

Draft: 10/21/22

MGMT B8536-001: Strategy and Competition in Pharmaceuticals and Biotechnology

Spring 2023 (B-Term); Tues./Thurs. 10:20am to 11:50am; [Geffen 520]

Professors: **Cliff Cramer**

Robert Essner

Email: cc2663@gsb.columbia.edu Robert.a.essner@gmail.com

CA:

Course Overview

This course examines the strategic, technological, competitive, economic, organizational, and political challenges impacting the pharmaceutical and biotechnology industry. Critical issues to be examined include:

- R&D - process of discovering, developing, and the approval of new drugs and biologics;
- Regulatory environment and IP/patents; generics and “biosimilars”;
- Pharma sales and marketing objectives and practices;
- Review of global launch and competitive market dynamics of new biopharmaceuticals – U.S. and international markets;
- Review of oncology category, and orphan drugs;
- Drug pricing and third-party reimbursement, including design of prescription drug plans and PBMs/contracting;
- Creating, managing, and investing in early/commercial-stage biopharma companies;
- Vaccines – development, regulatory, manufacturing, distribution, value/pricing;
- Health/drug policy and proposed reform initiatives impacting the sector;
- Financial characteristics, valuation, M&A, partnering in the biopharma sector.

The course is cross-functional in its approach, focuses on “real-world” problems currently facing senior managers in this sector, and identifies emerging trends that will materially impact future performance of “Big Pharma” companies, as well as specialty pharmaceutical and smaller biotechnology firms. This course will be useful for students interested in careers in pharmaceuticals, biotechnology, and health services, as well as management consulting, investment banking, equity research, venture capital, private equity, and investment management given the large and growing healthcare/ life sciences practices of such firms.

Connection to the Core

The learning in this course will utilize, build on and extend concepts covered in the following core courses:

Core Course	Connection with Core
Corporate Finance	1. Risk 2. Firm Valuation Model
Business Analytics	1. Modeling and Managerial Decision Making
Managerial Economics	1. Analyzing Complex Decision-making Under Uncertainty
Marketing Strategy	1. Company Analysis 2. Competitive Analysis
Strategy Formulation	1. Strategic Interaction Analysis 2. Diversification and Scope 3. Competing Firms 4. Global Strategy

Format, Approach

We will constantly seek to directly apply the information and ideas discussed in the classroom to issues currently confronting senior managers in this sector. We will pursue these critical issues in considerable depth. **Some understanding of, and/or experience in, the healthcare/pharma sector will be highly useful to understand course content and preparing writing assignments.** Prominent guest speakers from the pharmaceutical and biotechnology industry will provide additional real-world insight on key industry challenges and trends.

Materials, Classroom, Ground Rules

Certain readings will be posted on Canvas. Classroom norms will be discussed in the first class session. If you cannot attend a specific class let Prof. Cramer and the CA know in advance by email.

Method of Evaluation

Class Participation (20%): Students are expected to attend and participate in the class sessions. Students should reach out to the instructor or CA regarding excused absences (for religious observances; personal, medical, and family emergencies; military service; court appearances such as jury duty). Multiple unexcused absences will have a negative impact on a student's final grade, per School guidelines.

Writing Assignment (30%): For a mid-term writing assignment, students will be given a case study or series of questions for their written analysis and recommendations (3-4 page paper, excluding exhibits). This assignment will be due before class on Apr. 13th.

Final Paper (50%): 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 Apr. 13th, and be due May 4th.

Final grade distributions will be consistent with School guidelines for electives (i.e., no more than 50% of grades in “H” category; no less than 5% in “LP/P” category).

Class Schedule and Topics (tentative)

The following is the schedule of topics (**note: specific dates, topics and speakers may vary depending on schedules/availability**). See course web-site on Canvas for required and supplemental readings and information sources.

March 21st Course Introduction and Industry Overview

- Course objectives, syllabus, readings, exams/grading.
- Intro to the pharma industry - historical perspective; where pharma fits within the overall healthcare ecosystem.
- Current state of the pharma industry (“two factors collide”, working with FDA, changing focus of R&D, commercialization strategies, Rx pricing pressures, emerging markets).

