Syllabus

Instructor: Dr. Jared R. Mays
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Phone: x4815
Office Hours: Monday-Thursday: 11:00 am – 12:00 pm (or by appointment)

Course Title: Taking Our Medicine?: Drugs and the Pharmaceutical Industry

Course Description
The pharmaceutical industry is uniquely positioned at the interface of improving the quality of human life and the capacity for significant financial gain. This course will seek to unravel this apparent dichotomy by exploring the history, process, and ethics of pharmaceutical drug development, the factors which impact pharmaceutical marketing and pricing, and the role of physicians and pharmacists in the use (and abuse) of medications.

Course Outcomes (By the end of this course, students should be able to:)
1. Display knowledge of the development of drugs throughout history
2. Describe the stages in the drug development process
3. Explain connections between pharmaceutical intellectual property and patent law
4. Evaluate the relationship between drug pricing, marketing, and the drug life cycle
5. Understand the roles of the physician and the prescription in the regulation of drugs
6. Analyze the ethics and context of drug use and misuse

Required Materials
4. Other Supplementary Readings on Moodle

Lecture
MTWRF, 12:30 – 3:45 pm, GSC 201

Moodle
Copyrighted lecture materials (PowerPoint presentations, supplementary readings, some handouts) and student grades will be made available through Augustana’s Moodle website. Grades will be updated as assignments are completed. Moodle Website Link: http://moodle.augie.edu/moodle/login/index.php
CIVT 202A Section Code: ________________

Grading (400 points, total)
• Participation (100 points, total)
  1. Class attendance (25 points)
  2. Read, take notes, do the work (25 points)
  3. Participate in class discussions, ask questions, engage fellow students and instructors (50 points)

• Small Assignments (60 points, total)
Throughout the term, students will be tasked with a variety of smaller assignments. The nature of these assignments may range from short compositions and/or reflections, focused in-class projects, and other activities of similar size and scope.
Note: All written assignments MUST be type-written, single-spaced, and complete (as per assignment guidelines) at the time they are due, unless otherwise specified. No late assignments will be accepted unless discussed with the professor before it is due. Due dates will be provided with each assignment. Students should be prepared to discuss their responses in class.

• Exams (120 points, total)
Throughout the term, there will be two exams (each worth 60 points) covering the assigned readings, supplementary materials, class activities, and discussions. Please refer to the course schedule for the dates of each exam.
• **Group Project: Drug Use and Abuse (60 points)** → See assignment rubric on Moodle for additional info!

  Working in groups of two, each pair of students will give a 20-25 minute presentation to the class on topics pertaining to the use and abuse of a single class of drugs. Students will draw primarily from chapters in the course text, Drug Use and Abuse, 6th Edition, by Stephen A. Maisto, Mark Galizio, and Gerard J. Connors. The project will be evaluated with regard to both content and form and constitutes the formative assessment for Unit 3 of the course.

• **Final Term Paper (60 points)**

  Drawing on class resources, discussions, guest speakers, and any other additional resources, students will compose a term paper in which they critically reflect on the current state of drugs and the pharmaceutical industry. This term paper will be due at the start of the final day of class, Wednesday, January 28, 2015, and will constitute the final for the course.

**Academic Expectations**

<table>
<thead>
<tr>
<th>Points Earned</th>
<th>Letter Grade</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>400 – 360</td>
<td>A</td>
<td>Exceptional: The student has performed extremely well; has demonstrated the ability to be creative, interesting, well-researched, and strongly argued</td>
</tr>
<tr>
<td>320 – 359</td>
<td>B</td>
<td>Better: The student has performed basic tasks well and with some imagination, demonstrating a level of extra reflection, research, and care</td>
</tr>
<tr>
<td>280 – 319</td>
<td>C</td>
<td>Average: The student has performed basic tasks competently, on time, and completed assignments that meet specifications</td>
</tr>
<tr>
<td>240 – 279</td>
<td>D</td>
<td>Deficient: The student has barely met requirements, with notable deficiencies</td>
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</tbody>
</table>

