

Insights and Perspectives Series

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Pharmaceutical Commercial Forecasting: Distilling Insights from Primary Research

Pharmaceutical commercial forecasters commonly rely on a ubiquitous market research "haircut" to adjust physician-reported adoption for new products.

Triangle Insights proposes an approach to collect HCP adoption rates in a carefully constructed format and then to methodically adjust "raw" physician-reported share by accounting for estimated payer access, patient fill rates and commercial reach.

The disaggregation of adjustments can help inform strategies to optimize product uptake.

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Introduction -

If you are reading this, you know the drill:

To develop a revenue forecast for a new pharmaceutical product in development, primary research is conducted in which physician respondents are shown a target product profile and asked how much they would use "Product X" if it was available. Everyone who has experience doing physician market research will be quick to point out that one must apply a standard research "haircut" to account for bias. Take 50% off of physician-reported responses, they say. Or potentially chop based on a top two box score. Either way, it's acknowledged common practice, everyone does it. But an arbitrary standard haircut may not be appropriate for every market research study.

Physicians have a general idea of their historical prescribing, but asking them to estimate future prescribing share without putting their responses in the context of a structured process may result in a significant margin of error. Different biases may cause physicians to over-estimate stated prescribing share (HCP-Reported Adoption), particularly for new novel products.

Physician responses also typically do not account for other stakeholders such as payers and patients. Payers may manage access to certain products by implementing restrictions or placing them on non-preferred tiers (Payer Access). Patients are bearing an increased burden of pharmaceutical costs, as more and more patients are enrolled in high-deductible or high out-of-pocket maximum insurance plans. Determining patient "fill rates", or what percentage of patients pick up the prescription at the pharmacy, is key — particularly in conditions with very expensive or non-covered therapies (Patient Fill Rates) Lastly, because of patient volume or previous prescribing behavior, some physicians may never be detailed on a new product, and therefore should be accounted for differently in terms of commercial forecasting (Manufacturer Detailing Reach Adjustment).

The discounting methodology that Triangle Insights proposes is structured to allow for maximum transparency—so that the impact of each factor can be identified and analyzed to both arrive at the most accurate forecast (Share Used for Forecasting) and identify potential levers to optimize launch uptake.

Figure 1: Process Overview



HCP Reported Adoption _

Physicians do not treat all patients within a condition with the same therapeutic option. When asking physicians about the potential uptake of a new product, it is important to not only focus on the relevant patient segments but also to consider all current and future treatment options.

An example line of questioning may be:

- 1. For your <u>last</u> 20 mild patients, how many would receive (currently available) Competitor A? How about Competitor B?
- For your <u>next</u> 20 mild patients, how many would receive Product X (product being forecasted) vs. currently available options (Competitor A and B)?

3. For your first 20 mild patients <u>in 3 years</u>, after Product Y enters the market and Competitor B goes generic, how would you allocate treatment across all different options?

Using this methodology, the physician is forced to think about the tradeoffs of allocating patients to each of the potentially available products within a relevant patient segment, instead of simply estimating the share of patients that would receive the novel product that is being studied. This approach also allows pharma manufacturers to have visibility into which competitors they may be gaining or losing share against. The physician is ultimately asked to consider how the market might evolve as products become generic



and new products enter, generating a more dynamic and informed forecast estimate.

Exhibit 1: Physician-Reported Share for Product X

Item	Competitor A (Currently Available)	Competitor A (LOE in 1 Year)	Product X (Product Being Forecasted)	Product Y (Entering in 3 Years)
Last 20 Mild Patients	13 (65%)	7 (35%)	n/a	n/a
Next 20 Mild Patients	8 (40%)	5 (25%)	7 (35%)	n/a
First 20 Mild Patients in 3 Years	2 (10%)	10 (50%)	6 (30%)	2 (10%)

The physician-reported distribution in Exhibit 1 implies that Product X would capture 35% of the market if it launched today, and that percentage would be \sim 30% in three years after the launch of a new entrant (Product Y) and with Competitor B's product losing exclusivity.

