Prereq: Permission of instructor
G (Spring)
3-0-6 H-LEVEL Grad Credit
Focuses on economic issues in various health care and allied industries, such as the pharmaceutical, biotechnology, medical device, vaccine and diagnostic sectors. Addresses differences between health care and other industries; regulatory issues, in the US and globally, that involve establishment of the efficacy and cost-effectiveness of treatments; managing those who manage research and development; policies to incentivize research and development for neglected tropical diseases; strategic issues in global pricing and marketing; use of e-commerce and information technology; personalized/stratified medicines and diagnostic biomarkers; and formation and management of various alliances. Visiting speakers from academia, government, NGOs, and industry. Assignments include 4 to 6 essays. For credit registration only – Listeners not permitted.
E.R. Berndt

Spring 2015  Meets Wednesdays, 4-7 pm, E62-262.
Instructor: Prof. Ernst Berndt, eberndt@mit.edu, E62-518.  TA: Elizabeth Timbers btimbers@mit.edu.

Course Goals: Help you gain an understanding of the major economic, strategic and organizational issues facing management, investors, clinicians and policymakers in the various health care and allied industries, in the US and globally. The course provides a broad overview of how the various health care industries differ from other industries and from each other, the major stakeholders and their perspectives, and identifies reference sources from which more detailed information can be obtained.

Typical Class Session: 4:05 – 5:20 pm: Faculty leads discussion with powerpoint slides.  5:20–5:35 pm: Not too unhealthy snacks just outside classroom.  5:35 – 6:55 pm: Guest Speaker presentation. In most but not all cases, from 7:15 – 9:15 pm there’s an informal dinner with the guest speaker, TA and a few students – at the nearby restaurant EVOO. Prof. Berndt’s powerpoint slide presentation will be posted on Stellar before class. In most but not all cases, the guest speaker will also have a powerpoint presentation, which will in most cases be posted on Stellar as well (sometimes only after class meets).

Course Requirements: Attend class (allowed to miss no more than two three-hour classes); for EMBA virtual students, see next page re documenting attendance. Read assigned articles before class, be prepared with questions for guest speaker. No final exam. All students required to hand in first essay assignment, and then can choose which three of four remaining essays to write. Each is short (maximum of six doubled spaced, standard 12-point font pages).

Course Bonus: Most of the guest speakers have agreed to stay after class and go out for an informal dinner with several students, Betsy Timbers (the course teaching assistant) and Prof. Berndt. Meals are at a local restaurant (EVOO) immediately after class, and are funded by Prof. Berndt’s chaired professorship or the guest speaker. Students are given a chance to express their preferences to the course teaching assistant regarding their preferred choice of guest speaker with whom to dine.
Course Grade: The four essays account for 80% of the final grade, and class participation the remaining 20% (unless absences are excessive).

IMPORTANT NOTE: This course is unusual at Sloan in that registration and virtual participation will be permitted (our experiment with this format in Spring 2013 and 2014 was quite successful). Each class session will be captured by temporary video and audio, and streamed live to long-distance students via MIT Sloan Technology; EMBA virtual students can interact with the live class using the Bluejeans.com conferencing technology hosted by the Sloan Technology Services staff and the teaching assistant, Betsy Timbers. This technology will also allow students to “check in”, signaling virtual attendance. Because of time zone differences, long-distance learning EMBA students will be permitted to view the streamed class session until 9 am on Thursday morning following the Wednesday class (until up to 14 hours after the class ends), at which time the temporary video and audio capture file will be destroyed. Videos of class sessions cannot be downloaded and will not be archived. Since the class is being streamed live and is interactive, in person local students should be aware that they will be “on camera” during the entire class session, and distance learning students sitting by their webcam-enabled personal computer will have their faces displayed on a large side screen in the front of the E62-262 classroom during the entire class session. Regular MBA students must attend classes in person, not virtually.

PLEASE NOTE: The materials presented in this class are for the educational use of the students registered for this course. Materials include, but are not limited to, handouts, manuscripts and articles, slides, speakers, syllabi, and on-line materials. Students are not authorized to videotape, photograph or record classroom activities for future use including posting on the internet or any other forum without prior written consent by the professor. Also, students are not authorized to post any course materials on the internet, cloud or in any other forum without prior written consent by the professor. These restrictions do not expire and continue in perpetuity.

