

PHA 6273 The Structure, Process and Outcomes of Regulation

3 Semester Credit Hours

Course Purpose:

This course emphasizes the role of the legislative, executive and judicial branches of state and federal government in the establishment of standards for pharmacy practice and drug distribution. It also places special emphasis on the administrative rule making process. Additionally, the course focuses on the purpose of government agencies, the approach to standards setting by each type of agency, and the effects of regulation on public health.

Course Faculty and Office Hours:

Professor and Course Coordinator: **Graduate Teaching Assistants:**

W. Thomas Smith, Pharm.D., J.D. TBA

Email: tsmith@cop.ufl.edu

Professor:

Eli G. Phillips, Jr., Pharm.D., J.D. Affiliate

Clinical Assistant Professor

Email: eli.phillips@uiwtx.edu

Office Hours:

By appointment only

Place and Time of Class Sessions:

Adobe Connect classes are *generally* held from 6:30pm to 8pm on Sundays, and 8:30pm to 10pm on Thursdays. All times are Eastern Daylight Time. ***Please note the exception during Module IV. In the table below located in Appendix B.***

Course Objectives:

Cognitive Objectives:

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

1. Describe the structure and function of American Law and the American
2. Legal System.
3. Discuss the underlying purpose of regulation generally and health care regulation specifically.
4. Explain methods for regulating the assessment and improvement of quality in health care.
5. Describe the central principle of balance in health care regulation.

6. Discuss the legal status of clinical practice standards.
7. Describe regulatory approaches to medical errors.
8. Discuss the limits of health care regulation.
9. Describe the requirements for experimentation with human subjects.
10. Evaluate the effectiveness of licensure as a control on quality in health care.
11. Discuss the use of scope of practice in regulation.
12. List the requirements for a regulation to be justified as effective.
13. Describe the regulation of hospitals, nursing homes, and other health care institutions.
14. Discuss judicial risk-benefit balancing.
15. Explain the elements of a medical malpractice lawsuit.
16. Describe the standard of care for the proper utilization of medications.
17. Describe the legal process for implementing changes in existing laws.
18. Discuss the difference between outcomes-orientation and process-orientation.
19. Describe how empirical data and other facts help inform regulation.
20. Discuss the role of regulators as educators versus enforcers.
21. List the elements of “regulatory capture” in health care regulation.
22. Describe the attributes of a high quality health care institution.
23. Discuss possible reforms in health care regulation.

Skill Objectives:

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

1. Evaluate a healthcare website to determine compliance with relevant legal requirements.
2. Design a program for compliance with regulatory requirements applicable to a PBM.
3. Design a patient safety system for a hospital.
4. Develop a FDA-compliant REMS to promote safe and effective drug use.
5. Evaluate a drug use evaluation program to determine compliance with IRB criteria.

Pre-Requisite Knowledge and Skills:

No course serves as a prerequisite for PHA5239 and no special skills are required.

Course Structure & Outline/Activities:***Course Structure:***

Multiple self-directed learning activities are required (e.g., prerecorded lecture videos for homework, readings that involve critical thinking, and discussion board participation), and each week students come to class in Adobe Connect to discuss the materials assigned for the given week.

Course Outline/Activities:

The outline of course activities is listed at the end of this document in Appendix B.

Textbooks and Videos:**Required Text:**

- Sparrow, Malcolm, *The Regulatory Craft, Controlling Risks, Solving Problems, and Managing Compliance*, Brookings Institution, Washington, DC (2000) ISBN-10: 0-8157-8065-6.

