Innovative Approaches to Achieving High Performance Brands

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Claudio D’Ambrosio, PhD
Partner, Head of North America
The Agenda

Commercial Performance - More than just innovative pills

Challenges ahead for the business of Therapeutics

Pitfalls and risks of carrying on with business as usual Pharmaceutical Brand Strategy

Innovative Approaches to Achieving High Performance Brands
Commercial Performance - more than just innovative pills
In the eyes of most stakeholders the majority of drugs are going to be “value contenders” rather than “value creators”.

Criteria to meet Value Creator definition = Molecular Targeted therapy with Novel MoA or with demonstrated significant improvement in primary endpoint over Standard of Care or with Companion Diagnostic.
FDA offers shortcuts to “value creators” through Priority Reviews in a 1/4 ratio but it doesn’t enrich the market with stars.

On average FDA grants one Priority Review every three or four applications.

But therapeutics reviewed through either mechanism have similar chances of approval.
As a marketer you are more likely to inherit a drug addressing an old target, not a new one.

Intense in-market competition is an inevitable part of the therapeutic markets in which differentiation becomes a daunting challenge.

As a marketer you are more likely to inherit a therapeutic addressing an old target, not a new one.

In which of the two groups would you expect to find above average commercial performance?
First in Class or First to Market is not as strong a predictor of commercial performance as many would expect

First mover advantage on a particular target does not correlate with high performance

- Review of hundreds of commercial launches supports this observation*
- Innovators don’t seem to have a statistically significant advantage

The innovator does the heavy lifting

- The innovator creates the market from scratch and battles through skepticism to establish the class. Follow on competitors can focus on differentiating their products

Time pressure erodes strategic quality

- The innovator often faces a trade off between speed and planning rigour (eg LCM)

“Can a Late Mover Use International Market Entry Strategy to Challenge the Pioneer?”, Marc Fischer, Venkatesh Shankar and Michel Clement, in Marketing Science Institute Reports (2005)
“Launch Excellence”, Sarah Rockwood (IMS), in Pharmaceutical Executive (April 2009)
Regardless of the expectations, brands still fall short on their commercial objectives in many ways.

- **High potential assets are not fully pressure tested**
  - Fail to timely accrue the necessary evidence (e.g. payors’ endpoints, true SoC comparators)
  - Failure to integrate the impact of competitor’s counter-activities into a drug launch budgeting plan

- **Poor “think global act local” implementation**
  - One market being politically dominant (US, Japan) triggers one size fits all clinical programs that do not take different market realities into consideration

- **Launch excellence but lacklustre LCM**
  - Rapid market uptake followed by rapid loss of market share due to competition

SoC = standard of Care
The good drug bad drug preoccupation should be somewhat demystified

The Good News

• Commercialization of big hype drugs will not necessarily guarantee high performance in the market

The Bad News

• Whether it is a Breakthrough, a First in Class, or other, there are still many strategic traps and commercial hurdles that can work against the brand once in the market
Challenges ahead for the business of therapeutics
Where will Pharmaceutical Brands face the greatest challenges going forward?

- Reimbursement Resistors
- Logarithmic Competitive Intensity
- Upside Market Resistors
Reimbursement resistors increasingly eroding upside value are on everybody’s mind

More payers are increasingly expecting cost savings and relative clinical benefits

Payors implementing some form of outcome based arrangements are expected to nearly triple in the next 3 years

<table>
<thead>
<tr>
<th></th>
<th>Present (%)</th>
<th>≤ 3 yrs (%)</th>
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<tbody>
<tr>
<td>Bundled payment</td>
<td>13%</td>
<td>31%</td>
</tr>
<tr>
<td>Outcomes-based payment</td>
<td>16%</td>
<td>37%</td>
</tr>
<tr>
<td>Risk-sharing agreements</td>
<td>11%</td>
<td>31%</td>
</tr>
</tbody>
</table>

More payers are increasingly expecting cost savings and relative clinical benefits

Passing costs to patients reduces adherence
Copayment rates for generic medications were reduced from $5 to zero. Copays for brand-name drugs were lowered 50%

Adapted from PwC HRI payer value survey 2012 ©
Competitive Intensity: *in-class* competition alone is a logarithmic problem for Marketers to grapple with

The market exclusivity that a breakthrough drug enjoys before entry of follow on competitors has decreased enormously

Later entrants tend to come into the market even sooner after the first follow-on competitor

Today, most innovative therapeutics will have at least one in-class competitor already in phase III clinical development at the time of approval

Adis Data Information ©
...and unfortunately in-class competition is just the smallest part of the issue

**Out-of-class competition**

- For every in-class competitor there are on average 3 to 4 out-of-class competitors
- Most Brand teams regard out-of-class competition as important as in-class competition

**Generic use is growing YoY in most markets**

- Often in double digits

**Drug cocktails and patterns of drug sequencing is sharply on the rise**

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1. Deallus Consulting. 2. Isis. Top 10 US generic players grew at average of 13.2% (generics news, 2010). Global Generic markets will grow to US 221 billion by 2016
Pitfalls and risks of carrying on with business as usual Pharmaceutical Brand Strategy
The Imperative of Pharmaceuticals has been maximizing speed resulting in a task oriented approach to Strategic Planning.

