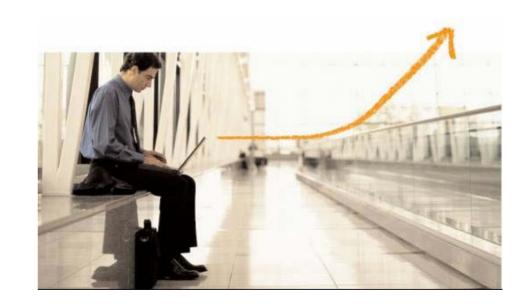


Maximizing New Product Launch Effectiveness

PMCQ Education Day

Rose Schuett, Director, Marketing - Launch Management



October 18, 2004

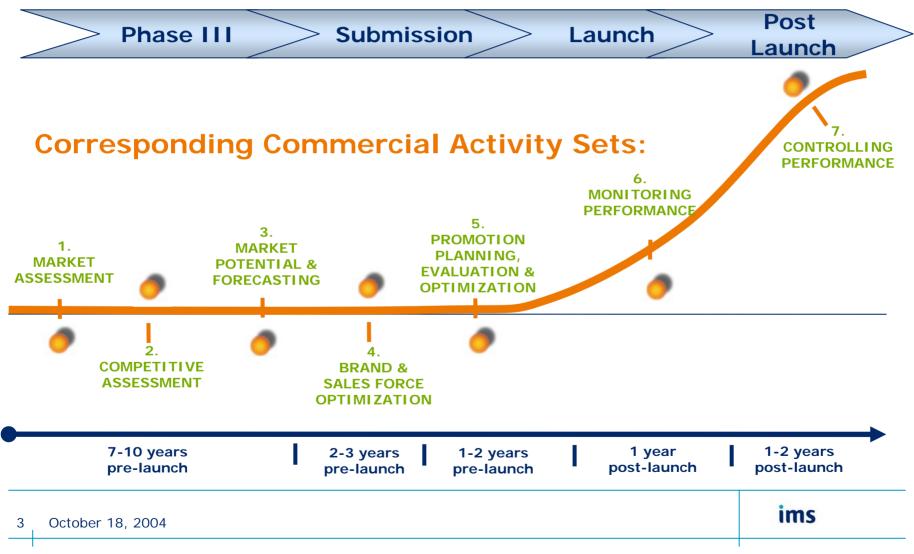
We are all familiar with benchmark reports and their recommendations

	PHASE 1	PHASE 2	PHASE 3	PHASE 4
Market Assessment	+			
Thought Leader Development		4		-
PR strategy			4	-
Health Economics		4		
Promotions Management			4	-
Numerous other activities	4			-

Then, why do so many products fail to meet expectations?

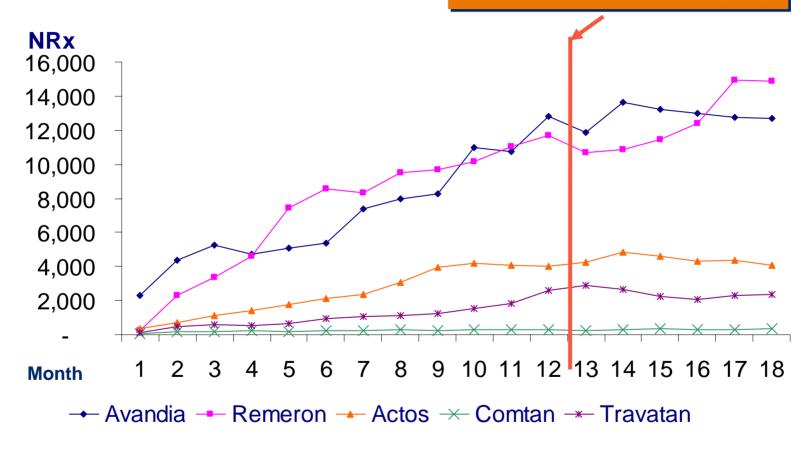
Launch Management Milestones

Clinical Development Phases:

