

**Biotech/Pharmaceutical Commercialization & Business Development Strategies**

**EMBA Course: Summer 2020**

**Schedule: A Term**

# Faculty

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***Guest Speaker (Session 1/3/6): Paul Clancy ’87, EVP/senior advisor, Alexion; former EVP and CFO, Biogen.***

**Course Description**

This cross-functional course focuses on ‘real-world’ issues for commercializing pharmaceutical drugs and building market leading therapeutic franchises in a rapidly changing and complex global business environment. This course will highlight the influential role external stakeholders (governments, regulators, payers, purchasing organizations, hospitals, physicians, pharmacies, patients, care givers and advocacy groups) and internal functions (early/late stage development, data management, manufacturing, medical affairs, market access and commercial teams) play along a brand’s lifecycle, driving commercial success. Importantly, it will review external growth strategies (acquisitions, JVs, licensing) that biopharma companies aggressively pursue to strengthen business growth objectives.

Key topics to be explored include:

* Market dynamics, competitive strategies, clinical practices, regulatory issues, market access challenges and lifecycle planning
* Internal and external stakeholders who influence the commercialization of the brand
* Brand strategy plans, brand forecasts, inputs into strategic clinical development options and communications strategies
* Strategies for pricing, market access and reimbursement in multiple geographies
* Financial characteristics of the industry (margins, growth rates, valuations, share price performance)
* Business development strategies and practices (M&A, JVs/partnering, licensing)

**Student Focus**

Students who are interested in gaining insight into this increasingly complex market environment, and desire to learn how to navigate the influencers and set the stage for commercialization of pharmaceuticals, & business development strategies will benefit from the curriculum. This course will assist students interested in careers in pharmaceuticals, biotechnology, and healthcare, as well as management consulting and the financial industry, given the large and growing pharmaceutical practices of such firms. Previous or current knowledge of the industry is highly recommended.

**Methods and Materials**

All readings and cases are provided by links in Canvas.  Some readings are meant as reference material and others are listed as “required readings” (please see course topics). Additional readings will be posted on Canvas as needed.

# Deliverables

Learning is driven through readings, class discussion and a series of guest speakers representing a wide range of global commercialization issues. Evaluation for course grades is based on class discussion, reading comprehension, case study reports and a group project.

* Class Participation 15%
* Individual Case Write-Up (EpiPen) 15%
* Team Case Write-Up (Gilead) 30%
* Team Project Presentation 40%

**Class Participation & Reading Comprehension**

This class promises to be intellectually stimulating and challenging. We highly value class participation and will constantly seek to directly apply the information and ideas discussed in the classroom to issues currently confronting Big Pharma. Each session, students are expected to review the required readings and come to class prepared to discuss and demonstrate the readings and cases. Class participation will be based on attendance using a sign-in sheet, as well as the extent and quality of contributions to class discussions. For those not as comfortable with speaking out in class, you can also contribute by sending relevant newspaper or other articles and/or communicating ideas and thoughts with the class using Canvas.

**Case Write-Ups. EpiPen case is an individual write-up. Gilead case is a team assignment – students should form teams (of 3 or 4 members) on the first day of class.** The EpiPen case is due prior to the second course session. The Gilead case is due prior to the fourth course session. Submit a written report that contains an *executive summary* and *analysis* not exceeding a total of four pages that describe *the recommendations* and *rationale* for those recommendations. Use the discussion questions as a guide in developing your recommendations. **The case write-ups are due on Canvas prior to class on the day of the case session.**

**Team Project (Written Presentation)**

Each team will be given a separate pharmaceutical brand (identified by Professors & Team) and develop a written “annual” brand plan presentation, theoretically to be delivered to Senior Executives from Pharma Companies. Students will develop their competencies in the analytic and systematic use of pharmaceutical commercialization concepts and methods to develop commercialization (re)launch plan for a brand. **The presentation is due on Canvas prior to the sixth (final) course session and will be presented in class.**

**Guest Speakers**

Prominent guest speakers from the pharmaceutical and biotechnology industry will provide additional real-world insight on key industry challenges, trends and experiences.

**Classroom Norms and Expectations**

Lectures, guest speakers, and class discussions are the major vehicles for learning the material. Therefore, it is imperative that **you attend all classes, arrive on time, and give speakers and your fellow classmates your full attention.** If you cannot attend a specific class or would arrive late or leave early, let the instructors know in **advance** by email. Please refrain from using electronic devices in class.

# Class Schedule and Topics

**Session 1: Industry Overview**

* Course Introduction & Professor/Student Introductions

**Biopharmaceutical Industry Overview**

* Structure of the industry (size, business mix, type of companies, geographic trends)
* R&D focus (diseases/unmet need, key therapeutic categories, small molecules vs. biologics, clinical and regulatory process, R&D spend as % of sales and vs. sales & marketing spend).
* Summary overview of commercialization strategies and challenges (goals of pharma marketing, sales force utilization, drug pricing & reimbursement/market access, etc.)
* Financial summary: industry sales and EPS growth rates, profitability/margins, valuation/PE
* How M&A has reshaped the industry over the past decade

# The Big Debate: The Cost of Medicine and the Value it Provides

* Costs of developing medicine
* Relative costs of medicines & Value of medicine

# Review of assignments, due dates, expectations & team assignments

***Guest Speaker: Paul Clancy ’87, EVP/senior advisor, Alexion; former EVP and CFO, Biogen.***

# Required Readings:

* Session 1 Pre-Read Deck
* IQVIA Report: The Global Use of Medicine in 2019 and Outlook to 2023

