

THE BUSINESS OF BIOLOGY

SYLLABUS - FALL 2018

During the past decade, advances in life science research, drug discover, and the development of medical devices have continued at a breathtaking pace. The most notable example is the growth of our understanding of the human genome, human genetic variation, and the role that genes play in our everyday health, response to treatment and susceptibility to disease. These advances -- coupled with faster, better and cheaper information technology -- usher in both opportunity and peril for individuals, companies and societies. Accelerating our progress toward “personalized health care” will require:

- Continued advances in the life sciences
- Improvements in technology to make these advances “work” in human populations
- Thoughtful commercialization to make these advances available to affected human populations on a safe and cost-effective basis
- Knowledge and empowerment to help consumers understand the individualized risks and opportunities that lie in genomic medicine
- Enlightened public and private policies to increase the value-added intersections between the life sciences, technologies, commercialization, and the consumer.

The objective in this interdisciplinary graduate course is to explore the intersections between science, technology, commerce and social policy as they come together to advance (and in some cases retard) progress toward more-personalized health care. The course is a salon-style sampling of the issues facing the core businesses of biology including large and small pharmaceutical companies and biotech, medical device and genetic testing companies. The course is intended for graduate students in medicine, biomedical and health-related science, public health, law, engineering, and business interested in the future of health care. It is designed to provide a framework to enhance the understanding of the complex scientific and socioeconomic trends, opportunities and challenges that are taking place in the rapidly evolving fields of personalized medicine, molecular diagnostics, and targeted therapeutics. Because of the variation in student backgrounds coming into the course, efforts are made at the beginning to establish a shared vocabulary and knowledge base across the disciplines.

A multidisciplinary faculty teaches in the course, supplemented by outside speakers with hands-on experience in their fields. Interdisciplinary student teams are assigned to research a particular company currently operating in the sector and explore it from the perspective of the issues raised in the course. Team reports on these findings will be made at a colloquium at the end of the course attended by faculty and students participating in the section.

Important Notice: The course meets from September 5th to October 15th on Mondays and Wednesdays from 8:20 to 9:50 am in Ross School of Business, Blau building, B3570. **There will be four additional required evening sessions: Thursdays 9/6, 9/20, 9/27, and 10/11.** The evening sessions will take place from 5:00-7:30pm.

COURSE MATERIALS

All required course reading will be available on the Canvas website. You will receive an email with an invitation to the course site.

CANVAS

Canvas includes announcements, the syllabus, assignments, readings, and the lecture presentations. Optional articles, a bibliography, and additional web resources may also be posted.

TIMES AND LOCATIONS

Regular class sessions are held Monday and Wednesday from 8:20 to 9:50 am in Ross School of Business, Blau building, B3570. Class will start **promptly** at 8:20 am.

In addition to regular class periods, four evening sessions have been scheduled. These sessions are an integral part of the course; any absence from them must be cleared with the instructor in advance:

- **Evening 1** **September 6, 2017** **5:00-7:30pm**
Location: Ross School of Business, Blau building, B3570
 - **Session Title:** The price of new drugs: are they justified and sustainable? Or is Big Pharma gouging the public? The impact of reputation on business.
 - **Speaker:** John LaMattina

- **Evening 2** **September 20, 2016** **5:00-7:30pm**
Location: Ross School of Business, Blau building, B3570
 - **Session Title:** Mid-term discussion / Animal Health
 - **Speaker:** David Canter/Raja Krishnan

- **Evening 3** **September 27, 2016** **5:00-7:30pm**
Location: Ross School of Business, Blau building, B3570
 - **Session Title:** Building a biotech business-the story of two Esperions
 - **Speaker:** Roger Newton

- **Evening 4** **October 11, 2016** **5:00-7:30pm**
Location: Ross School of Business, Blau building, B3570
 - **Group presentations of company case studies***
 - **External Evaluator:** Diane Bouis and Elke Lipka

* Each group will meet with me for an hour to help in the preparation of the company case presentation

I will hold a few small tutorials to help students who have missed one or two early classes in help them catch up. These tutorials are organized at short notice and as needed.

COMMUNICATION

Below is my contact information. Feel free to communicate with me as needed. E-mail is best for quick exchanges. If you want to talk by telephone, feel free to call. If you want to get together for an in-person discussion, please make an appointment in advance by contacting Ann Savory.

