MANAGERIAL CHALLENGES IN THE PHARMACEUTICAL, BIOTECHNOLOGY AND MEDICAL DEVICE INDUSTRIES  
(HEMA - 453)  
PROGRAM IN HEALTH ENTERPRISE MANAGEMENT  
KELLOGG SCHOOL OF MANAGEMENT  
NORTHWESTERN UNIVERSITY  

COURSE SYLLABUS  

Winter Quarter, 2016  
Jacobs Center, Room 101  
Wednesday Evenings  
6:30 – 9:30 pm  
Edward F.X. Hughes, M.D., M.P.H.  
Professor of Health Enterprise Management  
and Strategy  
Kellogg School of Management  
Professor, Preventive Medicine,  
Feinberg School of Medicine  

Office: #5233-Donald Jacobs Center, Evanston  
Office Hours: By appointment, 847/491-8384  
Home Phone: 847/864-3039 (after 8:00 p.m.)  
Cell Phone: 847/977-3075  

COURSE DESCRIPTION  

The course focuses on the managerial challenges that have evolved for the pharmaceutical, biotechnology and medical device industries as a result of changes at three critical interfaces: 1) the interface between the firms and society highlighted by both the contribution of the firms to the health of society and the latter’s imposition of extensive regulation; 2) the interface between the firms and science, the latter now characterized by entirely new scientific fields and technical approaches to product discovery and innovation; and 3) the interface between the firms and their customers, now characterized by entirely new classes of customers for the firms and the need for new and creative marketing and sales strategies. These latter changes have resulted largely from the growth of managed care within American health care. Further, Business Development and Ethics have grown to be critical areas of activity and interest in these industries with salient implications for them.  

The course will begin by focusing on the history of the pharmaceutical, biotechnology, and medical device industries and their significant and growing contribution to the health of the American people, and to that of the world as a whole, and on the evolving and growing importance of these industries within the health care delivery system of the United States and other developed nations. We will highlight the role that history has played in the development of the regulation concerning the industries. We will explore the origins and evolution of that
regulation; detail its specific requirements; and focus on its impact on the research and development processes, the marketing practices, “cost of doing business,” and pricing policies of these industries. We will also assess the impact of this regulation on product access to market, highlighting international differences.

We will then explore: 1) how the growth of this regulation and the changing environment of the firms has led to an enhanced strategic focus on the management of the research and development processes of these industries; 2) the new scientific fields available for the discovery phase of these processes, and 3) the managerial challenges therein and options to enhance the return to these processes.

We will explore in some depth the scope and significance of the changing environment for these industries in the United States, and increasingly internationally brought about by the advent and growth of managed care. We will explore how the latter is changing/has changed the nature of the firm’s customers, the latter's decision-making process, and the resulting implications of these changes for marketing and sales strategies. In this section of the course, particular attention will be directed to the growth of formularies, formulary decision-making, the growth and role of cost-effectiveness analysis, pharmacoeconomics, managed care contracting, risk-sharing, and the challenges therein to marketing and sales strategies.

Prominent in the above will be the emergence of, and role of, pharmacy benefit management firms and disease management and the changing nature of the "business" that pharmaceutical, biotechnology and medical device firms are now in.

We will explore the differentiating and complementary attributes of the three industries, the managerial challenges facing them, and highlight the opportunities for strategic alliances and other Business Development options among them as a means of surmounting those challenges. Emphasis will be placed on the critical issues now being addressed in the strategic management of pharmaceutical, biotechnology, and medical device firms. An entire evening will be devoted to the Ethical challenges of real and perceived facing these industries and the industries’ and society’s responses to the challenges. The course will provide substantial opportunities for dynamic in-class discussion and student presentations and will feature an in-depth project. Executives from the three industries will participate in the class in a targeted and focused fashion.
## MANAGERIAL CHALLENGES
### HEMA 453 – WINTER, 2016
### COURSE SCHEDULE

<table>
<thead>
<tr>
<th>Week/Date</th>
<th>Session(s)</th>
<th>Topic(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I 1/6/16</td>
<td>#1</td>
<td>Welcome, Introductions, and Overview of Course</td>
</tr>
<tr>
<td></td>
<td>#2</td>
<td>Overview of Course (Cont’d)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussion of Readings</td>
</tr>
<tr>
<td>II 1/13/16</td>
<td>#3 &amp; #4</td>
<td>The Strategic Management of a Pharmaceutical Firm</td>
</tr>
<tr>
<td>III 1/20/16</td>
<td>#5 &amp; #6</td>
<td>Some Basics of Biotechnology and the New Frontiers</td>
</tr>
<tr>
<td>IV 1/27/16</td>
<td>#7</td>
<td>The Strategic Management of the Drug Discovery Process</td>
</tr>
<tr>
<td></td>
<td>#8</td>
<td>The History of Regulation: The Milestones, Their Causes, Components, Impact, and Implications</td>
</tr>
<tr>
<td>V 2/3/16</td>
<td>#9 &amp; #10</td>
<td>The History of Regulation: The Milestones, Their Causes, Components, Impact, and Implications- (continued)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Trials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Approval Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Naming and Labeling -- In Brief</td>
</tr>
<tr>
<td>VI 2/10/16</td>
<td>#11 &amp; #12</td>
<td>The Elements of The Product Launch: Dynamics &amp; Pyrotechnics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pricing and Reimbursement</td>
</tr>
<tr>
<td>VII 2/17/16</td>
<td>#13 &amp; #14</td>
<td>Business Development</td>
</tr>
<tr>
<td>VIII 2/24/16</td>
<td>#15</td>
<td>The Strategic Management of a Medical Device Firm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Medical Device Approval Process</td>
</tr>
<tr>
<td></td>
<td>#16</td>
<td>Post-Marketing Surveillance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generics/BioSimilars</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Orphan Drugs</td>
</tr>
<tr>
<td>IX 3/2/16</td>
<td>#17 &amp; #18</td>
<td>Ethics</td>
</tr>
<tr>
<td>X 3/9/16</td>
<td>#19 &amp; #20</td>
<td>Student Presentations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Course Evaluation</td>
</tr>
<tr>
<td>XI 3/16/16</td>
<td></td>
<td>Term Papers Due</td>
</tr>
</tbody>
</table>
COURSE MECHANICS:

Evaluation

The final grade in the course will be a function of performance on five parameters:

- “The Week That Was”  20.0%
- Class Participation                        35.0%
- “Book Report”  10.0%
- Class Presentation   12.5%
- Term Paper/Class Project             22.5%

100%

“The Week That Was:” For the first 15-20 minutes of most classes (after “Introductory Comments’ etc.), we will throw the floor open for quick, rapid-fire reports from the students detailing events of interest that have occurred in the three industries over the previous week (since the previous class). Quick comments/questions on the event(s) from students are invited and/or may be offered by the Professor. Student participation will be recorded and the grade for this segment of the course determined by the frequency and the quality of the student’s participation.