# Session 2: Evolving Customers, Drug Commercialization, Pharma Marketing & Culture

**Customer Expectations**

* New business customer
  + Implications on B2B – the power shift
  + The value driven proposition.
* New healthcare consumer
  + Reputation matters
  + Snowball of change

**Essentials of Commercialization**

* Environment: intellectual property regime and established ownership over complementary assets such as manufacturing expertise or distribution channels
* Scientific innovation and its significance in drug commercialization

**Pharma Marketing**

* Accountabilities of marketing
  + P&L and cost centers
  + Differences between pharma marketing and consumer goods marketing
* Marketing constraints
  + Ethical considerations & public-policy scrutiny
  + Promotional regulations and impact

**Is culture the culprit in pharmaceutical companies?**

* Understanding the rationale and differences, as well as the strengths and weaknesses of three different cultures in the pharma industry

**Case Review**: EpiPen

# Required Readings:

* Session 2 Pre-Read Deck
* EpiPen Case

# EpiPen Case Write-Up Due (Individual; due on Canvas before class)

# Session 3: Building a Strategic Plan & Launch Strategies

**Developing a Brand Strategic Plan:**

* What is a strategic choice and how does it apply to the marketing of pharmaceuticals? What are the brand realization drivers? Where to play?
* SWOT analysis

**Creating actionable insights - the driver of competitive differentiation**

* *Patient Flow*: quantifying market potential by analyzing patient population dynamics
* *Patient Journey*: gaining insight from the patient’s interaction with his/her environment

**Launch Strategies**

# Archetypes

# How launches perform against expectations

**Specialty Categories: Multiple Sclerosis, Oncology & Rare Diseases**

* Understanding the disease and unmet need
* Unique clinical, regulatory, commercialization, pricing & access issues
* Evolution of therapeutic agents: Pipeline Compounds / new mechanisms of action in development and their potential impact on the category
* Impact of existing/future generics and biosimilars
* Commercial review of leading MS drug *Tecfidera* 
  + Launch strategy & positioning against standard of care
  + How did it defend against new competition in terms of pricing/market access/PBM strategies?
  + Lessons learned in the withdrawal and subsequent reintroduction of Biogen’s other MS drug *Tysabri,* including use of risk management plan
* Commercial review of the launch of Oncology drug Gleevec
  + How to translate innovative science into transformational therapeutic?
* What is an orphan drug?
  + Commercial review of Alexion’s *Soliris* (marketing strategy, how was the initial price set? reaction from payers/PBMs, innovative pricing models for these high-priced therapies)

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# Required Readings:

* IQVIA Supporting the Patient Journey infographic
* IMS White Paper: Patient Journey

**Session 4: Market Access and Pricing**

**Marketing & Market Access**

* Strategies for pricing, market access and reimbursement in multiple geographies & therapeutic categories
* Best-practice in developing a market access plan and the role of marketing therein

**Distribution Chain**

* Understanding how the supply chain works: role of Pharmacy Benefit Managers (PBM), wholesalers, retail pharmacies
* Site of care (hospitals, physician offices, outpatient) – benefits and conflicts

**Patient Access & Affordability**

* Payer mix and influence over price (government, private, direct pay)
* Programs, initiatives and start-ups helping patients access medicines

# Case Review:

* HBS Case Collection | July 2016 – Gilead: Hepatitis C Access Strategy by V. Kasturi Rangan, Vikram Rangan and David Bloom

***Guest Speaker: TBD***

# Required Readings:

* Gilead Case
* KPMG Report: pricing-for-survival

# Gilead Case Write-Up Due (Team Assignment; due on Canvas before class)

**Session 5: Commercialization Success - How cross-functional teams impact commercialization?**

Companies are usually organized in multiple customer-facing and/or functional silos and in a world where these organizational functions have converged, how is commercialization best managed? How internal stakeholders influence commercialization?

# Marketing Input into R&D

# How Unmet Medical Need and Disease Market Attractivenesshelp prioritizing areas of R&D and drive R&D strategic decisions

# Establishing the Target Product Profilebased on competitive landscape analysis

# Marketing-Medical Interface

* The impact of the migration of clinical data dissemination from the marketing to medical function
* Role of Medical Affairs: offer new value-added patient-centric services for customers

# Marketing-Digital

* How technology is impacting all areas of commercialization
* Digital therapeutics and the future

***Guest Speaker: TBD***

**Topic:** Pharmaceutical Advertising

# Required Reading:

* IQVIA Report on R&D - April 2019
* Medical-affairs-key-imperatives-article

**Session 6 –Economic Implications for Commercialization**

Each stakeholder has different interests and interacts in different ways, at different points of the value chain, with diverse motivations. Understanding the collective impact of the interplays across these differences is essential for the commercial success of a brand.

**Financial Characteristics of Biopharma Industry**

* Geographic distribution by sales, margin analysis, sales and EPS growth, market values of leading companies, stock price performance/PEs against market indices

**Business Development Strategies**

* Large acquisitions
* Targeted "bolt-on" acquisitions
* Partnerships - combination therapies and licensing deals
* Valuation methodologies used by biopharma companies when acquiring individual compounds/products, and early-stage “biotech” companies

**Internal Profit Levers**

* Multiple decision makers, often with competing economic interests
* R&D Efficiency: Past-Present-Future
* Expense evaluation, cost cutting, extension of the period of market exclusivity and real-world evidence

**External Profit Levers**

* US - GTN – impact on net revenue & profitability
* Patient Assistance Programs & Co-pay Card

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# Brand Plan Presentations

**Final Project Due (Team Assignment; due on Canvas before class)**