

**Business Communications and
Business Ethics
Course Number: 22:373:621
Course Title: Ethics in Pharma**

COURSE DESCRIPTION

The prescription drug industry provides important, sometimes life-saving, medical treatments for patients. Such treatments may treat symptoms, cure disease or even extend a patient's life. There are special considerations for their development and commercialization. For example, how is clinical research conducted to ensure that patient's rights are protected and what price is assigned upon product approval (and is financial assistance provided to those who cannot afford it)? Additionally, how is the product promoted so that healthcare providers and consumers alike receive lawful, nonmisleading communications without running afoul of off label promotion prohibitions? What about ensuring patient safety and making the right decisions to update product warnings or potentially withdraw a product from the market? In this course we will explore all of these issues and more as we consider the lawful and ethical marketing and sale of FDA-regulated unavoidably dangerous products.

In this course you will hear from three individuals with extensive experience in the pharmaceutical industry. We will share our unique perspectives (Legal/Compliance, Business/Management and Medical/Research) and highlight areas of heightened concern due to legal, regulatory or ethical considerations.

Classes will include traditional lectures, as well as interactive discussions about case studies and scenarios. Guest speakers from industry, and potentially the government, will also visit from time-to time to share their perspectives. It is important that you come prepared to class, having completed the assigned readings for that day's discussion.

COURSE MATERIALS

Textbook(s) (Required):

Schwarz Alan, ADHD Nation – Children, Doctors, Big Pharma, and the Making of an American Epidemic 2016 (ISBN 978-1-5011-0591-3).

Textbook(s) [Optional]:

- Dorfman HL (Ed). Practising Law Institute, Pharmaceutical Compliance and Enforcement Answer Book 2018 (ISBN: 978-1-4024-3139-5).

- Griffin JP, Posner J and Barker GR (Eds). *The Textbook of Pharmaceutical Medicine*. 2013. Wiley-Blackwell. BMJ Books. Oxford. (ISBN 978-0-470-65987-8).
- Santoro MA, Gorrie TM. *Ethics and the Pharmaceutical Industry*, 2005 Cambridge University Press. (ISBN 0-521-85496-2)
- Vernon, John A and Golec, Joseph H. *Pharmaceutical Price Regulation, Public Perceptions, Economic Returns, and Empirical Evidence*, AEI Press, 2008 (ISBN -13: 978-0-8447-4277-9)
- Bernard Clements et al (Editors): *The Economics of Public Health Care Reform in Advanced and Emerging Economies*, International Monetary Fund (2012) (ISBN 978-1-61635-244-8)

– Various Assigned Readings - *Check Canvas and your official Rutgers email account regularly.*

LEARNING GOALS AND OBJECTIVES

This course is designed to help students develop skills and knowledge in the following area(s):

This course will help aspiring executives in pharmaceutical companies to develop the knowledge, skills and ethical compass for success. You will develop an awareness of the medical, legal and regulatory framework for medicines development, clinical research, marketing and sale of prescription drugs. You will also be able to identify ethical considerations that should inform day-to-day business decisions. You will also compare and contrast health systems around the world and consider the business and policy implications of those differing approaches.

The discussion of the topics listed below should help the students acquire a sound understanding of pressing healthcare access, coverage, pricing and reimbursement issues as well as ethical and business imperatives and the incentives required for investment and innovation. The course will also shed light on healthcare decision-making tools, their uses and limitations. Finally, we will discuss various issues pertaining to public health, patient assistance programs and the appropriate roles of all relevant stakeholders.

– **Students who complete this course will demonstrate an understanding of the following:**

- 1) What is the difference between bioethics and business ethics? Why is business ethics important, and how do you foster a culture of performance with high integrity?
 - a. Examine the broader question of ethics and how it may frame company culture and decision making in pharma
 - b. Explore real-world examples of corporate lapses in business ethics, why these came about, and how, in some cases, they led to the downfall of the company and those involved
 - c. Consider different strategies for promoting integrity leadership and maintaining a culture of business ethics
- 2) Monitoring Drug Safety (During Drug Development, as Well as After FDA Approval and Commercialization), including