Class Participation: A central feature of the evaluation of class participation will be: 1) the demonstration of knowledge of the readings and issues under discussion elicited through “cold-calling;” 2) the quality of the responses to questions, as well as 3) the quality and frequency of questions asked by the student. Since “cold calling” in my classes is a friendly exercise, I call it “warm calling.”

Book Report: The "Book Report" will entail the selection and reading of a book dealing with the industries under study. There will be an “oral exam” on the book. The "Book Report" is an individual project with group interaction. A list of potential candidate books is given in Session 1 Appendix A (page __). Any other book may be chosen with the permission of the instructor. The parameters of the assignment will be discussed during the second week of class.

Term Paper/Class Project: Session 1, Appendix B contains a list of sample questions, one of which you may chose for the term paper. An additional option exists which is "any topic with the permission of the Instructor." You may work individually or in-groups. Of these two approaches, group efforts have many advantages and are preferred. For each group undertaking the paper, I would like to have a listing prepared by the group of the relative areas of responsibility and level of effort of each member of the team. This accounting information should be handed in with the paper.

The class on March 9 will be devoted to presentations of the term papers. The order of the presentations that evening will be chosen in an "enlightened-random" fashion. Owing to the number of projects to be presented, we may have voluntary, morning and afternoon, “over-flow” sessions that day for students whose schedules allow them to be free then. If a student participates in the morning or afternoon sessions, he/she does not need to attend the evening session. They are, however, welcome to do so.
The papers are due at 5:00 PM on March 16th. Please submit the papers electronically. If that is not possible, please deliver your hard copy to my assistant’s office, Room 5230, or, in extremis, to my home, 810 Lincoln Street, Evanston. If there is any "Confidential" information contained in any of the papers, the request for confidentially will be maintained.

**A Note on Grading:**

Towards the end of the fall quarter of ’08, all of the faculty teaching the quarter received the following e-mail. It, or some minor variations of it, have been sent to those of us teaching each quarter subsequently. I very much wanted you to see it:

From: kellogg-faculty-request@mail.kellogg.northwestern.edu on behalf of Sunil Chopra
Sent: Thursday, December 04, 2008 8:54 am
To: kellogg-faculty@kellogg.northwestern.edu; adjunctfaculty@kellogg.northwestern.edu
Subject: Grading

Dear Faculty:
As you prepare for grading for the fall quarter, please keep in mind that we are aiming for no more than 40% A grades in core classes and no more than 45 A grades in electives. In the core, we are aiming for around 10% C grades and in the electives around 5%. For course where multiple faculty are teaching, it is ideal to maintain some degree of consistency across the faculty. Thanks and all the best,
Sunil

Sunil Chopra
Senior Associate Dean for Curriculum and Teaching
IBM Distinguished Professor of Operations Management
Kellogg School of Management
Northwestern University, Evanston, IL. USA
s-chopra@kellogg.northwestern.edu
Welcome, Introductions, and Overview of Course

Welcome and Opening Comments

Introductions

Who are you?

What do you do/have done?

Why are you taking this course?

What do you want to get out of it?

Overview of Course: Goals, Methods of Procedure, Requirements, Evaluation Parameters, and Course Schedule

The Overall Intellectual and Pedagogical Goal of the Course:
- Life-Long Learning

What is in the Course:
- The Course Schedule
  - Rationale for Content

The relative emphasis of content across the three industries

Pedagogical techniques/goals

- Factual content and conceptual development
- Interactive approach
- No right answer(s)
- The application to these industries of the managerial knowledge learned in the core courses and other discipline-based courses
- As above, Life-long approach to learning
- The Relevance of the "Book Report" to this goal

The Issue of Bias

- Specification and openness of Bias
- Evolving views
- The issue of language
Evaluation and Its Specifics

“The Week That Was” 20.0%
Class Participation 35.0%
Book Report 10.0%
Class Presentation 12.5%
Term Paper 22.5%

Please see “A Note on Grading” - Page 5

“The Week That Was”
- First 15-20 minutes of class or less
- Rapid-fire reports on events
- Spontaneously offered by students
- Frequency and quality of contributions recorded

Class participation
- Its importance
- Various levels of experience within class
- The issue of intimidation
- Importance of questions
- Grading of interaction

The "Book Report"
- To be discussed below

The Term Paper/Class Project

Rationale for assignment

The specifics of the assignment
- The Instructor's questions plus any other with the permission of the Instructor

- Team work vs. individual approach

- Traditional Length: approximately 20 pages
  Double-spaced
  Traditional Font - 12
- "No fads or fancy stuff" re: covers etc.

- Citations to reflect source of quotes and ideas
  - Per the Honor Code

- Work Allocation Report to be handed in with paper
Précis due – January 20, 2016 or thereabouts

Term Papers Due March 16, 2016

Class presentations – March 9, 2016
- Importance of oral communication
- Possible voluntary morning and afternoon sessions and early start of evening session on March 11th to allow for time for all presentations
- Other "out-of-class" times to be utilized for presentations as needed and convenient for students
- Instructor availability for mutually convenient time as needed
- Strict time limits
- Visual aids welcome
  - Salient ideas, clarity and organization of presentations foremost
- Since Term Papers are not due until March 16, Professor understands that the presentations will be “a work in progress.”

The Course Reading
- Its Rationale and Size
- Constructive Redundancy
- No “Case Packet”
  - All Readings in “Public Domain”
- Weekly Readings Posted on Blackboard
  - In Folder for Week
  - “On-Time Delivery”
  - “Public Domain” Materials

Teaching style
- Board plan

The Availability of the Instructor
- Daily and weekly
- Home phone availability
- Cell phone availability
- If you e-mail the instructor, please include your phone numbers (both day and night) in the e-mail
- Curricular and career planning

- Explicit goals of this course: To assist you to get the job that you want in these industries

- To enable you to function more effectively in that job

- If you are already employed in these industries, to enable
you to function more effectively in your job.

-To enable you to advance more rapidly within the industries.

- Summer job assistance

Classroom etiquette

-Cleanliness
-Notice of planned absences or early departures
-Sitting still until class is formally dismissed
-“No-Hat” policy

Computer Policy

“Getting to know you”
-The 3x5 photo I.D. card
-Personal Info
-Please put business, home, and cell phone numbers on card
-Please provide a phonetic spelling of your name if its pronunciation is not immediately obvious to a neutral observer
-The photo ID card counts as a component of class participation
-Please put your phone number on all emails to the Professor
-If English is not your first language and you have challenges with pronunciation, I encourage you to sit in front of the class.