  The student has failed to meet requirements

**Grade Breakdown**

<table>
<thead>
<tr>
<th>Total Points</th>
<th>Grade</th>
<th>Total Points</th>
<th>Grade</th>
<th>Total Points</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 – 372</td>
<td>A</td>
<td>331 – 320</td>
<td>B–</td>
<td>279 – 268</td>
<td>D+</td>
</tr>
<tr>
<td>359 – 348</td>
<td>B+</td>
<td>307 – 292</td>
<td>C</td>
<td>251 – 240</td>
<td>D–</td>
</tr>
<tr>
<td>347 – 332</td>
<td>B</td>
<td>291 – 280</td>
<td>C–</td>
<td>&lt; 240</td>
<td>F</td>
</tr>
</tbody>
</table>

**General Written Assignment Guidelines**

1. **Margins:** 1” top/bottom, 1” left/right, 0.5” paragraph indent
2. **Font (size):** Arial (12 point)
3. **Spacing:** Single-spaced
4. **Page Numbering:** Please use page numbers on every writing assignment, located either in either the upper right corner or the bottom center.
5. **Footnotes:** Please use footnotes rather than endnotes.
6. **Title Pages:** Title pages which include the title of your assignment, your name, the class name, number and section are acceptable, however they do not count in your page total. Please do not number the title page. Title pages are not necessary for short written assignments (save paper!)
7. Do NOT use margins, fonts, or font sizes larger or smaller than these specifications, including on the title page and the first page.
8. Please print and bring your paper (already stapled) to class on the day it is due. Late papers will be lowered one letter grade for every day they are late. Please do NOT send papers via email unless pre-arranged with the instructor.
9. More specific guidelines regarding each assignment will be handed out later.

**Note:** Your grade throughout this class will not be based on whether the instructor agrees or disagrees with your conclusions regarding a specific issue. Rather, it will be based on how well you critically engage that issue, engage and interpret class resources in discussing the issue, present your conclusions, and defend those conclusions.
Class Conduct

1. All students are expected to participate regularly in class. This class represents a community and the contribution of each person is important and required. A large portion (25%) of your grade will be based on in-class and out-of-class (reading) participation. Students are expected to have read the material before class and have appropriate questions in mind before coming to that class session.

2. Students are expected to respect their fellow classmates and the instructor. Disruptive behavior will not be tolerated; the responsible students will be removed from the classroom for the day.

3. Sleeping in class will not be tolerated. If you are caught sleeping, you will be asked to leave for the day. Since attendance is a portion of the final grade, sleeping in class will negatively impact your final grade.

4. Learning in this class depends on every student (and the professor) being prepared for every class session. Therefore, students are expected to read all assigned readings and do all required work BEFORE the class period for which they are assigned.

Attendance

Students are expected to be present and on time for every class session. Regular tardiness will affect your final grade. The course instructor must be notified via email or phone of all absences, preferably in advance. In the event of an absence, students are responsible for finding out any announcements, turning in any assignments, and obtaining class notes from a classmate. Absence from laboratory or exams will be excused only because of illness or family emergency. Unexcused absences will result in a zero for the work missed.

Cell Phones

In order to avoid distracting the class, please ensure that your cell phone is on silent or turned off during class. Texting during class is not acceptable. Your compliance will help to maintain the positive learning environment of our class period.

Disabilities

Students with disabilities who believe they may need accommodations in this class are encouraged to contact Student Academic Support Services located in the Career Center Suite in the Edith Mortenson Building, room 100. Email (susan.bies@augie.edu) or call 605-274-5503 with your questions on documenting a disability and accommodations. Please do this as soon as possible to ensure that such accommodations are implemented in a timely fashion.

