

CLASS 1. SEMINAR AIMS AND SCOPE OF DRUG REGULATION

A. SEMINAR ORGANIZATION & OVERVIEW

Organization—topics, deadlines, research sources, goals
See handout

B. SCOPE OF DRUG/DEVICE REGULATION & RATIONALE

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Relationship to anti-freeze 231, n. 2

Statutory Milestones-1906, 1938, 1962, PDUFA, FDAMA-1997, MMA-2003,
PDUFA IV & FDA Amendments--9/07 ??

C. Product categories: defining drugs/ devices /intent 6-19

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+Ova II 12

+ New Drugs-50 Boxes 43-50

See class 8 on intent

[Implications of Chevron test 467 US 837--courts interpret statute independently
if Congress has “directly spoken to precise question” and defer to a reasonable
agency interpretation if “the statute is silent or ambiguous”]

[Dietary supplements-- How different??--structure & function but no disease claims;
need not be nutritional to be dietary--see 19-35 and F&D course]

Book is Noah Law Medicine & Medicine Technology, SECOND EDITION 2007
& Statutory Supplement by FDLI, 2d ed. 2005

Page numbers in the right hand column are to the Noah book

HO- indicates handouts. Page numbers next to the topic relate to page numbers in the handout..

Handout numbering is organized by the CLASS to which they relate. Material in brackets or
parenthesis is informational,. TBD-HANDOUTS TO BE DISTRIBUTED IN FUTURE

+ indicates matters for special emphasis in class

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+Abigail Alliance v. von Eisenbach 195
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*****DEADLINE FOR SUBMITTING TOPIC AND INITIAL OUTLINE*****

CLASS 5- POST-MARKET ADVERSE EVENTS: LESSONS FROM VIOXX

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B Pre-Vioxx Setting

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+New Warnings, Court Actions 293, n. 6

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+ Kweder Testimony HO

D. What Reform Needed See IOM Report

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Psaty, Editorial NEJM 5-29-07 HO

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 See Drug Firms Use Financial Clout
 WSJ, A1 , Sept 1, 2006 on negotiations HO

Should Drug Safety office be independent? –failed by one vote in Senate

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REMS for newly approved drugs- see risk management in IOM Report, E to G

Dispute resolution procedures in new law?
Civil Money Penalties

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Data-mining-how effective--will it lead to warnings

Pasty-criticism-Congress' Response? See Class 5

B. Preemption and FDA's Position

.+ FDA Preemption Statement-

71 Fed. Reg.3922, 3933

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Assessment of Statement

Apply to Vioxx
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Cert petition in Wyeth v, Levine-status 127 S. Ct. 2451/ drug case

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[Background- Patent Protections & additional uses, , p.788-826]

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21 U.S.C. 355(j)(2)(A)(vii)(I)-(IV) e

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+ For expansion, see R. Eisenberg, 5 Yale J. Health Pol'y, L. & Ethics 717, 728-30, 736-39	HO
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Boston Globe, 10-31-01	HO
Impact on insulin and growth hormone generics	
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[See The Drug Company and the Bogus Data, Able Labs put out bad pills	
in front of FDA for years, Star Ledger, 8-7-05, 2005 WLNR 12435121]	
 ++Presentation of Seminar Papers++	

Submission of draft seminar paper-1/3 grade reduction for first week late and 1/3 grade reduction for second week late.

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- Globalization–Execution of Head of China’s FDA HO
- Drugs for Developing countries, p. 825
- Free trade agreements, 826

III. Biotechnology and Ethics:

- +Growth hormones and children 985, note
 - Need for a distribution limit?
 - See class 6
- See President’s Task Force on Beyond Therapy-p. 281-
- appropriateness of human enhancement drugs HO

IV. Presentations

V. Exam review-MSJ’s

Final seminar paper due last day of EXAMS–Thereafter 1/3 grade reductions each week for a delayed submission