Within3

E-BOOK

The High Cost of Slow:

What Every Missed Signal Costs Launch & Growth Brands

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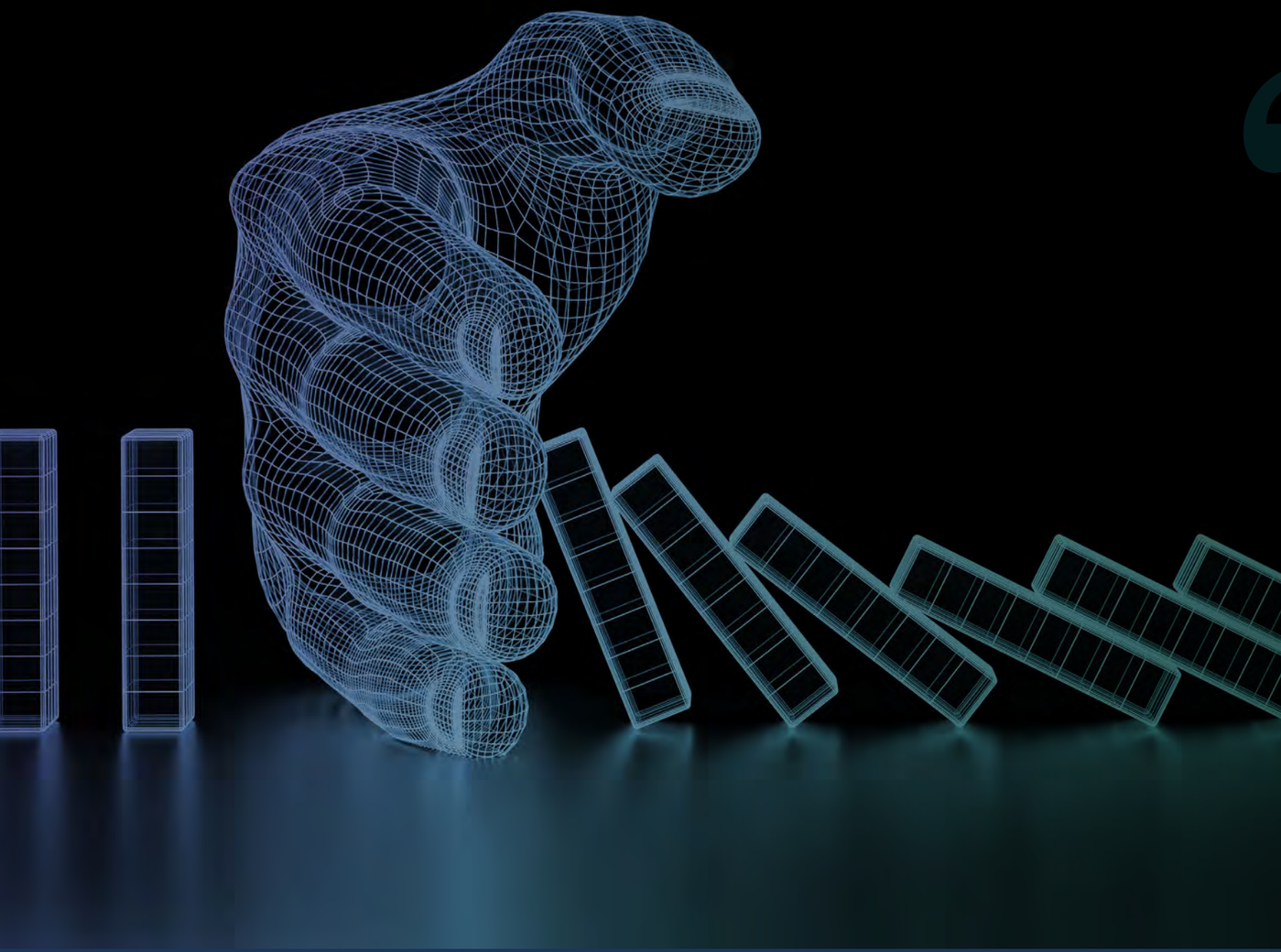

In today's high-velocity pharmaceutical market, even the most innovative therapies often fall short when launch execution lags. A few weeks of stalled decisions (or missing the mark) can equate to millions or even billions in lost revenue – and teams rarely recover once first-year momentum is gone:

> "Two-thirds of a sample of 210 launches failed to meet pre-launch consensus sales expectations for their first year on the market. Having done so, they were likely to continue to underdeliver in the next two years. Conversely, launches that managed to exceed year-one analyst expectations had a strong likelihood of continuing to outperform expectations for the next two years."
>
> – *MCKINSEY*

In this eBook, we'll explore real-world examples of blockbuster drugs that 'left money on the table' due to slow uptake or competitive outmaneuvering, before examining the common causes of poor launch performance. Finally, we'll discuss how launch teams can avoid missteps and find the agility they need to maximize performance.

