
BIO
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R&D Marketing Interface

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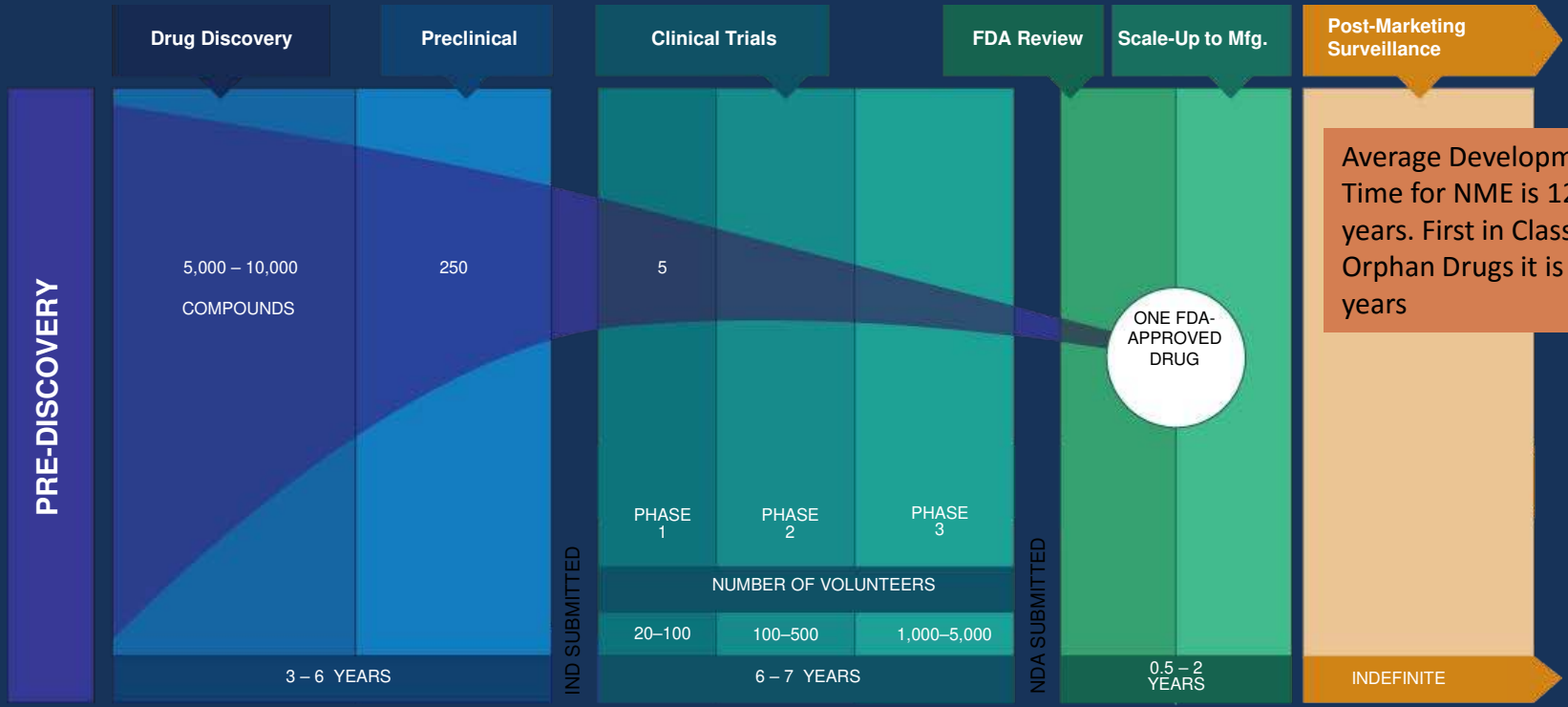
Learning Objectives

- Highlight the importance of commercial team input into product development strategy in a early stage biotech/medical device company
- Understand the role of marketing in early stage companies to shape the product life cycle to achieve the best commercial success.
- Describe the process of creating a commercially appealing target product profile (TPP).
- Learn how to develop a TPP framework to deliver better outcomes.

Trends

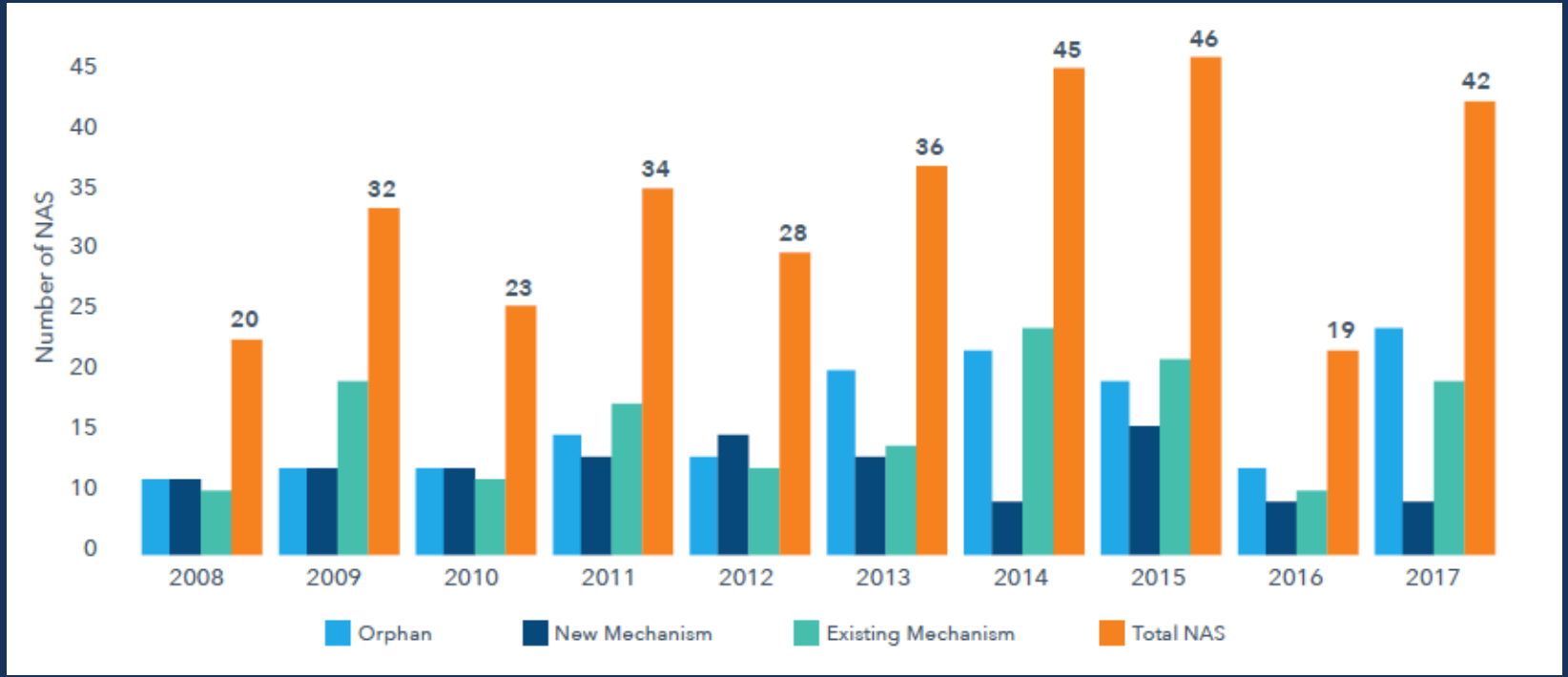
- Health care priority: cost control, access and price transparency
- Decreasing access to physicians
- Shifting power balance toward payers
- Reimbursement models focus on value/outcome
- Growth of alternative delivery models and partnerships
- Digital transformation enhancing patient centricity and engagement

DEVELOPING A NEW MEDICINE TAKES AN AVERAGE OF 10–15 YEARS



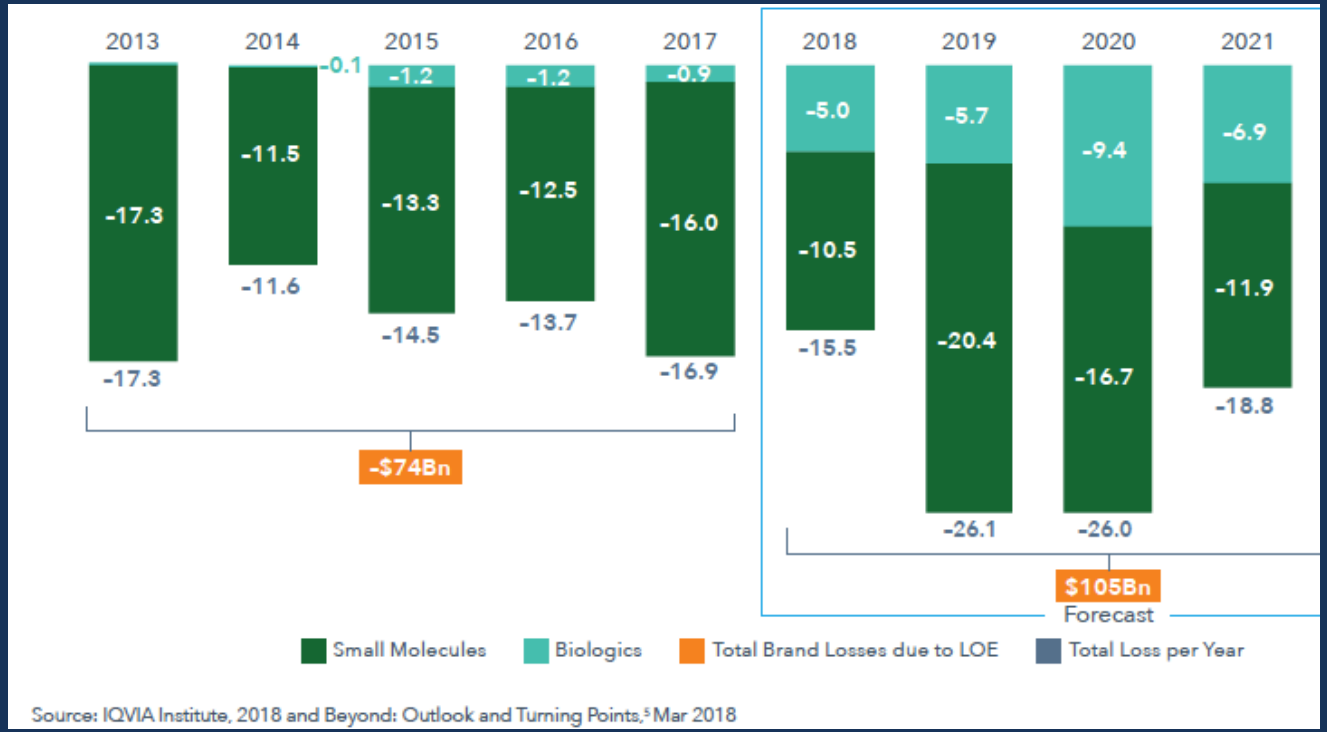
Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006, Tufts Center for the Study of Drug Development, Impact Report May/June 2018