Spring 2015 Detailed Class Schedule

Feb. 4, 2015   Introduction to the Health Care Industries

Prof. Berndt: “What Differentiates Health Care from Other Industries?”


Readings/Listenings (* denotes optional; ** denotes very optional – background material):


For a very readable and informative blog written by a former CEO and President of Beth Israel Deaconess Medical Center in Boston (and a former MIT faculty member, with lots of Sloan friends), go to the blog “Not Running A Hospital” by Paul Levy. Peruse the archived and recent blog entries – see the...
ones he wrote after speaking to this class on Feb. 4, 2009, and on February 9, 2011.
http://runningahospital.blogspot.com/.


Feb. 11, 2015 The Changing Architecture of the US Health Care System


Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


**Historical U.S. health care expenditure data and discussion of recent developments can be found at the Center for Medicare and Medicaid Services website: http://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage


Feb. 18, 2015 Historical and Current Tools to Manage Health Care Access, Quality and Costs


Readings/Listenings (* denotes optional; **denotes very optional – background reading):


Feb. 24, 2015, 5 pm First essay due – required – understanding accountable care organizations

Feb. 25, 2015 Managing Those Who Manage R&D


Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


March 4, 2015: The Business of Science: Designing and Managing Clinical Investigations

Prof. Berndt and Guest, joint presentation/discussion: “Establishing Efficacy and Safety Through Randomized Controlled Clinical Trials: A Review of Fundamental Tools, Issues and Strategies” and
guest: Willard H. Dere, MD, Former Senior Vice President and International Chief Medical Officer, Amgen, Thousand Oaks, CA, and now Clinical Professor, University of Utah Medical School, “Drug Development from Bench to Bedside: The Case of Denosumab”. Dinner.

Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


March 11, 2015  Principles and Practices of Cost-Effectiveness Analysis


Readings/Listenings (* denotes optional; ** denotes very optional – background reading):

***Note: I have posted on Stellar a 77-slide powerpoint presentation given by Gold et al. (see reference below), “Cost Effectiveness in Health and Medicine” at the National Institutes of Health in Bethesda, Maryland on November 25, 1996. This slide set should be a most useful reference in doing your Essay #2.

To gain some background concerning cervical cancer and recommended screening frequency for girls and women, listen to CNN’s Dr. Sanjay Gupta, interviewed by Saundra Young on November 20, 2009. Link to and click to play

Then go to the Harvard web site below and read the short summary of an interview by Focus magazine January 8, 2010, with Dr. Jane Kim, one of the study authors: http://focus.hms.harvard.edu/2010/010810/cervical_cancer.shtml.


Mar. 18, 2015  No Class – Sloan Innovation Period

Mar. 25, 2015  No Class – MIT Spring Break

March 31, 2015, 5 pm: Second essay due (optional one of three) – cost-effectiveness of the HPV vaccine Gardasil

April 1, 2015  New Therapies and Diagnostics for the Prevention and Treatment of Tropical and Other Diseases in Poor Countries

Prof. Berndt: “Alternative Policy Tools to Restructure Incentives for the Development of Medicines for Tropical and Other Diseases in Poor Countries”


*Readings/Listenings (* denotes optional):*


**April 8, 2015**  The Hype Over Personalized Medicine: Facts and Fairy Tales

Prof. Berndt “Medical Diagnostics and their Characteristics: A Primer”

Immunology Systems Pharmacology and Biomarkers, Janssen Research and Development, Springhouse, PA. Dinner.

Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


**Friday, April 10, 2015, 5pm:** Third essay due (optional one of three) – evaluating alternative innovation incentive tools

April 15, 2015  Analyses of Recent Drug Shortages in the US

Prof. Berndt: “Economic Issues Underlying the Recent Drug Shortages in the US”

Guests: Sylvia Bartel, MPH, RPh, Vice President Pharmacy and Clinical Support, Dana Farber Cancer Institute, Boston, MA, “Cancer Drug Shortages: Perspectives from a Hospital Pharmacy Director”. Dinner.

Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


**April 21, 2015 5 pm** Fourth essay due (optional one of three) – evaluating biomarker diagnostics for stratified medicine

**April 22, 2015** Biologics, Small Molecules and Biobetters: Comparisons and Contrasts of Scientific and Economic Issues

Prof. Berndt: “Pharmaceuticals, Biologics and Vaccines: Comparisons and Contrasts Through the Product Life Cycle”


*Readings/Listenings (denotes optional; ** denotes very optional – background reading):*


**April 29, 2015  Information Technology and Big Data in Healthcare**


Guest: **Marc Berger, M.D., Vice President, Real World Data and Analytics, Pfizer, Inc., New York, “Assembling and Analyzing Big Data at Pfizer”.** No Dinner.

Readings/Listenings (* denotes optional; ** denotes very optional – background reading):


*Axel Heitmueller, Sarah Henderson, Will Warburton, Ahmed Elmagarmid, Alex “Sandy” Pentland, and Ara Darzi, “Developing Public Policy To Advance The Use of Big Data In Health Care”, *Health Affairs* 33(9):1523-1530.


**May 5, 2015, 5 pm:** Fifth essay due (optional one of three) – evaluating the prospects for biosimilars

**May 6, 2015 The Global Pricing of Pharmaceuticals**


*Readings/Listenings (* denotes optional; ** denotes very optional – background reading):*


**May 13, 2015**

**Marketing Medicinal Products Directly to Consumers: Issues and Impacts**

Prof. Berndt: “The United States’ Experience with Direct-to-Consumer Marketing of Prescription Drugs: What Have We Learned?”


*Readings/Listenings (* denotes optional; ** denotes very optional):*


Classroom Values@MIT Sloan


The mission of the MIT Sloan School of Management is to develop principled, innovative leaders who improve the world and to generate ideas that advance management practice.

**Values@MIT Sloan**  [https://mysloan.mit.edu/offices/deans/values/Pages/default.aspx](https://mysloan.mit.edu/offices/deans/values/Pages/default.aspx)

The MIT Sloan Mission statement (above) provides the context for core values that express who we are at our best. These core values include **integrity**, **respect**, **collaboration**, **innovation**, and **positive impact**. We invite all members of our community – students, staff, faculty, alumni – to practice these values in all the ways we work together, both inside and outside of the classroom.

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**MIT Sloan Policy on Classroom Behavior**

In order to create a productive learning environment and to ensure mutual respect it is essential that the norms and rules of classroom etiquette and behavior reflect the highest standards. It is also important that these norms be consistently enforced by the faculty across all classes. Although in the final analysis each faculty member is responsible for his or her own classroom, there are significant negative consequences for other faculty and for the School if rules are not consistent and are not enforced. Therefore it is the policy of the MIT Sloan School that:

- Students are expected to arrive promptly on time and to stay for the entire class.
- Faculty are expected to begin and end class on time.
- Laptops and e-readers are not be open in the classroom except with explicit permission of the faculty (e.g., when used as part of the instructional program or when required by students because of physical or other challenges)
- Cell phones and PDAs are not to be used or permitted to ring in the classroom.
- Students are expected to attend all classes.

It is expected that faculty will articulate how these rules apply in their class as well as how the rules will be enforced.
A Note re Recruiting

Please note that in accordance with this policy, MIT Sloan requires that students schedule campus interviews outside of scheduled class times and to make every attempt to schedule second round interviews and site visits outside of class times. Classes missed for such activities are not excused absences and may count against your participation grade.

ACADEMIC HONESTY – INTEGRITY IN PRACTICE

As a member of the MIT Sloan academic community, you are expected to uphold the highest standards of academic integrity. Violations of academic integrity include, but are not limited to, cheating, plagiarism, unauthorized collaboration, and facilitating academic dishonesty. Please see the document Academic Integrity at the Massachusetts Institute of Technology: A Handbook for Students for further discussion of this topic. These standards are also discussed below, specifically regarding plagiarism, individual work, and team work.