Supplemental Reading Assignments (provided through online reserve):

- Brennan and Berwick, *New Rules: Regulation, Markets, and the Quality of American Health Care*.
- Institute of Medicine, *To Err is Human*.
- Knowlton and Penna, *Pharmaceutical Care*.
- Temin, *Taking Your Medicine: Drug Regulation in the United States*.
- Starr, *The Social Transformation of American Medicine*
- Millenson, *Demanding Medical Excellence*
- Bogdanich, *The Great White Lie*
- Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*
- Burns, *Pharmacists' Legal Responsibilities Under State & Federal Law*
- Donabedian, *Evaluating the Quality of Medical Care*

Commercially Available Videos:

- *Altered States: A History of Drug Use in America*
- *Legislating Morality: There Oughta Be a Law*
- *The Quality Gap: Medicine's Secret Killer*
- *Medical Mistakes*
- *A Questionable Doctor*
- *Oral Argument in Powers v. Your Druggist*
- *Debating Healthcare Reform: Rage on the Airwaves*

Prerecorded Video Lectures:

- *Law, Public Policy and Ethics*
- *The Role of Legislatures, Administrative Agencies and the Chief Executive*

- Licensure as Assurance of Competence
- Liability for Harm from Defective Products
- Principles of Legal Liability
- Reducing the Risks of Drug Testing & Use

Active Learning Requirements:

During each live, in-class session (in Adobe Connect) students are required to answer poll questions over the material assigned for that class. Class discussions are heavily based upon students' responses to these questions. Students are also highly encouraged to participate on the weekly course discussion boards by deliberating and chatting about core concepts assigned for the given week. Full credit for class participation requires five postings weekly on discussion board; two postings must be original threads, and three must be responsive postings in a thread started by someone else. A week begins at 12:01 am on Sundays and ends at 11:59 pm on Saturdays. Each of these postings should be relevant to the class and original to the student. In order to earn credit, all original threads must be posted by noon Eastern on Fridays in order to give students time to respond to the original threads. Full credit for class participation also requires attendance at every Adobe Connect class, adequate preparation for class, and appropriate participation in class. Those who participate very actively on discussion board may participate a little less actively in class, and vice-versa.

Student Evaluation & Grading:

Evaluation Methods:

Weekly Quizzes (7)	20%	Weekly Assignments (5)	20%
Class Participation and Discussion Board			10%
Midterm (over Modules I-III)			25%
Final (cumulative):			25%

Grading Scale:

92.5%-100%	A				
89.5-92.4%	A-	76.5-79.4%	C+	64.5-69.4%	D
86.5-89.4%	B+	72.5-76.4%	C	<64.4%	E
79.5-86.4%	B	69.5-72.4%	C-		

- See link regarding minus grades: <http://www.isis.ufl.edu/minusgrades.html>.
- No grade of "B-" will be assigned in this course.

- See link regarding University grading policies:
<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx#averaging>.

Class Attendance Policy:

Students will have an opportunity to be involved in this course through class discussion. It is therefore essential that students read all assigned course materials, watch and listen to all prerecorded videos, as well as attend each and every class. Attendance in live class sessions is mandatory. Student should, whenever possible, anticipate upcoming absences and speak with the instructors and/or TAs to make prior arrangements for make-up work. Students must contact the instructors and/or TAs as soon as possible following any unanticipated absence.

Quiz/Assignment/Exam Policy:

Quizzes:

- Weekly quizzes (7 total) will open at 10pm EDT on Thursdays, and will close at 12 noon EDT on Saturdays.
- Quizzes are located under the 'Assessments' tab in Sakai.
- Quizzes consist of 20 multiple-choice/true-false questions over the material assigned for the given week. Students will have 30 minutes to complete the quiz.
- Quiz scores are revealed upon submission. Quiz keys will be made available once all students have completed the quiz.

Assignments:

- Assignments (5 total) will be posted at 8pm EDT on Sunday, and are due by 6pm EDT on the following Sunday. Assignments are found under the 'Assignments' tab on Sakai.
- Responses to these assignments must be in essay format. Directions for formatting them will be provided in the 'Directions' section atop each assignment.
- Assignments are designed to provide students the opportunity to critically analyze an issue(s). These assignments foreshadow what students will see on exams.
- Please submit by uploading your response as a Word attachment. If you have any difficulty uploading your paper to Sakai – don't panic – simply email it to Dr. Smith at tsmith@cop.ufl.edu.
- Students who feel their writing skills are in need of improvement should contact Dr. Smith very early on in order to discuss an improvement plan.
- Please note that no assignments are assigned during Modules III & VII.