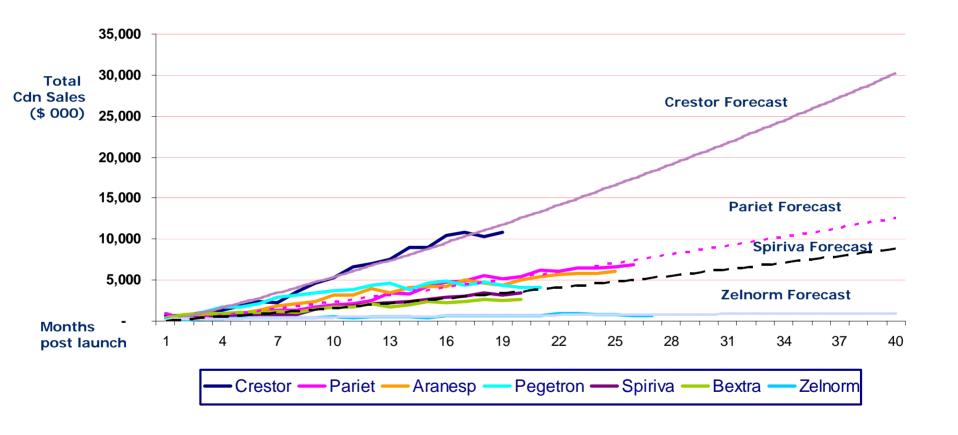


In nearly all markets, success is defined in the first 3 to 4 quarters

60% of monthly volume at year 3 achieved in first 12 months (CAN)

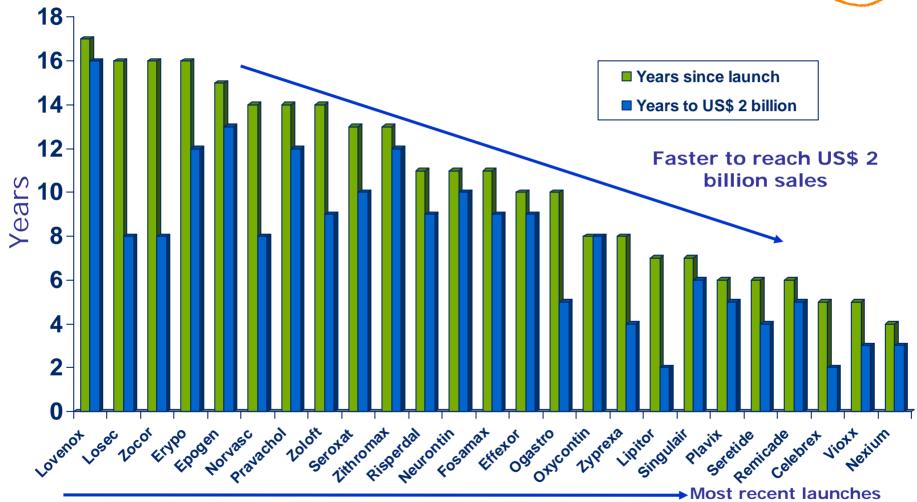


Companies are striving to... Maximize the uptake curve...