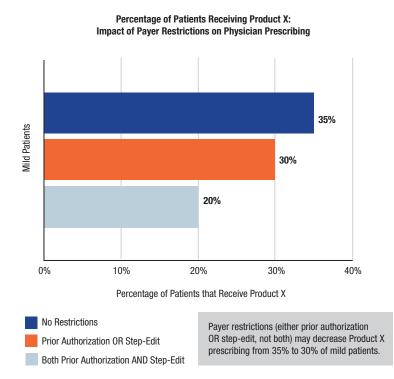
Payer Access and Competition _____

Payers determine the level of access (e.g., covered/not covered, preferred/not preferred) and restriction (e.g. prior authorization, step edit, new to market block) that a product will receive. Novel products that are classified as preferred or non-restricted may be prescribed more often than products with significant restrictions. Forecasters can assess likely formulary coverage by conducting primary research with payer decision-makers as well as exploring coverage for analog products.

In addition to payer research, discussions with physicians should be designed to understand prescribing behavior given different levels of access. By structuring the discussion around how a physician would prescribe under each access scenario, the researcher can proactively address potential payer influence.

It is important to understand the magnitude of impact that formulary tier and restrictions from a variety of payers may have on a potential new product. Not only can the effect of tier and restrictions vary greatly by therapeutic area and drug class, but the impact of these can potentially be mitigated by the manufacturer through measures such as contracting, copay support programs and specialty pharmacies. An understanding of the potential "lift" these strategies offer can help the manufacturer determine their attractiveness.

Exhibit 2: Product X Share Scenarios with Various Payer Restrictions





Patient Fill Rates -

For many therapeutic areas, the pharmaceutical industry has long been considered a price inelastic market, where the price of therapy does not significantly impact fill volumes. However, over the last decade average deductibles and out-of-pocket maximums have steadily increased and a growing number of patients are enrolled in high-deductible plans. As a larger portion of the pharmaceutical cost sharing burden is placed on the patient, patients are becoming increasingly sensitive to price.

Studies have found that when a patient's' out-of-pocket responsibility exceeds \$50, fill rates decrease dramatically. Some manufacturers attempt to maximize fulfillment with co-pay coupons or patient assistant programs, sometimes for the patient's entire out-of-pocket obligation, to remove price sensitivity from the decision-making process.

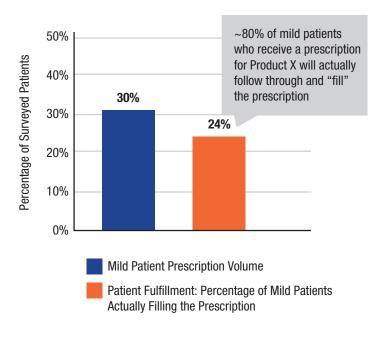
Other initiatives that may impact prescription volumes are direct-to-consumer or advocacy campaigns. These initiatives can impact the 'top of the funnel', prompting patients to ask their physician about a specific product; or at the end of the process, pushing the patient 'over the hump' to fill a prescription.

In many cases, forecasters would be wise to either identify fill rates for analog products or conduct patient research to understand willing

to pay under different out-of-pocket cost scenarios. The inclusion of patient input into product forecasting can often lead to more robust and reliable results.

Exhibit 3: Patient Fill Rates

Product X Patient Fill Rates



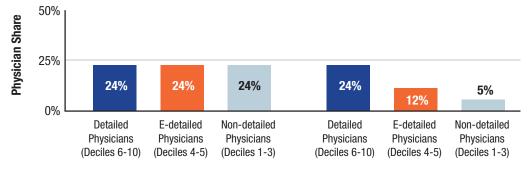
Adjust for Manufacturer Detailing Reach –

Physicians cannot prescribe a novel new treatment if they do not know about it. When conducting primary research to assess a new product opportunity, one must account for the eventual breadth of detailing upon launch. Forecast uptake should only account for physicians who will be detailed or become familiar with the product. One strategy may be to estimate the anticipated sales force coverage

based on a deciding report of a relevant analog basket, and use that as an adjustment factor in new product forecasting.

Physicians who are not directly contacted with the manufacturer's sales force may still receive e-detailing (low touch, electronic detailing) or become aware of a product through other means, such as industry conferences, presentations, medical journals, colleague

Exhibit 4: Detailing Reach Adjustment



Physician-Reported Share (After accounting for Access and Fill Rate)

Adjusted Share

In this example, a 36% adjustment is made for detailing reach.

