

**SEMINAR: THE HEALTH REGULATORY PROCESS**  
**(LAW 7397 — Spring, 2014)**  
**Prof. Mantel**  
**Syllabus and Course Policies**

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**Course Description**

Federal and State governments execute and enforce laws affecting almost every aspect of health care. This course explores how legal, policy, and political considerations influence legislative enactments and administrative agencies' regulatory policies in the health care arena. The first part of the course examines the policy and political reasons for government intervention at the state and federal levels and the regulatory tools used by government to achieve its health-related regulatory goals. The second unit explores the manner in which administrative agencies' implement health care statutes, with a focus on legal considerations that constrain agencies' discretion and how agencies employ cost-benefit analysis and scientific evidence and risk analysis. The third unit addresses health care enforcement and compliance issues, including an overview of the enforcement tools available to agencies, factors influencing agencies' exercise of their enforcement discretion, and approaches utilized by agencies other than enforcement actions that promote compliance with regulatory requirements. Finally, we will discuss the ways in which the political branches, namely Congress and the President, influence agencies' policymaking process.

**Course Materials:** Materials to be provided in hard copy or via the course website at <http://www.law.uh.edu/faculty/jmantel/health-regulatory-process.html>.

**Course Policies:**

**Grading:** The course grade will be based on four components: (1) class participation; (2) a client memorandum exercise applying the concepts covered in the first part of the course (Unit 1( II-V)); (3) a client memorandum exercise applying cost-benefit, scientific, and risk analysis principles (Unit 2); and (4) a final essay that addresses themes covered throughout the semester.

- (1) **Class Participation:** 15 percent of the course grade will be based on class participation. Please note that this is not a good class to take if you want to sit back and passively monitor the proceedings. Preparation and active participation will be expected. That said, I understand that illness or other situations may prevent you from being adequately prepared for class. If you are not prepared for class, I will give you a "pass" provided you ask me not to call on you prior to the start of class. You are allowed no more than two passes for the semester. If I call on you and you are unprepared, you will be required

to choose the classmate who must answer my question in your place. Pursuant to the Law Center's policy, you must attend at least 80% of all class meetings; however, you should strive to attend 100%. Missing more than 20% of classes will result in your being dropped from the course consistent with the law school's policies.

- (2) **Memorandum Exercise #1.** You will draft a 12-15 page client memorandum applying one or more of the concepts covered in the first part of this course. I will provide you with a list of essay topics. More details regarding the memorandum's format, content, and due date will be discussed later in the semester. 25 percent of the course grade will be based on the essay.
- (3) **Memorandum Exercise #2.** You will be asked to draft a 12-15 page client memorandum applying the principles we cover in the cost-benefit analysis and scientific evidence and risk analysis units to a hypothetical situation. Your analysis will be due approximately one week after we finish covering the scientific evidence and risk analysis unit. 25 percent of the course grade will be based on this exercise.
- (4) **Final Essay.** You will draft a 12-15 page essay discussing general themes covered throughout the course. More details regarding the final memorandum's format, content, and due date will be discussed later in the semester. 35 percent of the course grade will be based on the essay. This assignment is due on May 8<sup>th</sup> at noon.

**Seating Assignments:** After the first week of class, I will create a seating chart. You must sit in your assigned seat for the remainder of the semester.

**Cell Phones/Pagers:** During class, all electronic devices should be set to silent mode.

**Office Hours:** I will hold office hours in my office on Thursdays from 3:00-4:00 p.m. and by appointment. You may also email me questions. Please feel free to come by to see me not only about class matters, but for course selection guidance, career counseling, or any other matter related to your legal education and career.