New Active Substance (NAS) Launched in US 2008-2017



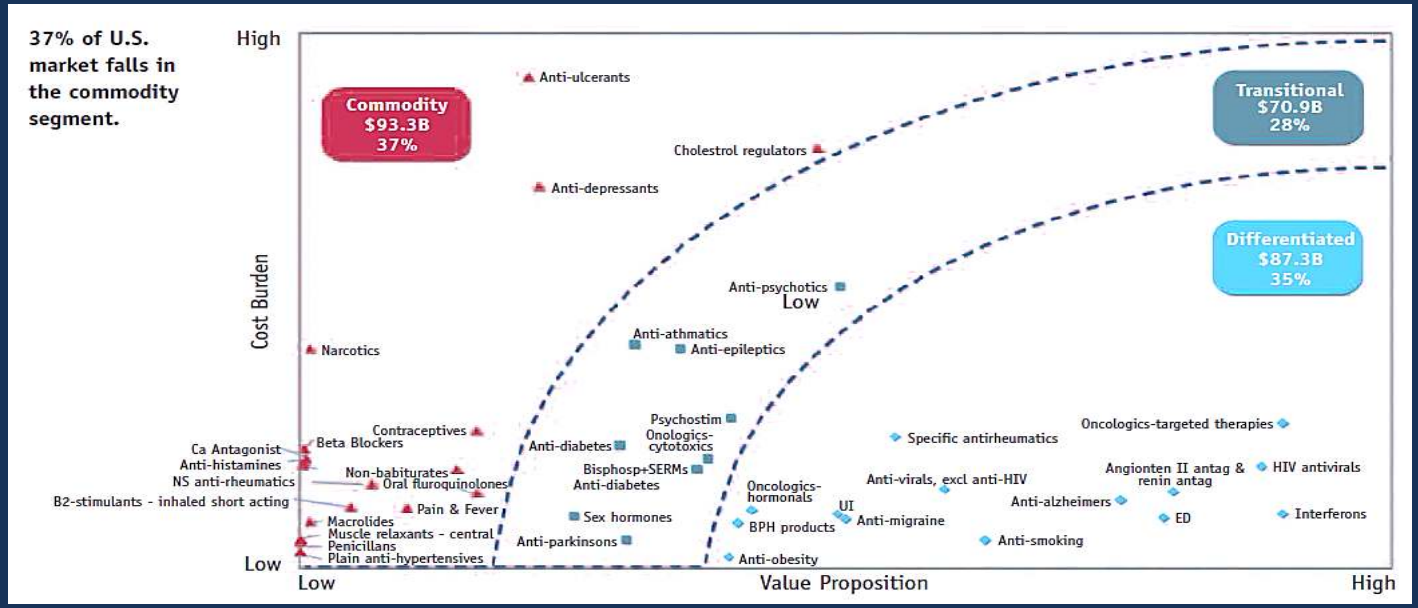
Source: Medicines use and spending in the U.S.– IMS Report, April 2018

Pharma Loss of Exclusivity



Source: Medicines use and spending in the U.S.– IMS Report, April 2018

Segments of Pharmaceutical Market



Source: Understanding the New Commercial Models in the Pharmaceutical Industry – An IMS Report, 2009

Brands vs. Generics Shares

Invoice Spending US$Bn	2012	2013	2014	2015	2016
Total U.S. Market	317.8	331.5	378.5	425.3	450.0
Branded	71.6%	71.2%	71.8%	72.9%	74.2%
Unbranded Generic	16.3%	16.7%	17.1%	16.5%	15.0%
Branded Generic	12.2%	12.1%	11.0%	10.6%	10.8%

Dispensed Prescriptions Mn	2012	2013	2014	2015	2016
Total U.S. Market	4,154	4,235	4,325	4,368	4,453
Branded	15.9%	13.5%	12.2%	11.3%	10.5%
Unbranded Generic	77.8%	80.5%	82.1%	83.4%	84.6%
Branded Generic	6.3%	5.9%	5.6%	5.3%	4.9%

Source: Medicines use and spending in the U.S.– IMS Report, May 2017

CMS Framework Categorizing Payments to Providers

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	Category 1: Fee for Service – No Link to Value	Category 2: Fee for Service – Link to Quality	Category 3: Alternative Payment Models Built on Fee-for-Service Architecture	Category 4: Population-Based Payment
Description	▪ Payments are based on volume of services and not linked to quality or efficiency	▪ At least a portion of payments vary based on the quality or efficiency of health care delivery	▪ Some payment is linked to the effective management of the population or an episode of care ▪ Payments still triggered by delivery of services, but opportunities for shared savings or 2-sided risk	▪ Payment is not directly triggered by service delivery so volume is not linked to payment ▪ Clinicians and organizations are paid and responsible for the care of a beneficiary for a long period (e.g., ≥1 year)
Medicare Fee-for-Service examples	▪ Limited in Medicare fee-for-service ▪ Majority of Medicare payments now are linked to quality	▪ Hospital value-based purchasing ▪ Physician Value Modifier ▪ Readmissions / Hospital Acquired Condition Reduction Program	▪ Accountable Care Organizations ▪ Medical homes ▪ Bundled payments ▪ Comprehensive Primary Care initiative ▪ Comprehensive ESRD ▪ Medicare-Medicaid Financial Alignment Initiative Fee-For-Service Model	▪ Eligible Pioneer Accountable Care Organizations in years 3-5 ▪ Maryland hospitals

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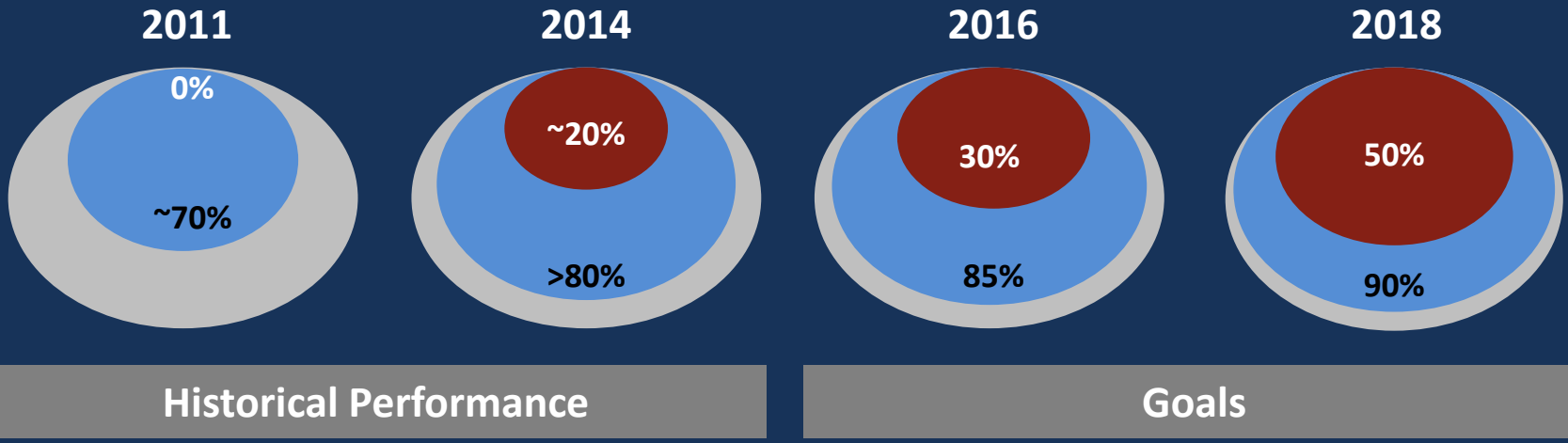
Source: Rajkumar R, Conway PH, Tavenner M. CMS – engaging multiple payers in payment reform. JAMA 2014; 311: 1967-8.

