Course Purpose:
This course is designed to provide an understanding of the regulation of drug products by the US Food and Drug Administration. There will be discussion of New Drug Applications, Abbreviated New Drug Applications and OTC monographs in addition to patient issues and market exclusivity.

Course Faculty and Office Hours

Course Coordinator:
Gary L. Yingling
Email: glyingling@verizon.net

Co-Coordinator:
Mark Bolin
Email: mcbolin@gmail.com

Chat Room Coordinator:
Kirk Seale
Email: kseale@ufl.edu

Office Hours
You can contact the Course Co-Coordinator Mark Bolin via email at mcbolin@gmail.com or Kirk Seale at kseale@ufl.edu.

Place and Time of Class Sessions
The eight pre-recorded lectures will be available at https://elearning2.courses.ufl.edu/portal. The eight weeks of class discussion will be Tuesday and Thursday evenings except Thanksgiving week (Monday and Tuesday) starting at 9:00 p.m. and ending no later than 11:00 p.m. The website is https://connect.cop.ufl.edu/pha6274_f2012 and you will be required to have your microphone so you can participate in class. There will be weekly questions posted after class on Thursday with a response due no later than midnight on Sunday. The final exam will be posted on December 7 at 6:00 a.m. and must be completed by December 8 at 6:00 p.m.

<table>
<thead>
<tr>
<th>Week One</th>
<th>Tuesday October 15</th>
<th>Pre-recorded lecture Lecture 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Thursday, October 17</td>
<td></td>
</tr>
<tr>
<td>Week Two</td>
<td>Tuesday, October 22</td>
<td>Lecture 2</td>
</tr>
<tr>
<td></td>
<td>Thursday, October 24</td>
<td>Lecture 2</td>
</tr>
<tr>
<td>Week Three</td>
<td>Tuesday, October 24</td>
<td>Lecture 3</td>
</tr>
<tr>
<td></td>
<td>Thursday, October 31</td>
<td>Lecture 3</td>
</tr>
<tr>
<td>Week Four</td>
<td>Tuesday, November 5</td>
<td>Lecture 4</td>
</tr>
<tr>
<td></td>
<td>Thursday, November 7</td>
<td>Lecture 4</td>
</tr>
<tr>
<td>Week Five</td>
<td>Tuesday, November 12</td>
<td>Lecture 5</td>
</tr>
<tr>
<td></td>
<td>Thursday, November 14</td>
<td>Lecture 5</td>
</tr>
<tr>
<td>Week Six</td>
<td>Tuesday, November 19</td>
<td>Lecture 6</td>
</tr>
<tr>
<td></td>
<td>Thursday, November 21</td>
<td>Lecture 6</td>
</tr>
<tr>
<td>Week Seven</td>
<td>Monday, November 25</td>
<td>Lecture 7</td>
</tr>
<tr>
<td></td>
<td>Tuesday, November 26</td>
<td>Lecture 7</td>
</tr>
<tr>
<td>Week Eight</td>
<td>Tuesday, December 3</td>
<td>Lecture 8</td>
</tr>
<tr>
<td></td>
<td>Thursday, December 5</td>
<td>Lecture 8</td>
</tr>
<tr>
<td>Final Exam</td>
<td>Saturday, December 7</td>
<td>Final Exam</td>
</tr>
</tbody>
</table>

**Course Objectives**

Upon successful completion of this course, the student will be able to:

1. List critical events in the evolution of U.S. drug laws.
2. Distinguish between drugs, dietary supplements, foods and medical devices.
3. Discuss the implications of “new drug” status.
4. Describe FDA practices and procedures.
5. Describe the process of drug discovery and testing.
6. List the criteria for IRB review of research with human subjects.
7. Explain the elements of an NDA and ANDA.
8. Describe the process of postmarketing surveillance.
9. List labeling requirements for drugs.
10. Discuss labeling and advertising regulations under the FDCA.
11. Describe Congressional oversight of FDA actions.
12. Understand the role of the FDA, the Courts and Congress in the regulation of drugs.

**Pre-Requisite Knowledge and Skills**

None.
Course Structure & Outline

Course Structure. Course will be 8 pre-recorded lectures, 16 online classes, a weekly graded question and a final exam.