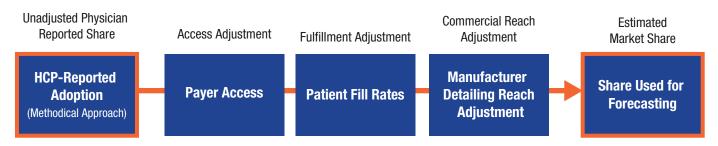
Adjustments for e-detailing and non-detailed physicians to be made based on relevant analogs.



referrals or news reports. This awareness effect outside of detailing may be more pronounced in certain therapeutic areas, where new product launches can potentially be headline news. However, there will still be a portion of non-detailed physicians who will not become aware of a new product, at least early in the product's lifecycle.

Share Used for Forecasting -

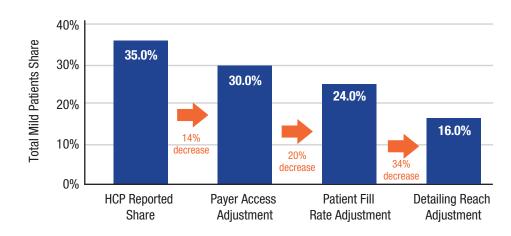
Figure 1: Process Overview



This structured approach took the 35% unadjusted physician-reported share derived from methodical questioning and applied adjustments for payer access, fill rates and detailing reach to arrive at a 16% final adjusted share (of mild patients) for our example Product X. The appropriate categories for adjustment will vary for each individual product.

Exhibit 5: Overall Product X Market Research Adjustment Summary







Implications -

By taking the raw physician-reported share figures from primary research and applying stakeholder adjustments based on a structured approach, we are not only generating a more precise estimate, but also creating a transparent process in which key levers can be identified, evaluated and utilized to facilitate commercial strategy:

- Payer access adjustments can potentially be mitigated with effective channel strategies or contracting
- Patient fill rates can be boosted with co-pay assistance programs, or even with direct-to-consumer advertising campaigns
- Physician awareness through detailing can be optimized and supplemented with alternative activities such as mail, tele-detailing, regional key opinion leader lectures or poster presentations

Exhibit 6: Share Evaluation Activities

	HCP Reported Share	Payer Access Adjustment	Patient Fill Rate Adjustment	Detailing Reach Adjustment
Share Evaluation Activities	Methodical interview structure to generate optimally precise share estimates	 Use of specialty pharmacy to mitigate PA Contracting strategies with payers Potential for HEOR studies to demonstrate value to payers 	 Copay assistance programs Detailing to retail pharmacies, if appropriate Direct to patient/ direct to consumer campaigns 	 Evaluation of sales force (profitability and break-even analysis) Asssessment of strategies for alternative detailing (mail, tele-detail, etc)



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.

For more information about Triangle Insights Group, visit www.triangleinsights.com or call (919) 813-6079.

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Has thirteen years of pharmaceutical and consulting experience. Gautam focuses on providing strategic guidance to clients within life sciences organizations. His recent engagements have involved commercial assessment, indication prioritization, white-space strategy, commercial model design and in-licensing/out-licensing support.

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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Has over fifteen years of pharmaceutical and biotechnology experience, with positions in discovery research, business development, and management consulting. His previous employers include GlaxoSmithKline, AVOS Life Sciences, and Campbell Alliance.

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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An experienced consultant to leaders of global pharmaceutical and biotechnology organizations, and to decision makers of large private equity funds. Ben has been a management consultant for more than twenty years. His perspectives on developments in the life sciences market are frequently published in industry and strategy journals.

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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An experienced life science consultant with original industry roots in pharmaceutical development. She has managed and led numerous global projects across a broad spectrum of therapeutic areas, including: oncology, orphan disease, gene therapy, diabetes, infectious disease, pain, psychiatric disease, women's health. She has developed a product and portfolio strategy focus and expertise across the biotechnology, pharmaceutical (branded and generic), biosimilar, diagnostic and medical food industries. Her recent project experience includes opportunity identification and assessment, portfolio and franchise vision and planning, competitive assessment and planning, customer prioritization and conversion (patient, provider and payer), partnering support, and the identification and prioritization of promotional targets and messaging.

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.