CMS Target Percentage of 'Alternative Payment Models' by 2016 - 2018

Alternative payment models (Categories 3-4)
FFS linked to quality (Categories 2-4)
All Medicare FFS (Categories 1-4)



Source: Rajkumar R, Conway PH, Tavenner M. CMS – engaging multiple payers in payment reform. JAMA 2014; 311: 1967-8., CMS website

Innovative Product

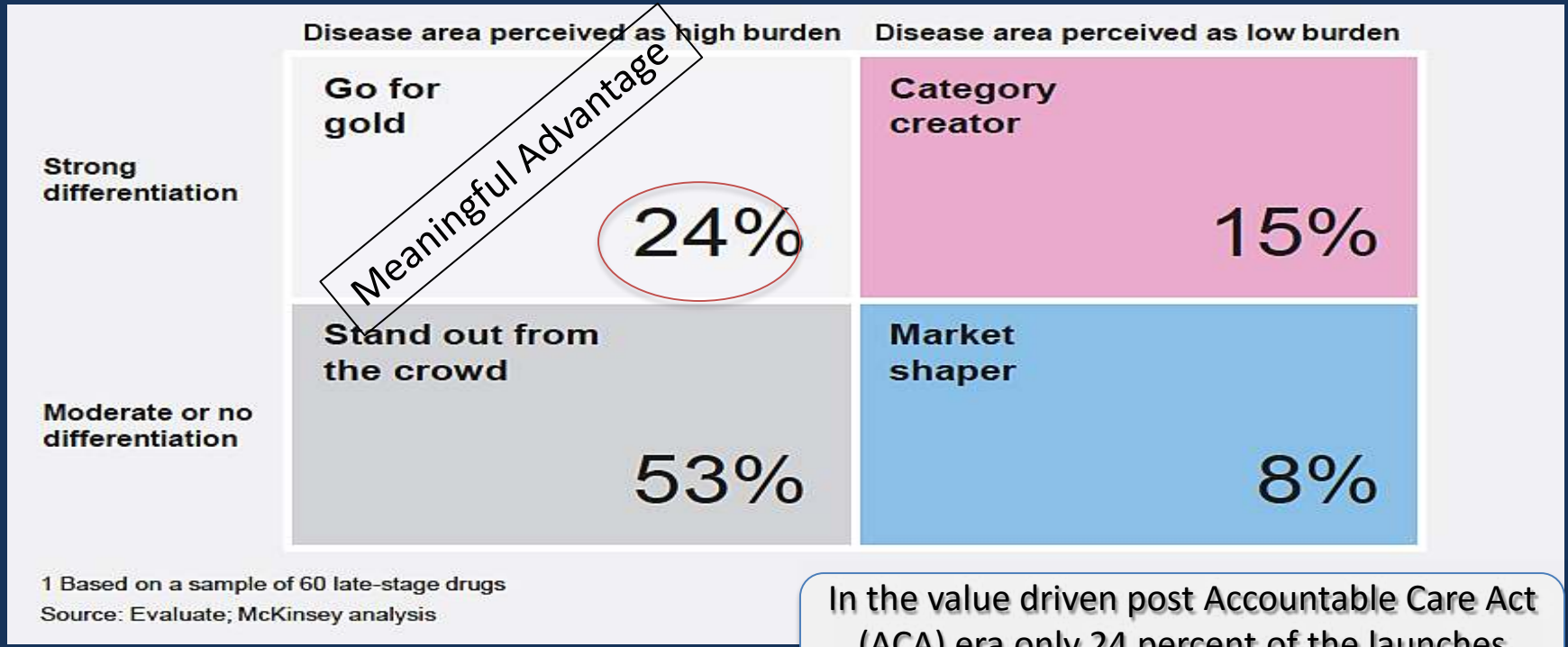
A differentiated product (solution) that offers a meaningful advantage (value) over existing treatments for a given condition

How can marketing shape the product?

Objectives, 4 P's, A's of Marketing

Objectives	4Ps	4As
Address Unmet Needs	Product	Acceptability
Value to Payers	Price	Affordability
Create Convenience	Place	Accessibility
Communication of Value	Promotion	Awareness

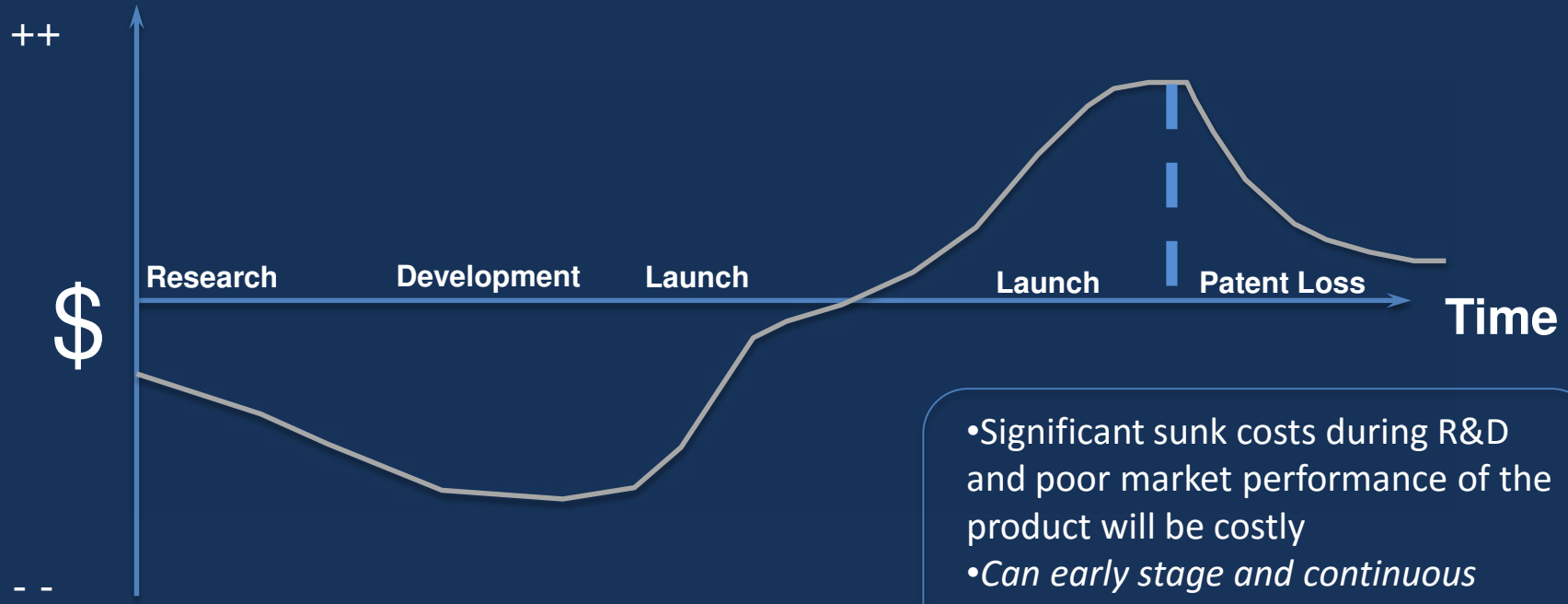
What Proportion of the Launches are Innovative?



In the value driven post Accountable Care Act (ACA) era only 24 percent of the launches would be truly innovative

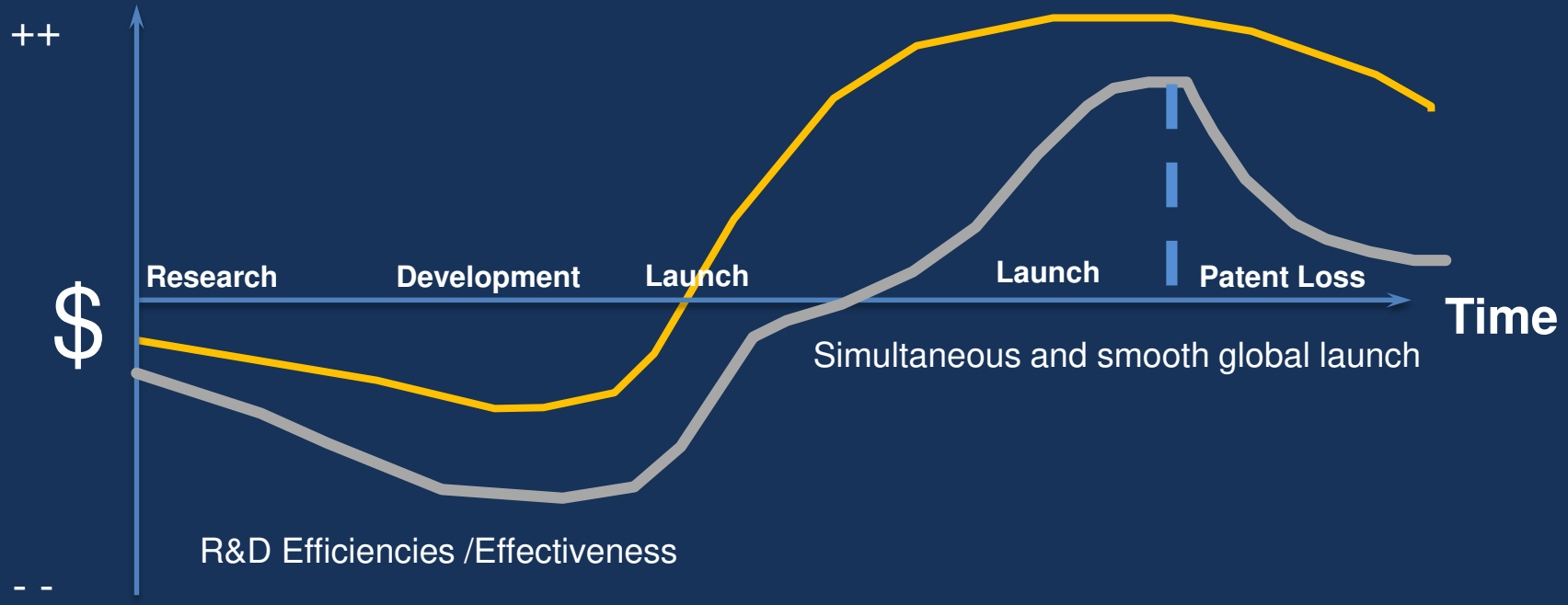
Source: Beyond the Storm: The Launch Excellence in the New Normal, McKinsey Report 2013, pp.6

How to Improve the Probability of Success?