*Continue to next page for reading list*

# **COURSE OUTLINE & READING LIST**

## **UNIT 1: REGULATORY GOALS AND METHODS OF REGULATION**

### **I. OVERVIEW OF FEDERAL AND STATE HEALTH AGENCIES**

- Lisa Schultz Bressman et al, *THE REGULATORY STATE*, 400-03 (2010)
- Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 *ADM. L. REV.* 343 (2009) (excerpt)

### **II. JUSTIFICATIONS FOR THE REGULATORY STATE**

#### **A. The Limitations of Tort Law and the Markets**

- Lisa Schultz Bressman et al, *THE REGULATORY STATE*, 59-61 (2010)
- Sidney Shapiro and Joseph Tomain, *REGULATORY LAW AND POLICY: CASES AND MATERIALS* 40-43, 49-62 (3d ed. 2003)

#### **B. Application: Ensuring the Quality of Care**

- Timothy Stoltzfus Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 *HOUS. L. REV.* 525 (1988) (excerpts)

#### **C. Application: Health Insurance and Health Care Reform**

- Bernadette Fernandez, CRS Report for Congress, *HEALTH INSURANCE: A PRIMER* (2005) (excerpts)
- The Patient Protection and Affordable Care Act, Pub. L. 111-148, § 1201 (specifically the amendments to §§ 2701, 2702, 2703, 2704, and 2705 of the Public Health Services Act); §§ 1401 and 1501

### **III. REGULATION AND POLITICS – AN INTRODUCTION**

#### **A. Public Choice Theory and the Problem of Collective Action**

- Sidney Shapiro and Joseph Tomain, *REGULATORY LAW AND POLICY: CASES AND MATERIALS*, 78-87 (3d ed. 2003) (includes excerpts from Michael Levine, *Revisionism Revised: Airline Deregulation and the Public Interest*, 44 *LAW AND CONTEMPORARY PROBLEMS* 179, 180-85 (1981) and James Q Wilson, *The Politics of Regulation*, in *THE POLITICS OF REGULATION* 367-72 (J. Wilson ed. 1980))

#### **B. Application: The Politics of the Medicare Prescription Drug Benefit**

- Jonathan Oberlander, *Medicare and the Politics of Prescription Drug Pricing*, 64(6) *N.C. MED. J.* 303 (2003)

#### IV. FEDERALISM ISSUES

##### A. Rationales Supporting State vs. Federal Action

- Bovberg, et al., *State and Federal Roles in Health Care: Rationales for Allocating Responsibilities*, in *FEDERALISM AND HEALTH POLICY* 25-57 (Holhan, et al. ed, 2003)

##### B. Application: Health Care Exchanges

- Reed Abelson, *Proposals Clash on States' Role in Health Plans*, N.Y. TIMES B1 (January 14, 2010)

#### V. REGULATORY TOOLS

##### A. Framework for Evaluating Regulatory Tools

- Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 FORDHAM URB. L.J. 1611 (2000) (excerpt)

##### B. Standard-Setting Regulations – Quality Standards for Nursing Homes

- Richard B. Stewart, *Beyond Delegation Doctrine*, 36 AM. U. L. REV. 323, 329-30 (1987)
- Avedis Donabedian, *The Quality of Care: How Can It Be Assessed?*, 260 JAMA 1743 (1980) (excerpt)
- Alexander D. Eremia, *When Self-Regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight Is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care*, 11 ANNALS HEALTH L. 93 (2002) (excerpt)
- Marshall B. Kapp, *Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Got To Do With It?*, 31 MCGEORGE L. REV. 707 (2000)

##### C. Financial Incentives – Pay For Performance

- Institute of Medicine, *REWARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE* (2007) (excerpts)
- Elliott S. Fisher, *Paying for Performance – Risks and Recommendations*, 355 NEW ENG. J. MED. 1845 (2006)

##### D. Provision of Information – Public Disclosure of Quality Information for Plans and Providers

- Timothy Stolfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825 (1995)
- E.C. Schneider and T. Lieberman, *Publicly Disclosed Information About the Quality of Health Care: Response of the U.S. Public*, 10 QUAL. HEALTH CARE 96 (2001)