...And reduce time to peak sales

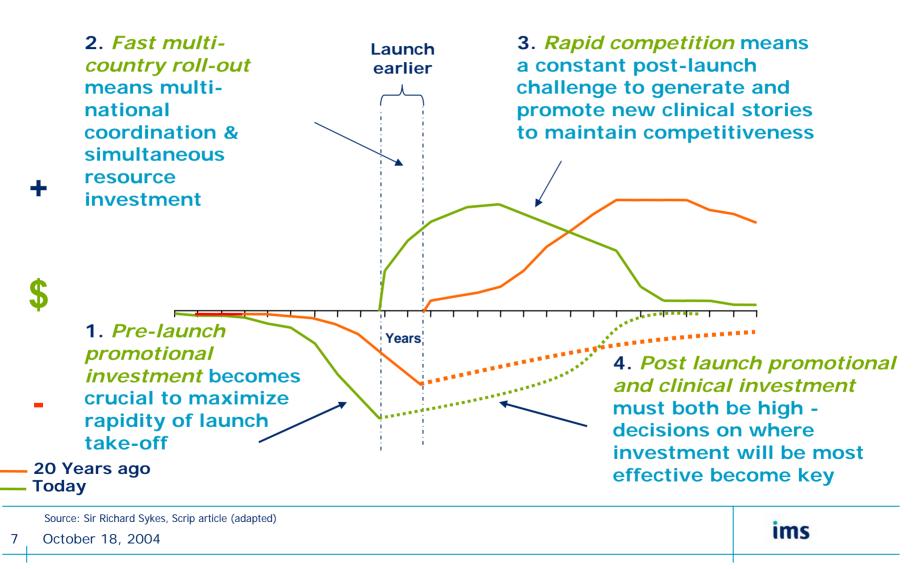




Source: IMS Health: MIDAS, MAT Dec 2003

October 18, 2004

Revenue expectations have changed and so have investments



A new reality is emerging

- Market access, including regulatory, pricing and reimbursement and formulary approval is becoming increasingly challenging and complex
- No evidence = no label, no formulary and high co-pay
- •FDA (& Health Canada) will mandate responsibility to pharma for risk management and post-marketing surveillance post-launch
- Increasing segmentation will challenge current sales force mantras on size, deployment and overall optimization
- More biotech and segmentation will change sales force skills portfolio requirements
- Patients are more accessible than previously thought and will demand increased attention





Maximizing New Product Launch Effectiveness

"BLOCKBUSTERS ARE NOT DISCOVERED, THEY'RE BUILT."

-Author Unknown

Pharmaceutical & Biotech Companies often fail to maximize product launches

An alternate 4P's for product launch success

1. Plan

Given the complexity of launching new products, a planning process can be <u>critical</u> to success

2. Positioning

Target appropriate audiences while maintaining a cohesive & consistent brand identity

3. Promotion

Brand management (not product marketing) aligned with product's positioning strategy

4. Product

P&R and distribution operational readiness including training and incentive programs

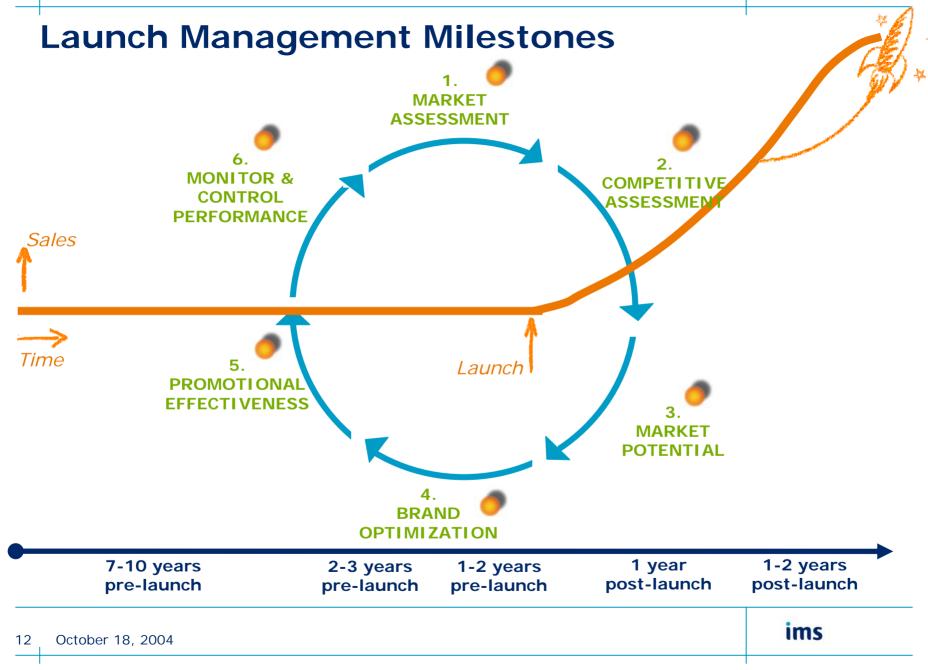
Launch planning can significantly increase the chances of success



- Flexibility is a key component of plan development
- About 70% of new product launches experience delays
 - Only 7% incorporate a crisis plan in their launch planning
- Scenario planning and wargaming can be extremely useful tools during launch planning

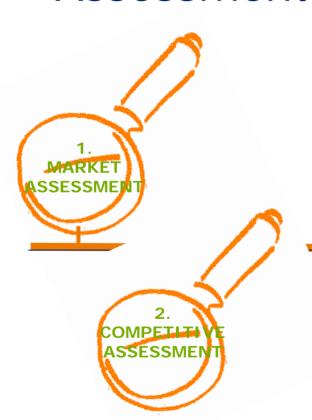
Source: Schneider & Associates and Boston University, 2001

October 18, 2004





Market & Competitive Assessment



Business Questions:

