Current

FOOD AND DRUG LAW

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Rutgers School of Law, Newark
Office Hours: T 1-3 pm and by appointment, Room 446
Class Meetings: M-W 9:30-10:45 am, Th reserved for make-up classes if necessary

Course description: This course is primarily an introduction to Food Drug and Cosmetic Act and the regulation of foods, drugs and devices by the U.S. Food and Drug Administration (FDA). Students will learn the basic statutory and regulatory authorities under which the FDA operates. Because the practice of food and drug law occurs in a rapidly changing technological legal, and policy environment, this course aims to give the student facility with the policy arguments that they will use and encounter in their client advocacy, and which will shape the food and drug regulatory system of tomorrow.

Learning Outcomes: After taking this course, students should be able to:

1. Display knowledge and understanding of both substantive and procedural law governing food, drugs, and devices
2. Develop strategies that involve interpreting, applying, and influencing the law from judicial, legislative, and administrative sources.
3. Draft proposed legislative amendments as a part of legal problem-solving

Course readings: The principal texts will be **HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS (4th ed. 2014)** and the **STATUTORY SUPPLEMENT: FOOD AND DRUG LAW.**[1] You will be responsible for looking up in the statutory supplement any statutory sections that are mentioned in the casebook readings. I have listed some of the most prominent in the syllabus, though my list is not exhaustive. You may also find it useful to consult the regulations that the FDA has developed over time to interpret the FDCA. Those can be found on the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. I will occasionally assign additional materials which will appear on the course Blackboard site.

Written/Skills Assignments: At least two written exercises will be assigned throughout the semester. The first will be ungraded, the remaining exercise(s) will represent 1/3 of your grade. In addition, class participation (including failure to do ungraded assignment) can result in a bump up or a bump down. Prior to the two written exercises, we will practice at least three of these exercises in class also so that you are familiar with what I expect. I have indicated in the syllabus roughly when in the sequence of reading I expect the assignments to be distributed and when I expect them to be due, but the actual dates will depend upon how quickly we proceed through the reading material, and will be discussed in consultation with you in class with plenty of notice. Late submission of the ungraded assignment will result in forfeiting of the opportunity to receive feedback from me, as well as potentially affecting the class participation grade. Late submission of the grade assignment will result in a 1/3 reduction in the assignment grade for each day the assignment is late.

[1] All page numbers refer to the primary casebook unless otherwise noted. The Statutory Supplement will be referred to as "Supp."

Exam: There will be a written take-home open-note exam conforming with Law School requirements. It will be similar in format to the written assignments that you practice during the semester. It will represent 2/3 of your grade. You will pick up the exam at Law School library the time appointed for exam to begin, and you will return it there anytime within 8 hours from the time you picked it up.

Expectations of time spent in and out of the classroom: For exam courses, students are expected to prepare a minimum of 2 hours outside of class for each hour (calculated on a 50-minute basis) of in-class time. For example, a four credit class will require a minimum of 8 hours of preparation outside of class per week. Note that the requirement of 2 hours of out-of-class work per week per credit hour represents a minimum standard. If students require more time to complete assignments satisfactorily, they are expected to spend whatever additional time is needed.

Attendance Policy. a. Prompt and regular class attendance, with preparation adequate for full class participation, is expected of all students. Students are prohibited from sitting for the final exam or otherwise receiving a passing grade in any course for which that student has attended fewer than 80% of the scheduled class sessions.
Specifically, a student missing 20% or more of the total scheduled class hours in a course, whether due to excused or unexcused absences, is presumed to not be attending regularly, subject to the discretion of the Dean. In the event that a student is deemed to not be attending regularly, the Dean shall determine whether the student receives a "W" or an "F" in the course.

b. Furthermore, when a student has unexcused absences that exceed the number of credit hours for the course (e.g., three absences in a three- semester hour class), a professor may choose to lower the student's grade by no more than 1/3 of a grade. The professor must clearly articulate such a policy to students in writing on or before the first class.