## **UNIT 2: STATUTORY IMPLEMENTATION BY AGENCIES**

### **I. WHY DOES CONGRESS DELEGATE TO AGENCIES**

- David Epstein & Sharyn O'Halloran, *The Nondelegation Doctrine and the Separation of Powers: A Political Science Approach*, 20 Cardozo L. Rev. 947 (1988) (excerpt)
- Shailagh Murray, *On Medical-Privacy Issue, the Doctor Finally May Be In*, Wall Street Journal (Aug. 20, 1999)
- Robert Pear, *Future Bleak for Bill to Keep Health Records Confidential*, NY Times (June 21, 1999)  
*\*Note: Due to the New York Times' high copyright fees, this article is not posted on the class web site. You can obtain the article on Westlaw (1999 WLNR 3104886).*

### **II. LEGAL CONSIDERATIONS**

#### **A. Overview of the Administrative Procedure Act (APA)**

- Re-read Lisa Schultz Bressman et al, THE REGULATORY STATE, 400-03 (2010)
- Student Health Insurance Coverage Proposed Rule (76 Fed. Reg. 7767 (2011)) and Final Rule (77 Fed. Reg. 16453 (2012))  
*\*Note: You need only skim these rules. The purpose of reading them is to give you an idea of what a proposed rule and final rule look like.*
- *Conn. Light and Power v. NRC*, 673 F.2d 525 (D.C. Cir. 1982)

#### **B. Judicial Review: Deference to Agency Interpretations, The Arbitrary and Capricious Standard**

- *Chevron v. Natural Resources Defense Council*, 467 U.S. 847 (1984)
- *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insur. Co.*, 463 U.S. 29 (1983)

#### **C. Statutory Constraints on Agency Action**

- American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, sections 4101 and 4102 (excerpt provided)  
*\*Note: When reviewing these statutory provisions, try to identify the extent to which Congress gave the agency discretion (e.g., which statutory terms are ambiguous, on what issues did Congress direct the agency to promulgate standards, in what ways did Congress limit the manner in*

*which the agency can exercise its discretion).*

### **III. COST-BENEFIT ANALYSIS AND QALYs**

#### **A. Introduction**

- B. Guy Peters, *AMERICAN PUBLIC POLICY: PROMISE AND PERFORMANCE* (6<sup>th</sup> ed., 2004) 447-461
- FDA's Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations, 58 Fed. Reg. 60856 (1991)
- OMB Circular A-4 (Sept. 17, 2003)
- Cass Sunstein, *Cost-Benefit Default Principles*, 90 MICH. L. REV. 1651, 1711-14 (2001) (excerpt #1)

#### **B. Valuing Life and Good Health**

- Frank Ackerman and Lisa Heinzerling, *PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING* (2004) (excerpts)
- David Fahrenthold, *Cosmic Markdown: EPA Says Life Is Worth Less*, WASHINGTON POST (July 19, 2008), at A1  
    *\*Note: You can obtain the article on Westlaw (2008 WLNR 13517008).*
- Ceri Phillips, *What is a QUALY?* (2009), available at [www.whatisseries.co.uk](http://www.whatisseries.co.uk).

#### **C. Final Thoughts**

- Cass Sunstein, *Cost-Benefit Default Principles*, 90 MICH. L. REV. 1651, 1711-14 (2001) (excerpt #2)

### **IV. SCIENTIFIC EVIDENCE AND RISK ANALYSIS**

#### **A. Introduction**

#### **B. Application – EPA Determination of Whether Formaldehyde is a Significant Risk**

#### **C. Application – FDA and Plan B**

**UNIT 3: CONTROL OF AGENCY ACTION  
BY THE POLITICAL BRANCHES**

- I. REASONS FOR OVERSIGHT**
- II. CONGRESSIONAL CONTROL OVER AGENCIES**
  - A. Introduction**
  - B. Application -- NIH Research Grants**
- III. PRESIDENTIAL CONTROL OVER AGENCIES**

**UNIT 4: ENFORCEMENT AND COMPLIANCE ISSUES**

- I. INTRODUCTION TO HEALTH CARE FRAUD AND ENFORCEMENT**
- II. PROMOTING COMPLIANCE**