Strategic Pricing for Optimal Valuation

Virtual Salon Takeaways by Ted Haack

On the 20th of May, 2021, Ted Haack moderated a virtual salon organized by DemyColton about the key pricing issues that will impact pivotal trials for commercialization, first product launch and business development activities.

There were of course far more topics than we had time to discuss at our virtualsalon, so I put together 10 points to summarize the panel's key takeaways and address a few new items. My gratitude to our fantastic panel of industry leaders Judy Campagnari, Jessica Martinez, Dennis Purcell and Denise Scots-Knight for a wonderful discussion.

Click https://www.youtube.com/embed/riFOoEqfZ_w for free access to the full session.

1. **It isn't 2004 anymore; don't treat access planning like the final baton pass after clinical development.**

Market access leaders have been stressing this for almost 20 years, yet it still happens (some call it "throwing the ball over the fence"). Fast-to-label trials will not optimize patient access (i.e., commercialization) if they do not include the payer-relevant evidence necessary to de-risk access issues. You have one chance to launch, make sure the pricing and access input is obtained early and integrated in the label-enabling trials.

2. **Don't get caught up in the US list price beauty pageant; net price pays the bills.**

Invest the time required to understand net pricing dynamics when proof of concept is established, then revisit your assumptions at every financing round and major milestone (e.g., competitor event, new data, legislation/policy change, etc.). Dennis highlighted the PCSK9 US pricing disconnect between payers and analysts. The subsequent 60% price cut showed that the US$14k list price was the basis for PBM rebate revenue. Don't be fooled by list prices; understand how competition and contracting impact net pricing.

3. **Don't base your ex-US launch pricing off your US pricing.**

Broadly speaking, 30-50% of global revenue is ex-US. Once you have your value proposition, it isn't too difficult to estimate the pricing in the top-10 countries via

competition and reference pricing algorithms. Further, biosimilar and generic prices will be used as a reference for new technology pricing, not the originator price. Humira is discounted 80-90% in EU; which is currently only ~5-10% of the current US list price (yes, you read that correctly). Lastly, ex-US prices only decrease over time, so plan for price erosion. If your forecast modelers say they can't calculate this, or it will cost US$100-200k per country to calculate, give me a call; I know some folks who do this extremely well.

4. **Payer mix and setting of care will impact net price and patient volume.**

Invest the time to understand the setting of care payment flows and the core US books of business when forecasting (i.e., Commercial, Medicare, Medicaid). Hepatitis C showed that Medicaid can be a major revenue source in certain diseases; gene therapies and other "qualified disability" diseases may create an even larger Medicaid issue given the million-dollar price tags. Similarly, hospital net prices are often less than pharmacy prices due to DRG payment systems, however some new technologies are eligible for add-on payment programs (e.g., US NTAP, German NUB, French liste en sus, etc.). Takeaway – analyze the funding and payment flows for your revenue model; it will make a real difference.

5. **Don't assume all payers love, desire or want to engage in outcomes-based contracts.**

Really. They don't and they won't. As an industry, we've been trying to implement these for over 15 years, and while they make sense on the surface, and have seen limited uptake in certain areas, these contracts have a host of administrative, legal, and competitive issues. Think of these as a contracting option, not a complete solution.

6. **Volume is valuable and evidence-based.**

There are 2 points here. First, many price-maximizing companies have spent literally *years* negotiating a launch price in a major market because they "didn't want to leave money on the table", only to fall back to a lower price after months of delay. That approach resulted in years of selling zero units, yet that wasn't considered leaving money on the table. Second, invest time to understand the accessible patient population based on how health technology assessment authorities (HTA's) will evaluate your product. The epidemiology and the number of patients that can access your medicine are likely not one and the same. The absence of payer-relevant evidence and high target prices will limit the reimbursed patient population, yet many are (still) surprised by this.

7. **Experience matters; hire high-quality access skills.**

Lean headcount in clinical stage companies necessitates that your functional leaders have great depth of experience, including Market Access. Whether you hire or outsource your market access skills, invest in the same level of experience that you do for your other senior leaders. If you hire a junior colleague, you will lack the depth of strategic insight and their voice will likely be ignored by the SVP's and C-levels. Denise discussed her rationale for hiring a top-tier market access leader to run commercialization at Mereo, which has proven very beneficial. Judy highlighted, and our entire panel reinforced, that access and pricing assumptions will be a significant and detailed debate with any potential partner, thus an experienced voice will reinforce your credibility.

8. **Think about the patient experience and your public image.**

Globally there are almost 2,000 GoFundMe pages for "gene therapy", 20,000 that mention "rare disease", over 400,000 that mention "cancer", and adacanumab is a whole other story. Many of these are from countries with poor health systems or inequitable access; one is named the United States of America. Have the difficult pricing conversations with your leadership and board and define your company's role and philosophy for ensuring patient access and system sustainability. Create your communications plan and be ready to discuss your rationale for pricing vs. allowing increased access with patients, advocacy organizations, and the public.

9. **Make payer interviews optional.**

Asking payers how they reimburse a drug is often paying them to read their rules and regulations, which is something any junior consultant can tell you. Invest in payer interviews for areas of true strategic ambiguity, not for the basics or to learn what the rules say. I was at a market access conference about 8 years ago where the host asked us "why do you all spend so much money on questions that you already know the answers?" This is still true today; invest wisely.

10. **Revenue Fade is real and can be reduced.**

Jessica discussed the industry's consistent underperformance vs. launch forecasts and the key causes, many of which are pricing and access related. McKinsey has recently published a bit more on "first time drug launchers", which underscores the question of whether first-time launchers can "get it right". If you can reduce Revenue Fade by 1-3 percentage points, you have been very successful, performing access and pricing due diligence can help you optimize.