I. INTRO

1. Background Reading Assignment:
    - For those who have not taken Administrative Law
        i. Procedural Review
            a. 29-33 (Notice-and-Comment Rulemaking)
            b. 49-50, 52-53 (Formal Rulemaking)\
            c. 55-59 incl. n. 1, 61-62 n. 2-4 (Guidance/Policy)
        ii. Substantive Review
            a. 62-65 (not incl. notes)
            b. 66-75, 171-174 (Jurisdictional/Justiciability Issues, *Heckler v. Chaney*)
        iii. Administrative Law "Lite" Slides (Blackboard)
    - For those who have not taken Legislation/Statutory Interpretation
        i. Outline of the Tools of Statutory Interpretation (Blackboard)
        ii. Optional: Theories of Statutory Interpretation excerpt (Blackboard)

2-4.The Jurisdiction and Regulatory Paradigms of the FDA: Product Definitions

- 77-80 (*Bacto-Unidisk*, not including *Tuente Livestock*) and 85-9 (*Nutrilab)*,

- 89 (from drugs and devices incl. dietary supplements) – 98 (intended use, *Nat'l Nutritional Foods Ass'n v. Mathews, U.S. v. Travia*), 98-101 (*Sensor Pad for Breast Self-Exam*)
- 124-9 (letter on Verichip, incl notes 1-6)
- 135 – 46 (tobacco and biologics, *Brown & Williamson*)
- 151-4, 155-6 notes 1-3 (labels/labeling, *Kordel*)
- (skim FDCA §§901 et seq., §201(rr), §403(a), §502(n) and (r), §707, PHSA §351)
- §§301(a), 301(d), 505(a), 201(f), 201(g), 201(h), 201(m) , 201(k)

II. FOOD

5-6. Adulteration and Misbranding
   a. Identity, Quality, Wholesomeness (adulteration and misbranding)
      i. 325-333 (history of food standards)
      ii. 339-345 (*Quaker Oats*), 347-350 notes 4-5 (identity standards, *62 Cases of Jam*)
   b. Identity, Quality, Wholesomeness (new standard)
      i. 350-55, 358-370 incl. notes (decline of food standards, safe and suitable, food names, *AFFI v. Mathews*, imitation) 372-5 (nutrient content claims/descriptors)
      ii. 375-9 (econ adulteration, *Bireley's*)
      iii. §§401, 403(g), 701(e), 403(i), 403(c), 402(b)(4)
      iv. 21 C.F.R §10.30

7-8. Misbranding continued
   a. Misbranding/Labels, Labeling, Claims
      i. False or Misleading in any particular
         a. 379-81, 383-7 (starting with the note 3, false or misleading statements, Apple *Cider Vinegar*, *Farinella* and note 1 on 386-7)
         b. 451-469 (certain voluntary claims such as diet, natural, organic, fresh)
         c. PREVIEW material on genetically modified 458-69, and BLACKBOARD: Fed Reg excerpt, legislation
      ii. 389-403 (required disclosures)
      iii. 317-8 FDA/USDA jurisdiction
      iv. Blackboard: POM Wonderful v. Coca-Cola (TBD)

9. Misbranding continued
   a. Nutritional Labeling 403-409
   b. Nutrient Content Claims/Descriptors 413-418 (nutrient claims), review 372-5
   c. §§201(k) and (n), 403(a), 403A, 403B, 701(a), 403(e), 201(n), 403(f), 403(q), 210(n)
   d. 21 C.F.R. 130.10

13-14. Adulteration continued
   e. Adulteration: Sanitation and Safety
      i. 469-77, 479-487 (*Tomato Paste*, aesthetic adulteration, unfit for food, *Ski Slide Brand Asparagus*)
      ii. 479-86 (insanitary conditions, *Pasteurized Whole Eggs, Berger TBD*)

iii. 528-32 incl. note 1 (*Nova Scotia*)
iv. 489-518 (§402(a)(1), added and non-added, *Am. Beauty Oysters, Lexington Mill, Anderson Seafood, Young v. CNI*) also 171-174 *Heckler v. Chaney*
v. §§402(a)(1 through 4), 406, 408, 344, 309, PHSA §361

15-16. Adulteration:

f. Adulteration: Food Constituents and Functional Ingredients
i. 554 – 568 (additives incl. Olestra)
ii. GRAS 574-77 (GRAS) 579-81 (reg and notes)
iii. 586-602 (GRAS letters, GMO *Alliance for Biointegrity*)
1. And REVIEW material on genetically modified 458-69, and BLACKBOARD: proposed reg on GM disclosure, legislation on GM disclosure, citizen petition and *In re Frito Lay* (state law case on "GM" and "natural" labeling).
iv. 603-7 (Hutt on the overall additive history/scheme)
v. 617-20 (color additive) 634-7
vi. §§201(s), 409
vii. DISTRIBUTE FIRST ASSIGNMENT

