Examine the Pitfalls of Managing Promotion Throughout Product Lifecycle

Katie M. Graham, PharmD, MS
Assistant Professor
Dept of Regulatory & Quality Sciences
USC School of Pharmacy

► Fierce Pharma PRC West Sept 2022

Christine H. Smith, PharmD

Senior Director

Global Regulatory Affairs

Aurinia Pharmaceuticals Inc.



Disclaimer

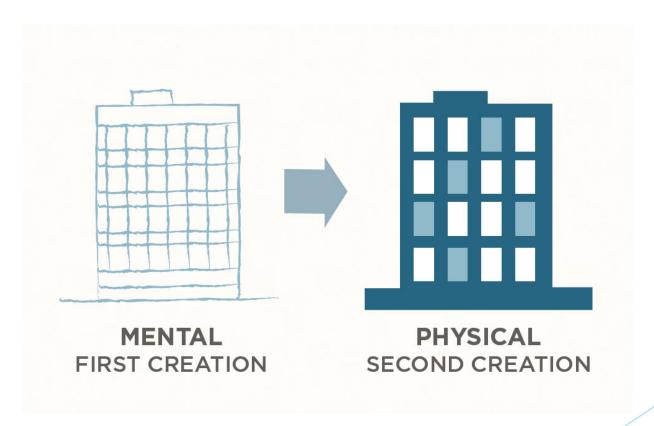
Thanks to Fierce Pharma for the opportunity to speak today

The views expressed here are our personal views and do not reflect the institutions we represent

Agenda

- Describe considerations for commercialization preparation during product development
- Discuss changing strategic marketing direction with product lifecycle evolution
- Review the challenges and opportunities in reviving an old brand with remaining patent life

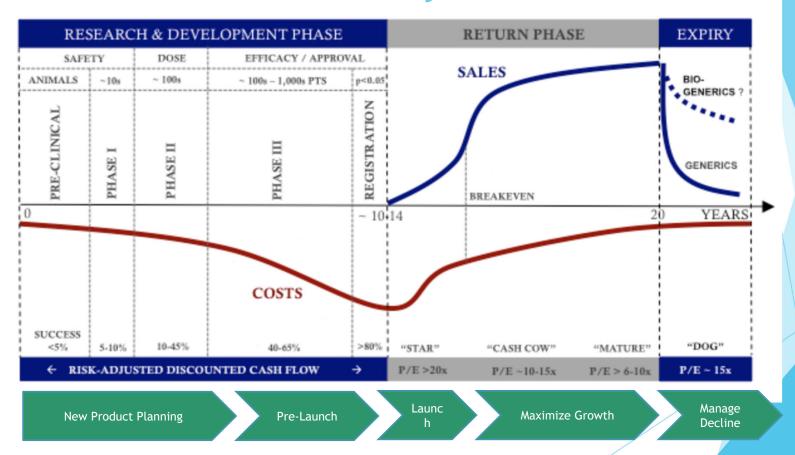
Begin with the end in mind



https://www.franklincovey.com/the-7-habits/habit-

2.html#:~:text=Begin%20with%20the%20End%20in%20Mind%20means%20to%20begin%20each,develop%20a%20Personal%20Mission%20Statement.