Honor Code

As a community of scholars, the students and faculty at Augustana College commit to the highest standards of excellence by mutually embracing an Honor Code. The Honor Code requires that examinations and selected assignments contain the following pledge statement to which students are expected to sign: “On my honor, I pledge that I have upheld the Honor Code, and that the work I have done on this assignment has been honest, and that the work of others in this class has, to the best of my knowledge, been honest as well.”

Faculty members are responsible for investigating all instances involving any student who does not sign the Honor Pledge or who bring forward an academic integrity concern. The complete Honor Code can be found at www.augie.edu/honor.

If a student in this course is found in violation of the academic honor code, minimally:

1. The student will receive a zero for the assignment in which the honor code was violated.
2. The student will no longer be eligible to withdraw from the course (with instructor approval).
3. A formal letter describing the incident and its resolution will be filed with the Associate Dean of Academic Affairs.

**Depending on the severity and circumstances surrounding the violation, additional penalties may be levied on the student, up to and including failing the course.
<table>
<thead>
<tr>
<th>Week</th>
<th>Class Period</th>
<th>Tentative Lecture Topic(s)</th>
<th>Reading Assignment(s) for Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>M 5-Jan</td>
<td>5-Jan</td>
<td>Introduction Activities, Syllabus &amp; Schedule</td>
<td>None</td>
</tr>
</tbody>
</table>
| T 6-Jan | 6-Jan        | Drugs in History                                   | 1. Ng, *Drugs: From Discovery To Approval*, Appendix 1 (pg. 391-397)  
| 1 W 7-Jan | 7-Jan        | Drug Discovery (Targets)                           | 1. Ng, *Drugs: From Discovery To Approval*, Section 1.2 (pg. 2-5)  
2. Ng, *Drugs: From Discovery To Approval*, Sections 2.1-2.8 (pg.19-46)                                                                                                        |
| R 8-Jan | 8-Jan        | Small Molecule Drug Development                    | 1. Ng, *Drugs: From Discovery To Approval*, Section 1.5 (pg. 12-14)  
2. Ng, *Drugs: From Discovery To Approval*, Sections 3.1-3.7 (pg.53-84)                                                                                                          |
| F 9-Jan | 9-Jan        | Guest Webinar; John Morris, PhD, Preclinical Drug Evaluation | 1. Ng, *Drugs: From Discovery To Approval*, Sections 5.1-5.6 (pg. 136-161)                                                                                                                                             |
| M 12-Jan | 12-Jan       | Clinical Trials and FDA Drug Regulation             | 1. Ng, *Drugs: From Discovery To Approval*, Sections 6.1-6.6 (pg. 176-200)  
2. Ng, *Drugs: From Discovery To Approval*, Sections 7.1-7.2 (pg. 208-214)  
3. Ng, *Drugs: From Discovery To Approval*, Sections 8.1-8.2 (pg. 231-250)                                                                                               |
2. PDF: Kolassa, *The Strategic Pricing of Pharmaceuticals*, Chapter 2 (pg. 11-30)                                                                                                       |
| F 16-Jan | 16-Jan       | Pharmaceutical Pricing                             | 1. Ng, *Drugs: From Discovery To Approval*, Section 1.4 (pg. 10-12)  
| R 22-Jan | 22-Jan       | Regulation of Drug Use, Guest Speaker Panel       | 1. Maisto, Galizio, and Connors, *Drug Use and Abuse*, Chapter 1 (pg. 1-21)  
| M 26-Jan | 26-Jan       | Group Projects                                     | None                                                                                                                                                                                                                       |
| T 27-Jan | 27-Jan       | Group Projects                                     | None                                                                                                                                                                                                                       |
| 4 W 28-Jan | Final Essay Due, Drugs in the Future               | None | 1. Ng, *Drugs: From Discovery To Approval*, Sections 11.1-11.17 (pg. 359-387)                                                                                                                                          |
| R 29-Jan | 29-Jan       |                                                    |                                                                                                                                                                                                                             |
| F 30-Jan | 30-Jan       |                                                    |                                                                                                                                                                                                                             |