MGMT B8536-001:
Biotech/Pharmaceutical Commercialization & Business Development Strategies
Spring 2020 (B-Term); Tues/Thurs, 10:45am to 12:15pm, Online

Faculty
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Course Description
This cross-functional online course that 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 and a series of guest speakers representing a wide range of global commercialization issues. Evaluation for course grades is based on the following:

- Joining Online Class & Participation 25%
- Case Write-Up (Gilead) 25%
- Final Paper 50%

Joining Online Class & Participation
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 to issues currently confronting Big Pharma. Each session, students are expected to review the required readings and join class prepared to discuss and demonstrate the readings and cases. Class participation will be based on attendance, as well as the extent and quality of contributions to class participation.

Case Write-Up
The Gilead case is a team assignment – students should form teams (of 5 members or less) during first week of class. The Gilead case is due prior to the 6th course session on April 9, 2020. 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 session.

Final Paper
There will be a final paper (3-5 pages, excluding exhibits) on topics reviewed in class during the course. The final will be posted on or about April 16th and be due May 4th.

Final Grade Distributions
Grade distribution will be consistent with School guidelines for electives (i.e., no more than 50% of grades in “H” category; 5-10% in “P” category).
Guest Speakers
Prominent guest speakers from the pharmaceutical and biotechnology industry will provide additional real-world insight on key industry challenges, trends and experiences.

Norms and Expectations
Lectures and guest speakers are the major vehicles for learning the material. Therefore, it is imperative that you join all classes and give speakers your full attention. If you cannot join a specific class or would join late or leave early, let the instructors or TA know in advance by email.

Class Schedule and Topics

Session 1 - March 24, 2020: Industry Overview
Course Introduction & Professor/Student Introductions
Review of assignments, due dates, expectations

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

Required Readings:
• Session 1 Pre-Read Deck

Session 2 - March 26, 2020: Value of Medicine and Evolving Customers
The Big Debate: The Cost of Medicine and the Value it Provides
• Costs of developing medicine
• Relative costs of medicines & Value of medicine

Customer Expectations
• New business customer
  o Implications on B2B – the power shift
  o The value driven proposition.
• New healthcare consumer
  o Reputation matters
  o 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

Required Readings:

- Session 2 Pre-Read Deck
- IQVIA Report: The Global Use of Medicine in 2019 and Outlook to 2023

Session 3 - March 31, 2020: Pharma Marketing & Culture

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:

- EpiPen Case

Session 4 – April 2, 2020: Building a Strategic Plan

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
- Forecasting
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

**Required Readings:**
- IQVIA Report: Talking the Patients’ Language

**Guest Speaker:** Thomas A. Bock, MD, MBA ’06 - Founder and past CEO of HeritX; Chair of the Columbia Business School Healthcare Advisory Board; and former Senior Vice President, Global Head of Medical Affairs at Alexion Pharmaceuticals.

Session 5 – April 7, 2020: Market Access and Pricing (part 1)

**Supply Chain Structure and Dynamics**
- 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

**Reimbursement & Cost Containment**
- Payer mix and influence over price (government, private, direct pay)
- Patient Assistance Programs & Co-pay Card
- Start-ups helping patients access medicines

**Required Readings:**
- WSJ Drug Pricing Video
- KPMG Report: pricing-for-survival
- The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians

**Guest Speaker:** Yin Ho, MD, MBA – Chief Product Officer, Aetion

Session 6 – April 9, 2020: Market Access and Pricing (part 2)

**Global 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

**Case Review:**
Guest Speaker: It’s a surprise!

Required Readings:
- Gilead Case - Team write-up due on Canvas by 8 am on April 9th

Session 7 – April 14, 2020: Launching a Blockbuster
Launch Strategies
- Archetypes
- How launches perform against expectations

Commercial review of the launch of Oncology drug Gleevec
- How to translate innovative science into transformational therapeutic?

Required Readings:
- Session 7 Pre-Read Deck

Session 8 – April 16, 2020: Vaccine Development
- Understanding the diseases that require vaccines and unmet need
- Unique clinical, regulatory, commercialization, pricing & access issues
- Public perception vs reality
- COVID-19

Guest Speaker: TBD

Session 9 – April 21, 2020: Commercialization Success - How cross-functional teams impact commercialization? (part 1)
Marketing Input into R&D
- How Unmet Medical Need and Disease Market Attractiveness help prioritizing areas of R&D and drive R&D strategic decisions
- Establishing the Target Product Profile based 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
Required Reading:
  - IQVIA Report on R&D - April 2019
  - Medical-affairs-key-imperatives-article

Session 10 – April 23, 2020: Commercialization Success - How cross-functional teams impact commercialization? (part 2)

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

External Ecosystem
The external ecosystem – how to work together
  - Agencies / Promotional Communications / Market Research / Public Relations

Guest Speaker: TBD

Session 11 – April 28, 2020: Economic Implications for Commercialization (part 1)

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

Guest Speaker: Paul Clancy ’87, former CFO, Alexion; former EVP and CFO, Biogen

Session 12 – April 30, 2020: Economic Implications for Commercialization (part 2)
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.

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 Cards