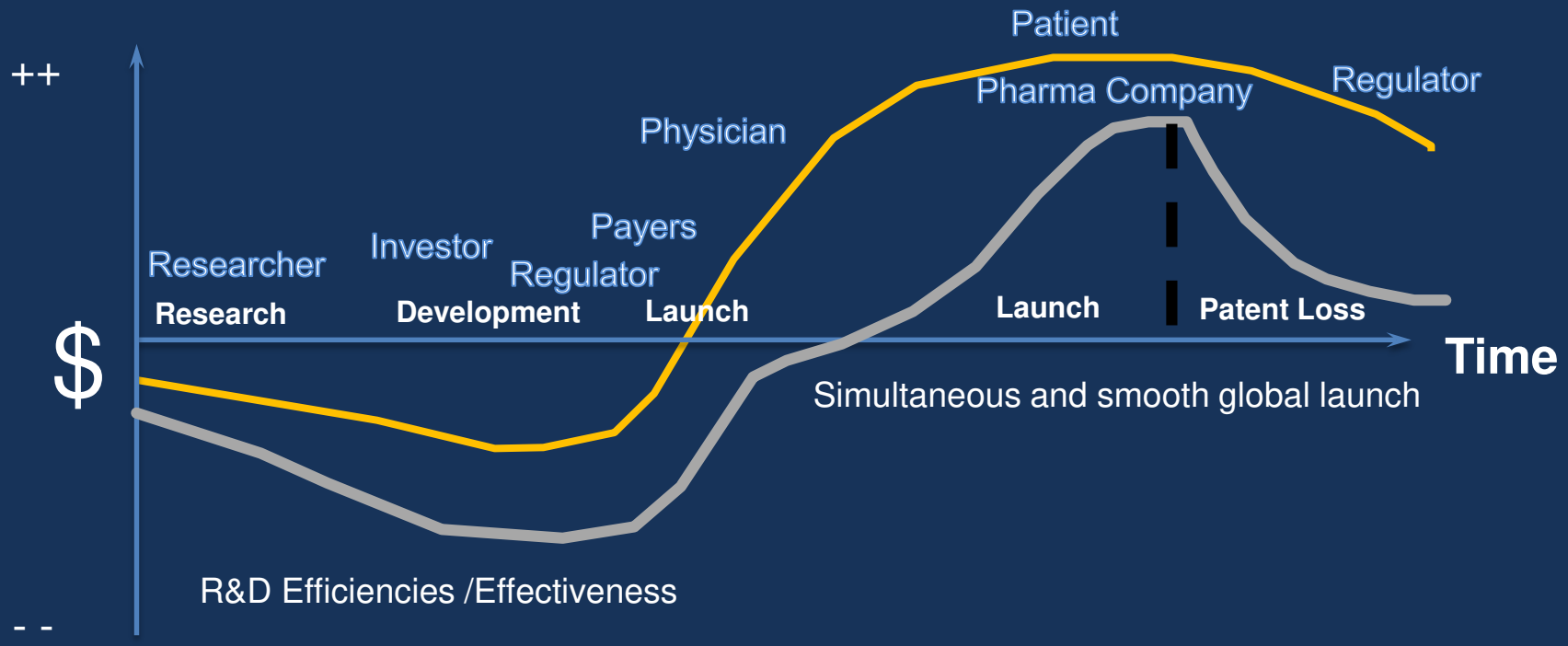


- Significant sunk costs during R&D and poor market performance of the product will be costly
- *Can early stage and continuous marketing input change this?*

