Strategy and Competition in Pharmaceuticals and Biotechnology
MGMT B8799-017:

Spring 2014 (B-Term); M-W (12:30-2:00pm); Uris 303

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Course Overview

This course examines the strategic, technological, competitive, organizational, and political challenges impacting the pharmaceutical and biotechnology industry. Its perspective is global, including developed markets such as the U.S., and emerging markets such as the BRIC countries. Critical issues to be examined include:

- Strategies and process of discovering, developing, and the approval of new drugs and biologics;
- Impact of government oversight and regulation;
- Patents on pharmaceuticals and biologics;
- Franchise/ R&D portfolio management;
- Drug pricing and third-party reimbursement;
- Pharmaceutical supply chain; design of prescription drug plans; PBMs/contracting;
- Rx product life cycle management;
- Int’l/ emerging markets – business strategies and growth prospects;
- Vaccines – development, regulatory, pricing, distribution;
- Health policy matters impacting this sector;
- M&A in the biopharmaceutical 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 “small-cap” 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 and 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

Certain readings will be distributed on the first day of the course. Additional readings will be handed out in class as needed, or posted on course web-page.

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. 16 (before class).

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

Class Schedule and Topics

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

Mar. 24th (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. 26th (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. 31st (M) 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, former chairman/CEO, Pfizer – tent
Apr. 2\textsuperscript{nd} (W) \textbf{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
- \textit{Guest speaker: Robert Ruffolo Ph.D., former president of Wyeth research - tent}

Apr. 7\textsuperscript{th} (M) \textbf{Franchise Case Studies: Rheumatoid Arthritis and [TBD]}

- 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: TBD

Apr. 9\textsuperscript{th} (W) \textbf{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. 14\textsuperscript{th} (M) \textbf{Franchise Case Studies: [TBD]}

- 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: TBD

Apr. 16\textsuperscript{th} (W) \textbf{Review of Mid-Term Assignment; Generics and Biosimilars; Business Mix and Diversification Strategies (pros/cons)}

- Review of mid-term assignment.
- Strategic and financial considerations of diversification activities (consumer health, vaccines, emerging markets, non-pharma).
- Analysis - Novartis vs. Bristol Myers Squibb; Abbott “break-up”.

Apr. 21\textsuperscript{st} (M) \textbf{Creating and Managing Early-Stage Biopharmaceutical Companies}

- 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
- \textit{Guest speaker: John Crowley, CEO, Amicus Therapeutics - tent}

Apr. 23\textsuperscript{th} (W) \textbf{Vaccines - Development, Regulatory, Marketing, Pricing, Distribution}

- Evolution of the vaccines business.
- Unique development, regulatory, manufacturing and distribution issues.
- Vaccines “case study”.
- \textit{Guest speaker: Emilio Emini Ph.D., head of vaccines research, Pfizer –tent}
Apr. 28th (M) 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. 30th (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?