REGULATORY ANALYSIS OF PHARMACEUTICALS AND MEDICAL DEVICES

Professor Catherine Sharkey
NYU School of Law
July 2018

Course Description: The regulation of pharmaceuticals and medical devices—fields of rapid technological growth and innovation—is a topic of legal, economic, and policy significance. Our study of regulation will encompass an exploration of such direct controls as governmental legislation and agency directives and indirect controls like products liability litigation, insurance, and antitrust regimes. We will study how technological advances in the pharmaceutical and medical device industry challenge and demand redefinition of the institutional relationships between agencies and courts, and of the mechanisms of supervision and control provided by the market, government, and common law litigation.

Readings: Paginated packets for Parts I, II, and III. **[pp. x-y]** denotes pages in relevant packet.

Course Requirements/Grades: Final grades will be determined by class participation (25%) and 24-hour take-home final examination (75%).

PART I. GOVERNMENTAL REGULATION

Class 1: Introduction: The Regulation of Pharmaceuticals & Medical Devices

- Shavell, "Liability for Harm Versus Regulation for Safety," 13 *Journal of Legal Studies* 357 (1984), excerpted in FOUNDATIONS OF TORT LAW (2009) **[pp. 1-18]**

- Sharkey, *An Institutional Perspective on the Regulation of Products in the United States*, in NEW FRONTIERS OF CONSUMER PROTECTION: COMBINING PRIVATE AND PUBLIC ENFORCEMENT (2009) **[pp. 19-30]**

Class 2: The Role of Agencies: FDA Premarket Approval & Postmarket Surveillance

- Epstein, "Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex," 5 *Yale Health Policy, Law & Ethics* 741 (2005) **[pp. 31-57]**

- Philipson & Sun, Cost of Caution: The Impact on Patients of Delayed Drug Approvals, *Project FDA Report* (Manhattan Institute, June 2010) **[pp. 58-77]**

Class 3: The Dissemination of Information: Labeling & Advertising

- Kenkel & Mathios, *Promotion to Physicians and Consumers*, *in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (2012) **[pp. 78-108]**

- Hayes, "Drug Labeling and Promotion: Evolution and Application of Regulatory Policy," 51 *Food & Drug Law Journal* 57 (1996) **[pp. 109-122]**

- Woosley, "Drug Labeling Revisions—Guaranteed to Fail?" 284 *Journal of American Medical Association* 3047 (2000) **[pp. 123-125]**

- Gibbons et al., "Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents," 164 *American Journal of Psychiatry* 1356 (2007) **[pp. 126-132]**

PART II. PRODUCTS LIABILITY LITIGATION

Class 4: Tort Claims against Pharmaceutical Companies

- Conk, "Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?" 109 *Yale Law Journal* 1087 (2000) **[pp. 1-35]**

- *MacDonald v. Ortho Pharmaceutical Corp*., 475 N.E.2d 65 (Mass. 1985) **[pp. 36-46]**

- *Asahi Kasei Pharma Corp. v. Actelion Ltd*., 222 Cal. App. 4th 945 (2014) **[pp. 47-53]**

Class 5: FDA-Approved Drugs & Devices: Federal Preemption of Tort Claims

- Malani & Philpson, *The Regulation of Medical Products*, *in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (2012) **[pp. 54-94]**

- *Wyeth v. Levine*, 555 U.S. 555 (2009) [brand-name drug preemption] **[pp. 95-117]**

- Kesselheim et al., "Who is Now Responsible for Discovering and Warning About Adverse Effects of Generic Drugs?" 310 *Journal of American Medical Association* (2013) **[pp. 118-119]**

- Berndt & Trusheim, *The Economic Impacts of Eliminating Federal Preemption for Medical Devices on Patients, Innovation and Jobs* (2009) **[pp. 120-148]**

Class 6: The Special Case of Vaccines

- Sloan, *The Economics of Vaccines*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (2012) **[pp. 149-176]**

- Arnould & DeBrock, "The Application of Economic Theory to the Vaccine Market," in SUPPLYING VACCINES: AN ECONOMIC ANALYSIS OF CRITICAL ISSUES (Pauly et al. eds. 1996) **[pp. 177-192]**

- Darrow & Kesselheim, "A New Wave of Vaccines for Non-Communicable Diseases: What Are the Regulatory Challenges?" 70 *Food & Drug Law Journal* (2015) **[pp. 193-208]**

- Sharkey, "Against Categorical Preemption: Vaccines and the Compensation Piece of the Preemption Puzzle," 61 *DePaul L. Rev.* 1301 (2012) **[pp. 209-226]**

PART III: ECONOMICS & INNOVATION POLICY

Class 7: Economics of Innovation: Price, Insurance Coverage & Market Exclusivity

- Danzon, *Regulation of Price and Reimbursement for Pharmaceuticals*, *in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (2012) **[pp. 1-36]**

- Danzon & Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," 22 *Health Affairs* W521-W536 (2005) **[pp. 37-52]**

- Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS," *Health Affairs*, Sep/Oct 2001, at 241 **[pp. 53-62]**

- Eisenberg, "The Role of the FDA in Innovation Policy," 13 *Michigan Telecommunications & Technology Law Review* 345 (2007) **[pp. 63-106]**

Class 8: Innovation Policy: Market Exclusivity, Competition & Antitrust

- Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *N.Y.U. Law Review* 1553 (2006) **[pp. 107-137]**

- Hemphill & Sampat, "Drug Patents at the Supreme Court," 339 *Science* 1386 (March 2013) **[pp. 138-139]**

- Edlin et al., "Activating Actavis," 28 *Antitrust* 16 (2013) **[pp. 140-147]**

- Simas, "US v. EU: Pay-for-delay Settlements," *Berkeley Technology Law Journal* (2015) **[pp. 148-150]**