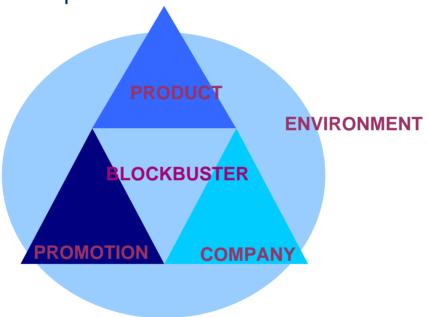
- -What is the size of the market?
- -What is driving the growth and how does this vary by channel?
- -What are the treatment patterns in this TC?
- -How many patients are suffering from this disease?
- -What stage is this market: growth, maturity, or decline?

Business Questions:

- -Who are the players in the market? Today? Tomorrow?
- -What products are driving volume? Who is on formulary?
- -Is market share by player growing or declining?
- -What channels do they play in and how much do they spend to promote their products?

Environment as a driver of blockbuster growth

A blockbuster is the product of its environment as well as promotional activity, product development and the company or companies that launch it



The development of a detailed product launch plan can dramatically improve the probability of a successful launch

Market & Competitive Assessment

Key Business Outcomes:

- 1. Provide a macro-level assessment of the target market, the potential patient population, and early indicators of market entry opportunities and challenges.
 - The outcome of this assessment forms the basis for initial market segmentation, opportunity sizing, and performance expectations, and highlights critical assumptions to test throughout the launch process.
- 2. A comprehensive competitive assessment should provide indepth information about the current and future participants in this market. This set of activities should result in a SWOT Analysis (Strengths, Weaknesses, Opportunities, and Threats) for the launching product.



Market Potential

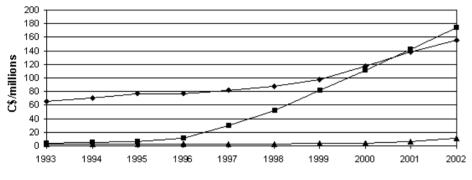
Business Questions:

- -What is the forecast for patients, prescriptions, and sales of the brand and its therapeutic category?
- -What are the potential uptake curves and forecast launch milestones?
- -What can we learn by evaluating past (analog) launches?
- -What indication(s) will be promoted at launch?
- -How does this impact our estimate of market potential?

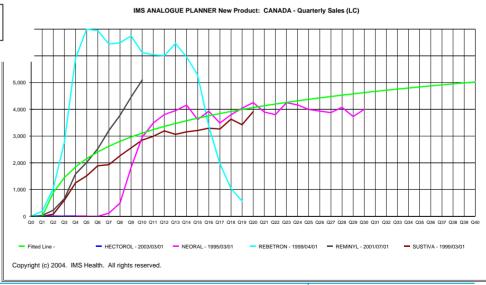


Gain insight into the therapeutic class and then, use analogs to inform your baseline forecast

Evolution of HRT, M5B and H4A sales 1993-2002







Market Potential & Forecasting

Key Business Outcomes:

 This activity results in an initial sales and prescription forecast that should be refined as you progress through the Launch Management process and acquire new insights about your brand and its opportunity in the marketplace.



Brand & Sales Force Optimization Business What are

Business Questions:

- -What are the physician and sufferer attitudes about current treatments?
- -How should the market be segmented?
- -Which prescribers should be profiled and targeted based on:
- -Adoption patterns?; Prescribing pot intial?
- -Switching vs. loyalty?; Attitudes, values & beliefs?
- -What is the ideal messaging strategy for the brand?