Textbooks

Active Learning Requirements
Reading assignments, videotapes.

Student Evaluation & Grading

Evaluation Methods
Students will be evaluated by the grades they get on the weekly question, the grade on the course final, class participation and participation on chat board. The final will count for 50%, the weekly question 40%, class participation 5%, and chat board 5%. The class participation grade will be based on their discussion of the case or cases assigned and in responding to questions asked during class. The chat board grade will be based on participation. A failure to respond will be non-participation.

Grading Scale

<table>
<thead>
<tr>
<th>Grade Range</th>
<th>Letter Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>95-100</td>
<td>A</td>
</tr>
<tr>
<td>90-94</td>
<td>A-</td>
</tr>
<tr>
<td>86-89</td>
<td>B+</td>
</tr>
<tr>
<td>83-85</td>
<td>B</td>
</tr>
<tr>
<td>80-82</td>
<td>B-</td>
</tr>
<tr>
<td>76-79</td>
<td>C+</td>
</tr>
<tr>
<td>73-75</td>
<td>C</td>
</tr>
<tr>
<td>70-72</td>
<td>C-</td>
</tr>
<tr>
<td>66-69</td>
<td>D+</td>
</tr>
<tr>
<td>60-62</td>
<td>D-</td>
</tr>
<tr>
<td>&lt;60</td>
<td>E</td>
</tr>
</tbody>
</table>

Class Attendance Policy
Every student is expected to participate in the weekly on-line classes. To be excused, please contact a TA concerning your inability to attend. Failure to notify will be marked as non-participation.

Quiz/Exam Policy
Any questions about quiz or final exam grades should be addressed to Mr. Yingling or Mr. Bolin.

Make-up Quiz/Exam Policy
No make-up quizzes or exams.

Policy on Old Quizzes and Assignments
No old quizzes will be provided.

Assignment Deadlines
For quizzes, one point will be deducted for late paper. A late final will be penalized.

General College of Pharmacy Course Policies
The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accomodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

Complaints
Should you have any complaints with your experience in this course please visit:
http://www.distancelearning.ufl.edu/student-complaints to submit a complaint.

Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty
Contact should be to the Course Co-Coordinator Mark Bolin via email at mcbolin@gmail.com

Instructors

Gary L. Yingling, RPh, JD
Morgan, Lewis & Bockius LLP
glyingling@verizon.net

Mark Bolin, JD, LLM
Morgan, Lewis & Bockius LLP
mcbolin@gmail.com

Kirk Seale
kseale@ufl.edu
# Summer 2014 Course Schedule

<table>
<thead>
<tr>
<th>Activity</th>
<th>Dates</th>
<th>Reading Assignment</th>
<th>Video Recommendation</th>
<th>Elluminate Class</th>
<th>Learning Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outline 1 The Food and Drug Administration: Its Laws and Regulations</td>
<td>October 15-17</td>
<td>F&amp;D Law pp. 1-27, 1531-1533 Definitions: Interstate Commerce [FFDCA Sec. 201(b)] “The Story of Laws Behind the Labels” <a href="http://www.fda.gov/AboutFDA/AboutTheFDA/History/Overviews/ucm056044.htm">http://www.fda.gov/AboutFDA/AboutTheFDA/History/Overviews/ucm056044.htm</a></td>
<td>1 and 2</td>
<td>October 15 and 17</td>
<td>- Reading - Video - Discussion Board - Weekly Quiz</td>
</tr>
</tbody>
</table>

*Definitions: Interstate Commerce [FFDCA Sec. 201(b)]

“*The Story of Laws Behind the Labels”