David Canter
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Course Assistant:
Ann Savory
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734-615-5242

STUDENTS WITH DISABILITIES

If you think you need an accommodation for a disability, please let me know at your earliest convenience. Some aspects of the course, the assignments, the in-class activities, and the way we teach may be modified to facilitate your participation and progress. As soon as you make me aware of your needs, I can work with the Office of Services for Students with Disabilities to help determine appropriate accommodations^{**}. I will treat information you provide as private and confidential.

RELIGIOUS HOLIDAYS

I know several religious holidays occur during the course period and I respect the needs of those students who observe these holidays. Please talk to me early about missing class.

COURSE SCHEDULE: WEDNESDAY, SEPTEMBER 5TH – MONDAY, OCTOBER 15TH 2017

Pre-class work:

1st Assignment: Complete and Submit assignment and survey to asavory@umich.edu, by Noon Tuesday Sept 4th

"American Patients First" The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, May 2018.

Session 1 Wednesday, September 5th

Topic	Introduction to the course; issues affecting the drug industry; Business perspective based on ROI/cost-to-play for development and marketing of drugs (Part 1)
Leader	David Canter
Reading(s)	Pollack, A. (2014, Jul 12). A fitness test, on the smallest scale. <i>New York Times</i>
Assignment	2nd Assignment: Brief analysis of a company. Discussion at September 10th class. Email finished assignment to asavory@umich.edu by 8am, 9/11.

Session 2 Thursday, September 6th EVENING SESSION

Topic	The Price of new drugs: are they justified and sustainable? Or is Big Pharma gouging the public?
Leader	John LaMattina, PhD Past President of Research and Development, Pfizer, Inc.
Reading(s)	Hwang, Thomas J.; LaMattina, John L. "Measuring the Value of New Medications and Implications for Medicare's Proposed Part B Drug Payment Model" <i>JAMA Oncology</i> , 2016; 2 (9), 1125-1126. LaMattina, John L. "Approving New Drugs", <i>Science</i> , 2017, Volume 355, 777. LaMattina, John L. "There Go Those Drug Companies Inventing Disease Again" <i>Forbes.com</i> , June 20, 2018. LaMattina, john L. "How Much profit should Novartis Earn By Curing A Childhood Leukemia?" <i>Forbes.com</i> , February 12, 2018.

Session 3 Monday, September 10th

Topic	Business perspective based on ROI/cost-to-play for the discovery/development and marketing of drugs (Part 2)
Leader	David Canter
Reading(s)	n/a
Assignment Due	2nd Assignment Due - Company Analysis Email finished assignment to asavory@umich.edu by 8am, 9/11.

Session 4 Wednesday, September 12th

Topic	Genetics Research and Genomic Medicine – A View From a Physician/Scientist
Leader	David Ginsburg, MD Investigator, Howard Hughes Medical Institute James V Neel Distinguished University Professor of Internal Medicine, Human Genetics, and Pediatrics
Reading(s)	Allyse MA, Robinson DH, Ferber MJ, Sharp RR. Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing. <i>Mayo Clin Proc.</i> 2018 Jan;93(1):113-120. Burke, W. and S. B. Trinidad (2016). "The Deceptive Appeal of Direct-to-Consumer Genetics." <i>Ann Intern Med</i> 164(8): 564-565. Le Tourneau, C., et al. (2015). "Molecularly targeted therapy based on tumour molecular profiling versus conventional therapy for advanced cancer (SHIVA): a multicentre, open-label, proof-of-concept, randomised, controlled phase 2 trial." <i>Lancet Oncol</i> 16(13): 1324-1334

Session 5 Monday, September 17th

Topic	Intellectual Property & the Biopharmaceutical Industry, Foundations & Controversies
Leader	John Osborn, JD, MIPP Senior Advisor, Hogan Lovells; Industry Advisor, Warburg Pincus; Affiliate Professor, Univ of Washington; Contributor, Forbes.com
Reading(s)	Loomis, Tamara, "Settling for More", <i>IP Law & Business</i> , May 2006 Osborn, J. (2013, June 26). "Supreme Court Punts on Pay For Delay, But Will Generic Filings Under Hatch-Waxman Decline?" Gilead letter Burrone, E., <i>WIPO Patents at the Core: the Biotech Business</i> (2006) Why Don't More Americans Use PrEP?, <i>New York Times</i> (July 17, 2018). March-In Rights Under the Bayh-Dole Act, <i>Congressional Research Service</i> (Aug 22, 2016) Break the Patent! https://breakthepatent.org
Assignment	3rd Assignment - Personal Genomics. Due 9/24

