New Summer Course

Drug Product Liability Litigation:
Principles and Practice

This June (A Term), Peter Grossi, Senior Counsel and former chair of the Litigation Group at Arnold & Porter, Washington, D.C., will present his course on drug product liability litigation (3 credits) -- a course he developed and has taught at the law schools of the University of Pennsylvania and University of Virginia. Mr. Grossi, who joined A&P in 1974, has been trying and teaching other attorneys to try product cases for over 25 years -- the last 12 serving as the National Counsel for Wyeth in its Diet Drug cases -- over 100,000 individual lawsuits which some observers have labeled as the largest set of cases filed against any one defendant. Last year Chambers USA named Mr. Grossi the “Senior Statesman” of the American product liability bar.

The course combines lectures and discussions on the legal issues in such cases (such as adequacy of warnings, the learned intermediary doctrine, the effect of FDA regulation, and the constitutional limits on punitive damages), but also the practical problems in preparing and presenting them to juries (discovery techniques, the special problems in examining medical experts, jury selection strategies, and the way graphics can be used to present complicated scientific and regulatory facts).

Students who have taken the course at other law schools have commented that “Mr. Grossi is obviously the leader in this field and knows the law backwards and forwards. His personal experiences make every class interesting.” Another wrote, “This is the best class I have taken in terms of preparing me for actual practice.”

No prerequisite; take-home exam.

3 Credits
More product liability lawsuits are filed against prescription drug manufacturers than against all other industries combined. As one legal scholar put it, the pharmaceutical industry is now “in tobacco-land in terms of how much people hate it,” and drug product liability litigation is now a “growth industry.”

This course, which the instructor normally gives at Penn and UVA Law Schools, will consider the theory and practice of such lawsuits before, and now after, the Supreme Court’s recent landmark decision in Wyeth v. Levine (2009). At the outset, we will focus on the similarities and differences between such litigation and other product liability cases, using the “Phen-Fen” cases tried by the instructor as a model, and on the special context of FDA regulation. We will then consider the legal principles governing such lawsuits, such as inadequate warning; the learned intermediary doctrine; and medical causation.

The course will also consider the practical application of these doctrines, including the problems when doctors are witnesses; discovery strategies; techniques to present complex information to juries; and jury selection strategies.

**No Prerequisite.**

**3 Credits**

**Course Requirements:** Class participation; take-home final exam (open book).

**See Attached Syllabus.**
Drug Product Liability Litigation: Principles and Practice

(Peter Grossi)

1. Introduction to Drug Product Liability Litigation
   A. The Distinctive Features of Such Cases
   B. A Short History of One Litigation -- The Tale of Phen-Fen
   C. Anatomy of a Pharma Case -- Course Overview

2. The Context of FDA Regulation
   A. The Drug Approval Process
   B. Brief Overview of Other FDA Regulations

3. General Legal Principles
   A. A Brief Review of Traditional Tort and Product Liability Principles
   B. The Special Applications of Those Principles to Drug Cases
   C. Section 402A, Comment k of Second Restatement v. Section 6 of Third

4. Actions Based on Failure to Warn
   A. State-of-the-Art; Reasonable Conduct
   B. Label Analysis in Failure-to-Warn Cases

5. Actions Based on FDA Violations and Pre-Empption After Levine
   A. Attempted Actions Based on Regulatory Lapses -- Buckman
   B. Levine and Pre-Empption Today

6. Actions Based on Inadequate Testing
   A. The Law
   B. Competing Study Designs
7. **General Medical Causation**
   A. Legal Principles of Epidemiological Proof
   B. Critical Analysis of Medical Studies
   C. Expert Witnesses -- Daubert Issues
   D. Use and Misuse of Adverse Event Reports

8. **Specific Medical Causation**
   A. The Legal Standard for Alternative Risks
   B. The Use of Treater Testimony
   C. Expert Witness Reliance on Personal Clinical Experience
   D. Features of Mass “Medical” Screening Programs

9. **The Learned Intermediary Doctrine**
   A. The Classic Rule
   B. The Heeding Presumption
   C. Judicial Rejection Based on Direct-to-Consumer Promotion
   D. Features of Prescriber Testimony

10. **Damages in Drug Cases**
    A. Compensatory Damages -- Past, Present, Future
    B. Punitive Damages -- Constitutional and Statutory Limits

11. **Organizing the Trial -- Logical Framework and Presentation**
    A. Organization of the Medical Case For a Jury
    B. Organization of the Liability Case For a Jury
    C. Juror Questionnaires/Voir Dire
12. Discovery Issues/Practical Applications
   A. Discovery from Drug Manufacturers
   B. Discovery from FDA -- Evidentiary Limitations
   C. Discovery from Plaintiff/Family/Friends

13. Other Legal Issues Affecting Trial
   A. Venue Issues -- Fraudulent Joinder in Drug Cases
   B. Admissibility of Label Changes
   C. Motions to Limit Adverse Evidence Concerning Plaintiff

14. Other “Real World” Problems -- Student Choice