It is your responsibility to make yourself aware of MIT’s rules of academic integrity and to adhere to them. When students are found to have violated academic standards, disciplinary action will result. Possible consequences include grade reduction, an F grade, a transcript notation, delay of graduation, or expulsion from MIT.

This discussion of academic integrity below is not exhaustive, and there may be areas that remain unclear to you. If you are unsure whether some particular course of action is proper, it is your responsibility to consult with your professor and/or teaching assistant for clarification.

Plagiarism

Plagiarism occurs when you use another’s intellectual property (words or ideas) and do not acknowledge that you have done so. Plagiarism is a very serious offense. If it is found that you have plagiarized -- deliberately or inadvertently -- you will face serious consequences, as indicated above.

The best way to avoid plagiarism is to cite your sources - both within the body of your assignment and in a bibliography of sources you used at the end of your document.

Materials gathered through research via the Internet must be cited in the same manner as more traditionally published material. Lack of such citation constitutes plagiarism.

To review rules of citation: http://libguides.mit.edu/content.php?pid=80743&sid=598642
Individual Assignments

Many assignments in MIT Sloan courses are expected to be done individually. The information below outlines what is meant by “individual” work. These rules should be observed unless otherwise defined by the instructor.

When you are asked to do individual work, you are expected to adhere to the following standards:

- Do not copy all or part of another student’s work (with or without “permission”).
- Do not allow another student to copy your work.
- Do not ask another person to write all or part of an assignment for you.
- Do not work together with another student in order to answer a question, or solve a problem, or write a computer program jointly.
- Do not consult or submit work (in whole or in part) that has been completed by other students in this or previous years for the same or substantially the same assignment.
- Do not use print or internet materials directly related to a case/problem set unless explicitly authorized by the instructor.
- Do not use print or internet materials without explicit quotation and/or citation.
- Do not submit the same, or similar, piece of work for two or more subjects without the explicit approval of the two or more instructors involved.

Please note that many classes will require a combination of team work and individual work. Be sure that you follow all the guidelines for individual work when a faculty member identifies an assignment as an individual one.

Team Assignments

When you are asked to work in teams, there is a broad spectrum of faculty expectations. Three general types of appropriate collaboration on team assignments are described below. The instructor will indicate in the syllabus what his/her expectations are. If there is any uncertainty, it is the student’s responsibility to clarify with the professor or TA the type of team work that is expected.

Type 1 collaboration:
The professor states that collaboration is allowed, but the final product must be individual. An example of this might be a problem set.

- You are allowed to discuss the assignment with other team members and work through the problems together.
- What you turn in, however, must be your own product, written in your own handwriting, or in a computer file of which you are the sole author.
- Copying another’s work or electronic file is not acceptable.
Type 2 collaboration:

The professor states that collaboration is encouraged but that each person's contribution to a given deliverable does not have to be substantial (allowing groups to take a "divide and conquer" approach). An example of this might be a brief progress report that is part of a more extensive collaboration (as a whole, the more extensive collaboration may be Type 3).

- Each team member is encouraged to contribute substantially to the team assignment, however, the team may choose to assign one or more team members to prepare and submit the deliverable on behalf of the team.
- Regardless of how work is shared or responsibilities are divided among individual team members, each member of the team will be held accountable for the academic integrity of the entire assignment. If, for example, one member of the team submits plagiarized work on behalf of the team, the entire team will be subject to sanctions as appropriate.
- The team may not collaborate with other students outside of the team unless the professor explicitly permits such collaboration.

Type 3 collaboration:

The professor states that collaboration is expected and that each team member must contribute substantially to the deliverable. An example of this might be the 15.311 OP project.

- Each team member must make a substantial contribution to the assignment. It is not, for example, acceptable to divide the assignments amongst the team members (e.g., part of the team completes the OP Project while the rest of the team prepares a team case for DMD), though the team may divide the work of any one assignment to complete it as they deem appropriate.
- The team may not collaborate with other students outside of the team unless the professor explicitly permits such collaboration.

*If you are unsure whether some particular form of interaction is proper in individual or team work, it is your responsibility to consult the instructor and/or teaching assistant for clarification and guidance.*