- a. Considerations Impacting Product Label Updating or Market Withdrawal
 - b. Recent Product Liability Case Law & Associated Risks
- 3) Statutory & Regulatory Requirements for Lawful, Non-Misleading Drug Promotion, including
- a. Recent First Amendment Challenges to FDA Restrictions (Amarin, Pacira)
 - b. Legal Considerations for "Hub" Services for Specialty Pharmaceuticals
 - c. Expectation of Separation of Commercial & Medical Functions (including use of Medical Science Liaisons)
 - d. "Consistent with Labeling" Draft FDA Guidance & Expanding the Marketing Message
- 4) How Government enforcement gave rise to a profession
- a. Corporate history: who's been around longer, legal or compliance? b.
 - c. How did the compliance profession spring to life?
 - d. Given all the sanctions, why do violations continue?
 - e. Can there be individual liability?
 - f. Advice for future business leaders
- 5) Increased global focus on high cost medicines and devices
- a. Cost concerns about, contributions and value of pharmaceuticals
 - b. Perceptions of pricing of past and present drugs and link to economic sustainability
 - c. Present vs Future Patient and Societal Needs and Incentives for Innovation
- 6) Intellectual Property, Rewards for innovation and Access
- a. The importance of IP - scope and limits
 - b. Role of generics and biosimilars
 - c. How to balance access and innovation?
 - d. CLs, Tiered pricing, Pooled Procurement
- 7) Global Health Care Systems and Experiences: Reform Agendas, Challenges and Opportunities
- a. Global questions – Advanced economies vs developing countries
 - b. Universal healthcare reform and payment system changes
 - c. Medicare for All – Proposals and Debate on Single Payer Systems in the US
 - d. The link between Investment in health and healthcare/pharmaceuticals and economic development
- 8) Introduction to Healthcare Evaluation
- a. Efficiency vs Cost-containment
 - b. International Models: QALY based models vs other options: applications and pitfalls
 - c. Global collaboration and cross pollination among HTA system
 - d. Difference between drugs and other medical products/devices

- 9) Patient Access, Global Public Health CSR: Role of various stakeholders
 - a. Purpose, Types and Impacts of Patient Access programs
 - b. Vaccines, Infectious Diseases, New Treatments for Pandemics
 - c. CSR vs Global Community Impact
 - 10) State/Federal Laws on Sunshine Act Disclosures, Code of Conduct Adherence, Price Disclosures & Related Topics
 - 11) Pre-Approval Outreach, Payor-Directed Communications & Health Economic Outcomes Research
 - a. Review of 21st Century Cures Act and FDA Guidance on Payor-Directed Communications
 - b. Academy of Managed Care Pharmacy Dossier Development
 - c. Use of Budget Impact Models & Non-Clinical, Retrospective Data to Show Drug “Value”
 - 12) The primacy of good governance in pharma and enterprise risk management
 - a. Considerations in global reporting lines
 - b. Conducting business directly or through 3rd parties
 - c. Elements of an effective compliance program
 - d. What is enterprise risk management?
 - e. Oversight by senior leadership and the board of directors
 - f. Importance of good communication and concept reviews
 - 13) Global trends in legal enforcement
 - a. Bribery and corruption
 - i. Growing number of world-wide laws
 - ii. Basic requirement across these laws
 - iii. International corruption index
 - iv. Key topics and cases
 - v. LATAM – the battle to rise above corruption
 - b. International pharmaceutical industry codes
 - c. International transparency requirements
 - 14) Spotlight on patient advocacy
 - a. The rise of patient-centricity and the purpose of patient advocacy
 - b. Governance considerations
 - c. Donations to foundations
 - d. Patient field interactions
 - e. An area of future enforcement?
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PREREQUISITES

Students should come to class prepared to share their perspectives on current industry standards and precedent (based on pre-reading materials), as well as consider best practices and approaches in light of legal, regulatory and ethical considerations.

ACADEMIC INTEGRITY

I do NOT tolerate cheating. Students are responsible for understanding the RU Academic Integrity Policy (<http://academicintegrity.rutgers.edu/>).

I will strongly enforce this Policy and pursue *all* violations. On all examinations and assignments, students must sign the RU Honor Pledge, which states, “On my honor, I have neither received nor given any unauthorized assistance on this examination or assignment.” I will screen all written assignments through *SafeAssign* or *Turnitin*, plagiarism detection services that compare the work against a large database of past work. Don’t let cheating destroy your hard-earned opportunity to learn. See business.rutgers.edu/ai for more details.

ATTENDANCE AND PREPARATION POLICY

- Expect us to attend all class sessions. We expect the same of you. If we are to be absent, our department chair or we will send you notice via e-mail and Canvas as far in advance as possible. If you are to be absent, report your absence in advance at <https://sims.rutgers.edu/ssra/>. If your absence is due to religious observance, a Rutgers-approved activity, illness, or family emergency/death and you seek makeup work, also send us an e-mail with full details and supporting documentation within 7 days of your first absence.
 - For weather emergencies, consult the campus home page. If the campus is open, class will be held.
 - Expect us to arrive on time for each class session. We expect the same of you.
 - Expect us to remain for the entirety of each class session. We expect the same of you.
 - Expect us to prepare properly for each class session. We expect the same of you. Complete all background reading and assignments. You cannot learn if you are not prepared. The minimum expectation is that for each two hours and fifty minute class session, you have prepared by studying for at least twice as many hours.
 - Expect us to participate fully in each class session. We expect the same of you. Stay focused and involved. You cannot learn if you are not paying attention.
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CLASSROOM CONDUCT

Students should show respect for others by raising their hands before speaking and also being prepared to contribute if called upon to answer a question or share a perspective. Cell phones should not be out during class (except in case of emergency) and the sending of texts or emails during class is strongly discouraged as it can be distracting for you and your classmates.