March 23rd Regulatory Environment, Patents, Generics, Biosimilars

- Forces shaping the environment (key players and issues)
 - Players: FDA, CMS, OIG, DOJ, States, etc.
 - Issues: safety, pricing, marketing practices, etc.
- Patents on pharmaceuticals and biologics
- Hatch-Waxman (generics); “biosimilars”.
- Orphan Drugs – regulation, pricing, and marketing

March 28th Financial Characteristics of Pharma Companies; Business Mix; M&A Trends; Preview Midterm Assignment

- Industry margins, growth rates, valuations, PEs, relative share price performance.
- Business mix/ diversification strategies.
- Overview of M&A, licensing, and financing trends.
- Preview midterm assignment.

March 30th Pharma R&D and Drug Approval Process – Interactions with FDA

- Research/discovery and clinical development process, strategies, cost structure.
- Review of regulatory environment and drug approval process – U.S. and selected int’l markets.
- Strategies re: working with the FDA in the current environment.
- The future of pharmaceutical R&D.
- ***Guest speaker: Robert Ruffolo PhD, former president of R&D, Wyeth Pharmaceuticals (acquired by Pfizer).***

- April 4th** **Commercial Organization, Role of Marketing, Global Launches**
- Structure of a commercial organization in a global pharma company.
 - Focus/role of marketing during product life cycle.
 - Who pays for drugs, and how are drug prices set (US, other markets).
 - Market access – pricing/reimbursement strategies.
 - Global launch strategies – case study: [product TBD]
 - **Guest speaker:** *Alan Bash '99, former SVP Commercial, Bristol Myers Squibb and CEO, Checkmate Pharmaceuticals*
- Apr. 6th** **PBMs/Formulary Management**
- Role of Pharmaceutical Benefit Managers (PBMs); design of prescription drug plans; formulary management; utilization tools, data analytics, etc.
 - Evidenced-based payer value propositions; performance-based pricing and other risk-sharing arrangements.
 - **Guest speaker:** *PBM executive from Optum Rx, CVS Health, or Express Scripts*
- April 11th** **Category Review: Oncology**
- Understanding the disease category, evolution of therapeutic agents, clinical development/regulatory, competitive landscape, pricing & reimbursement, personalized medicine/ use of biomarkers, immuno-oncology therapies, CAR-Ts, etc.
 - **Guest speaker:** *Herve Hoppenot, Chairman & CEO, Incyte Corp.; former CEO, Novartis Oncology*
- April 13th** **Mid-Course Review/ Q&A; Preview Final Assignment**
- April 18th** **Vaccines – R&D, Regulatory, Mfg., Distribution, Value/Pricing**
- Nature and brief history of vaccines, and impact on public health.
 - Unique development, regulatory, manufacturing and distribution issues.
 - Change in the vaccine value proposition.
 - Challenges facing the vaccines R&D enterprise.
 - Objectives and focus of HIV program at Gates Foundation.
 - **Guest speaker:** *Emilio Emini Ph.D., HIV Program Director, Bill & Melinda Gates Foundation; former head of vaccines research at Pfizer, Wyeth, and Merck.*
- April 20th** **Investing in Early-Stage “Biotech” Companies**
- Therapeutic categories and technologies that are of greatest interest of life science venture firms, and the key macro risks to the biotech sector.
 - How life science venture firms assess scientific, regulatory, financial, and commercial risks, as well as management teams and Boards.

- Trends in development and commercialization strategies for early-stage biopharma companies (e.g., go-it-alone vs. partnering/outourcing)?
- Current state of the financing and IPO market for early-stage biopharma companies, including primary funding sources (venture/PE firms, larger pharma companies, etc.)?
- **Guest speaker: Stacey Seltzer, former Partner, Aisling Capital**

April 25th Biopharma Valuation Methodologies; Mergers & Acquisitions - Strategies and Notable Transactions

- Current biopharma M&A and financing trends.
- Financing/IPO environment for early/commercial-stage “biotech”.
- Common valuation methodologies and M&A deal structures.
- Case study: TBD.
- Role of private equity in biopharma sector.
- Outlook for future M&A activity in the industry.
- **Guest speaker: Senior healthcare investment banker TBD**

April 27th Future Outlook of the Global Pharma Industry/ Careers

- Will we see enhanced R&D productivity – which research targets are most promising – what are the prospects for “personalized medicine”?
- What changes in market structure and selling dynamics will take place?
- What legislative/policy changes might we see that will impact this sector?
- Will pharma companies become more focused or diversified over time -- will we see more consolidation?
- Functional roles/career advancement in the biopharmaceutical industry.
- Course evaluations.