnostics manufacturers, medical device companies, and private equity investors.

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Gautam has provided strategic advice to a wide range of clients, spanning Top-5 pharmaceutical manufacturers, emerging biotechnology manufacturers, bio-pharmaceutical investors, and service providers to bio-pharmaceutical companies. He has spoken at several industry conferences (LES, CED, EBD, BIO-Windhover, CHLA, Banff Venture Forum) and has published a peer-reviewed article on deal timing.

His previous employers have included GlaxoSmithKline, Boston Consulting Group and Campbell Alliance, where he was a Senior Practice Executive and led business/corporate development efforts for the central region. Gautam received his M.B.A. from the Fuqua School of Business at Duke. He holds an M.S. and a B.S. in Bio-Statistics from UNC-Chapel Hill.

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Chris has worked as a Senior Practice Executive with Campbell Alliance where he led the company's Business/Corporate Development efforts for the NY and NJ region. His recent management consulting experience has centered on corporate strategy and market opportunity assessments for life science companies and investors.

While at GlaxoSmithKline, Chris's scientific accomplishments led to multiple patent authorships and peer-reviewed publications, as well as discoveries resulting in over $30 million in company cost savings. In business development roles, Chris was responsible for corporate strategy and reviewing in-licensing and out-licensing opportunities. Chris earned an M.B.A. from the University of North Carolina Kenan-Flagler Business School as a member of Beta Gamma Sigma academic honor society. He has an M.S. from the University of Buffalo and a B.S. in Biochemistry from the University of Rochester.

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Recent by-lined articles have appeared in Pharmaceutical Executive, InVivo, Nature Biotech, RPM Report, and Scrip. In addition, Ben's case studies on the pharmaceutical industry have been used in graduate business programs.

Ben is the chairman of the Life Sciences Sector of the Licensing Executive Society. He has also been a member of the program committee for the BIO International Convention. Prior to the founding of Triangle Insights Group, Ben was the leader of the Business Development Practice at Campbell Alliance and a partner in the Strategy practice at Oliver Wyman (formerly Mercer Management Consulting/Strategic Planning Associates). Ben earned an M.B.A. from the Stanford Graduate School of Business and a B.S. from Duke University.

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Kate's previous strategic consulting experience includes: Platform Advisors, Campbell Alliance, and Deloitte. Kate also has research experience in discovery and development at AlphaVax, Inc., Research Triangle Institute, and Walter Reed Army Institute of Research.

Kate received her M.B.A. from Kenan-Flagler Business School at UNC Chapel Hill. She also holds an M.S. in Biotechnology from Pennsylvania State University and a B.S. in Biology from Texas A&M University.

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Has led a wide spectrum of strategic engagements with life science industry clients ranging from large multinational pharmaceutical companies to venture-backed start-ups. Recent engagements have included orphan drug commercial assessments and diligence, an oncology franchise strategy, and biosimilar opportunity assessments.

Barrett's previous management consulting positions in the life sciences industry were with Campbell Alliance and Boston Healthcare Associates. He also founded an independent life sciences consulting firm prior to the founding of Triangle Insights.

His background also includes client-side experience within the pharmaceutical industry. For plasma manufacturer Grifols Therapeutics (previously Talecris), Barrett led market intelligence for the pulmonary franchise including Prolastin-C, an orphan drug indicated for alpha-1 antitrypsin deficiency. Barrett received his M.B.A. from the Tuck School of Business at Dartmouth College. He holds a B.A. from the University of Virginia. He has been a lecturer at several life science industry conferences.