Product Lifecycle



Types of Materials Evaluated by Review Team During Development

Clinical Study Recruitment Materials

Medical Affairs Materials

Labeling Content

Disease Awareness

Container Packaging/Samples

Promotional Press Releases

Payor Content/

Government Pricing



Considerations between Large and Small Pharma **Companies**

Responsibilities

Headcount

Budget

Processes

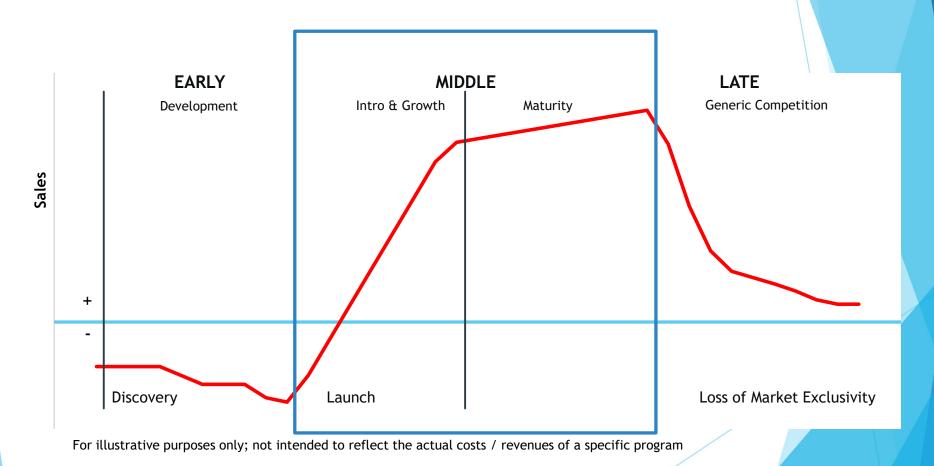
Infrastructure/Efficiencies

Internal vs Contracted thirdparties

Profits



Typical Lifespan of a Therapeutic Drug





THE GROWTH SHARE MATRIX RELATIVE MARKET SHARE **CASH GENERATION** LOW HIGH MARKET GROWTH RATE CASH USAGE HGH LOW ESSENTIAL MARKETING MODELS HTTP://BIT.LY/SMARTMODELS

Types of Materials Evaluated by Review Team During Commercialization

Promotional Materials

Speaker Materials Corporate Materials

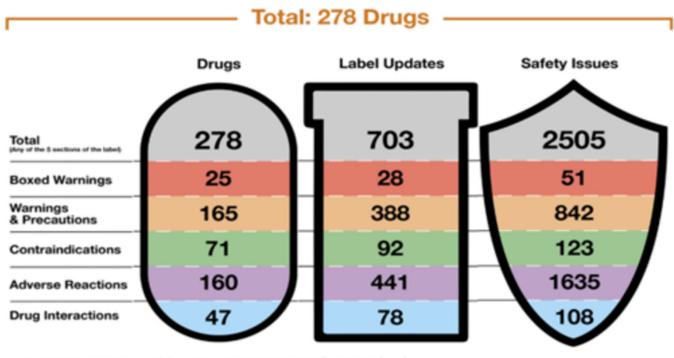
Advocacy Materials

Sample Program QA/Customer Complaints

Safety and PV

Label Changes



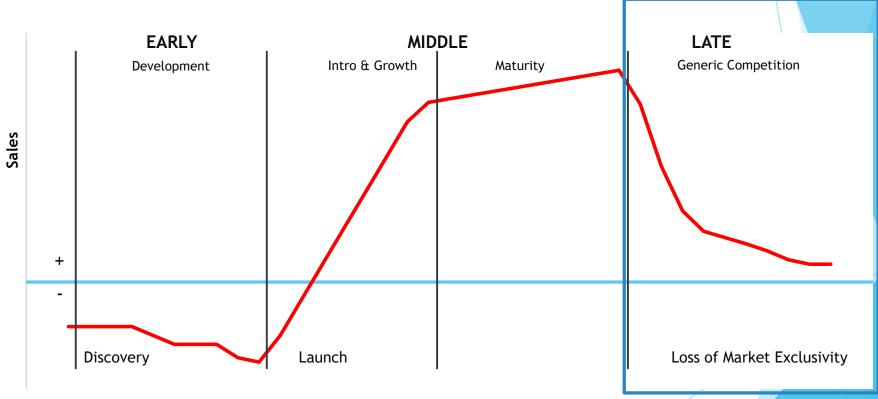


Source: Pinnow et al. Clin Pharmocol Ther 2017 Dec 20 doi: 10.1002/cpt.994 [Epub ahead of print]

278 new molecular entities were approved by CDER between 2002 and 2014. These drugs were followed over time to evaluate safety label changes

https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-tracking-andacting-safety-data-throughout-drugs-lifecycle

Typical Lifespan of a Therapeutic Drug



For illustrative purposes only; not intended to reflect the actual costs $\ / \$ revenues of a specific program

Late-Stage Marketing

Focus is on newer company product(s)

Stay the course

Generic competition starts

Branded Generic



Late-Stage Marketing Direction

Strategic Late-Stage Marketing Direction

Refresh campaigns

Keep what's Working

Drop what isn't working

Maintain existing patient base

Narrow target audience

Refocus spend

Questions?