[http://www.fda.gov/AboutFDA/AboutTheFDA/History/Overviews/ucm056044.htm](http://www.fda.gov/AboutFDA/AboutTheFDA/History/Overviews/ucm056044.htm)
<table>
<thead>
<tr>
<th>Activity</th>
<th>Dates</th>
<th>Reading Assignment</th>
<th>Video Recommendation</th>
<th>Elluminate Class</th>
<th>Learning Responsibilities</th>
</tr>
</thead>
</table>
| Outline 3 Enforcement            | October 29 and 31 | F&D Law pp. 1262-1266, 1270-1271, 1281-1282, 1282-1286, 1309-1319, 1310-1313, 1313-1319, 1303-1308 | 6, 7 | October 29 and 31 | - Reading  
- Video  
- Discussion Board  
- Weekly Quiz |
United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947), cert. denied, 332 U.S. 851 (1948)  
FFDCA Sections: 301(a), 301(d), 301(f), 301(e), 301(k), and 301(p). | | |
| Outline 4 Investigational New Drug Applications and Filing New Drug Applications | Nov. 5 and 7 | F&D Law pp. 624-626, 631, 653-654, 676-677, 770-771 | 8, 9, 10 | Nov. 5 and 7 | - Reading  
- Video  
- Discussion Board  
- Weekly Quiz |
<table>
<thead>
<tr>
<th>Activity</th>
<th>Dates</th>
<th>Reading Assignment</th>
<th>Video Recommendation</th>
<th>Elluminate Class</th>
<th>Learning Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Drugs, and Marketing Exclusivity for NDA’s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>Dates</td>
<td>Reading Assignment</td>
<td>Video Recommendation</td>
<td>Elluminate Class</td>
<td>Learning Responsibilities</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>-----------------------</td>
<td>-----------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Outline 8 Drug Master Files</td>
<td>Dec. 3 and 5</td>
<td></td>
<td>Dec. 3 and 5</td>
<td></td>
<td>- Reading&lt;br&gt;- Discussion Board</td>
</tr>
<tr>
<td>FINAL EXAM</td>
<td>Dec. 7</td>
<td>Posted at 6AM on 12/7, due at 6PM on 12/8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Video Content**

**Potions or Poisons**
In the late 19th century, costumed performers dressed as Indians and exotic witch doctors roamed rural America entertaining people and selling vast quantities of medicinal preparations. Usually neither beneficial nor healthy, their ingredients often included opium, cocaine, mercury and grain alcohol. POTIONS OR POISONS tells how a reform movement led by Dr. Harvey Wiley of the Food and Drug Administration, and spurred on to action by journalist Samuel Hopkins Adams, who wrote a searing expose of the phony medicines in *Colliers* magazine, led to the end of the medicine shows. But it was not the end of the “miracle tonics.” In fact, it was merely the beginning of a long dance with three partners, those who develop the supposed cures, a public eager to swallow their stories, and the government, which must continually scramble to keep up with the latest trends in alternative healing. From patent medicines to the internet, from old-time medicine shows to new-age scams, POTIONS OR POISONS? is a fascinating look at the promise of health in a bottle. 50 min

**Elixir of Death**
In September and October of 1937, people across the country started dying after drinking a new cough medicine known as Elixer Sulfanilamide. Produced by the S.E. Massengill Company in response to consumer demand for a liquid cough medicine, it was released to the public after testing for flavor, appearance and fragrance—but not toxicity. At the time, federal regulations did not require companies to certify that their drugs were safe, and the solution used to liquefy the sulfanilamide was diethylene glycol, a deadly poison that is found in anti-freeze. From the first death to the FDA’s no-holds-barred response, ELIXER OF DEATH tells the remarkable story of the incident that led to passage of the 1938 Food, Drug, and Cosmetic Act, which increased the FDA’s authority to regulate drugs. Survivors recall their harrowing ordeals, and FDA historians reveal how agents located 234 of the 240 gallons produced—often one bottle at a time! 50 min

**Inside the Pill: The Startling Facts about Dietary Supplements**
In this program, ABC News correspondent Arnold Diaz reports on the potential dangers of dietary supplements. Pharmacologist and radio host Joe Graedon; Tod Cooperman, president of ConsumerLab.com; and David Seckman, executive director of the National Nutritional Foods Association, speak out about misleading labeling, the need for governmental regulation, and the popular misperception among consumers that supplements such as chondroitin, SAM-e, ginseng, ginkgo biloba, and St. John’s wort are harmless. The bottom line? Herbals have medicinal qualities, so safe use requires that dosage levels and possible interactions with pharmaceuticals be strictly taken into account. (14 minutes)

