MGMT B8536-001: Strategy and Competition in Pharmaceuticals and Biotechnology
Spring 2015 (B-Term); M-W (12:30-2:00pm)

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Course Overview

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

- Process of discovering, developing, and the approval of new drugs and biologics;
- Impact of government oversight and regulation;
- Patents on pharmaceuticals and biologics; generics and “biosimilars”;
- Franchise/ R&D portfolio management;
- Drug pricing and third-party reimbursement, including design of prescription drug plans and PBMs/contracting;
- Rx product life cycle management;
- International/emerging markets – business strategies and growth prospects;
- Vaccines – development, regulatory, pricing, distribution;
- Orphan drugs – development, regulatory, pricing, patient advocacy;
- Health policy/reform impacting this sector;
- External growth strategies/ mergers & acquisitions 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, insurance, and investment management given the large and growing healthcare/pharmaceutical practices of such firms.

Format, Approach

We highly value class participation and 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, or experience in, the healthcare/pharma sector will be valuable. 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 Prof. Cramer know in advance by email. Please refrain from using laptops, IPads, cellphones, etc. in class.

**Course Requirements and Evaluation**

**Participation (25%)**: 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.

**Writing Assignment (25%)**: For a mid-term writing assignment, students will be given a case study or series of questions for their written analysis and recommendations (2-4 page paper, excluding exhibits). **Due: Apr. 13.**

**Final Paper (50%)**: There will be a final paper (3-5 pages, excluding exhibits) on topics reviewed in class during the course. **Due: May 4.**

**Class Schedule and Topics**

The following is the schedule of topics (**Note: specific dates, topics and speakers may vary depending on schedules/availability**).

**Mar. 23rd (M)**

**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. 25th (W)**

**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. 30th  Pharma CEO Perspective – Regulation, Health Policy, Company Stakeholders

- Perspective on competitive and environmental issues facing Big Pharma CEOs, including regulatory issues, impact of health policy/reform, enhancing shareholder value, Board and shareholder relations, etc.
  *Guest speaker: Jeffrey Kindler, retired chairman/CEO, Pfizer - tent*

Apr. 1st  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 Ph.D., former president, Wyeth research*

Apr. 6th  Market Access, Pricing & Reimbursement, Value Proposition

- Pricing/reimbursement strategies; impact on product development.
- Health technology assessments and pricing & reimbursement submissions (NICE, other country submissions).
- Evidenced-based payer value propositions.
- Performance-based pricing and other risk-sharing arrangements.
  *Guest speaker: TBD*

Apr. 8th  Franchise Case Studies: Rheumatoid Arthritis and Depression

- Understanding the disease category, evolution of therapeutic agents, clinical development/ regulatory, competitive landscape, global marketing strategies, pricing & reimbursement, personalized medicine/ use of biomarkers, etc.

Apr. 13th  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.
  *Guest speaker: Perry Karsen, Chief Operations Officer, Celgene - tent*

Apr. 15th  Int’l/Emerging Markets – Business Strategies and Growth Prospects

- Unique regulatory, intellectual property, pricing, cultural, political, economic, and structural issues in these markets.
- Business strategies of multi-national companies operating in these markets
- Record of success of public-private partnerships in developing countries.
  - Guest speaker: TBD

**Apr. 20th (M)**  
**Review Mid-Term Assignment: Mergers, Acquisitions, and Alliances in the Pharma/Biotech Sector**

- Considerations in pursuing and structuring mergers and acquisitions
- JV and licensing considerations.
- Outlook for future M&A activity in the industry (“Big Pharma”, specialty pharma/generics, small-cap biotechnology firms).

**Apr. 22nd (W)**  
**Vaccines - Development, Regulatory, Marketing, Pricing, Distribution**

- Evolution of the vaccines business.
- Unique development, regulatory, manufacturing and distribution issues.
- Vaccines “case study”.
  - Guest speaker: Emilio Emini Ph.D., head of vaccines research, Pfizer

**Apr. 27th (M)**  
**Creating and Managing Early-Stage Biopharmaceutical Companies: Orphan Drugs – Development, Regulatory, Pricing**

- Building a management and scientific team
- Access to capital/ funding strategies (including working with VCs)
- Partnering strategies to access R&D and commercial infrastructure
- Corporate optimization strategies/ exit options & timing
  - Guest speaker: John Crowley, CEO, Amicus Therapeutics - tent

**Apr. 29th (W)**  
**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?
- How large a role will emerging markets play?
- Will pharma companies become more diversified -- will we see more consolidation?
- What margins & growth rates will pharma companies have in 2020?