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

Spring 2024 (B-Term); Tues./Thurs. 10:50am to 12:20pm; Kravis 690 (tentative)

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Course Overview

This course examines the strategic, technological, competitive, economic, organizational, and political challenges impacting the pharmaceutical and biotechnology industry. Learning outcomes to be gained by the students include:

- R&D - process of discovering, developing, and approving new drugs & biologics;
- Regulatory environment and IP/patents; orphan drugs; generics and "biosimilars";
- Global launch and competitive market dynamics of new biopharmaceuticals – U.S. and international markets;
- Oncology category: clinical/regulatory, commercial issues/pricing & reimbursement, personalized medicine/ use of biomarkers, etc.
- Drug pricing and third-party reimbursement, including design of prescription drug plans, role/practices of PBMs, and drug provisions of the Inflation Reduction Act;
- Unique challenges of creating, managing, and investing in early/commercial-stage biopharma companies;
- Vaccines – development, regulatory, manufacturing, distribution, value/pricing;
- 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. Foundations of Valuations

	2. Corporate Finance
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.

Classroom Norms and Expectations (per Columbia Business School)

Core Culture

Students are expected to adhere to CBS Core Culture in this class by being Present, Prepared, Participating.

Inclusion, Accommodation, and Support for Students

At Columbia Business School we believe diversity strengthens any community or business model and brings it greater success. The School is committed to providing all students with equal opportunity to thrive in the classroom by providing a learning, living, and working environment free from discrimination, harassment, and bias on the basis of gender, sexual orientation, race, ethnicity, socioeconomic status, or ability.
Students with documented disabilities may receive reasonable accommodations. Students are encouraged to contact Columbia University's Office of Disability Services for information and to register for services.

Columbia Business School adheres to all community, state, and federal regulations as relate to Title IX and student safety. Read more about CBS' policies to support Inclusion, Accommodations and Support for Students.

Honor Code and Academic Integrity

The Columbia Business School Honor Code calls on all members of the School community to adhere to and uphold the notions of truth, integrity, and respect both during their time in school, and throughout their careers as productive, moral, and caring

participants in their companies and communities around the world. All students are subject to the Honor Code for all of their academic work. Failure to comply with the Honor Code may result in Dean's Discipline. Here you can review examples of Academic Misconduct which may result in discipline.
Course materials (videos, assignments, problem sets, etc.) are for your use in this course only. You may not upload them to external sites, share them with students outside of this course, or post them for public commentary without the instructor's permission.

Materials, Classroom, Ground Rules

Certain readings will be posted on Canvas. We will try to have lecture notes available in advance of each class (subject to guest speaker preference). It is important that you attend all class sessions, arrive on time, and give speakers and your fellow classmates your full attention. Please refrain from using laptops and smartphones in class; CBS-issued tablets are permitted for note-taking.
If you cannot attend a specific class or have to arrive late let Prof. Cramer and the TA know in advance by email (per School guidelines, excused absences may include religious observances, personal, medical, and family emergencies, jury duty, other).

Generative AI Policies

Students in this course may only use Generative AI tools, such as ChatGPT, for idea generation and must include a citation describing any usage. Using these tools to generate responses to assignments violates CBS's Honor Code.

Method of Evaluation

Class Participation (20%): Students will only get out of this course as much as they put in. It is therefore important that students take an active role in classroom activities and discussions and come fully prepared. The class participation grade will reflect class attendance and the quality of the student's involvement in class discussion. Multiple unexcused absences will have a negative impact on a student's final grade, per School guidelines.

Writing Assignment (40%): 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. 11th.

Final Paper (40%): There will be a final paper (3-4 pages, excluding exhibits) on topics reviewed in class during the course. The final will be posted on or about Apr. 11th, and be due April 30th.

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). S**ee course web-site on Canvas for required and supplemental readings and information sources**.**

March 19th **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 21st **Understanding Regulation; Patents; Generics/Biosimilars; Orphan Drugs --- Preview Midterm Assignment**

- 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); biologics and "biosimilars".
- Orphan Drugs – regulation, pricing, why pharma is interested
- Preview Midterm Assignment.

March 26th **Pharma R&D and Drug Approval Process – Interactions with FDA**

- 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) - *tentative.***

March 28th **Commercial Organization, Role of Marketing, Global Launches**

- 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 process/strategies – case study: *Sotyktu* (psoriasis/other)
- ***Guest speaker:* Alan Bash '99, CEO, ZielBio; former SVP Commercial, Bristol Myers Squibb and CEO, Checkmate Pharma - *tentative***

April 2nd **PBMs/Formulary Management**

- Role of Pharmaceutical Benefit Managers (PBMs); design of prescription drug plans; formulary management; utilization tools, data analytics, etc.

- PBM economics, revenue sources, how rebates work.
- ***Guest speaker:*** ***Jeff Grosklags, CFO, Optum (United Healthcare) – or - Lisa Gill, Managing Director and Head of JP Morgan's Healthcare Services Team - tentative***

April 4th **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 - tentative***

April 9th **Financial Characteristics of Pharma Companies; Business Mix**

- Profit margins, growth rates, valuations, PEs, and relative share price performance of selected biopharma companies.
- Business mix – review of recent restructurings, divestitures, and spin-outs.

April 11th **Drug Policy Initiatives; Review Midterm Assignment (due before class); Preview Final Assignment**

April 16th **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.
- ***Guest speaker:*** ***Emilio Emini Ph.D., CEO, Bill & Melinda Gates Medical Research Institute; former head of vaccines research at Pfizer, Wyeth, and Merck - tentative***

April 18th **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/outsourcing).
- Current state of the financing and IPO market for early-stage biopharma companies, including primary funding sources.
- ***Guest speaker:*** ***Stacey Seltzer, Partner, Gurnet Point Capital; former partner, Aisling Capital - tentative***

April 23rd **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.
- Role of private equity in biopharma sector.
- Outlook for future M&A activity in the industry.
- ***Guest speaker:*** ***Catherine Arnold, Partner, Centerview Partners - tentative***

April 25th **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.