Auditor Sign-in Sheet

The availability of students

-Notice of planned absences or early departures

Volunteer “runners/faculty meet and greeters”

-Sign-up Sheet

Honor Code

- Precedents and Origins
- Definition of "Intellectual Responsibility"
- Relevance to this course
- Citation of sources in papers and presentations

Course is an approved elective in 2 majors:
- Health Enterprise Management
Questions and/or comments  
-On the above

Auditors/Spouses/Significant Others/Family Members  
All of the above are welcome.  
Enthusiastic participation is encouraged

Student Liaison  
-To be discussed, and chosen in class

Other issues

The "Book Report"  
-Origins and rationale

-The Choices  
-Recommended List below  
-Other possibilities

-Individual Oral Exams by E.F.X.H.  
-Dates to be determined in last two weeks of course

Specific book selection to be determined by January 20th or thereabouts  
-Please email Professor with notice of your book choice or submit written notice in class

The Questions to be addressed in The Book Report:

1. What is the book about?

2. Why did you chose it?

3. What did you learn from it?

4. Would you recommend this book to others? Why?

5. Should the book be kept as an option for the “Book Report?”
Title: **Overview of Course: Goals, Methods of Procedure, Requirements, Evaluation Parameters and Course Schedule (Cont’d)**

**Discussion of Readings**

**Required Readings:**

Some brief readings gathered from an interesting source highlighting some of the history of the three industries and, implicitly, their achievements:


I-6  Wade, N: “Francis Crick, Co-Discoverser of DNA, Dies at 88,” *The New York Times*, July 30, 2004, pg. A1. *(Note: I strongly encourage you to read this obituary, the possible exception being those of you with a deep, prior knowledge of its scientific contents. It is beautifully written and describes in clear detail the process of, and the elements of, Watson and Crick’s discovery of the structure of DNA as well as conveying a nice portrait of Francis Crick himself. I actually knew Dr. Crick. During medical school, I spent a summer at Strangeways Research Laboratory in Cambridge, England working on methotrexate analogs to treat childhood leukemia. We were directly across the street from the new Medical Research Council building in which was located Dr. Crick’s laboratory as well as that of Dr. Max Perutz, another Nobel Prize winner also mentioned in the obituary. We had lunch together many times and it was always scintillating experience. Not only does the obituary, as stated above, beautifully describe Watson and Crick’s DNA discovery but it also clearly and succinctly describes Crick’s later work and its significance. I was enormously impressed with that work. For what it is worth, I have also met Watson. I can share the details of that)*
experience with you in class.)


I-8 Hevesi, D: “Ralph F. Hirschmann, Leading Scientist on Early Enzyme Research, Dies at 87,” New York Times, July 19, 2009, pg. 28Y. (Note: I found this obituary fascinating. It points to the significant contribution of pharmaceutical companies in advancing the basic science of medicine. There is a remarkable amount of information in it.)

I-9 Weber, B: “Ruth Lilly, Drug Heiress and Poetry Patron, Dies at 94,” New York Times, January 1, 2010. (Note: Every year, I debate whether to remove this quixotic obituary from the reading or not. Invariably, I keep it in, particularly because of the second to the last paragraph. What positive irony – consistent, by the way, with one of the major themes as to why these obituaries are included in the course’s readings. I also found the first two thirds of the obituary fascinating (you can skim that part fast) as to what happens ultimately to some earnings of pharmaceutical firms. I have some personal experiences with the philanthropy of Mrs. Lilly’s brother, J.K. Lilly III, which I will relay in class. On a further note, I found the name of her husband fascinating (How would you like to have a name like that?)


I-11 Martin: D: “Dr. William F. House, Inventor of Pioneering Ear-Implant Device, Dies at 89” New York Times, December 16, 2012, pg. 34. (Note: Note how often Dr. House’s innovations/ideas for innovation were resisted by the establishment – there is a long and sad list of such resistance through the ages.)


I-13 Weber, B: “Gerald M. Edelman, Nobel Laureate and ‘Neural Darwinist,’ Dies at 84,” New York Times, May 22, 2014, pg. A21. (Note: I include this obituary because of its emphasis on the brain, an organ that one might characterize as the last/next frontier in physiology/pathophysiology. Dr. Edelman’s Nobel Price work on antibodies and immunoglobulin is fascinating enough, let alone his extrapolations of it to the brain. As murky as these extrapolations may have seemed to Mr. Stent, cited in the article, they presaged the opening of a whole new field of scientific endeavor—one from which great dividends will ultimately and consistently be reaped. As you move onto the obituary of Dr. Glimcher below, please note where Dr. Edelman did his internship!)

Times, May 31, 2014, pg. B12. (Note: Nice reading for all, especially biomedical engineers. Dr. Glimcher was appointed Chairman of the Department of Orthopedic Surgery at the Massachusetts General Hospital when I was a student at the Harvard Medical School. I rotated through that Department shortly thereafter but never met him—too bad! He was already a legend at that time.)

I-15 Martin, Douglas: “Guinter Kahn, Inventor of Baldness Remedy, Dies at 80” New York Times, September 19, 2014, pg B13. (Note: A fascinating obituary setting forth a fascinating story of intellectual acumen, serendipity, greed, and skullduggery in the “discovery” of a blockbuster use of a drug, a drug that, in its day, was a media sensation if not a sensation in any number of other ways.)


APPENDIX A

Book Report Options:


Extremely Recent Additions


Davies, Kevin: The $1,000 Genome: The Revolution in DNA Sequencing and the New Era of Personalized Medicine, Free Press, 2010.


“More Recent” Additions:


Meier, B: “Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death,” Rodale Distributed by St. Martin’s Press, 2003. (Note: This book came highly recommended from one of last year’s students. By a New York Times journalist, with a long track record of “sticking it” to the pharmaceutical industry, sometimes without rigorous empiricism, it recounts a dark chapter in the history of pharmaceuticals and medicine. Interestingly, a graduate of the second year of this course and the student who first suggested that we have the Book Report took a job with Purdue Pharmaceuticals upon graduation. He did not remain there long. I believe the reason for his departure was a positive pull elsewhere.)


Petersen, M: “Our Daily Meds: How the Pharmaceutical Companies Transform Themselves to Slick Marketing Machines and Hook the Nation on Prescription Drugs,” Sarah Cricton Books, Farrar, Strauss, and Giroux, New York, NY, 2008. ISBN 13:978-0-374-22827-9. (Note: I believe I saw a positive review of this book. It is written by a former New York Times reporter who covered the pharmaceutical industry. I hate say it but it probably just reiterates the usual industry bashing. I have eliminated other books doing that from the recommended section of the Book Report. Hence, it’s probably worth reading to get a sense of the arguments and be able to evaluate them effectively. Many of Ms. Petersen’s articles have been in my courses in past years.)


Singh, S. and Ernst, E: “Herbal Legends: Trick or Testament,” Norton Publishing, New York, NY, 2008. (Note: In previous years, from the beginning of the course, I have had a section of readings on “Alternative Medicine/Complementary Medicine,” (AM/CM) even thought we did not explicitly discuss the topic in class. I included the readings because of periodic student interest and the importance of the topic to an overall understanding of the role of pharmaceuticals et al. in our health system and lives. My own bias regarding AM/CM is identical to that of the former editor of New England Journal of Medicine who stated: “There is no such thing as alternative/complementary medicine, there is only untested medicine.” Every year the list of articles would grow and grow as more and more studies were done on the efficacy of AM/CM, particularly herbal remedies. Invariably the studies showed that the remedies were not efficacious.