Exams:

- There are two exams in this course – a midterm and a cumulative final. ○ The midterm exam will be posted at 9am EDT Sept. 8, and is due at 6pm EDT Sept. 9. ○
 - The final exam will be posted at 9am EDT Oct. 6, and is due at 6pm EDT Oct. 7.
 - Please be sure to set aside at least six to eight hours during these weekends to work on your exams.
- Please download the exam as close to 9am on Saturday as possible, and save it to your computer. Accessing the exam early on Saturday allows for an opportunity to address unforeseen technical glitches in a timely manner.
- Exams consist of four questions similar to assignments
- Exams are found under the 'Assignments' tab on Sakai.
- Please submit by uploading your responses to each of the four questions as a single Word attachment. If you have any difficulty uploading your exam to Sakai – don't panic – simply email it to Dr. Smith at tsmith@cop.ufl.edu.
- Exam comments will be returned to students in a timely fashion.

Make-up Quiz/Exam Policy:**Quizzes:**

- Generally, make-up quizzes will not be offered. However, Dr. Smith will entertain a student's request to make-up a quiz and make his decisions based on the student's special circumstances.

Exams:

- Students who must miss an exam due to an **excused absence only** shall notify Dr. Smith by email as soon as possible. Failure to do so will render the student unable to make up the missed exam regardless of the reason. Exceptions for extreme circumstances may be granted by an instructor.
- Excused absences include auto accident, illness (documentation required), death or illness of family members, etc.
- Format of make-up exams is at the discretion of the faculty.

Policy on Old Exams, Quizzes and Assignments:

- Previously administered quizzes, assignments, or exams will not be made available to students.

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

1. Academic Integrity Policy
2. How to request learning accommodations
3. Faculty and course evaluations
4. Student expectations in class
5. Discussion board policy
6. Email communications
7. Religious holidays
8. Counseling & student health
9. How to access services for student success Please see the following URL for this

information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

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:

- Please post on the discussion board questions regarding the substantive material covered in this course.
- Please contact Dr. Smith for personal matters that may affect your performance in this course.
- Please contact the professors and/or the TAs for questions about the assignments.
- Please contact mediahelp@cop.ufl.edu for technical issues involving either Sakai or Adobe Connect during business hours (i.e. 8am to 5pm EDT M-F).
- Please contact forensicsupport@cop.ufl.edu for technical issues that arise after hours.

Appendix B: Schedule of Course Activities/Topics:

Adobe Connect classes are *generally* held from 6:30pm to 8pm on Sundays, and 8:30pm to 10pm on Thursdays. All times are Eastern Daylight Time. ***Please note the exception during Module IV. in the table below.***

Activity	Week	Reading Assignment	Legal Case Study	Video Assignments	Learning Responsibilities
Course Orientation Adobe Connect class on 8/16	8/12 to 8/18	None	None	None	Use of Adobe Connect and Sakai
Module I Reasons to Regulate Adobe Connect class on 8/19 & 8/23	8/19 to 8/25	- Sparrow; introduction - Brennan Chapter 1 - Temin Chapter 1 - Donabedian article	<i>Ancheff v. Hartford Hospital</i> , 799 A.2d 1067	- Law, Public Policy & Ethics - Altered States	- Discussion Board - Quiz 1 - Assignment 1
Module II (cont. on p. 8) Ways to Regulate Adobe Connect class on 8/26 & 8/30	8/26 to 9/1	- Sparrow Chapters 1 & 5 - Brennan Chapter 4	<i>Smith v. Heckler</i> , 747 F.2d 583	- The Role of Legislature, Administrative Agencies & Chief Executive - Legislating Morality	- Discussion Board - Quiz 2 - Assignment 2
Module III Regulating Health Professions Adobe Connect class on 9/2 & 9/6	9/2 to 9/8	- Sparrow Chapters 7 & 8 - Knowlton & Penna Chapter 10 - Starr Chapter 3	<i>Hoover v. AHCA</i> , 676 So.2d 1380	- Licensure as Assessment of Competence - The Quality Gap	- Discussion Board - Quiz 3 - No Assignment this week.