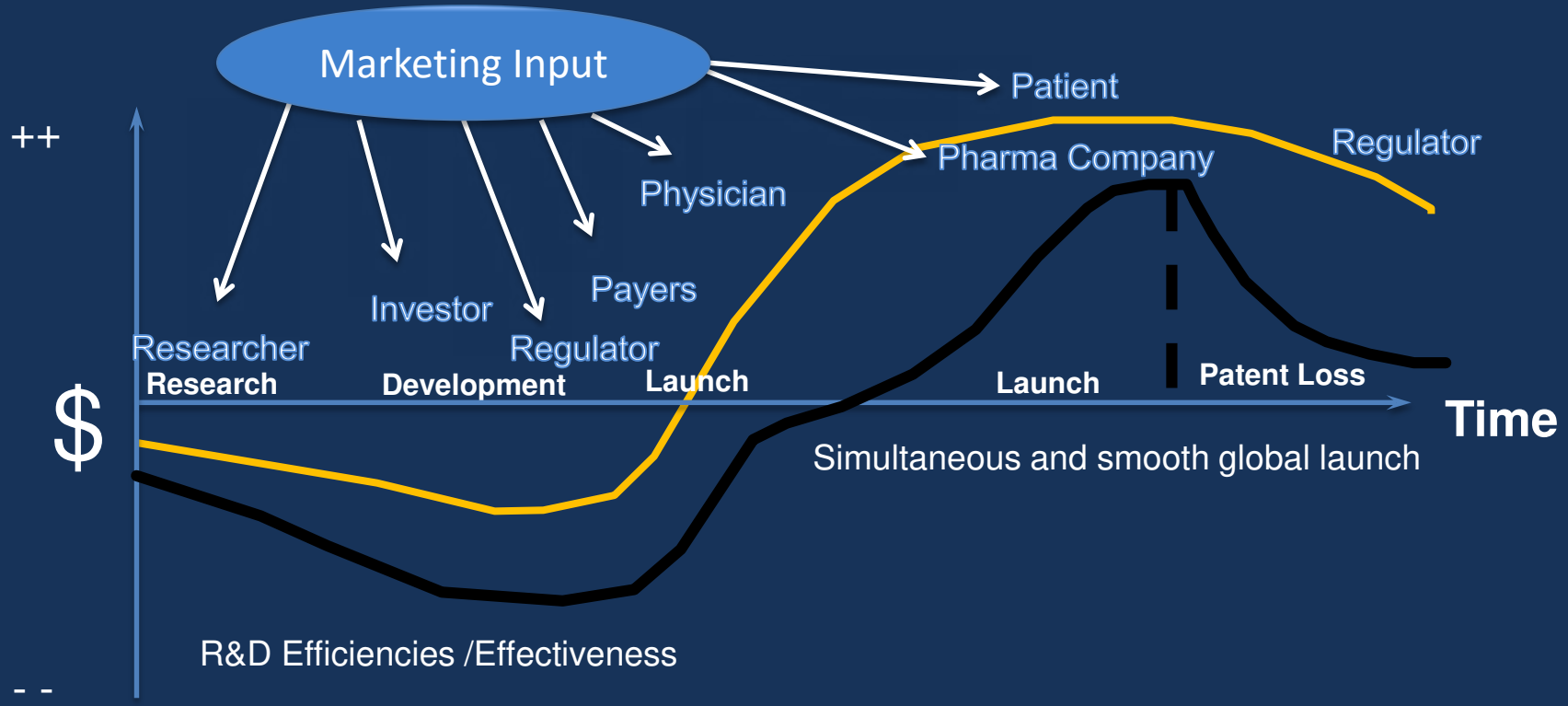
Ideal Product Life Cycle



Meeting Stakeholders Needs

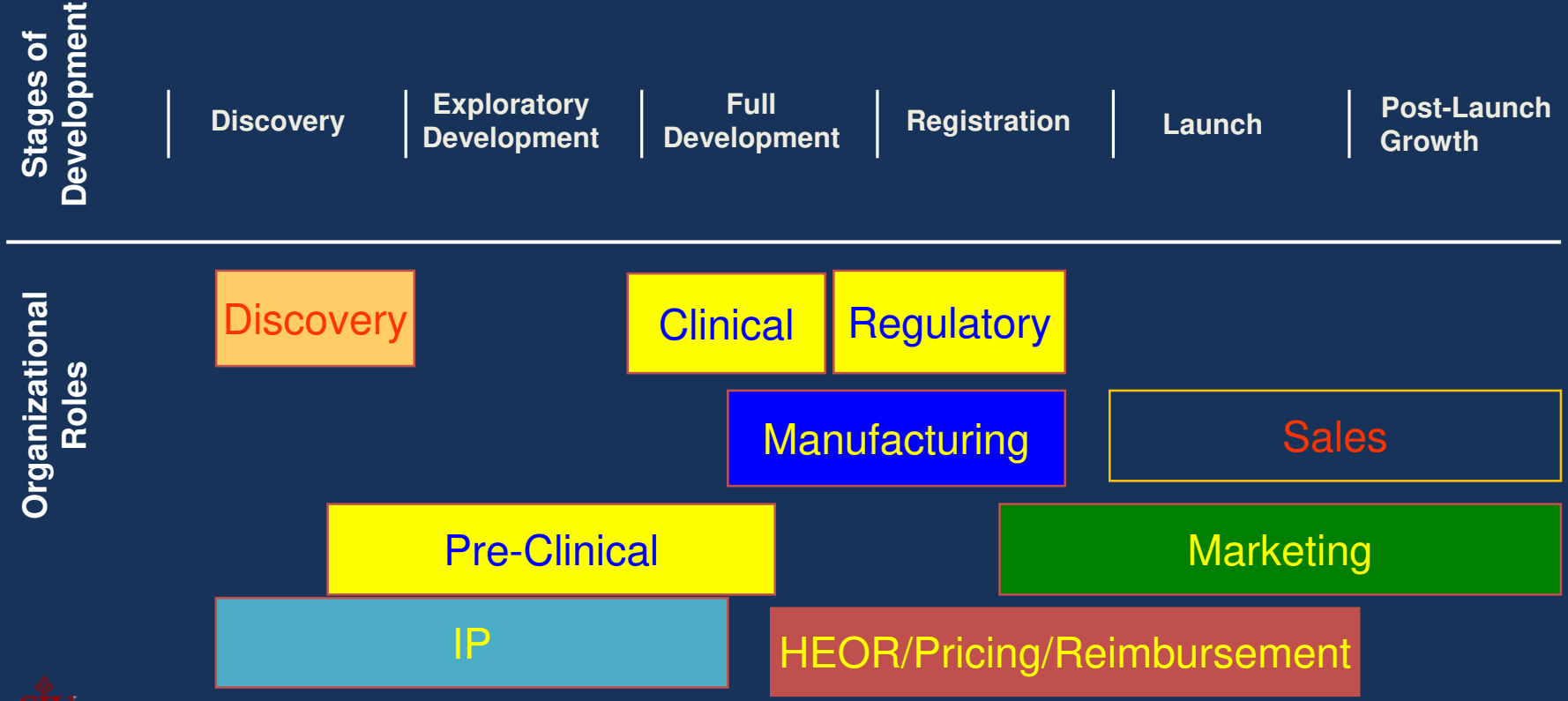


Early Marketing Input Can Improve Product Success



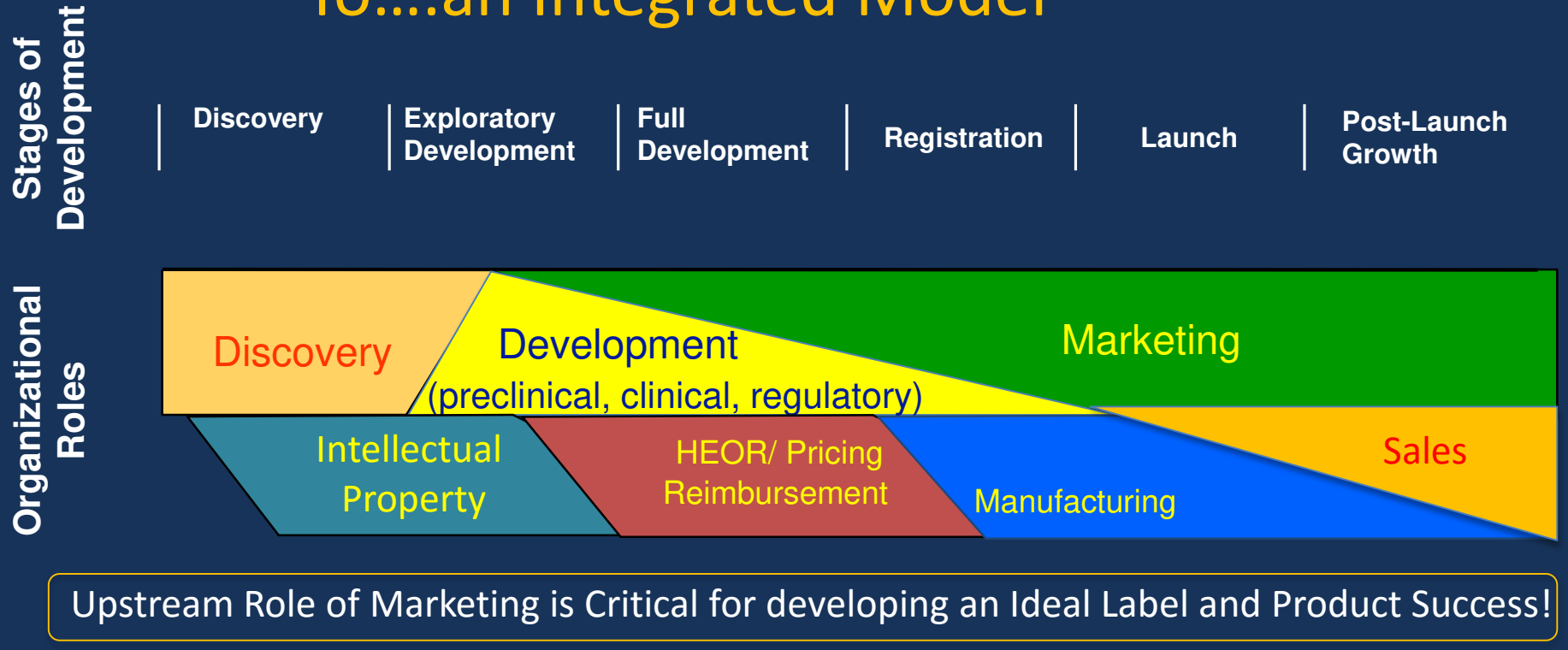
What will Collaboration Achieve…?

From….



What will Collaboration Achieve…?

To….an Integrated Model



Upstream Role of Marketing is Critical for developing an Ideal Label and Product Success!

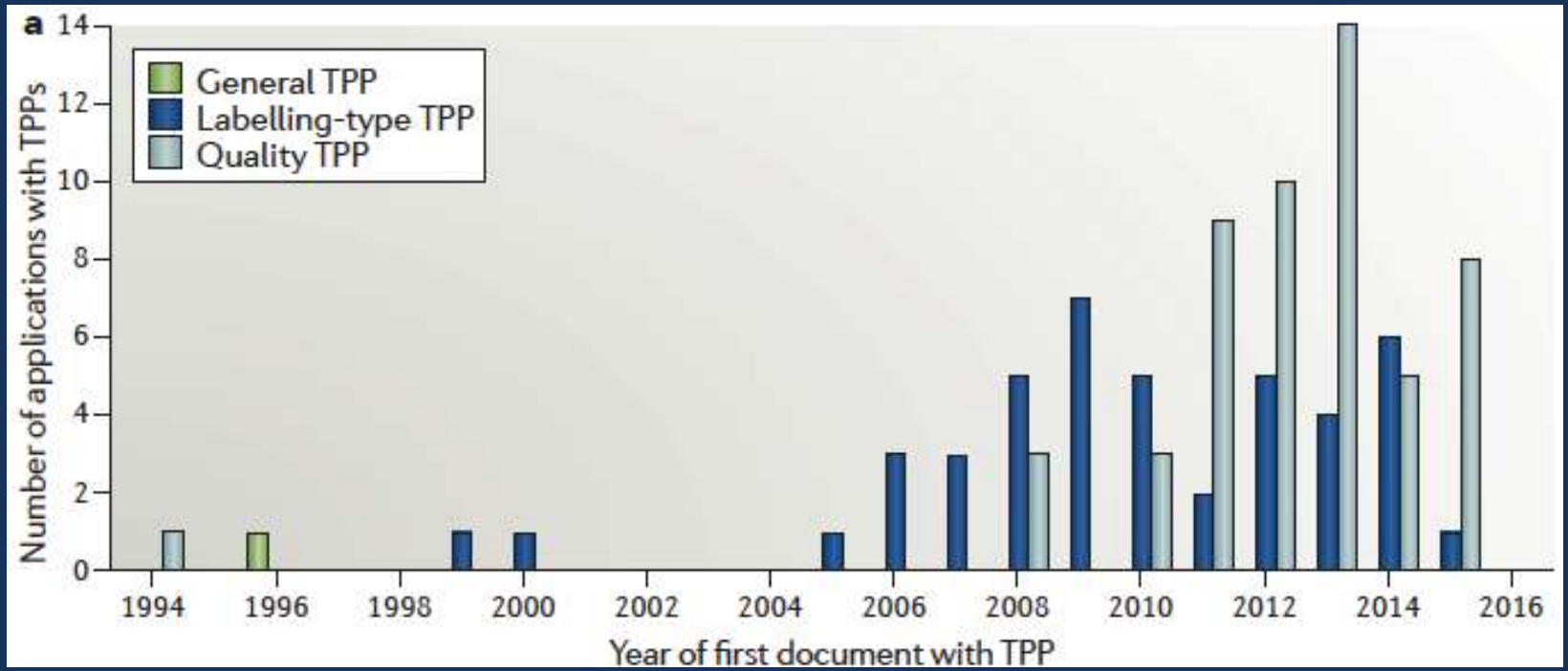
Marketing Facilitate Cross-Functional Decisions

Source: Jambulingam, T. (2018), The R&D Marketing Interface in BioPharma and MedTech, Journal of Commercial Biotechnology, 24(1), 48-55.

What is TPP?

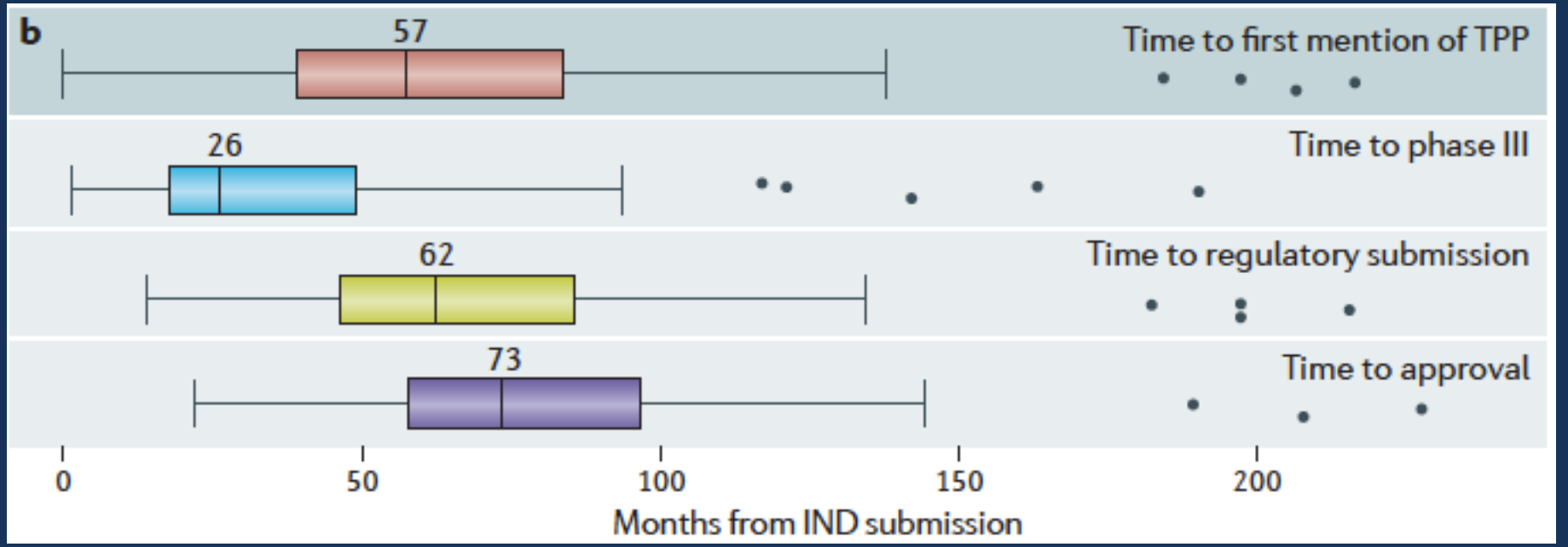
- In 2007 FDA created a guidance document on TPP as a strategic process development tool to facilitate effective communication between the industry and review staff
- TPP is the directional tool that has a significant impact on the drug development process and in particular, its marketing organization
- TPP convert discoveries into companies!
- Marketing as part of commercial team can shape the TPP