The book was positively reviewed in the Wall Street Journal on August 19, 2008. I have not yet read it but include it in as a Book-O-Rama option for those who might be interested in the topic. We will not otherwise explicitly discuss the topic in the course.


Arrison, S: “The 100 Plus,” Basic Books, 2011, (Note: I am listing this book out of the author’s alphabetic order because of its relevance to the book above. Yet another testament to the importance of pharmaceutical, biotechnology, and medical device industries’ to the remarkable increase in life expectancy over recent decades.)


Venter, C: “A Life Decoded: My Genome: My Life” Viking Published by the
Recommended: The Tried and True:

Angell, M, “The Truth About The Drug Companies: How They Deceive Us and What to Do About It,” Random House, New York, NY, August 2004. (Note: This book is biased but important. It may have been superseded by M. Petersen’s new book.)


Vagelos, R. and Galamboc, L: Medicine, Science and Merck, Cambridge University Press, 0-521-662958, 2004


Books Positively Received by Students but With a Narrower or More Specialized Focus Than The Above:

Avorn, J: “Powerful Medicines,” Vintage Publishing of Random House, NY, August, 2004, IBSN #1400030781 (Note: This book could almost be a text book for the course. Jerry Avorn is a talented and knowledgeable professional.)


Goozner, Merrill: The Eight-Hundred Million Dollar Pill” The Truth Behind The Cost of New Drugs, Berkeley, U of C Press, 2004, ISBN 0-520-23945-8, 2004 – (Note: This book is really little more than a one trick pony and we would all most likely be better served if it were a chapter rather than a book. Marcia Angel addresses the same topic, among others, in her book.)


Tucker, J: Scourge: The Once and Future Threat of Smallpox, Atlantic Monthly Press, New York, NY, 2001. (Note: This is a very interesting book and should be read by all. It is, however, limited in scope compared to many of the other books.)


Books on Previous Years’ Reading Lists but Not Widely Read By Students, If At All:


Less Recommended:


Gessen, M: “Blood Matters: From Inherited Illness to Designer Babies, How the World and I Found Ourselves in the Future of the Gene,” Harcourt, New York, NY, 2008. (Note: This book focuses on the challenges facing women, with the highly hereditary form of breast cancer. It was well reviewed in the New York Times Book Section. I started it with great interest. It soon degenerated into a rant against mothers, the author’s in particular. I stopped at that point. I include it in the Book Report hoping it gets better.)


Kessler, A: “The End of Medicine,” Collins Publishing, July 1, 2006, ISBN006113029X (Note: I do have not yet had a chance to read it. This book was favorably reviewed in the Wall Street Journal. The title is regrettable. The book focuses on innovations in the medical device industry and, to a lesser extent, the biotechnology industry, alleging that these innovations will radically change medicine and eliminate certain diseases (hence the title). The students who read the book last year found it narrow and repetitive and were mixed on whether it should be retained in the course. There are very few books focusing on the medical device industry. I include the book for those of you who are interested in this industry and might enjoy reading it despite its limitations.


Krueger, G: “Hope and Suffering: Children, Cancer, and the Paradox of Experimental Medicine,” Johns Hopkins University Press, 2008 ISBN 978-0-8018-8831. (Note: This book was highly recommended in a Book Review in the New England Journal of Medicine, January 1, 2009. My experiences as a medical student on the childhood cancer rotation at the Boston Children’s Hospital were harrowing and I cite them in my speeches. I also spent a summer at Strangeways Research Laboratory in Cambridge, England working with a colleague of Sidney Farber in the development of methotrexate and, hence, am close to the story. Based on the Book Review, my knowledge of the history and the issues the book addresses, and the goals of the Book Report, I highly recommended this book upon publication. A student read it, however, and found it highly disappointing. Hence, its current place in the “Less Recommended” category.

Miller, H.I: *To America's Health: A Proposal to Reform The Food and Drug


APPENDIX B

Sample Questions for the Term Paper/Class Project:

Question #1:

To a large extent, biotechnology and medical device firms, compared to pharmaceutical firms, represent smaller, often start-up or “relatively” recent start-up operations. What is the industrial profile of these two industries? What are the managerial challenges the firms face and what are the requirements for success in meeting these challenges? What are the strategic options available to them to achieve success? What are the strengths and weaknesses of each? Which of them have been proven effective? In what situations and why? What has not proven effective and why not? What does the future hold for the firms in these industries and why? You may write about either or both industries. (You may also configure the question to address the pharmaceutical industry if you’re interested in writing about it. Similarly, you may address this question from the perspective of the challenges that you would face, and how you would overcome them, were you to start a new firm in one of these industries. If you were to take this approach, I would like to have you focus, to the maximum extent possible, though not exclusively, on the challenges, if any, that may be unique to the industry in question, and how you would address and surmount them.)

Question #2:

One of the principle challenges in biotechnology is obtaining patents or other forms of exclusivity for the products developed by a firm. Why are the challenges here in biotechnology different from the classical pharmaceutical and medical device industries? What are the critical issues in patent law for biotechnology products? What are the costs broadly construed of these challenges and to what extent do they or do they not impede product development in the industry or otherwise influence firm behavior? What is the array of ways in which the issues have been and/or can be resolved? What are the strength and weakness of each? What has been, can be, the resulting impact on the firms involved? What solutions would you propose to enable socially optimal solutions to be found in this area?

You may configure this question to address the issue of “gene patenting,” a case involving which was recently heard by the United States Supreme Court. What were the issues involved in the case and what was the Court’s decision? Why are they important or not? What are the stakes of the game? Who are the potential winners and losers in the case? How would you advise the legal system and private firms to proceed and why?

Question #3:

The past few years have seen a flurry of horizontal consolidation in the pharmaceutical industry. What has been the rationale for this merger activity and how has it fared? A number of studies are emerging with conflicting evidence regarding the strategic advantages, if any, to the firms that have engaged in this consolidation. Has it conferred competitive advantages? If so, why; if not, why not? If the evidence is still wanting for added value, what further would need to be
done, if anything, to gain such value? Please be as specific as possible in addressing this question.

Question #4:

One of the criticisms of the pharmaceutical, biotechnology, and medical device industries is that their products are priced inappropriately high. A few years ago, full-page advertisements were taken out in major newspapers across the country castigating one firm for the prices of its cholesterol-lowering products. If anything, prices seem to be higher, and substantially so, for life-saving medicines, e.g. for cancer, or life-saving devices. Charges of monopoly collusion among firms also exist. How do the firms set their prices? The firms traditionally have defended their pricing in terms of the high costs of research and development of their products and the need to achieve an appropriate return on investment for those expenditures. How valid is the response of the industries? How valid are the calculations regarding the costs of new drug development? How valid are the assumptions underlying them? Are they skewed to inflate the costs and therein provide "political cover" for the firms? The latter is a widespread impression in the payor community? How valid are the accusations about industry pricing? How valid is the response of the industries? To what extent is there monopolistic or collusive behavior? If there are social sub-optimalities in the pricing of these industries' products, what might be done to bring about a more equitable pricing behavior? A recent phenomenon (front page Wall Street Journal!) has been the dramatic (hundred to thousand fold) increase in the price of drugs on the market for a long time. What is going on here? How justified are the prices? What can/should be done about them?