Blockbuster Potential, Unfulfilled Promise

Even the most commercially promising therapies aren't always a golden ticket for the companies that develop them. Drugs don't sell themselves – nor does the market stand still.

The following real-world examples illustrate how even highly-organized, talented teams developing drugs with genuine blockbuster potential can still miss expectations due to missed signals or slow market response times.

1

UNTAPPED PROMISE MEETS UNFORESEEN DISRUPTION

Tepezza, a thyroid eye disease medication, gained FDA approval in early 2020, before launching the following month as a first-in-class medication. Unfortunately, Tepezza's launch coincided with the greatest period of market disruption in modern times: the COVID-19 pandemic. When the US government invoked the Defense Production Act to prioritize COVID-19 vaccine production, capacity to produce Tepezza was dramatically reduced – causing a 90% decline in prescription volume and necessitating a costly relaunch. Tepezza eventually rebounded from this supply chain disruption, but the recovery was slow and costly.

Although no one could have anticipated or prepared for COVID's effect on global markets, better market intelligence might have allowed a more effective launch and a faster recovery. Part of the reason Tepezza failed to meet its early sales forecast was that it initially focused only on oculoplastic surgeons – meaning provider adoption beyond these specialists was low, and the drug did not gain a broad foothold before the downturn. With the benefit of richer launch intelligence (particularly better mapping of provider and referral networks), Horizon Therapeutics might have expanded engagement to a wider range of HCPs, including endocrinologists, general ophthalmologists, and even primary care physicians – accelerating uptake and adoption at launch and relaunch.

2

BEING FIRST TO MARKET MATTERS – BUT YOU CAN'T STOP THERE

A head start can be a powerful advantage. When Esbriet launched in Europe four years before its direct competitor, Ofev, it had the IPF market to itself – clearing more than $230 million in EU sales and gathering critical real-world data long before any rival existed. That's the upside of speed.

But a head start alone isn't a sustainable moat. Despite its four-year lead, Esbriet lost its leadership position when Ofev entered the market in 2015 with a broader label and strong clinical evidence for slowing disease progression. By 2021, generics had further eroded Esbriet's share, and sales fell 70% to 202 million Swiss francs by 2023 (Reuters).

The lesson? Speed to market is a significant determining factor in commercial performance – but it has to be paired with ongoing strategic intelligence. Real-time market insights might have helped Esbriet's launch team anticipate competitive threats and pursue a label expansion strategy before Ofev could close the gap. First-mover advantage only buys you time. To hold your position, you have to use that time to learn more about the market and reinforce your defenses.

3

LACK OF CLARITY CAN RUN YOUR STRATEGY INTO A WALL

> "The first U.S.-approved peanut allergy treatment… has struggled with a slow launch." - *REUTERS*

In January 2020, the FDA approved Palforzia for use as the first drug specifically designed to treat peanut allergies. Analysts projected annual peak sales approaching $2 billion. Unfortunately, they didn't fully consider the patient burden: Palforzia required frequent doctor visits, a challenging treatment regimen, and high costs – leading many patients to simply continue avoiding peanuts instead.

Since its launch, Palforzia has changed hands twice and still hasn't approached its peak sales forecasts. Palforzia's issue was not speed to market but market clarity: a better understanding of patient and caregiver needs and preferences. "*There remains a massive disconnect between what investors want and what the food allergy community needs*," as one patient advocate told The BBC.

In this example, real-time market intelligence would have helped the launch team recognize key pain points on the patient access journey that were critical to the success of the drug – allowing them to anticipate problems and adapt expectations and strategy. Two years post-launch, new owners Nestlé were "*exploring strategic options*" for the therapy – far too late to turn its fortunes around.

4

INNOVATION MUST BE RELEVANT TO PATIENT NEEDS

Developing a viable alternative insulin delivery system has proven a tough nut to crack for pharmaceutical companies. The FDA approved Exubera, the first-ever inhaled insulin for diabetics, in 2006, with blockbuster sales expected. But despite high hopes for Exubera, it garnered few prescriptions. Per Forbes, both patients and HCPs disliked the device, and the therapy was comparatively expensive (costing around twice as much as standard insulin at launch). Contraindications in smokers and patients with lung disease were also significant obstacles for Exubera, with Pfizer ultimately suffering a $2.6 billion pretax loss.

