MGMT B8536-001: Strategy and Competition in Pharmaceuticals and Biotechnology
Spring 2020 (B-Term); Tues/Thurs, 10:45am to 12:15pm

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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”;
- Rx sales and marketing objectives and practices;
- Review of global launch and competitive market dynamics of new biopharmaceuticals;
- Review of oncology therapeutic category, including orphan drugs;
- Drug pricing and third-party reimbursement, including design of prescription drug plans and PBMs/contracting;
- Creating and managing early-stage biopharma companies;
- Vaccines – development, regulatory, pricing, distribution;
- Health policy/reform impacting this sector;
- Mergers & acquisitions and licensing 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 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/pharmaceutical 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:

<table>
<thead>
<tr>
<th>Core Course</th>
<th>Connection with Core</th>
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<tbody>
<tr>
<td>Corporate Finance</td>
<td>1. Risk</td>
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<td></td>
<td>2. Firm Valuation Model</td>
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<tr>
<td>Decision Models</td>
<td>1. Decision Making Under Uncertainty and Risk</td>
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<tr>
<td>Managerial Economics</td>
<td>1. Analyzing Complex Decision-making Under Uncertainty</td>
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<tr>
<td>Marketing Strategy</td>
<td>1. Company Analysis</td>
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<td></td>
<td>2. Competitive Analysis</td>
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<td>Strategy Formulation</td>
<td>1. Strategic Interaction Analysis</td>
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<td></td>
<td>2. Diversification and Scope</td>
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<td>3. Competing Firms</td>
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<td>4. Global Strategy</td>
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**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 distributed in class or 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 classes, arrive on time, and give speakers and your fellow classmates your full attention. If you cannot attend a specific class or have to arrive late let the professors and TA know in advance by email. Please refrain from using laptops, IPads, cellphones, etc. in class.

**Method of Evaluation**

**Class Attendance/Participation (25%):** Students are expected to attend each class. Students should reach out to the instructor or TA regarding excused absences (for religious observances; personal, medical, and family emergencies; military service; court appearances such as jury duty). Students are encouraged to take an active role in classroom activities and discussions and come fully prepared. The class participation portion of the grade will reflect class attendance and the quality of the student’s involvement in class discussion. For example,
multiple unexcused absences will negatively affect your course grade. Attending classes but having no meaningful input into classroom discussion will be viewed neutral. Those participating in class discussion and adding value to the course content will be viewed favorably in your course grade.

**Writing Assignment (25%)**: For a mid-term writing assignment, students will be given a series of questions for their written analysis and recommendations (2-4 page paper, excluding exhibits). This assignment will be due before class on Apr. 16. Grading rubric will be provided prior to due date.

**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. 16, and be due May 4. Grading rubric will be provided prior to due date.

**Final grade distributions** will be consistent with School guidelines for electives (i.e., no more than 50% of grades in “H” category; 5-10% in “P” category).

**Class Schedule and Topics**

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.

**Mar. 24th**  
Course Introduction and Industry Overview  
- Course objectives, syllabus, readings, exams/grading.  
- Environmental assessment and summary of key challenges and opportunities in the global pharmaceuticals business.  
- Major strategic issues/alternatives facing executives at “Big Pharma”, specialty pharma, and early-stage biopharma companies.

**Mar. 26th**  
Regulatory Environment, Intellectual Property/ Patents  
- 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; “biosimilars”.

**Mar. 31st**  
Clinical Development and the Drug Approval Process – Interactions with the FDA  
- Clinical development process and strategies  
- Review of drug approval process – U.S. and selected int’l markets  
- Strategies re: working with the FDA in the current regulatory environment  
  - **Guest speaker**: Robert Ruffolo PhD, former president, Wyeth R&D

**Apr. 2nd**  
Sales & Marketing; Drug Pricing; Global Launch Strategies and Competitive Market Dynamics for New Rx Drugs  
- Goals of pharma marketing; role of sales reps; DTC advertising, etc.
• Who pays for drugs, and how are drug prices set (US, other markets).
• Global Rx launches: regulatory and commercial strategies of launching a novel therapeutic.
• Competitive market dynamics of a recently launched drug (expanding market size and share, new indications/combinations, pricing, product life cycle management).

Apr. 7th  **Orphan Drugs for Rare Diseases; Case Study: Amicus Therapeutics**

• Orphan drugs for rare diseases (Orphan Drug Act of 1983, regulatory, development, pricing/reimbursement; commercialization issues).
• Case study: *Galafold* (migalastat) -- Fabry disease.
• Amicus Therapeutics – overview and key strategic issues

Apr. 9th  **Franchise Case Study: Oncology**

• Understanding the disease category, evolution of therapeutic agents, clinical development/regulatory, competitive landscape, global marketing strategies, pricing & reimbursement, personalized medicine/ use of biomarkers, etc.
• Incyte Corp. (biopharma) – overview and key strategic issues.
• **Guest speaker:** Herve Hoppenot, Chairman & CEO, Incyte Corp.; former CEO, Novartis Oncology.

Apr. 14th  **Perspective on Biopharma Industry Trends and Growth Catalysts; Case Study of Early-Stage Public “Biotech” Company: Agios Pharma**

• Perspective on macro trends/catalysts impacting biopharma sector.
• Unique issues/strategies of managing early-stage “biotech” company (building mgt. teams/culture, research targets, commercialization and partnering strategies, funding options, investor relations, long-term objectives, etc.).
• Career advice for MBAs in mid-size and early-stage biopharma companies (large vs. small company, functional roles, etc.).
• **Guest speaker:** Jackie Fouse PhD, CEO, Agios Pharmaceuticals; former President, Chief Operating Officer, & CFO, Celgene.

Apr. 16th  **Interim Course Review; Review Midterm Assignment; Preview Final Assignment**

Apr. 21st  **PBM/Fomularies Management**

• Role of Pharmaceutical Benefit Managers (PBM); design of prescription drug plans; formulary management; utilization tools, etc.
• Evidenced-based payer value propositions; performance-based pricing and other risk-sharing arrangements.
• **Guest speaker:** Jeff Grosklags, CFO, OptumRx
Apr. 23rd  Vaccines and HIV – R&D, Marketing, Pricing, Distribution
• Evolution of the vaccines and HIV businesses and franchises.
• Unique development, regulatory, manufacturing and distribution issues.  
  Guest speaker: Emilio Emini Ph.D., HIV Program Director, Bill & Melinda Gates Foundation; former head vaccines research, Pfizer

Apr. 28th  Financial Characteristics of Pharma Companies; M&A and Partnering Trends and Strategies
• Margin analysis, growth rates, valuations, share price performance.
• M&A environment and trends – overall and healthcare/pharma.
• Considerations in pursuing and structuring mergers, acquisitions, and JVs in biopharmaceuticals.
• Outlook for future M&A activity in the industry (“Big Pharma”, specialty pharma/generics, small-cap biopharma companies).
• Financing/IPO environment for early-stage “biotech”.
  Guest speaker: Naomi Leslie ’10, managing director, Goldman Sachs – tent.

Apr. 30th  Future Outlook of the Global Pharmaceutical Industry
• 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 diversified -- will we see more consolidation?
• Functional roles/career advancement in the biopharmaceutical industry.

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