Question #5:

In a well-received book, Dr. Marcia Angell, then an Executive Editor of the New England Journal of Medicine reviewed the scientific literature and found that there are no negative health outcomes associated with silicone gel breast implants. Despite this negative evidence, juries have consistently found in favor of plaintiffs forcing the bankruptcy of at least one medical device firm. On the pharmaceutical side, Lilly won virtually all of the cases alleging negative behaviors associated with the use of Prozac while other firms have set aside hundreds of millions of dollars in anticipation of possible adverse settlements regarding their drugs or have lost huge sums in jury trials or judgments. What is the extent of the product liability problem in the three industries being studied in this course? What is the extent of its costs broadly construed? How, if at all, does it influence firm behavior? How valid are the accusations against the firms and their products? If they are not scientifically valid, why do the firms lose and why not? How valid are the firms' defenses and what, if anything can be done to strengthen them? What might be done to bring about a more socially appropriate resolution(s) in this important area? You may address one or all three of the industries in your response. Please be as specific and concrete in your examples and suggestions as possible.

Question #6:

Playing a critically important role in the history of the pharmaceutical industry and in the distribution of its products has been/is the profession of pharmacy. Many observers have felt in
recent years that the talents of the members of the profession are no longer being adequately tapped to warrant the long and costly education required becoming a registered pharmacist. The recent evolution of clinical pharmacy, combined with the increased technical sophistication of today's products and the advent of managed care, has brought new and important clinical and managerial opportunities for the profession. What are the current clinical and social contributions of the profession, e.g. “pharmaceutical care.” To what extent is the investment in pharmacy education being realized? Where are the areas of greatest potential opportunity for the profession and what must occur for these opportunities to be realized? What are the critical challenges facing the profession and how might they be surmounted? Are there any implications of ObamaCare for the profession? Please be as specific as possible. Are there any major differences in the use/professional prerogatives and potential of pharmacists in nations other than the United States? How important are these and what opportunities might they present?

Question #7:

A recent major development in the pharmaceutical and biotech industries has been the emergence of pharmacy benefit management firms (PBM's). Last year, they attracted increasing attention due to Express Scripts discontinuing its Walgreens contract, only recently resolved, and heightened recent merger activity in the industry. Another recent development has been the growth, and acquisition of “Specialty Pharmacy” PBM’s. What are the origins of PBM's and what do they do? What is their business proposition? How do they create value, if at all? What are the strategic challenges facing them? Who are their customers and how are PBM's attempting to provide value to the various classes of customers? How are they attempting to differentiate themselves and how successful have they been in their efforts? What are specialty pharmaceuticals? What is, has been and will be the role of PBM’s and what has been, and will be, their impact, if any. The more distant past has seen the acquisition of PBM's by pharmaceutical firms and then their divestiture. Why did these phenomena occur? Are there any ethical issues involved in the ownership of a PBM by a pharmaceutical firm? How were these issues being addressed and how should they be addressed? What do you see as the future for PBM's and what role do you see them playing in our health system?

Question #8:

One of the major developments of the last few years has been the emergence of “Disease Management” (DM) within the pharmaceutical industry, and to a lesser extent, the biotechnology and medical device industries. A number of firms have gone so far as to establish subsidiaries or participate in joint ventures to develop and sell DM services. Many observers see DM as “changing the business that the pharmaceutical (et al.) firms are in” to bring about an enhanced collaborative relationship with their customers fostering cost-effective health care outcomes. Others see the firms' involvement in DM as yet another cynical ploy on the part of pharmaceutical, biotechnology and medical device firms to enhance profits at the expense of their customers. What is DM and where did it come from? Why have the firms embraced it the way they have, and what do they see as the strategic advantages in doing so? To what extent have any of these advantages been realized or stand a chance of being realized? What do you see as the future for DM and the firms commercializing it? What are the requirements for financial success in this new area? Who might be among the winners, if any, and why? Please be as
specific as possible in your response.

**Question #9:**

Increasingly, we have seen pharmaceutical firms making major investments in biotechnology firms either through outright acquisition, partial acquisition, or strategic alliances. These relationships address the needs of biotechnology firms for capital and pharmaceutical firms to maintain a cutting edge in innovation. Describe a number of these relationships. To what extent have these relationships been successful or not? What are the ingredients for success? Have the biotechnology firms been able to maintain innovation in the face of their new relationship with a larger company? What does the future hold for these collaborative relationships? Who will be among the winners, if any, and why? Please be as specific as possible in answering this question, citing specific cases etc.

**Question #10**

A lot of attention has been directed at the alliances between pharmaceutical firms and biotechnology firms. Generally neglected in all of this discussion, however, are alliances between major pharmaceutical firms? What is the nature of these relationships? Why do they form? What are their types? How successful are they? What factors might be viewed as responsible for this success of lack thereof? What role do you see these relationships playing in the future?

**Question #11**

A number of pharmaceutical firms have recently taken their products from a prescription-only status to over-the-counter status or are in the process of preparing for such conversions and other firms have seen their efforts to do so thwarted by the FDA. What has been the rationale for these conversions and how have they fared? What are the pros and cons of such a conversion? What firms may be perceived as having succeeded in such a conversion and which not? What elements might be viewed as contributing to a competitive advantage in a conversion and what are the critical managerial challenges that must be overcome to ensure success in such conversions? What is the future for such conversions? How widespread will they be in the future? What percentage of today's prescription drugs might be subject to such conversions? What should be the appropriate regulatory criteria and processes guiding conversions to ensure a socially optimal outcome? Please be as specific and concrete as possible.

**Question #12:**

The regulation of the pharmaceutical, biotechnology, and medical device industries varies dramatically from nation to nation -- regulation not only of research and development, but of pricing, advertising, etc. What are some of the major differences across countries and how do they affect the way firms do/must behave across these countries? Are there any implications for the relative investment in research and development in the various countries? Are there any implications for "brain drain"/"firm migration" from one country, specifically from the United States, to another and vice versa? Are there any implications of the regulation for the balance of
trade, etc? To what extent, if any, is the United States, as a result of some of this regulation, “subsidizing” research and development for other countries, Canada being one possible example? What should be done, if anything, to lessen inappropriate regulatory burdens in the U.S. and abroad and therein enhance international competitiveness of the firms in these industries? Are there any additional positive policy changes that might be undertaken to enhance the competitiveness of U.S. firms in these industries? What might be their effect and what would need to be accomplished to have them implemented? You may write about one, two, or all three of the industries. Please be as specific as possible in your examples and recommendations.