The FDA approved another inhaled insulin product, Afrezza, in 2014 – and this one fared little better. While the device was smaller and more practical, sales still fell short of projections – with the same contraindications severely limiting eligible patients. Per Reuters, Sanofi's internal assessment of the drug was blunt: "*the product never met even modest expectations and we do not project Afrezza reaching even the lowest patient levels anticipated.*"

Both companies expected their new products to capitalize on patient resistance to injections, but in the end, neither inhaler offered enough tangible benefit to get patients to switch. Had these companies leveraged market intelligence, they might have avoided taking such losses. Launch intelligence could have provided a more realistic market assessment. Afrezza could have learned more from Exubera's experience by leveraging claims and EHR data to reveal how contraindications in smokers and lung patients had proved problematic. Additionally, both launch teams could have tracked HCP and patient sentiments in real-time – providing deeper insight into patient thinking about injections in the overall context of therapy, and revealing that delivery method was not a key consideration for diabetics and their treaters.

5

A BLOCKBUSTER ON PAPER, BUT NOT IN PRACTICE

Addyi, the first FDA-approved therapy for hypoactive sexual desire disorder in premenopausal women, gained regulatory approval in 2015. This was a drug with a huge addressable patient population and true blockbuster potential, but immediate post-launch sales were disappointing – with just 227 prescriptions being recorded in the first few weeks.

> "Addyi… was touted as a potential blockbuster drug that would command much of what analysts had said could be a $2 billion market. But sales of the pill have been sluggish." – *REUTERS*

Significant labelling issues contributed to the drug's slow uptake, with a prominent boxed warning about the risks of taking Addyi with alcohol creating a significant impediment for a drug intended to improve sexual spontaneity. Patients, payers, and physicians did not respond to the drug as the company had expected, and sales remained well below blockbuster predictions.

In the case of Addyi, as with many of these examples, the issue was never with the science. The drug exhibited modest efficacy, but it was the market access strategy that ultimately left money on the table. With more robust market intelligence, Sprout might have anticipated payer pushback, defined a narrower subpopulation, or developed a better communications strategy in anticipation of concerns about the boxed warning. Peri- and post-launch, social listening could have provided insights into patient and physician responses – allowing the company to pivot quickly once early signals indicated that the strategy was out of alignment with the market.

What Causes Poor Launch Performance and Missed Market Signals?

The cost of missed signals at launch is clear – even where potential blockbuster drugs are concerned. But hindsight is 20/20. After the fact, it's easy to look at drugs that failed to live up to their expectations and figure out why. But what stopped the right signals from reaching the right stakeholders in the first place? Why are teams sometimes slow out of the gate or slow to respond when market conditions change?

There are multiple factors at play:

MARKET ACCESS ISSUES

Deloitte puts 57% of launch failures down to market access issues. These issues can include pricing pressures, regulatory hurdles, market competition, and the difficulty of negotiating favorable reimbursement terms across different regions and models. Of these potential challenges, regulatory hurdles alone are thought to prevent or delay launch in a staggering 91% of cases. Gaining access is a complicated process, and laying the groundwork for success means considering scientific, medical and real-world evidence needs – as well as anticipating HCP and patient needs and perspectives. Without a robust insight process, pieces of this puzzle can be overlooked – crippling the launch.

"*There's a regulatory gauntlet that keeps increasing*," explains Jason Smith, CTO, AI & Analytics at Within3. "*Consumers have this perception that we can move faster, but drug companies are struggling with the reality of how to move through market access*."

SILOED DATA

It's no secret that many pharma organizations struggle to achieve genuine cross-functional alignment. This often goes hand in hand with ineffective integration of critical data sources. A recent Within3 survey found that only 31% of respondents use data across both medical and commercial teams, largely because their data remains siloed. Even more concerning, just 11% are capable of producing unified, multi-source insight reports. When data is fragmented, and teams lack true collaboration, signals move slowly through the organization—if they move at all—significantly delaying market response times.

"*You have this paradox where yes, there's more data out there, but finding signals through the noise continues to be a challenge*," Jason explains. "*Being agile starts with developing a different thought process. It's breaking down silos – not only in terms of data, but data plus communication plus strategy. It's a holistic change in how you think about launch*."

STRATEGIC RIGIDITY

Pharma organizations often default to familiar strategic planning, reusing playbooks from prior launches and struggling to execute a fluid go-to-market approach that supports timely pivots as market conditions evolve. In a recent poll from Impatient Health, 42% of pharma teams revealed they ignore market signals they didn't expect to see, while another Impatient poll highlighted how only 37% agree that changes in strategy occur in the majority of launches. This strategic rigidity means early momentum can easily be lost if market conditions change unexpectedly.

‘TRIED AND TRUSTED’ METHODOLOGIES

Impatient Health highlights how pharma teams have a tendency to fall back on approved methodologies they’ve relied on in the past. Impatient refers to these processes as ‘tried and trusted’ – the implication being that they haven’t truly been tested. This mindset means critical insights often go overlooked in favor of the known and expected – to the detriment of agility and innovation.