- Market Sizing (Initial forecast)
- Medical Unmet Needs
- KOLs ID and Management
- TPP Drafting
- Patient Flow
- Competitive Pipeline Analysis
- Leverage points analysis
- Analogue analysis
- Life Cycle Planning
- Label Drafting
- SWOT analysis
- Buying Process Analysis
- Pricing & Reimbursement (Value story)
- Positioning and Messaging
- Sales and Marketing plan
- Launch Plan

*Not exhaustive and not strictly in the time order depicted.
Global top-down plans dominate the industry. Poorly leveraged local institutionalized knowledge creates dangerous information asymmetry.

Inputs to Strategy  Number of Assumptions  30,000 feet Global view

Local inputs  Market Knowledge  Local view

Institutionalized knowledge  PC – p I  p II  p III  launch
Many organizations still await for pivotal phase III data before conducting the most critical assumption testing activities.

Assumption testing activities include Leakage and Leverage Analysis, War Gaming, Patient Flows, Label Scenario analysis, Payor Consensus Studies.
Overreliance on analogue analyses carries the risk of leaving implicit assumptions about market performance untested.

<table>
<thead>
<tr>
<th>Patient Flow</th>
<th>Analogue Product</th>
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<tbody>
<tr>
<td><strong>Prevalent patient Population</strong></td>
<td>000,000’s</td>
</tr>
<tr>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Seeking Treatment</strong></td>
<td>000,000’s</td>
</tr>
<tr>
<td>95%</td>
<td>90%</td>
</tr>
<tr>
<td><strong>Seeing Doctor</strong></td>
<td>000,000’s</td>
</tr>
<tr>
<td>87%</td>
<td>85%</td>
</tr>
<tr>
<td><strong>Diagnosed</strong></td>
<td>000,000’s</td>
</tr>
<tr>
<td>75%</td>
<td>72%</td>
</tr>
<tr>
<td><strong>Diagnosed and Treated with Rx</strong></td>
<td>000,000’s</td>
</tr>
<tr>
<td>70%</td>
<td>65%</td>
</tr>
<tr>
<td><strong>Market share</strong></td>
<td>000’000’s</td>
</tr>
<tr>
<td>25%</td>
<td>15%</td>
</tr>
<tr>
<td><strong>Value (Patient)</strong></td>
<td>$$$</td>
</tr>
<tr>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td><strong>Sales</strong></td>
<td>$$$</td>
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<tr>
<td>%</td>
<td>%</td>
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Creating a High Performance Pharmaceutical Brand today is akin to an engineering problem.

Effective Product Strategy = An Engineering Feat

The intricacies to Launch and Manage a High Performance Brand today resemble the complexity of an engineering problem.

- ‘System design’
- Testing > Intuition
- Data Integrative

* Includes Value Contenders and Value Creators
Innovative Approaches to Achieving High Performance Brands
Drawing from the engineering world. Think how you would plan if you were not allowed to fail

**Whole system design/thinking**

- All-at-once design
- Focus is on creating the *broader* experience

**Assumption Testing**

- Augment Intuition with Testing
- Performance under changing external conditions / scenarios ('crash tests')

**Data Integration**

- Integration of different data sets into one operational platform
From the concepts....

High Performance

Whole System Design

Assumption Testing

Data Integration
......flows our framework

Whole System Design -> High Performance -> Data Integration

Assumption Testing

Simulations

Product Marketplace Map

Provoke Estimate Integrate
High Performance Brands pivot on the concept of Brand Value Resources

- Product Marketplace Map
- Simulations
- Provoke Estimate Integrate
- Brand Value Resources
A new approach to Brand Strategy for therapeutics that have achieved Proof of Concept

What are the key *resources* in this *market* for the Brand to succeed?

What are the key *resources* in the *organization* for the Brand to succeed?