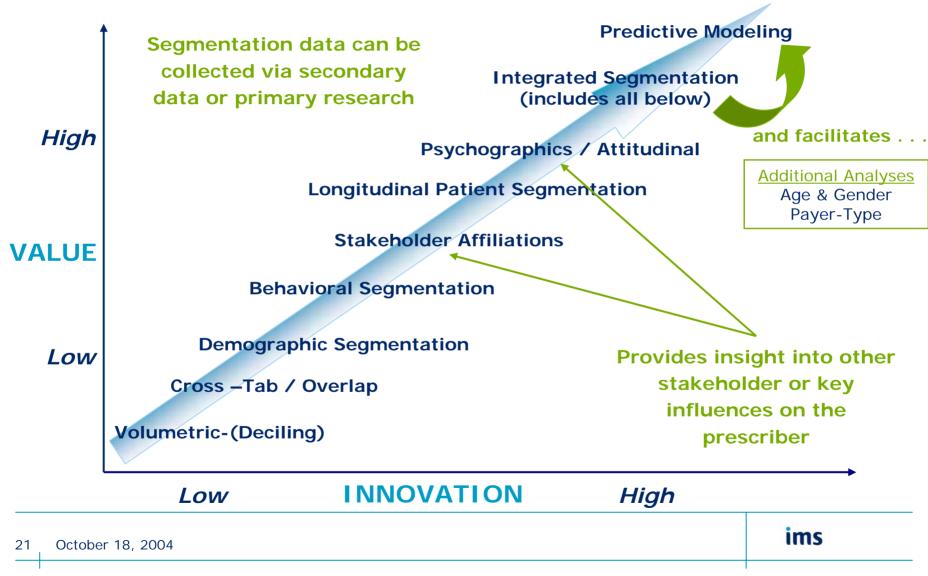


Getting it "Right" through all phases of the New Product Launch!

----- Driven by the Right Segmentation -----

Right Customers	Right Frequency	Right Message	Righ	t Size
Actionable customer segments reflecting true opportunities	How often to call on each customer; coordinate routing across multiple sales forces	Positions product based on physician's segment profile, and use commensurate collateral	struc	your size and ture reflect th opportunities?
Right Deployment	Right Training	Right Tools	Right Motivation	
Unbalanced territories will negatively impact growth	Enables reps to deliver quality calls consistently	Allows sales force to focus on selling	Does incentive compensation drive behavior consistent with company's growth strategy?	
20 October 18, 2004				ims

Segmentation is the cornerstone from which other critical launch activities are grounded. . .



Effective segmentation combines behaviors, attitudes and longitudinal insight...

Behaviors

Rx share trends
Adoption & Switching
Prescribing concentration
Group Practice Influence
Managed Care Influence
Rx volume/share
Demographics

ongitudinal Insigh

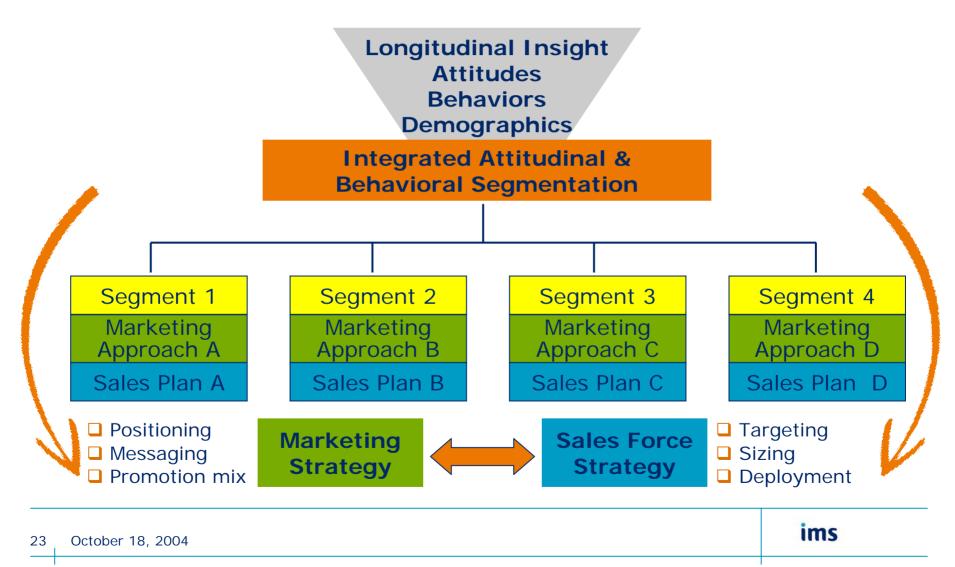
Titration
Patient switching
New therapy starts
Concomitant medication
Continuing therapy
Practice profiles
Compliance

Attitudes

Managed care
Treatment approaches
Communication preferences
Reimbursement issues
Clinical concerns

Integrated Attitudinal & Behavioral Segmentation

...to drive Sales and Marketing Strategies by Segment



Analytics - Case Study

Anticonvulsant Market Integrated Segmentation

Client problem/opportunity

- 2-year old AED product experiencing flattened growth
- Specialty field force competing with "mega" field forces
- Product was the basis (funding) for a 2-3 year gap in the portfolio pipeline