Research shows TPP is valuable but underused



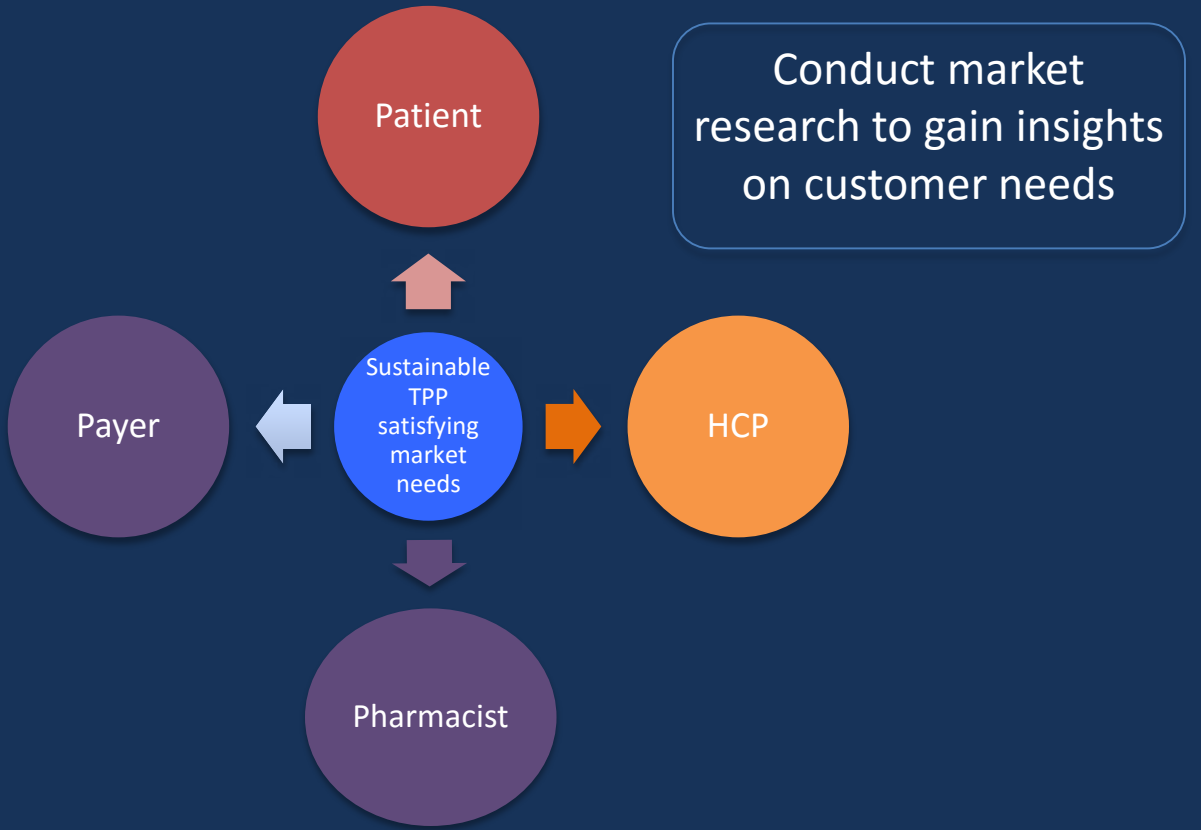
Source: Tyndall et.al. The TPP as a tool for regulatory communication: advantageous but underused, Nature, March 2017, pp. 156

Research shows TPP Valuable but Underused



Source: Tyndall et.al. The TPP as a tool for regulatory communication: advantageous but underused, Nature, March 2017, pp. 156

Start with end in mind: How should the label look to meet customer needs ?



How can TPP be shaped by Marketing?

TPP

- Indication
- Dosage form
- Dose, frequency
- Differentiation
  - Efficacy
  - Safety
  - Economic

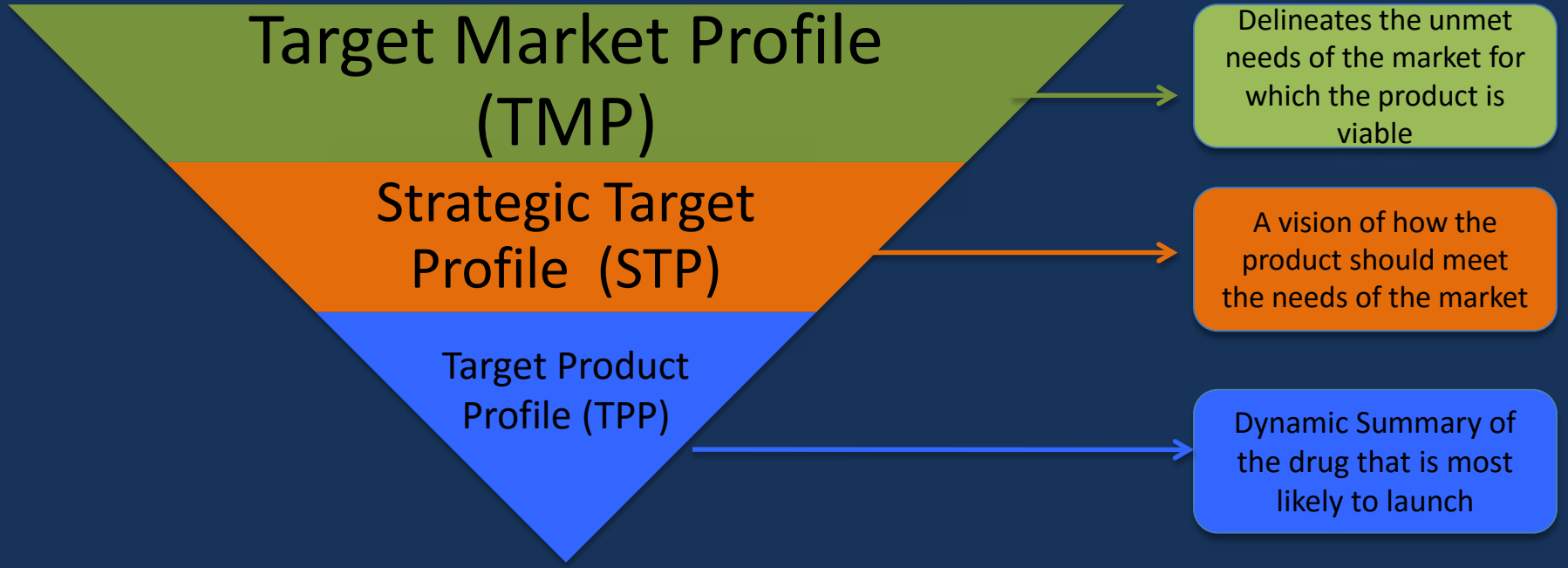
Attributes Shaped by Marketing

- Proposed indication
- Develop formulation
- Develop trade-dress
- Establish efficacy/superiority
- Establish safety advantage
- Develop for pediatric use
- Pharmacoeconomic data

Who should work together?

Goal: To deliver strong development plan with superior clinical performance, patient benefit and health economic value

STRATEGIC FRAMEWORK



Source: Tebbey, Paul W. and Charles Rink, "TPP: A Renaissance for its Definition and Use, Journal of Medical Marketing, Vol. 9 (4), 301-307.

Strategic Framework

	Target Market Profile (TMP)		
Purpose	Captures all the key information about the market		
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease		
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events		

Strategic Framework

	Target Market Profile (TMP)	Strategic Target Profile (STP)	Target Product Profile (TPP)
Purpose	Captures all the key information about the market	A vision for a product that will meet the needs of the market	
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease	Target attributes (desired profile) • Value drivers/Positioning • Global Reach • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties	✓Positioning ✓Global Sales Forecast ✓Developmental Logic ✓Regulatory and Reimbursement Strategy ✓Product Value
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events	Set at the beginning of clinical development and updated only when necessitated by changes in the TMP	

Strategic Framework

	Target Market Profile (TMP)	Strategic Target Profile (STP)	Target Product Profile (TPP)
Purpose	Captures all the key information about the market	A vision for a product that will meet the needs of the market	A record of the drug that is most likely to launch
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease	Target attributes (desired profile) • Value drivers • Global • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties	Indications and usage (label) • Dosing and administration • Contraindications • Warnings and precautions • Adverse reactions • Description • Clinical Pharmacology • Clinical Studies • Storage and handling
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events	Set at the beginning of clinical development and updated only when necessitated by changes in the TMP	Updated as clinical and pharmacologic findings emerge and in response to guidance from regulatory authorities