Midterm Exam Posted 9am EDT Sept. 8, Due 6pm EDT Sept. 9

Module IV Regulating Health Care Institutions Adobe Connect class 9/10 (Monday) & 9/13	9/9 to 9/15	- Sparrow Chapter 9 - Millenson Chapter 12 - Bogdanich Chapter 4	<i>Thompson v. Nason Hospital</i> , 591 A.2d 703	- Reducing Risks of Drug Testing & Use - Medical Mistakes	- Discussion Board - Quiz 4 - Assignment 3
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<p>Module V</p> <p>Regulatory Responses to Medical Error</p> <p>Adobe Connect class 9/16 & 9/20</p>	<p>9/16 to 9/22</p>	<p>- Sparrow Chapters 10 & 11</p> <p>- Brennan Chapter 3</p> <p>- IOM Report Chapter 8</p>	<p><i>State v. Naramore</i>, 965 P.2d 211</p>	<p>- Liability for Harm from Defective Products</p> <p>- A Questionable Doctor</p>	<p>- Discussion Board</p> <p>- Quiz 5</p> <p>- Assignment 4</p>
<p>Module VI</p> <p>Liability as Regulation of Health Care</p> <p>Adobe Connect class 9/23 & 9/27</p>	<p>9/23 to 9/29</p>	<p>- Sparrow Chapters 16, 17</p> <p>- Burns Chapter 8</p> <p>- Noah Article</p>	<p><i>Harco v. Holloway</i>, 669 So.2d 878</p>	<p>- Principles of Legal Liability</p> <p>- Oral Argument: <i>Powers v. Thobani</i></p>	<p>- Discussion Board</p> <p>- Quiz 6</p> <p>- Assignment 5</p>
<p>Module VII</p> <p>The Future of Health Care Regulation</p> <p>Adobe Connect class 9/30 & 10/4</p>	<p>9/30 to 10/6</p>	<p>- Sparrow Chapters 19 & 20</p> <p>- Brennan Chapter 7</p>	<p><i>Wyeth v. Levine</i>; <i>Hopper v. Solvay Pharmaceuticals</i>; <i>Abigail Alliance v. von Eschenbach</i>; <i>Stormans, Inc. v. Selecky</i>; & <i>Sanchez v. Wal-Mart</i>.</p>	<p>- Debating Healthcare Reform: Rage on the Airwaves</p>	<p>- Discussion Board</p> <p>- Quiz 7</p> <p>- No Assignment this week.</p>

Final Exam Posted 9am EDT on Oct. 6, Due 6pm EDT Oct. 7

MODULE

Overview

I, August 19 through August 25

of Class for August 19:

The purpose of this introductory class is to describe the basic approaches to regulation and consider the reasons for regulating in the best interests of the public health.

As you study for this class, pay particular attention to the challenge of balance in regulation. Is there a good rubric to use in deciding when to be tough and when to be soft in regulation? Do we really have a regulatory system, or is it a nonsystematic collection of somewhat related rules? Are more regulations necessary to improve health care, or would it be sufficient to improve the efficiency of existing regulations?

Assignment:

- Read Sparrow Introduction
- Read Brennan Chapter 1
- Read Donabedian Article
- View Video Lecture: Law, Public Policy and Ethics

Overview of Class for August 23:

The purpose of this class is to consider how drugs are regulated, as opposed to health care institutions and health care professionals, and to examine the interface between health care regulation and drug regulation.

As you study for this class, ask yourself whether FDA regulations adequately accommodate individual variation in health care practices. Does drug regulation inappropriately and pointlessly attempt to homogenize the practice of health care? How can the public exercise its right to use drugs in individual ways, within the framework of a federal system that attempts to protect the public from harm caused by unscientific drug use? Is science always the appropriate basis for evaluating the correctness of drug use?

Assignment:

- Read *Ancheff v. Hartford Hospital*
- Read Temin Chapter 1
- View Video: Altered States: A History of Drug Use in America

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MODULE

Overview

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on August 23 and closing on August 25.

Submit your response to Assignment 1 by 6pm Eastern on September August 26.