Question #13:

One of the critical issues in pharmaceutical marketing and sales is direct-to-consumer (DTC) advertising. It has been hotly debated within firms – with some initiating high profile, well-financed initiatives and others holding back. What are the issues in DTC advertising? What are its benefits; what, if any, are its potential liabilities? What is the return to it? How is this return measured and how valid are these measurements? What ethical issues, if any, are involved in DTC? What are the views of it of: 1) the traditional primary customers of the pharmaceutical industry, physicians, 2) managed care entities; 3) regulatory agencies, and 4) consumers and consumer groups? What, if anything, are these constituencies doing to counter/abet DTC? To what extent do they represent a threat to DTC and why? If a firm desires to pursue DTC, how might it effectively respond to the objections raised to it by these entities while still obtaining the benefits of it and continuing to interact effectively with the various constituencies?

Question #14:

One of the stealth issues in the health care industry is laboratory costs. This issue is becoming especially acute as a result of the almost exponential growth of expensive diagnostic test especially genetic testing. What is the scope of this issue? To what extent have the costs been rising and why? What does the future hold? What is the future of genetic testing? What are its implications and what is being done to manage its costs?

Question #15:

One of the more critical issues facing society is the growth of drug-resistant organisms. What is the scope of this problem? What are some of the specific components of the problem and its scope? How severe is the problem? What is its trajectory? What are the stakes of the game? What are its origins? What can be/should be done about it? What is the role of the pharmaceutical and biotechnology industries in it – as well as other components of the health industry? What if anything is the pharmaceutical/biotechnology industry doing about it? You may write about the problem as a whole or one specific component of it, e.g. tuberculosis.

Question #16:

One of the frontiers in the marketing and sales domain of the three industries being studied in this course is Social Media. What is the potential opportunity in the use of Social Media for these purposes, or any other purpose, by these industries? To what extent are the firms
capitalizing on opportunities in Social Media? What is the upside, downside? Are there any regulatory issues involved and what is being done/can be anticipated being done in that domain? What do the firms need to do to prevent excessive regulatory involvement? You may write about any one of the industries or all of them. Please be as specific as possible.

**Question #17:**

The focus on biotechnology in this course is on its application to human health. The biotechnology industry, however, has major innovative programs in the areas of agriculture and the environment. What have been the contributions to date here? What are the controversies? What products are currently under development and what does the future hold? What are the dynamics and strategies of the various firms in this area? To what extent are they “stand alones” or components of larger firms? What has been the extent of the merger, acquisition and alliance activity in this sector of the industry? What has been driving it and what does it portend for the future of the industry? What is the ultimate market potential in this area and what strategies would appear most effective in garnering this potential market? What are the challenges the firms are facing and what must they do to surmount these challenges to achieve competitive advantage in their areas of focus?

**Question #18:**

One of the fields central to drug discovery is “Bio-Informatics.” What is it? What have been its accomplishments? What are the challenges facing it? How is it being used by firms to achieve a competitive advantage? How can it be more effectively used? What further needs to be accomplished in the field to have its potential be realized?

**Question #19:**

One of the barriers to the progress of biotechnology – especially in, but not limited to, Europe and agriculture -- has been the origin of special interest groups opposed to its spread. These groups have mounted major campaigns against firms, the research they are undertaking, the commercialization of products etc. Who are these groups; who comprises them; and what are the issues they are raising? How valid are these issues? How powerful are these groups? To what extent do the groups and their issues represent a problem for the field of biotechnology? What has been the response to date of the industry overall and its firms to the “threat” posed by these groups? How effective has been the response? What, if anything, further should the firms be doing to counter these groups? Why? And why do you believe what you recommend would be effective?

**Question #20:**

An area receiving increasing attention in the lay and medical media, the courts, the FDA, managed care organizations, and traditional medicine itself is "Alternative Medicine." What is alternative medicine? What distinguishes it, if anything, from traditional medicine? What is the
size of the "industry?" Who are its firms and what are their revenues? What are its products? Who are its customers? What is its standing vis-a-vis regulation? Why does the industry appear to be free of much of the regulatory burden of the traditional pharmaceutical industry? What are the critical issues at the interface of this industry and the various constituencies mentioned above: traditional medicine, the FDA, managed care, etc. and how should they be, will they be, resolved? What are your observations, conclusions and suggestions here and why? Note: Alternative medicine encompasses a broad array of interventions. If you address this question, please be specific regarding which elements of alternative medicine you are addressing as you proceed through the question.

Question #21:

A critical issue in American health care, as well as in all developed nations, is rising drug costs – (I use the word “drug” in this sentence because pharma and biotech are lumped together in discussions/publications on this issue). In fact, at various times in recent years, a number of observers have stated that it is the most pressing issue facing American health care. What are the parameters of the issue? How serious is it? Has the issue modulated in recent years (If so, why?) or is it as acute as ever? What are the views of the various parties involved as to its seriousness, appropriateness and possible resolutions? What suggestions do you have for a positive resolution, if any in this area? What do you think is going to happen and why? What do you think public payors (government) and private payors have done/are going to do in this area? What do you see as the implications for the pharmaceutical or biotechnology industry? If you were the president of a major pharmaceutical or biotechnology firm, what, if anything, would you be doing about this issue and why? What would you expect to be the outcomes and why?

Question #22:

Many observers have noted a distinction, if not a gulf, in the biotechnology industry between product companies and platform companies. What is meant by this distinction? How valid is it? Who are some of the leaders in each group? What are some of the platforms that the platform companies are developing and commercializing? What do you see as the future of these firms as platform companies? There have been a number of recent indications of platform companies attempting to diversify into product companies. To what extent is this true? What strategies have the firms used/are using to effectuate this diversification? How successful do you believe these strategies will be and why? How necessary do you believe it is for platform companies to pursue them? What do you see the future holding for the two types of companies and why? Please be specific as possible.

Question #23:

Many biotech products are enormously expensive and beyond the ability of patients to pay for them. What programs, if any, e.g. patient assistance programs, have the biotechnology firms producing these high-priced products developed to address the disparity between the costs of their often life-saving products and the ability to pay for them? What are the relative strengths and weakness of each approach? How effective have they been in achieving their goals? How aware do you believe biotechnology firms are overall in the need for such programs? Is there a
need? How much publicity have the firms given to these programs and how difficult is it for a patient to access them? To what extent does the high cost of certain biotechnology products represent for the industry as a whole a serious threat over the long term vis-a-vis public policies such as governmental price controls and third party payor refusals to pay for them? How effective are the programs mentioned above as strategies to forestall such price control efforts? What would you recommend the biotechnology firms with high cost products do in this area and why? Please be as specific as possible.