Questions that needs to be asked and answered during the TPP process

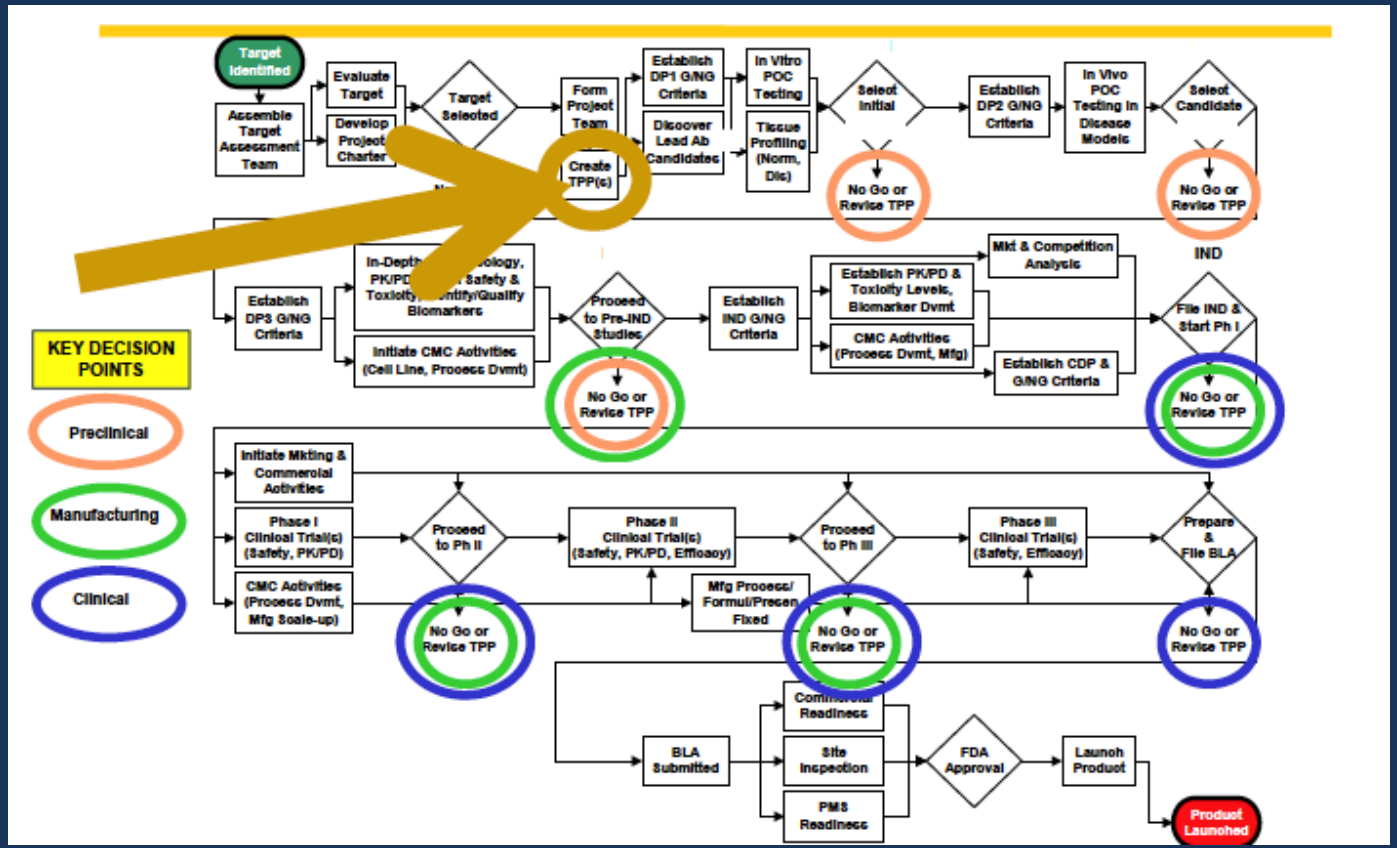
- What is the product description?
- What data or literature is available for review for the various indications and claims?
- What is the unmet need, clinical benefit or value to others?
- Will the product be used for a new or existing procedure?
- What is the standard of care (SOC) for this indication?
- What is the future direction of SOC?
- What is the market potential for each indication and claim?
- What is the probability of success for each indication and claim?
- What are the product's possible differentiating features and will they be obsolete in 5 years?
- What are all of the possible indications for this product (neurovascular, pulmonary, peripheral vascular, gastrointestinal, etc.)?
- What are all of the possible differentiating claims?
- Can premium pricing be justified?
- If so, will payors directly reimburse?
- How is the competitor successful?
- Where does the competition fall short?
- Does IP exist or can it be created?
- Can exclusivity be achieved with a more complex regulatory or clinical strategy?
- If so, what is the company's tolerance or resource availability for such complexity?
- What are the COGS?
- How do development costs compare against five-year return on investment (ROI)?
- How does the net present value (NPV) or ROI compare against other projects?

Source: Begin with End in Mind – White Paper Premier Research, 2015

Portfolio Optimization – Go/No Go

- Specification – TPP – Current, Minimal, Ideal & Expected
- Resources – Manpower and Cost
- Timeline – Milestone Schedule
- Risk – Probability of Success (Technical, Commercial)

TPP in Go/No Go Decisions



TPP Criteria

	Current	Minimum	Ideal	Expected
Efficacy One	52%	33%	75%	60%
Efficacy Two	80%	75%	95%	84%
Safety One	67%	60%	85%	82%
Safety Two	45%	50%	30%	35%
Convenience	25%	20%	40%	30%
Cost	$XXXXX	$YYYYY	$ZZZZZ	$AAAAA

Sample TPP

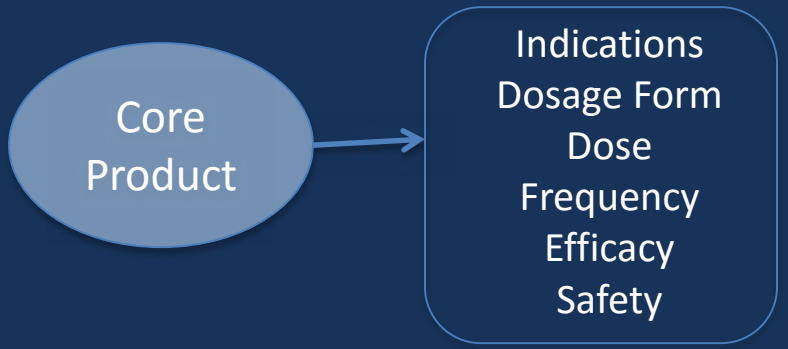
Product Properties	Minimum Acceptable Result	Ideal Result
Primary Indication	Relief of pain symptoms in diabetic neuropathy	Relief of symptoms in neuropathic pain syndromes
Patient Population	Adults with diabetes who experience neuropathic pain	Adults and children with neuropathic pain
Treatment Duration	Chronic	Chronic
Delivery Mode	Oral	Oral
Dosage Form	Tablet or capsule	Tablet or capsule
Regimen	1–2x/day	1x/day
Efficacy	A 40% decrease in pain score in 30% of patients	A 70% decrease in pain score in 50% of patients.
Risks/Side Effects	Devoid of opioid side effects Devoid of GI side effects from Non-steroidal anti-inflammatory drugs (NSAIDs) Minor or moderate CNS side effects	Devoid of opioid side effects Devoid of GI side effect from NSAIDs No CNS side effects

Source: https://neurosciencebluepr int.nih.gov/resources/target-product-profile.htm, accessed June 14, 2017

Best Development Strategies…

- Use the strategic framework (TMP, STP) to shape TPP and define clinical and commercial value
- TPP provides developmental logic and saves cost to drug discovery and development program and meet the needs of the market place
- Encourages right dialog within the company and with the FDA to optimize label and promotability for commercial success
- The ideal development strategy identify key milestones -critical times, when the ability of a project to attain its TPP can be assessed - and establish “go / no go” success criteria

Marketing Create “Beyond the Pill” Solution



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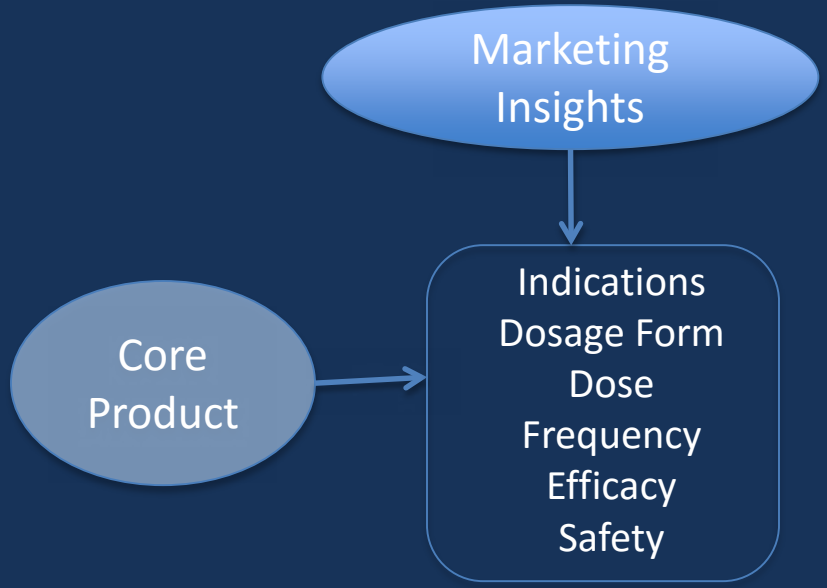
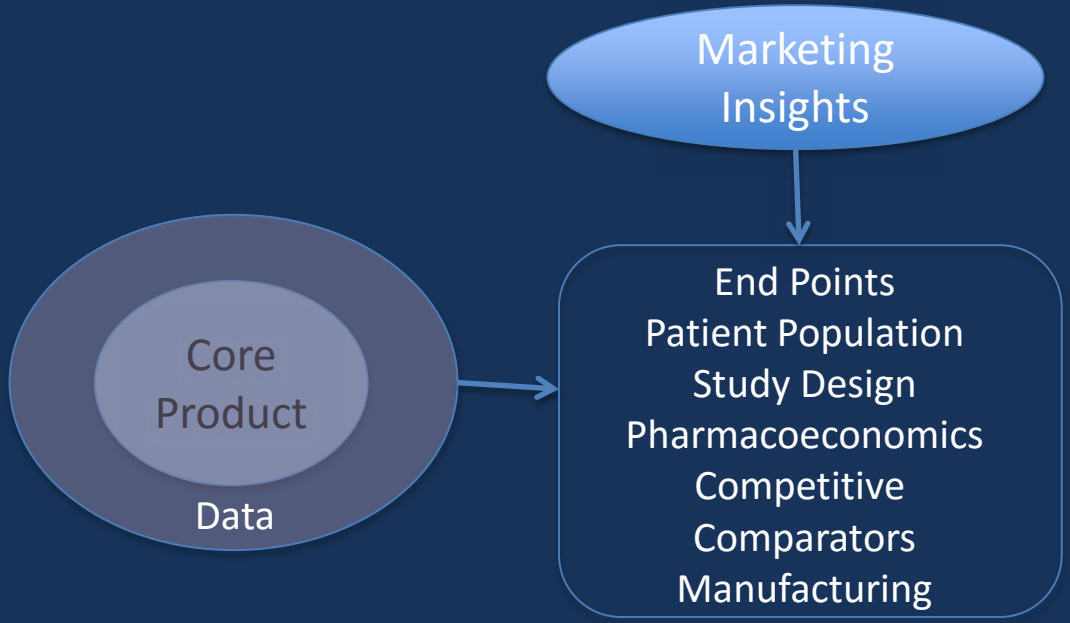