Session 6 Wednesday, September 19th

Topic	The Cost of Regulation on the Medical Device Industry
Leader	Scott Merz, PHD Chief Executive Officer and Co-Founder, MC3 Cardiopulmonary
Reading(s)	Bomey, Nathan, "After 'systematic breakdowns' and \$35 million FDA fine, Terumo Cardiovascular Systems promises fixes", <i>The Ann Arbor News</i> , Apr 10, 2011 FDA Impact on U.S. Medical Technology Innovation, A Survey of Over 200 Medical Technology Companies, November 2010 McKinsey & Company; Capturing the value of good quality in medical devices. Feb 2017. http://time.com/5346330/what-the-netflix-documentary-bleeding-edge-gets-right-about-the-dangers-of-medical-devices-in-america/
Assignment	Group Project Assigned September 19th

Session 7 Thursday, September 20th EVENING SESSION

Topic	1) Mid-course discussion 2) The business approach to research in animal health, medicine, and vaccines
Leader	David Canter Raja Krishnan Senior Director, Companion Animals and Equine Biologicals, Global Biologics Research
Reading(s)	Animal Health R&D A Business Approach to Research presentation pdf and discussion topics pdf.

Session 8 Monday, September 24th

Topic	Building value in an early stage drug discovery and development company
Leader	Gary Hammer Professor of Internal Medicine Co-founder, Millendo Therapeutics Julia Owens Co-founder and CEO, Millendo Therapeutics
Reading(s)	Orphan drugs attract rich returns for pharmaceuticals. <i>Financial Times</i> , Andrew Jack, February 27, 2017. OvaScience and Millendo Therapeutics Announce Merger to Create Leading Rare Endocrine Disease Company, <i>Business Wire</i> , August 9, 2018. AstraZeneca Spins Out Women's Health Treatment To \$62M Startup, Millendo. <i>Forbes</i> , Luke Timmerman, January 5, 2016.
Assignment Due	3rd Assignment Due – Personal Genomics Submit by 5 pm, Thursday September 24th email to asavory@umich.edu

Session 9 Wednesday, September 26th

Topic	Healthcare Venture Capital Investing
Leader	Paul McCreadie Managing Director, Aboretum Ventures
Reading(s)	Venture Capital Presentation Session #9. pdf

Session 10 Thursday, September 27th EVENING SESSION

Topic	Founding and Leading Biotech Businesses in Michigan: The Story of Two Very Different Companies named Esperion Therapeutics
Leader	Roger Newton, PhD Founder, Executive Chairman and Chief Scientific Officer, Esperion Therapeutics
Reading(s)	Awakening The Biotech Entrepreneurial Spirit, <i>Life Science Leader</i> , Camille Mojica Rey (June 2017). Pinkosky, S. L., Newton, R. S., Day, E. A., Ford, R. J., Lhotak, S., Austin, R. C., ... & Steinberg, G. R. (2016). Liver-specific ATP-citrate lyase inhibition by bempedoic acid decreases LDL-C and attenuates atherosclerosis. <i>Nature communications</i> , 7, 13457 State Funding Fuels Michigan's Life Sciences Industry, <i>Life Science Leader</i> , Camille Mojica Rey (April 2017). Esperion Executives Defend Their Drug After Stock Crashes, Forbes, May 2, 2018

Session 11 Monday, October 1st

Topic	Ethical Issues Now and Later
Leader	Liz Barry Special Counsel to the President, University of Michigan
Reading(s)	Susannah Baruch, J.D., "Pre-implantation genetic diagnosis and parental references: Beyond deadly disease" 8 HOUS. J. HEALTH L. & POL'Y 245-270 ISSN 1534-7907 "Parents' Interest in Predictive Genetic Testing for Their Children When a Disease Has No Treatment" Pediatrics 2009;124:e432; Beth A. Tarini, Dianne Singer, Sarah J. Clark and Matthew M. Davis 10.1542/peds.2008-2389 Kolata, G. (2014, Feb 04). Gene tests, healthy children and ethical doubt. <i>New York Times</i> Genetically testing human embryos: what you need to know about the debate. <i>The Conversation</i> , Darren Griffen, Alan Thornhill, Cagin Ogur July 16, 2018.

