Course Description
This cross-functional course focuses on ‘real-world’ issues for commercializing pharmaceutical drugs 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 development, late stage development, data management, manufacturing, medical affairs, market access and commercial teams) play along a brand’s lifecycle, driving commercial success.

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

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, 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 report and a group project.

- Class Participation 15%
- Reading Comprehension 15%
- Case Write-up (Metabical) 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 (surprise quizzes) 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 – Students should form teams (of 4 members or less) on the first day of the class. Case will be a Team Assignment. The Metabical case write-up is due prior to the third session of the course. The team will submit a written report that contains an executive summary and analysis not exceeding a total of four pages that describe the team's recommendations and rationale for those recommendations. Use the discussion questions as a guide in developing your recommendations. The case write-ups are due on line prior to class on the day of the case session.

Team Project (Written Presentation)
Each team will be given a pharmaceutical brand (identified by Professor) 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.

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 & the Evolving Customers

- Course Introduction & Professor/Student Introductions

Biopharmaceutical Industry Overview

- Key market dynamics
  - Size and projections of the pharmaceutical industry
  - Revenue and geographic trends
  - Where is Pharma focusing and why?
  - R&D spend vs. advertising to healthcare professionals & consumer
  - Competitive strategies, clinical practices, regulatory issues and access challenges in key pharmaceutical markets

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

- Costs of developing medicine
- Relative costs of meds
- Value of medicine

Customer Expectations

- New business customer
  - Implications on B2B – the power shift
  - The value driven proposition.

- New healthcare consumer
  - Reputation matters
  - Snowball of change
  - Liquid expectations
  - Technology is the emperor of change

Review of assignments, due dates, expectations & team assignments

Required Readings:

- Session 1 Pre-Read deck
- IQVIA Report: The Global Use of Medicine in 2019 and Outlook to 2023
Session 2: Drug Commercialization, Pharma Marketing & Culture

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
- Strategy Framework: benefits and costs of alternative strategies for securing profits and competitive advantage through innovation

Pharma Marketing
- Accountabilities of marketing
  - P&L and cost centers
  - Differences between pharma marketing and consumer goods marketing
  - The four “old” 4 “P’s” & the four “new P’s” & the four “new A’s”
- Pharmaceutical 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:
  - Sales Driven
  - Product Innovation
  - Market-led

Case Review: EpiPen

Required Readings:
- Session 2 Pre-Read deck
- EpiPen case
Session 3: Building a Strategic Plan & Big Data

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? The SWOT analysis
- How do you get customer information?
- Segmentation / Positioning / Marketing Mix / ROI trap
- How to forecast sales?

Case Review:
- HBS Case Collection | July 2010 - Metabical: Positioning and Communications Strategy for a New Weight Loss Drug by John A. Quelch and Heather Beckham

Big Data in Pharma – Guest speaker

Required Readings:
- Metabical Case

Metabical Case write up due (Team Assignment)
Session 4: Launch Strategies for Commercialization Success & Stakeholders

Launch Strategies
- Archetypes
- Guiding Principles & Recipe
- How launches perform against expectations

Creating actionable insights - the driver of competitive differentiation
- *Patient Flow*: quantifying a brand’s market potential by analyzing patient population data & dynamics
- *Patient Journey*: gaining insight from the patient’s interaction with his/her environment

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?

Internal ecosystem: How internal stakeholders influence commercialization?

External ecosystem: How to work together with external partners?
- Competitive Intelligence
- Contract Research Organization
- AOR - Digital
- Promotional & Medical Coms (and the difference between the two)
- Market Research
- Public Relations / Investor Relations

Guest Speaker:

Required Reading:
- IQVIA Supporting the Patient Journey infographic
- IMS White Paper: Patient Journey
Session 5: How cross-functional teams impact commercialization?

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 the medical function
- Role of Medical Affairs: offer new value-added patient-centric services for customers

Marketing & Market Access
- Strategies for pricing, market access and reimbursement in multiple geographies
- Best-practice in developing a market access plan and the role of marketing therein
- Understanding how the supply chain plays a role in access to medicines

Market Access and Pricing
Guest Speaker:

Required Readings:
- Medical-affairs-key-imperatives-article
- KPMG Report: pricing-for-survival
Session 6 – December 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.

**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
- Global practices

**Guest Speaker:**

**Final Project Due**