Results

- Net gain of \$28M in revenue the first year
- Deployed against targets as a company, not just a field force
- Representative buy-in and motivation fueled success

How IMS made the client successful

- Completed an in-depth Integrated Segmentation
- · Worked with the client to pilot and implement the segmentation in the field force
- Worked with the client and their agency to update product positioning and messages.
- Tracked and reported on success, while assisting on teams to address "hot spots"

Brand & Sales Force Optimization

Key Business Outcome:

 Optimizing a brand requires intimate knowledge of the customers and competitors. Having pulled together this intelligence, the detailed marketing and sales strategies as well as objectives for launching the new drug can be established.



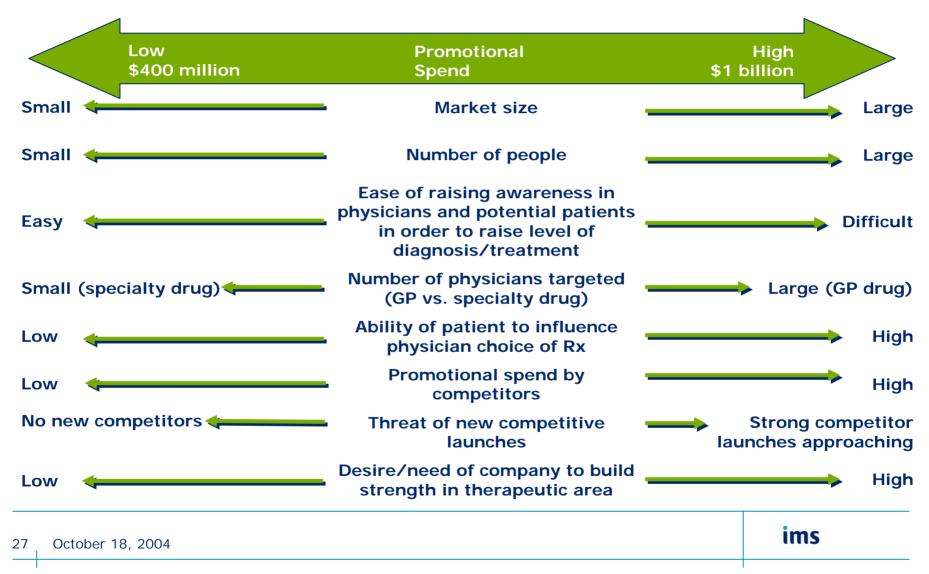
Promotional Planning, Evaluation & Optimization

Business Questions:

- -Which combinations of activities will have the greatest impact?
- -Did the promotion change physicians' prescribing behavior?
- -Which physicians were most impacted?
- -Did the promotion have the desired financial impact?

5.
PROMOTIONAL
PLANMING,
EVALUATION &
ON MIZATION

Key drivers determine promotional spending for potential blockbusters



A web of influencers has increased the complexity & number of pre-launch & launch activities

Successful companies select critical activities / emerging strategies for specific market constituents

Opinion leaders Physicians



- Advocate Development
- Publications
- Medical Marketing
- · Continuous relationship marketing

Patients



- DTC patient advertising
- Continuous relationship marketing

Payers



- Medical Marketing
- Pharmaco-economic trials
- Customers require about 9 promotional encounters to sufficiently raise awareness and use.
- Customers only notice 1 in 3 promotional activities

Leading companies have begun to target an expanded view of decision makers and the customer interaction process

Direct Interactions

Reps

Medical Liaisons

Programs/Sponsorships

Information Center

Product Info Requests

Journal Advertising

Conferences

Payer Interactions

Public & Private, CDR

Patient Out of Pocket



Prescribing Behavior (Not necessarily decision-making)

Patient Types

Requests/Preferences

Caregivers

Consumer Interactions

Peer / Staff Interactions

Hospital

CME

Group Practice

Key Opinion Leaders

Referring Network

Nurses / NPs

Innovative customer models:

- ✓ Enhance direct interactions
- ✓ Influence physicians *indirectly*

Gleevec commands a global niche market with clear differential advantage

Gleevec approached the market with a new strategy

Data-Driven Positioning

- Gleevec stressed its targeted nature and its out-standing clinical data
- The message was "precise targeting of the molecular abnormality that leads to CML"
- Key communication points were "outstanding hematological response", "unprecedented cytogenetic response" and "welltolerated and convenient"
- Novartis used evidence based marketing – most KOL's were investigators and brand champions