GRADING POLICY

Students will be expected to complete three written assignments (one per instructor). More instructions about each written assignment will be given in class. Each of the three assignments will be either a paper or take-home fact pattern test.

Each instructor will assign one grade. The three instructors' grades will be added together and divided by three to arrive at your final class grade. Extra credit assignments will not be offered for this class.

Your final grade is not subject to negotiation. If you feel we have made an error, submit your written argument to us within one week of receiving your final grade. Clarify the precise error we made and provide all due supporting documentation. If we have made an error, we will gladly correct it. But we will adjust grades only if we have made an error.

COURSE SCHEDULE

This is a course offered in the Newark and New Brunswick campuses. The class is taught by 3 professors. The professors have pre-determined which of the above subjects they will teach and typically only one professor will teach on any given day. () teaches from the New Brunswick campus. () teaches at either the New Brunswick or Newark campus. () teaches from the Newark campus. Both campuses will be connected by video monitor and students have the option of participating in each class from either location.

SUPPORT SERVICES

If you need accommodation for a *disability*, obtain a Letter of Accommodation from the Office of Disability Services. The Office of Disability Services at Rutgers, The State University of New Jersey, provides student-centered and student-inclusive programming in compliance with the Americans with Disabilities Act of 1990, the Americans with Disabilities Act Amendments of 2008, Section 504 of the Rehabilitation Act of 1973, Section 508 of the Rehabilitation Act of 1998, and the New Jersey Law Against Discrimination. More information can be found at ods.rutgers.edu.

[Rutgers University-New Brunswick ODS phone (848)445-6800 or email dsoffice@echo.rutgers.edu]

[Rutgers University-Newark ODS phone (973)353-5375 or email ods@newark.rutgers.edu]

If you are ***pregnant***, the Office of Title IX and ADA Compliance is available to assist with any concerns or potential accommodations related to pregnancy.

[Rutgers University-New Brunswick Title IX Coordinator phone (848)932-8200 or email jackie.moran@rutgers.edu]

[Rutgers University-Newark Office of Title IX and ADA Compliance phone (973)353-1906 or email TitleIX@newark.rutgers.edu]

If you seek ***religious accommodations***, the Office of the Dean of Students is available to verify absences for religious observance, as needed.

[Rutgers University-New Brunswick Dean of Students phone (848)932-2300 or email deanofstudents@echo.rutgers.edu]

[Rutgers University-Newark Dean of Students phone (973)353-5063 or email DeanofStudents@newark.rutgers.edu]

If you have experienced any form of ***gender or sex-based discrimination or harassment***, including sexual assault, sexual harassment, relationship violence, or stalking, the Office for Violence Prevention and Victim Assistance provides help and support. More information can be found at <http://vpva.rutgers.edu/>.

[Rutgers University-New Brunswick incident report link: <http://studentconduct.rutgers.edu/concern/>. You may contact the Office for Violence Prevention and Victim Assistance at (848)932-1181]

[Rutgers University-Newark incident report link: https://cm.maxient.com/reportingform.php?RutgersUniv&layout_id=7 . You may also contact the Office of Title IX and ADA Compliance at (973)353-1906 or email at TitleIX@newark.rutgers.edu. If you wish to speak with a staff member who is confidential and does **not** have a reporting responsibility, you may contact the Office for Violence Prevention and Victim Assistance at (973)353-1918 or email run.vpva@rutgers.edu]

If students who have experienced a temporary condition or injury that is adversely affecting their ability to fully participate, you should submit a request via <https://temporaryconditions.rutgers.edu> .

If you are a military ***veteran*** or are on active military duty, you can obtain support through the Office of Veteran and Military Programs and Services. <http://veterans.rutgers.edu/>

If you are in need of **mental health** services, please use our readily available services.

[Rutgers University-Newark Counseling Center: <http://counseling.newark.rutgers.edu/>]

[Rutgers Counseling and Psychological Services–New Brunswick: <http://rhscaps.rutgers.edu/>]

If you are in need of **physical health** services, please use our readily available services.

[Rutgers Health Services – Newark: <http://health.newark.rutgers.edu/>]

[Rutgers Health Services – New Brunswick: <http://health.rutgers.edu/>]

If you are in need of **legal** services, please use our readily available services: <http://rusls.rutgers.edu/>

Students experiencing difficulty in courses due to **English as a second language (ESL)** should contact the Program in American Language Studies for supports.

[Rutgers–Newark: PALS@newark.rutgers.edu]

[Rutgers–New Brunswick: eslpals@english.rutgers.edu]

If you are in need of additional **academic assistance**, please use our readily available services.

[Rutgers University-Newark Learning Center: <http://www.ncas.rutgers.edu/rlc>]

[Rutgers University-Newark Writing Center: <http://www.ncas.rutgers.edu/writingcenter>]

[Rutgers University-New Brunswick Learning Center: <https://rlc.rutgers.edu/>]

[Optional items that many faculty include:

- Students must sign, date, and return a statement declaring that they understand the RU Academic Integrity Policy.

- Students must sign, date, and return a statement declaring that they understand this syllabus.]