Question #24:

In his lecture a few years ago specifying the components of the then newly enacted Medicare Drug Benefit (MDB), Mr. Peter Johnson of Eli Lilly & Co., speculated on the implications of the various components of the drug benefit for the pharmaceutical and biotech industries. His speculations could only be termed “dire.” What are the various components of the Medicare Drug Benefit? What assumptions underlie the structure of the MDB and why? How valid are those assumptions? How did the implementation of the Act proceed? How important, if at all, were the Managed Care plans in its implantation and success/failure? What has been its impact for Medicare beneficiaries as well as on pharmaceutical and biotech firms? Did the ObamaCare legislation impact on the MDB? If so, how and to what degree? What is the current status of the MDB? What are the current policy issues, if any, regarding the MDB and how do you see them being resolved? How are “dual eligibles” being treated? What must the pharmaceutical industry now do to enhance the likelihood of a positive future for itself, for Medicare beneficiaries, and for society as a whole? What are the implications of the MDB for Patient Assistance Programs of the industry? What should the industry do about these programs and why? What is your summary judgment regarding the MDB and why? Have Mr. Johnson’s “dire” predictions proven out? What would you tell the Chairman of the Pharmaceutical Research Manufacturers of America and/or the CEO of the pharmaceutical/biotechnology firm that you are advising to do? Please be as specific as possible in answering this question.

Question #25:

One of the most critical challenges facing the pharmaceutical and the biotechnology industries, at this moment in time, is the threat of generics. This threat for the biotechnology industry has increased substantially with the provision of a “bio-similar” pathway in the ObamaCare legislation. What are the components of that pathway? How, and why, do they differ from that of the small-molecule pharmaceutical industry? What implications do these differences have for the threat to biotechnology firms at this moment? What factors are contributing to the intensity of the threat? How valid are the rationales supporting these factors? What are the implications of the generic challenges for the pharmaceutical and the biotechnology industries? What are the implications for society? Should there be any reform regarding the issue of generics? What should that reform consist of? What should the pharmaceutical industry and biotechnology do to insure a positive future for themselves and for society as a whole? What else, if anything, should be done from a public policy perspective in this domain? Please be as specific as possible in answering this question.

Question #26:
It is alleged that one of the crucibles of the biotechnology industry as well as the medical device and pharmaceutical industries, past and present, is the academic medical center and often Universities as a whole. What evidence exists to support this allegation? Is it simply hype spun by academics to advance their social image or is it for real? If real, how does/has the incubation process work/worked? Who are the key players, generically speaking? To what extent have academic institutions, directly or indirectly, purposefully or by happenstance, advance the pharmaceutical, biotechnology and/or medical device industries? If academic medical centers are the fertile fields they are alleged to be, what are the industries doing, if anything, to identify promising leads in academic medical centers and abet their commercialization? What models appear to be most productive in this regard? What evidence can be adduced to support your case in this area? What are academic medical centers doing, if anything, to advance the commercialization of their products? Again, what models appear to work best and why? What are other actors such as venture capitalists doing, if anything, to abet the transition from academic research to commercial products? What has been the track record? What works and what doesn't in this important area? What have been the benefits, if any, of this process of commercialization to academic medical centers? Are there any downsides to the process? How are academic medical centers reacting to the issue and what are the strengths and weaknesses of their response(s)? Should anything be done from a societal perspective to advance the commercialization of products of academic research? Please be as specific as possible.

Question #27:

One of the critical issues periodically facing the pharmaceutical industry and, to a lesser extent, biotechnology is that of drug re-importation. What are the critical elements in this issue and why? How valid are the arguments on both sides? Who are the critical actors and what is each trying to do? Why? How much of a challenge do you believe re-importation is to the pharmaceutical and biotechnology industries and how effective do you believe they have been in dealing with it? Where does this issue now stand with: 1) states and municipalities, 2) the courts, 3) the Congress, 4) the FDA, 5) the rest of the Executive Branch, and 6) patient and community activists etc? What do you think will the ultimate outcome(s) of the issue? Why? What would you recommend that the pharmaceutical industry do as well as the other principals, e.g. the FDA, do to bring about a socially positive outcome to this issue and why? Please be as specific as possible.

Question #28:

Note: This question is written in terms of the Pharmaceutical Industry but it could be addressed from the perspective of the Biotechnology and/or Medical Device Industries or all three.

Many within the pharmaceutical industry argue that the emphasis of the costs of pharmaceuticals is inappropriate because pharmaceuticals actually save money. Is this true? To what extent might it be true or not? In which instances? What is the evidence? To what extent are those who argue for the cost reducing aspect of pharmaceuticals overstating their case? What are the implications of this overstatement? To what extent do those who stress the costs of
pharmaceuticals also give appropriate weight to the benefits of pharmaceuticals? What might be some of these “ignored” benefits and how are they measured? How valid are these measures? Why do these benefits, if any, tend to be ignored? What is the overall picture of costs versus benefits? To what extent might the empiricism underlying the appropriate weighing of costs and benefits and the drawing of valid conclusions therein be used in the public policy arena to advance the overall public health? What specifically can, and should, the pharmaceutical industry do, if anything, to advance the public policy debate on this issue? What form should their advocacy efforts take? To whom should they appeal and how? What should they avoid? Please be as specific as possible.

**Question #29:**

There are many who believe that the pharmaceutical industry is not a major source of innovation but rather that pharmaceutical innovation comes mainly from the National Institutes of Health and/or other not-for-profit sources such as academic medical centers, all supported by public funds, and is subsequently appropriated by the industry with all profits accruing to them. Books have been written on the topic. Peter Johnson commented on the prevalence of this belief in his lecture last year. To what extent is this perception true? What is the evidence on the question, one way or the other? To what extent do pharmaceutical firms use, extend, or appropriate the hard-earned work of others? To what extent are they genuine innovators developing their own products for the betterment of mankind? To the extent such imitative/appropriating behavior exists, should pharmaceutical firms be allowed to profit from this? Should there be some sort of sharing of the profits? What public policy initiatives have been undertaken in this area? What were their goals and to what extent were they or were they not successful? What, if anything, do you believe should be done and why? What mechanisms exist to reward or protect the non-profit innovators? Are more needed? What is an optimal “solution” for this issue, if any? Should they be taxed for, or otherwise forced to share, these allegedly appropriated profits? What public policy initiatives might be undertaken to achieve or approximate on “optimal”, win-win solution? To the extent to which the perception of the industry as an appropriator exists, what should the pharmaceutical industry do to counter it? Please be as specific as possible.

**Question #30:**

One of the major domestic policy thrusts at the local level is to create “biotechnology incubators” or “science clusters” to emulate in certain municipalities or regional zones successful biotechnology industry focus of Northern California, the San Diego region, Cambridge, MA and to a lesser extent, the Baltimore region. New York City’s recent competition for a “developer” of such a focus on Roosevelt Island and the “Prize” award to Cornell University is only one in a long list of these initiatives and one that would appear to have a reasonable chance of being successful. What are the elements of these initiatives? What are they offering and why? What has been the success of these initiatives to date? Why? What is your view on the potential success of these initiatives overall? Why? One of the areas attempting to create such an incubator is the Chicago/Evanston community. How is it organized? Who are the principal actors and proponents? What is being proposed? Why? How successful have they been? How successful do you believe they could be? What advice would you give to the proponents and why? What advice would you give to biotech firms being solicited and why? Please be as
specific and concrete as possible.