II, August 26 through September 1 of

Class for August 26:

The purpose of this class is to consider alternative means of regulation and the reasons why some critics of regulation have contended that regulators cause more problems than they solve.

As you study for this class, ask yourself how regulations should be kept up-to-date. Should regulation lead development in industry, or should regulation follow natural developments? Who sets the standard for appropriate regulation of health care? How can regulation be evaluated to determine whether its existence is justified? Who oversees regulatory agencies to assure that they are performing as expected?

Assignment:

- Sparrow Chapters 1 & 5
- View Video: The Role of Legislature, Administrative Agencies & Chief Executive

Overview of Class for August 30:

The purpose of the class is to consider how regulation improves the quality of health care practice and of drug use.

As you study for this class, ask yourself whether regulation should focus on the outcomes of care or on processes. What is the difference between an outcomes orientation and a process orientation? How do data help inform regulation? How are standards developed against which the regulated industry is measured? How can inspections of health care institutions assure good quality care? What are the limits of regulation?

Assignment:

MODULE

Overview

- Read Brennan Chapter 4
- Read *Smith v. Heckler*
- View video: Legislating Morality

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on August 30 and closing on September 1.

Submit your response to Assignment 2 by 6pm Eastern on September 2.

III, 2 through September 8

of Class September 2:

The purpose of this class is to provide an overview of the means through which health care professionals are regulated to assure their competence.

As you study for this class, ask yourself whether regulators best serve the public by functioning as educators or enforcers. Is it really possible for regulatory agencies to form productive partnerships with those who are being regulated? What are the appropriate measures of regulatory success in oversight of the health care professions? What are the barriers to improving professional regulation, and how can those barriers be overcome?

Assignment:

- Read Sparrow Chapters 7 & 8.
- View Video Lecture: Licensure as Assessment of Competence

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Overview of Class for September 6:

MODULE

Overview

The purpose of this class is to consider the professional responsibilities of those who practice in the field of health care, and how regulators can ensure that health care professionals have the combination of knowledge, skill and caring that serves as the basis of effective health care practice.

As you study for this class, reflect on the goals of regulation. Ask yourself whether regulatory agencies exist simply to provide assurance to the public that tax dollars are being well spent, or should regulatory agencies actually improve the level of care provided to patients? Is a regulatory agency an arm of the profession it regulates or is it an arm of the government? Should we resign ourselves to the reality that some people simply will receive better products and services than others, and that there is really nothing to be done about it?

Assignment:

- Read Knowlton & Penna Chapter 10.
- Read Starr Chapter 3.
- Read *Hoover v. AHCA*.
- View Video: The Quality Gap

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on September 6 and closing on September 8.

No Problem to turn in this week.

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MODULE

Overview

IV, 9 through September 15

of Class September 10:

The purpose of this class is to start considering how to develop a process of regulation that can make a difference in people's lives.

As you study for this class, ask yourself what role the public has can play in insisting that the quality of health care be as high as possible and that regulatory agencies respect the right of the public to insist on quality. What is a high quality hospital? How would you know a high quality hospital if you saw one? How can drugs and health care services be evaluated to facilitate their regulation for quality?

Assignment:

- Read Sparrow Chapter 9.
- Read Millenson Chapter 12.
- View Video: Reducing Risks of Drug Testing & Use.

Overview of Class for September 13:

The purpose of this class is to examine regulatory efforts to produce patient safety programs that control medical errors.

As you study this module, reflect on the difficulty of detecting subtle errors in medical practice. Are there traditions in medicine that impede the implementation of programs that will improve quality and protect patients? How can health care professionals within institutions be incentivized to improve the quality of what they do, given barriers to change present in any institution?

Assignment:

- Read Bogdanich Chapter 4.
- Read *Thompson v. Nason Hospital*
- View Video: Medical Mistakes

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Do not forget to post regularly on the discussion board. Remember, original threads due by Friday. Take the Quiz opening on September 13 and closing on September 15.

Submit your response to Assignment 3 by 6pm Eastern on September 16.

MODULE V, 16 through September 22

Overview of Class September 16:

The purpose of this class is to provide an overview of actions taken by regulatory agencies in response to public concern over the increased incidence of medical error.

