MGMT B8536-001: Strategy and Competition in Pharmaceuticals and Biotechnology
Spring 2021 (B-Term); Day/Time TBD

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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”;
- Pharma sales and marketing objectives and practices;
- Review of global launch and competitive market dynamics of new biopharmaceuticals;
- Review of oncology therapeutic category, and orphan drugs;
- Drug pricing and third-party reimbursement, including design of prescription drug plans and PBMs/contracting;
- Creating and managing early/commercial-stage biopharma companies;
- Vaccines – development, regulatory, manufacturing, distribution, value/pricing;
- Health 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:

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<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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<td>Managerial</td>
<td>1. Analyzing Complex Decision-making Under Uncertainty</td>
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<td>Economics</td>
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<td>Marketing Strategy</td>
<td>1. Company Analysis</td>
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<td>2. Competitive Analysis</td>
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<td>Strategy Formulation</td>
<td>1. Strategic Interaction Analysis</td>
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<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 posted on Canvas. We will try to have lecture notes available in advance of each class on Canvas (subject to guest speaker preference). If you cannot attend a specific class let Prof. Cramer and the TA know in advance by email.

**Method of Evaluation**

**Class Attendance:** Students are expected to attend each class session. 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). Multiple unexcused absences will have a negative impact on a student’s final grade, per School guidelines.
**Writing Assignment (35%)**: 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. 1st.

**Final Paper (65%)**: 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. 1st, and be due Apr. 19th.

**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 (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.

**Mar. 9th Course Introduction and Industry Overview**
- Course objectives, syllabus, readings, exams/grading.
- Historical perspective, situational 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. 11th 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. 16th 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 (now Pfizer), and SVP of R&D, Smithkline Beecham (now GlaxoSmithKline).

**Mar. 18th 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).

Mar. 23rd  **PBM Formulary Management**
• Role of pharmaceutical benefit managers (PBM); design of prescription drug plans; formulary management; utilization tools, etc.
• PBM market players and share; PBM economics.
• U.S. pharmacy distribution and reimbursement system.
• Evidenced-based payer value propositions; performance-based pricing and other risk-sharing arrangements.
• **Guest speaker: Jeff Grosklags, CFO, OptumRx**

Mar. 25th  **Category Review: Oncology; Case Study: Incyte Corporation**
• 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.
• Incyte Corp. – overview and key strategic issues.
• **Guest speaker: Herve Hoppenot, Chairman & CEO, Incyte Corp.; former CEO, Novartis Oncology.**

Mar. 30th  **Perspective on Biopharma Industry Trends and Growth Catalysts; Case Study: Agios Pharma (Commercial-Stage “Biotech” Company)**
• Perspective on macro trends/catalysts impacting biopharma sector.
• Unique issues/strategies of managing commercial-stage “biotech” company (building mgt. teams/culture, research targets, commercialization and partnering strategies, funding options, investor relations, near-term vs. long-term objectives, etc.).
• Agios Pharma – overview and key strategic issues.
• **Guest speaker: Jackie Fouse PhD, CEO, Agios Pharmaceuticals; former President, Chief Operating Officer, and CFO, Celgene.**

Apr. 1st  **Review Midterm Assignment; Preview Final Assignment; Strategic Analysis of Selected Biopharma Companies**

Apr. 6th  **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. 8th  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.

Apr. 13th  Financial Characteristics of Pharma Companies; M&A and Partnering Trends and Strategies
• Industry margins, growth rates, PEs, relative share price performance.
• Valuation methodologies – biopharma companies and products.
• Considerations in pursuing and structuring mergers, acquisitions, JVs and licensing 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/commercial-stage “biotech”.

Apr. 15th  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 focused or diversified over time -- will we see more consolidation?
• Functional roles/career advancement in the biopharmaceutical industry.