Patient-Driven Demand

- Unlike most biologics, Gleevec's demand was driven by patient demand from the earliest development phase
- Novartis was able to rally patient activists who aggressively lobbied for early access and fast-track approval
- A key segmentation base was "Internet-positive" patients, who created a world-wide network and petitioned the company and regulators to accelerate approval

Comprehensive Access Program

- Novartis employed an innovative pricing strategy - \$2,200 per month with potential indefinite use
- HE studies in the US and the UK aimed to show that Gleevec was cost-effective compared to usual care
- A global assistance program extended exceptionally broad discounting to uninsured
- Novartis offered the following terms in the US:
 - Free drug for < \$43,000 per yr
 - Drug cost capped at 20% for \$43,000 - \$100,000 per year

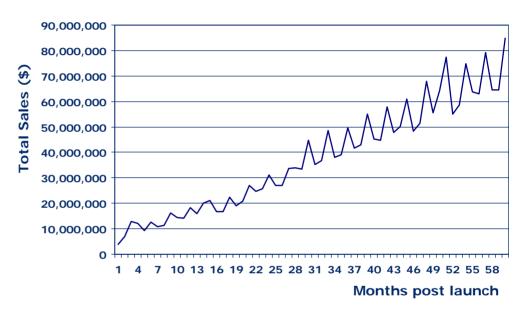
Source: Building Global Biobrands - Simon & Kotler

Fosamax – Redefining a Market

- · Fosamax was first to market
- Osteoporosis had low awareness
- There were no globally accepted disease definition
- Osteoporosis was traditionally defined as fractures
- Existing treatments ranged from Calcitonin & Vitamin D to Fluoride



- 1. Expanding diagnosis
- 2. Obtaining multiple indications
- 3. Developing new formulations



- Merck worked with manufacturers of densitometry and even took equity positions
- Merck funded and managed the National Osteoporosis Risk Assessment program
- Low-cost scanners started to appear in physician offices and osteoporosis managements started to move from the specialty offices to PCP's



Promotional Planning, Evaluation & Optimization

Key Business Outcome:

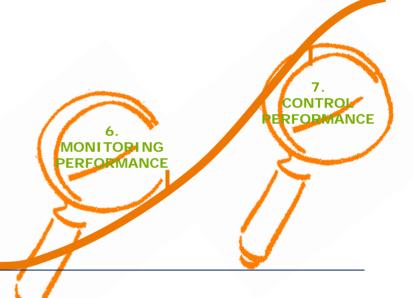
- 1. A thorough analysis of the level and effectiveness of various promotional vehicles in this market establishes the framework for the launch promotional plan, including:
 - Definition of promotional elements to be used
 - Required budget
 - Resource allocation



Monitor & Control Performance

Business Questions:

- -What are the key drivers of launch performance to be monitored?
- -What performance metrics best support our product's marketing and financial objectives?
- -What information will be shared throughout the organization?
- -What is the product uptake, penetration and usage over time?
- -How is our product performing against plan and Corporate expectations? Vs. the Competition?



Monitor and Control Performance

Key Business Outcome:

- 1. Effective Monitoring of Launch Performance requires:
 - The definition of key performance indicators, which enable the organization to get a timely and actionable read on their in-market results.
 - The implementation of efficient and effective enterprise-wide communications and reporting procedures, enabling the entire organization to have the same read on results.
- 2. This activity generates the "risks and contingencies" of the launch plan providing insight and direction to the team during the critical first 12 to 24 months on the market.

Conclusions – Maximizing Launch Effectiveness

- •NPLs are processes, not events they require on-going management and measurement
- •Products may fail to attain their maximum potential due, in part, to the complexity of the commercialization process
- •Launch success is multi-factorial, is enhanced by skilled and trained individuals, and organizations that have a sense of urgency, flexibility and willingness to be innovative
- Commercialization success is boosted by meticulous planning, independent of strategies and tactics
- •Organizations that plan for and review NPL metrics as standard practice, better position themselves for timely, focused responses to market results
- •At the end-of-the-day, the company that knows their customers best and develops brand loyalty will win
- •The right strategy and tactics are by-products of customer and marketplace intimacy





Thank You.