As you study for this class, ask yourself how a regulatory agency can approach problem solving when a public mandate for change is issued. How can management of a regulatory agency assure that changes in policy are purposeful and not counterproductive? Does mandatory continuous quality improvement effectively replace punishment of error?

Assignment:

- Read Sparrow Chapters 10 & 11.
- Read Brennan Chapter 3.
- View Video Lecture: Liability for Harm from Defective Products.

Overview of Class for September 20:

The purpose of this class is to reflect on the standard of medical practice, and ask whether a practice that is unusual is below the standard and therefore in error.

As you study for this class, reflect on how standards of medical practice are developed. Do the majority of practitioners set the standard? What if there is a substantial minority opinion—is anyone in the minority necessarily wrong in the way they practice? How can the public evaluate the quality of medical practice? What role do the courts play in reviewing evaluations of quality in medical practice?

Assignment:

- Read IOM Report.

- Read *State v. Naramore*.
- View Video: A Questionable Doctor.

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on September 20 and closing on September 22.

Submit your response to Assignment 4 by 6pm Eastern on September 23.

MODULE VI, September 23 through September 29

Overview of Class September 23:

The purpose of this class is to provide an overview of medical malpractice liability as a mechanism to assure and improve the quality of health care.

As you study for this class, ask yourself how those in regulation can evaluate those being regulated. Is it really possible for those who do not practice a profession on a day-to-day basis to know what can and cannot be done within a health care practice? How can the discretion of a reviewer of quality be used judiciously to allow for variations in quality? What does it mean to be “negligent” in the practice of a profession?

Assignment:

- Read Sparrow Chapters 16, 17.
- Read Burns Chapter 8.
- View Video Lecture: Principles of Legal Liability.

Overview of Class for September 27:

The purpose of this class is to consider how an individual or group of individuals can meet its professional duty to patients, when there are competing interests.

As you study for this class, ask yourself at what point a health care professional has a responsibility to set aside her/his interests and risk the loss of a job as a matter of principle in the defense of a patient’s best interests. How certain can a health care professional be that a particular course of action is the right course of action? When should a fellow health care professional be challenged if

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science is never absolute and there is no real way to know what approach to care is the best approach?

Assignment:

September

- Read Noah Article.
- Read *Harco v. Holloway*.
- View Video: Oral Argument: *Powers v. Thobani*

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on September 27 and closing on September 29.

Submit your response to Assignment 5 by 6pm Eastern on September 30.

MODULE VII, September 30 through October 6**Overview of Class September 30:**

The purpose of this class is to develop proposals for reform in health care regulation.

As you study for this class, ask yourself what additional information you would need to know in order to redesign health care regulation to be more effective. How would you go about obtaining that information? Have recent reforms in health care regulation really just be Band-Aids that perpetuate the traditional problems while putting a new coat of paint on the standard regulatory techniques? How can an outcomes orientation become the cornerstone of health care regulation?

Assignment:

- Read Sparrow Chapters 19 & 20.
- Read Brennan Chapter 7

Overview of Class for October 4:

The purpose of this class is to examine the interface between federal and state authority.

As you study for this class, reflect on the role of federal regulators and the rights of local governments to conduct experiments in regulation that may prove to be worthwhile. Is there any point in trying to do things differently when so many people oppose anything that is different? Have the media hijacked the opportunity for frank and open discussion as they compete to present the most outrageous and pointless programming? Can emotion and politics be separated from objective evaluation of regulatory policies? Does an independent judiciary play a role in maintaining objectivity in the face of emotion and personal animosity?

Assignment:

- Read Cases: *Wyeth v. Levine*; *Hopper v. Solvay Pharmaceuticals*; *Abigail Alliance v. von Eschenbach*; *Stormans, Inc. v. Selecky*; *Sanchez v. Wal-Mart*.
- View Video: Debating Healthcare Reform: Rage on the Airwaves.

Do not forget to post regularly on the discussion board. Remember, original threads due by Friday.

Take the Quiz opening on October 4 and closing on October 6.

No Problem to turn in this week.