**Question #31:**

One of the more critical current issues in the pharmaceutical domain is “Drug Shortages.” The amount of front page press devoted to this issue last year was striking, especially the focus on shortages of “life-saving” drugs, e.g. for cancer, and pain medication. Why have these shortages occurred? Are there different causes for the different shortages? Who/what is to “blame” for them, if that is an appropriate term? What can be done, and should be done, to ensure that not only are these shortages corrected but they do not occur in the future? Please be as specific as possible.

**Other Topics:**

The above 31 “Sample Questions” gives you a sense of the issues to be addressed in each of the topic areas. In the interest of time, I will list below a number of other topic areas on which papers could be written. Please note that neither the above “Sample Questions” nor the list below is meant to be a restrictive list only from which paper topics can be chosen. There are many other very exciting topics that you may write on, particularly ones relevant to your current job, some of its challenges, and/or future career interests or aspirations.

A1) **Organ Transplantation:** To what extent does the demand for transplantation exceed the supply? What can be done ethically to increase the supply? What is the most equitable way to ration organs? Should people be allowed to sell their organs? Should people be compensated for the costs incurred in donation beyond direct medical costs? What is the status and implications of the “organ trade?” This overall topic is very important and stealth.

A2) **The Impact of ObamaCare on the Three Industries:** There are many implications of ObamaCare for these industries. What are they? How positive or negative are they? What are the industries doing about them/should be doing about them? You may write on any and all of the industries and/or on any specific item impacting on any one industry.

A3) **Implications of the New Excise Tax on Medical Devices:** This is a sub-set of the above issues but worthy of special attention.

A4) **The Medical Device 501 K Approval Imbroglio:** Origins, Seriousness, and Implications for the Industry?

A5) **Manufacturing “Snafus:”** There have recently been a number of very expensive, high profiles snafus. What is going on and why? Implications?

A6) **Cloning:** Where are we at the moment and what does the future hold?

A7) **Stem Cells:** Where are we and what does the future hold?

A8) **Contract Research Organizations (CROs), Contract Manufacturing, Contract Sales Forces**

A9) **Strategic Challenges and Potential Strategies Regarding the Management of Sales Forces**
A10) Genetic Testing: Past, Present, and Future: Efficacy and Ethical Issues (A reprise, in part, of Question #14)

A11) Regulatory Affairs: What is “Regulatory Affairs?” What is the role(s) of Regulatory Affairs Professional in the firms under study and external to them? How important is the role? How effectively are the firms managing this area and this pool of human capital? What does the future hold for the profession and how can its effectiveness be enhanced, if at all?

A12) Medicaid Fraud Settlements and other Medicaid/Three Industry Issues: There is virtually no firm that has escaped suits from Attorneys General for Medicaid fraud, specifically pricing issues and truth in advertising. What is going on? Why? How valid are the suits? To what extent do they represent a “witch-hunt” by publicity seeking and revenue seeking Attorneys General (think Elliot Spitzer!) or real issues? Should the firms settle? What should firms do about the issue?

A13) Autism and Vaccines: Last year, Peter Johnson referenced this issue in his presentation. What is the history of it and what are some of its outcomes and implications? How valid is the science underlying the concerns? What can be done in the future to prevent such miscarriages of reason and justice? There are similarities to the silicon breast implant issue addressed in a previous question.

A14) Off-Label Promotion: Within the last few months, a “higher” U.S. Court (I don’t have the details of which court in front of me as I write this question) ruled that FDA bans on a pharmaceutical sales representative advocating off-label use of a product violates the right of free speech. What is the background, potential impact, and fate of this ruling?

A15) Compounding Pharmacies: What is a compounding pharmacy? What do they do/are they supposed to do? Why were they in the news big time a year ago? What should be done/is being done about them? Implications?

A16) PhRMA, BIO, AdvaMed: What are these organizations? What do they do? How effective are they? Why are they/are they not effective? Examples? If you were a consultant to them, what would you tell them to do, if anything?

A17) Comparative Effectives: What is it? What relevance is it to the three industries being studied in this course? How is it being operationalized? What could be its impact? What should the three industries being studied in this course do about it?

A18) Prescription Drug Abuse: One of the more recent “crises” to emerge in the United States is that of “Prescription Drug Abuse.” What are the parameters of this crisis? How severe is it? Why did it happen? What has propelled it? What can/should be done about it? How has the pharmaceutical industry specific firms responded? If you were the CEO of a pharmaceutical firm whose products were being “abused,” what would you do about it? If were the Chairman of PhRMA, what would you do about it?

A19) Emerging Markets: For many years, when profits and growth were robust, U.S. pharmaceutical, biotechnology, and medical device firms, shied away from emerging markets. Among their concerns were: issues of pricing and potential patent infringement; corruption and cronyism; government regulation and roadblocks, e.g. the need to partner with an indigenous firm; lack of infrastructure etc. With profits/growth in more established markets more challenged, firms in the three industries under study are entering/have entered into emerging markets, some very aggressively. What strategies have been employed? What has worked/has the potential to work? What hasn’t? Are there any success stories/failures? What lessons can be learned from both of these types
of examples/experiences that other firms can learn from and adopt? There have been, over the past year, major ethical allegations, and indeed even potentially criminal prosecutions leveled on a number of the major pharmaceutical firms by the governments of China and Japan among others. What are the issues in these cases and why? To what extent are the charges justified? What do you believe will be the outcomes? How would you advise firms in the industries under study in this course to proceed when contemplating entering an emerging market?

A20) **Counterfeit Drugs:** An issue that has emerged with particular poignancy over the last year is “Counterfeit Drugs.” What is the scope and seriousness of the problem? Why is it a problem? How has it been allowed to become the problem it is? Who has it affected and why? What can and should be done about it?

A21) **Post Marketing Surveillance:** One of the outgrowths of the 2007 Prescription Drug User Fee Act (PDUFA) was increased emphasis on “Post- Marketing Surveillance” (PMS). What is PMS? What are its components? How important is it? What is a “Risk Evaluation and Mitigation Strategy (REMS)? What is it used for; when is it required, why? etc. If you were a pharmaceutical/biotechnology CEO, what emphasis would you be placing on PMS and why? How would you manage it?

**Précis of the Assignment**

Please prepare a "précis" of your choice of the assignment, indicating the topic, your preferred approach, data sources, etc. Please identify your team members, if any, in the précis. The précis is informational in nature and not evaluative. One page maximum -- one to two paragraphs preferred. It is due on or about January 20, 2016 – or earlier per your convenience. The latter date is flexible and is meant to facilitate your getting an early start on focusing on the project.