Session 12 Wednesday, October 3rd

Topic	How Regulatory Agencies shape business decisions in drug development
Leader	Mark Ammann, PharmD President, Catalyst Regulatory Services Toni Marie Nearing Senior Director, Regulatory Strategy, Catalyst Regulatory Services
Reading(s)	How Orphan Drugs Became a Highly Profitable Industry Government incentives, advances in technology, and an army of patient advocates have spun a successful market—but abuses of the system and exorbitant prices could cause a backlash. Posted on May1,2018. By: Diana Kwon Taking New Steps to Meet the Challenges of Rare Diseases - FDA Marks the 11th Rare Disease Day. Posted on February 26, 2018 by FDA Voice. By: Scott Gottlieb, MD. Watch these series of three videos: https://www.youtube.com/watch?v=F1TbvdjmXJ8 – Introduction to Orphan Drugs https://www.youtube.com/watch?v=x1Vn0kqSvfk – Orphan Drug Costs https://www.youtube.com/watch?v=rZhE2GcFid0 – Gaming the System

Session 13 Monday, October 8th

Topic	The commercial potential of personalized medicine
Leader	Robert Penny, MD, PhD Founder & CEO Paradigm. Past Co-founder & CEO International Genomics Consortium
Reading(s)	Precision Medicine: Technology, Regulations and Challenges. March 11,2016 Precision medicine: drowning in a regulatory soup? J lawBiosci (2016) doi: 10.1093/jlb/lsw018 The Economist: Health care, All about the base, (June 2016). Immunotherapy: beyond melanoma and lung cancer treatment. Crow, David. The Financial Times. March 5, 2018.

Session 14 Wednesday, October 10th

Topic	Big Data and Healthcare: How do companies create value in this area?
Leader	Alfonso Y. Chang, CFA Managing Director The AC ³ Group
Reading(s)	Kayyali et al. "The 'Big Data' Revolution in Healthcare." McKinsey & Company, Center for US Health System Reform Business Technology Office, January 2013. Marr, Bernard. "How Big Data is Changing Healthcare." Forbes, April 21, 2015. Eastwood, Brian. "In Evolving Healthcare Business Model, Tech Plays Vital Role." CIO, September 23, 2014. MapR Guide to Big Data in Healthcare, Data Convergence in Healthcare (2016) pp 4-7.

Session 15 Thursday, October 11th EVENING SESSION

Instructions	Group Project – slide presentations and bibliography are due to Ann Savory by noon. Please email as attachments to asavory@umich.edu
Topic	Group Presentations of Company Case Studies
External Evaluator	Diane Bouis, PhD, MBA Director of Innovation Programs, The Inovo Group Elke Lipka, PhD, MBA President, TSRL, Inc
Final Exam Assigned	Take home – Return by 5:00 pm October 16th email to asavory@umich.edu and canterd@umich.edu

Session 16 Monday, October 15th

Topic	New Models and Emerging Trends in Biotech
Leader	Craig Parker CEO, Surrozen Inc.
Reading(s)	Deloitte Centre for Health Solutions, "A new future for R & D (2017) Deloitte 2017 Life Sciences Outlook

COURSE ASSIGNMENTS AND GRADING

30%	Class preparation including the assigned readings and active class participation. There will be a sign-in for recording attendance. Name tags are required to be displayed in class. I ask that laptops, cell phones, pagers, etc. not be used in class.
30%	Group Project: progress note will be due 9/26 at 11:59 pm Presentations on October 11th, 5:00-7:30 pm
40%	Take-Home Final Exam – due by 5:00 pm 10/16/18 email to asavory@umich.edu and canterd@umich.edu

****Important - Procedures for Accommodating Student Disabilities (e.g. requests for extra time)**

The University of Michigan is committed to providing equal opportunity for participation in all programs, services and activities. Students wishing to receive testing accommodations must register with the UM SSD ([Services for Students with Disabilities](#)) as soon as possible. Students must then submit their Verified Individualized Services and Accommodations (VISA) form via online web form as early as possible, but no later than two weeks prior to the first test or quiz for which accommodations are requested.

Requests must be sent using the [Accommodations Request Form](#) and must include a scanned or photographed copy of the VISA form. This form only needs to be submitted once during your academic career with Ross unless your accommodations expire.

Questions can be directed to the Accommodations Coordinator at RossAccommodationsCoordinator@umich.edu.

In rare cases, the need for an accommodation arises after the two-week deadline has passed (for example, a broken wrist). In these cases, the student should still contact SSD and the Ross Accommodations Coordinator at RossAccommodationsCoordinator@umich.edu, however, due to logistical constraints we cannot guarantee that an accommodation can be made after the two-week deadline has passed.