How do we *increase* the *resources*?
How do we *protect* the *resources*?
Thinking in terms of Value Resources provides immediate and tangible advantages

Perception of Clinical Benefits

- Standard of Care as comparator
- Quality of Life data
- Real World Evidence
- Number of patients already treated
Thinking in terms of Value Resources provides immediate and tangible advantages

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Grade III-IV side effects
Black Box Warning
Drug-drug interactions
Poor Adherence

Example 1

REMS Risk Evaluation and Mitigation Strategies
Value Resources help focus on what *drives* performance and what *hinders* performance.

**Effectiveness of MSL engagements**

- Number of loyal KOLs (innovators)
- Clinical program run in Centers of Excellence
- EAP run in Centers of Excellence

**Example 2**

- Effectiveness of competitor’s MSLs
- # KOLs loyal to competitor
- Sunshine Provision

Adoption cycle of new products/technologies - Adapted from Geoffrey - Crossing the Chasm ©
EAP Expanded Access Program
Provoke ideas, Estimate their impact and Integrate the assumptions into the Brand plan.

Accrue and publish Quality of Life data from global clinical program.

Perception of Clinical Benefits

Build a best practice guide for effective management of Grade III-IV Side Effects.

Grade III-IV Side Effects

Leverage

Mitigate

Quality of Life data

Provoke

Ideas --> Initiatives

Estimate

Time Investment Effort Impact

Integrate

Data & Assumptions

Tap = Business Lever
An engineer’s view of the world: a Marketplace Map where to PEI and action business levers to optimize strategy
Framing your strategies over the Marketplace Map will help see the forest for the trees

1. Focus on the broader experience – think beyond just the product clinical attributes
2. Prioritize ‘asymmetric’ resources (fast to build, slow to be drained)
3. Benchmark the resources with competitors
4. Design synergistic initiatives by activating multiple levers simultaneously
5. Embrace novel marketing data to track resources and performance (CLTV, CDI)
6. Perform (crash) tests - what if we had no Sales Force? Which business levers would be able to compensate for in such scenario?

CLTV Customer-Life-Time-Value; CDI Coefficient Degree of Influence
Model external changes and Simulate your competitors in the marketplace

Scenario Analysis
When there is sufficient uncertainty in the more distant and broader environment that the risk surrounding strategic decisions and investments executed today must be mitigated

Hybrid Strategy Game
When there is sufficient uncertainty in the broader environment in the mid term that the company existing (and competitor) strategies must be reviewed in light of the potential changes

Positioning Workshop

War Game
Ahead of a marketplace move by yourself or a competitor or when the near term competitive landscape is liable to change

Defence Plan Workshop
Red team/Blue Team
Ahead of or in response to a likely near term tactical move by an existing competitor

Brainstorming
Used in all strategic games to optimise the ideas and creativity of the collective group

Pre-Proof of Concept  Post PoC <-> Pre-Launch  Launch Maximization  Post-Launch
Competitive Simulations with what-if Scenarios help prepare Brand Teams build contingencies for High Performance

We are here

2009
Initiation of PIVOTAL trial Competitor B

Overall Survival
- Label 1

No Overall survival
- Label 2 (scenario 2)
- Label 3 (scenario 3)

We are here

Hybrid Strategy Game

Expansion in First Line?

2009
Initiation of PIVOTAL trial Competitor B

Interim Data Read Out Competitor B

Overall Survival
- Label 1

No Overall survival
- Label 2 (scenario 2)
- Label 3 (scenario 3)

Expansion in First Line?

We are here

Competitive Data

Plausible Scenarios

Contingent Strategies
So when is the best time to apply this whole approach to Pharmaceutical Brand Strategy?
Achieving high performance means designing detailed strategic plans *earlier* in the product life cycle.

Uncertainty* based on Attrition Rates at each phase. *Tufts Center for the Study of Drug Development*

Assumption Testing activities include War Gaming, Leakage and Leverage Analysis, Payor Consensus Studies, Patient Flows, Label Scenario analysis.
Conclusions

Commercial Performance poorly correlates with technological advancement or first mover advantage

Pharmaceutical Brands face enormous reimbursement and competitive challenges

Business as usual Brand Strategy will unlikely withstand the future marketplace challenges

The framework proposed here gives marketers a powerful tool to create High Performance Brands
Let’s not leave it to intuition

Lord Kelvin (1895): Heavier than air flying machines impossible!

Indeed, eight years before Orville and Wilbur Wright took their home-built flyer to the sandy dunes of Kitty Hawk, cranked up the engine, and took off into the history books, Lord Kelvin, the President of the Royal Society of England made a forceful declaration. "Heavier than air flying machines are impossible," said this very powerful man of science....Rumor has it Lord Kelvin was slightly in error.
Any Questions?

claudioD@deallusconsulting.com