**NewsHour Drug Safety**
Margaret Warner interviews FDA Commissioner Dr. Andrew Von Eschenbach about administrative changes designed to improve oversight of prescription drugs. 16 minutes
King of the Infomercial: Kevin Trudeau
He’s been banned, sued, even imprisoned—and now he’s topped the best-seller list. This ABC News program enters the disturbing world of Kevin Trudeau—a figure well-known to late-night TV viewers through his frequent infomercials, in which he hawks “cures” for cancer, diabetes, and other diseases. In a contentious one-on-one interview, Trudeau discusses his past legal troubles, his questionable products and medical research, and his new blockbuster advice book. The fast-talking impresario pulls no punches in his criticism of the FDA and the medical establishment, all the while defending his high-flying CEO-style accoutrements and even suggesting he will one day run for office. Original ABC News broadcast title: Infomercial King. (12 minutes)

NewsHour Conducting Drug Research in India:
Fred de Sam Lazaro visits India, exploring the controversial decision by many pharmaceutical companies to conduct clinical trials there. 12 minutes

Biomedicine and Biotechnology
In the era of Big Pharma, why are researchers looking more and more to nature—and the human body itself—to provide tomorrow’s medical cures? This program illustrates how scientists are growing and harvesting pharmaceuticals from common plants and farm animals, attempting to replicate organs, and transferring much-needed islet cells to patients with diabetes. The next big breakthrough in medical care is as likely to come from a rainforest or a goat as it is from a petri dish or a test tube. (47 minutes)

peRx Module I: “Why and how are drugs approved?”
Overview of drug research and development in the United States; the FDA drug approval process. 24 min

Frontline: Dangerous Prescription
As medications play an ever-increasing role in modern health care, the importance of FDA approval to consumers, it would seem, has never been greater. For many, the phrase “FDA approved” signifies that a drug or product is completely safe and without risk. But just how much does the average American know about the FDA approval process and what it can—and cannot—do? How good is the FDA’s system for identifying drugs that don’t work or cause harm? And what happens when a harmful product makes its way into consumer’s hands. Frontline investigates the FDA and drug safety, and questions whether the current system is adequate for protecting the public.

Death of a Wonder Drug: The Vioxx Recall
On September 30, 2004, pharmaceutical giant Merck voluntarily withdrew its popular painkiller Vioxx after it was linked to increased risks of heart attack and stroke. Was Merck’s move driven by genuine concern for patients? Or, given findings from earlier studies, was the recall a self-protective move that came too late? This CNBC investigation takes viewers through the process by which one of Big Pharma’s most widely prescribed products was tested, approved, and marketed—at the expense, many say, of thousands of consumers. Several medical experts provide commentary, in addition to FDA whistle-blower David Graham, who has cited numerous faults in the government’s handling of Vioxx testing. (44 minutes)

Drug Deals
Vanessa Young was 15 years old when she died suddenly from cardiac failure. Four days later, a prescription drug that she was taking was removed from the market. Did the drug have a potentially fatal side effect? If so, why was it being sold?
While the prescription drug industry strives to develop life-saving medicines, it is also a lucrative business with billions of dollars of revenue at stake. This gripping documentary asks whether corporate pressure is causing new drugs to be released before they are adequately tested. Probing each phase of clinical research, approvals, safety monitoring and marketing, Drug Deals investigates the potentially far-reaching influence of drug companies. Featuring interviews with researchers, doctors, government regulators and a grieving family.

**NewsHour Debating Drug Company Gifts**
Gwen Ifill and two experts discuss a report in the *Journal of the American Medical Association* on Big Pharma marketing tactics—and their effects on patients. 12 minutes

**peRx Module II “There’s no such thing as a free lunch...or dinner”**
Overview of pharmaceutical marketing practices, scientific evidence on the effect of marketing methods on prescribing behavior (drug samples, free meals, interactions with drug industry representatives, industry sponsored CME and lectures at national conferences, free gifts, office supplies). 27 min

**peRx Module III “Is this the right thing to do?”**
Overview, discussion and presentation of opposing views regarding the ethical dimensions of pharmaceutical marketing and direct-to-consumer advertising; conflict of interest debate; effect on costs to patients and health care system as a whole. 21 min

**peRx Module IV “How can I improve my practice?”**
Overview of strategies to improve prescribing, i.e. evidence-based prescribing vs. market-based prescribing; cost-effective prescribing; strategies to improve interaction with representatives; critical evaluation techniques of pharmaceutical company information (data and claims). 20 min

**Online Patent Law Basics Video**