“*Many large companies have the structure in place, they’ve launched before, they have all the in-house capabilities*,” says Tony Page, SVP of Insight Analytics at Within3. “*They have a formula in place, and they keep reusing that same formula. It might work, or it might not. Launch strategy needs to be dynamic, and falling back on formulas can inhibit creative thinking and quick reactions*.”

ROI PRESSURES

For some smaller pharmaceutical companies, where a single asset may represent the entire business, ROI pressures can be even more intense – and a launch can determine the company’s survival. “*Smaller biotechs are often ‘all in’ on one molecule – dependent on investor confidence and ongoing capital raises to fund future development and basic operations*,” says Trey Riley, Within3’s VP of Solutions Engineering. “*If early sales underperform, investors can quickly lose confidence, funding can dry up, and the company may be forced to sell or shelve the asset rather than continue to develop or commercialize it*.” In this context, poor launch performance is not just a temporary setback. It’s a potentially terminal event, creating far greater pressure to get the launch – and every strategic decision and pivot – right and on time.

By contrast, larger pharma companies typically have more diversified portfolios and stronger balance sheets, giving them greater ability to absorb setbacks on individual products – but they also face significant internal pressure to meet aggressive portfolio-level targets, which can drive tough decisions about how long to support an underperforming launch. Multiple irons in the fire also mean that larger companies are more likely to push for a ‘fast fail’ approach, which depends on robust intelligence to inform go/no-go decisions on assets that impact both patients’ lives and the company’s bottom line. “*Larger companies often need to show a quicker return on investment*,” Tony adds. “*If something isn’t meeting a projection, first quarter, second quarter, they pull away*.” This is often a case of misinterpreting launch signals rather than missing them – for example, treating poor commercial performance as terminal rather than temporary. “*Sometimes you might need a little bit of patience to really understand why things aren’t going well*,” explains Tony.

Prevent Underperforming Launches by Staying Agile

In today's highly-competitive pharma market, it really does pay to be fast. Every day lost through delayed market response times can cap post-launch momentum, erode market share, delay regulatory approval and payer negotiations, and result in companies being outmaneuvered by their competitors. What's more, these small setbacks are compounded over time. As the above examples demonstrate, there are millions to be made in being first to market, but then, teams must make hay while the sun shines. Once generic competitors and biosimilars enter the fray, a drug can expect to lose up to 90% of its market share within just two years.

For organizations seeking to achieve launch excellence, success is often a case of 'less haste, more speed'. "*A lot of companies make assumptions, but then never validate those assumptions*," says Tony. "*I might assume that if a patient is already injecting themselves with insulin, then they're not going to mind injecting my drug, whereas in reality the patient feels they can't handle another injection.*"

As we saw in our case studies, acting on these assumptions without taking the time to validate them can scuttle the hopes of even a potential blockbuster. The key to speed is having validated strategic information that allows for confident and decisive action – before the window of opportunity closes. With a unified, real-time view of the market powered by pharma-trained AI, teams can precisely answer their most critical strategic questions in minutes, not months.

"*AI can be applied to monitor your strategy as new data comes in, new data sets get refreshed, and you're marching towards your strategy and your go-to-market plans*," explains Jason Smith. "*What's shifting in the sands beneath your feet that requires a pivot or change? AI and data collection can run in the background as you go, so you're not having to look over that information again and again.*"

"*Deploying that technology earlier – leveraging it sooner in your process – not only creates good workflows but means you can react if the market starts to shift around you, pivot quickly, and then track that pivot.*"

Within3 Launch Intelligence™ eliminates silos by transforming fragmented data – including field activity, HCP asynchronous engagements, social sentiment, claims data, congress activity, and more – into decision-ready launch intelligence. Teams get evidence-based answers that empower them to act at the speed of launch, before market opportunities pass them by – whether executing in the heat of market entry, or sustaining post growth. It gives organizations the power to see exactly what's happening right now, respond faster than the competition, set proactive rather than reactive strategies, and make smarter decisions based on real-time information.

Book a demo of Launch Intelligence™ today to find out how you can eliminate the 'high cost of slow'.

ABOUT WITHIN3

Within3 empowers pharma leaders to make confident and timely launch decisions. Our Launch Intelligence™ platform unifies field insights, stakeholder engagement, social, claims, and market signals into a single connected view that surfaces what matters most. Powered by a life-sciences trained AI architecture and guided by expert strategists, Within3 helps launch teams move with clarity and speed, turning complex evidence into decisive action.

Trusted by all of the top 20 pharmaceutical companies, Within3 is the partner modern launch leaders rely on to align teams, act faster, and accelerate outcomes across the product lifecycle.

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