Marketing should shape the “Label” for the product

Marketing Create “Beyond the Pill” Solution



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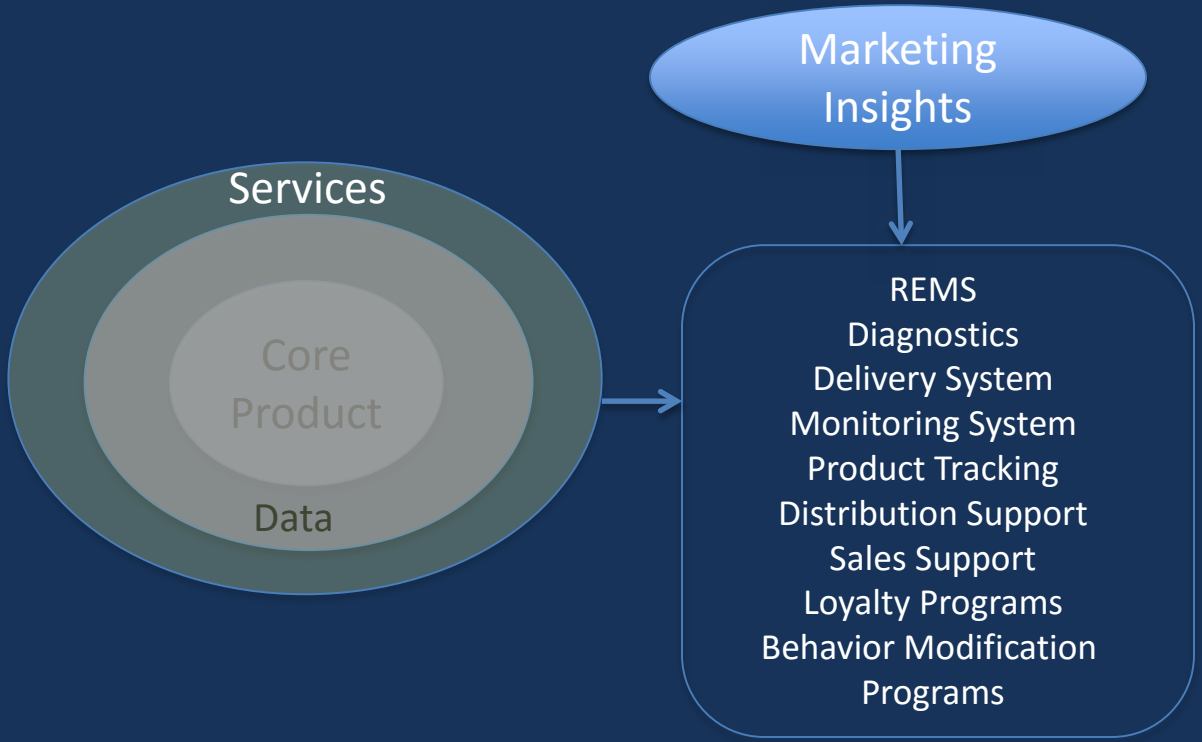

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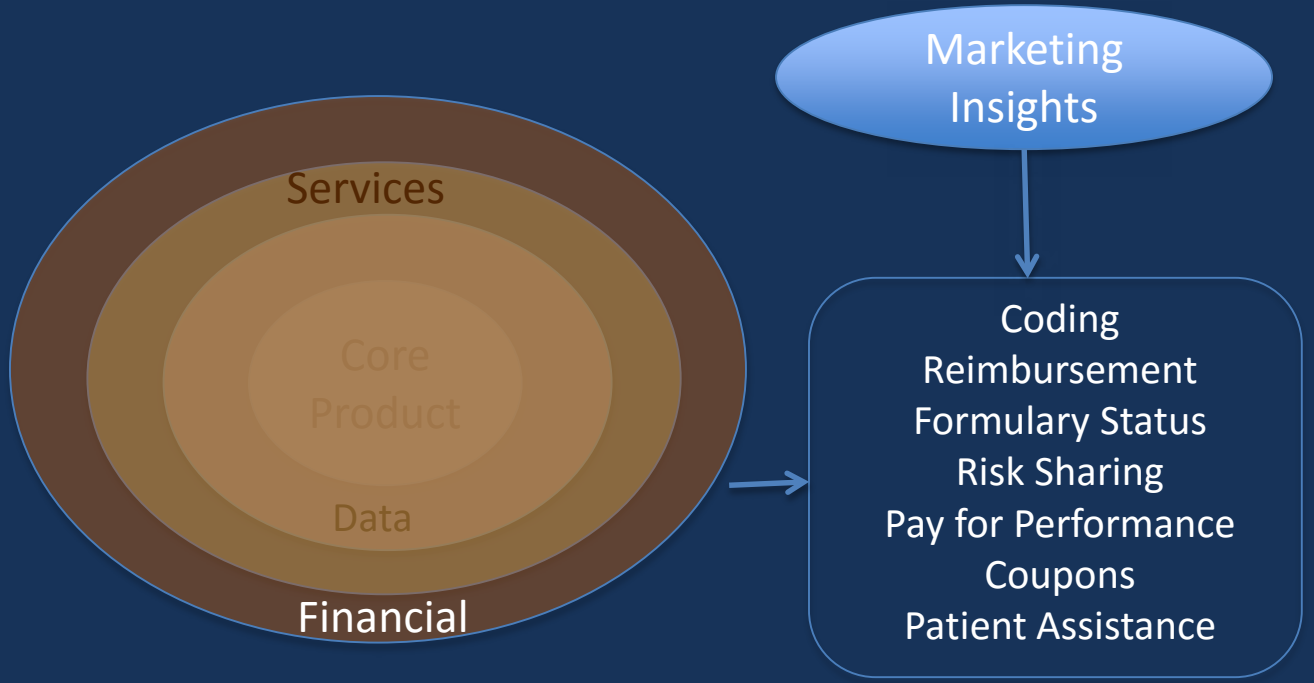

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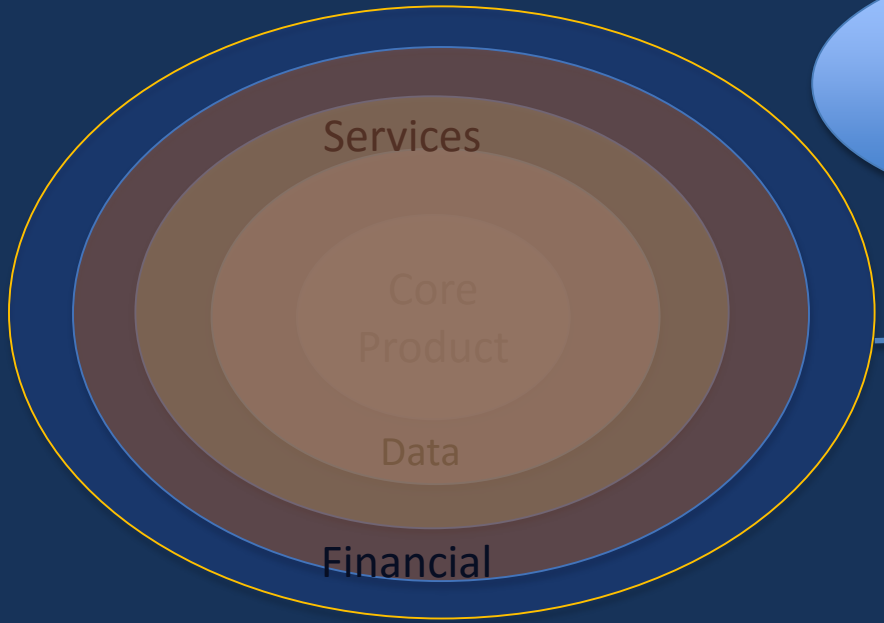

Marketing Insights to Manage Trust and Perceived Value

→ Perceived Value

Final Remarks

- Start with end in mind
- Strengthen the R&D Marketing (Commercial) interface
- Assemble cross functional commercial development team
- Assign a marketing manager to the development team
- Incorporate market research and competitive intelligence in clinical trial planning and label development
- Engage payers early on to get valuable input in development
- Success is when the final version of TPP is similar to the annotated draft labeling!

Questions?