17-18. Dietary supplements and claims, First Amendment

viii. 319-20 (special dietary foods and passage of DSHEA and NLEA) 101-4 (DS and vitamins and minerals exemption from drug def'n, exemption from food additive), 323 note 4 (§411)
ix. 418-451 (health claims, *Pearson, Whitaker, Fleminger*), 627-33
x. 403B, §§201(ff), 201(s)(6), 201(g)(1)(D), 403(j), 411(c)(1)(B)(i), 413(a)(1), 413, 402(f), 403(r)(1)(A) and (B), 403(r)(3), 403(r)(5)(D), 403(r)(6).

19. Preemption

- 289-90, 292-314 (*Hillsborough Cty v. AML, Fl. Lime & Avocado Growers, Jones v. Rath, GMA v. Gerace*)
- §§521, 403A, 310(b), 751, 916(a)(2)
- FIRST ASSIGNMENT DUE

III. DRUGS

20-21. Drug Efficacy Pre-1962

- 642-9 incl. note (regulatory efforts before pre-market approval, *U.S. v. Johnson, McAnnulty, Eckman's Alternative, Research Laboratories*)
- 660-665 incl. note 3 (*Hynson Westcott & Dunning*, new drug, GRAS/GRAE)
- 926-8, *Alberty Foods* (on Blackboard 479-81), notes 931-32 (new drug "use," adequate directions for use)
- §§ 502(a), 201(n), 201(p), 505(a), 301(d), 505(b)(1), 505(d), 505(e), 502(f), [501(a)(2)(B)]
- 21 C.F.R. 201.100(c)(2), 201.100(d)

<u>Pre Market Approval Regime: Leading up to the Approval (Substance and Process)</u>

22-4. Drug Clinical Trials and Basics of the Modern Regime (Substance)

- 669 through 672, 674-676, 678-687 to the notes (introducing IND, testing phases, design and standards for clinical trials)
- 720 from the safety std-732 incl note 1 (safety and effectiveness stds)
- 692 from SPA-700 not incl GMP, 701 from DMC-706 not including FDA/SEC (subpopulations, endpoints, trial design)
    i. Optional: preview 676 from Meetings-top of 678, (process to get approval, meetings)
    ii. Optional: preview 733-38 (internal process, advisory committees)
- Blackboard: Clinical Trial Tutorial for Research Advocates
- §§505(i), 502(o), 505(a), 505(d) & (e), 505(b)(4) & (5), 561, 564, 528 (refers to 526), 505A, 505B, 503B
- skim 21 CFR Part 312 (especially 312.83, 312.320, 312.305, 312.310, 312.315, 312.2), 21 CFR §314.126 especially (a) and (e)

25. Challenges to the Pre-Market Investigational Regime
- 763-773 not incl notes, 654-60 (*Abigail Alliance*, expanded access to investigational drugs)
- Blackboard: *Right to Try* legislation

26-28. Leading Up to the NDA (Process): Creeping Proceduralization
- 709-11 (purpose and form of the NDA)
- 712 from user fees-718 (user fees)
- 676 from Meetings-top of 678, (process to get approval, meetings)
- 751-63 (expedited variants of the process, CDER MAPP 6020.3, orphan *Genentech v. Bowen*)
- 733-38 (internal process, advisory committees)
- §§505(b)(1)(B) and (C), and 505(b)(5)(B) and (C), 505(c), 735-6, 506, 505(f), 505(h), 505(n), 505(k), 505-1, 505(o), 505(p), 505(r), 505(s), 506, skim 506B, 803(c), 524, skim 525-528
- 21 CFR 314.101

29. Challenging FDA PMA Decisions and Post-Approval
a. 835-38, 738-42 *Ubiotica* and note cases, 848-59 (*Hynson* again, final approval/denial and postapproval, withdrawal of approval, Imminent Hazard *Forsham v. Califano*).
b. 828-32 *Am. Pharm. Assn. v. Weinberger* and REMS
c. §§ 505(h), 505(e), 505(f), 506C

<u>Labeling, Advertising, Promotion (and preemption)</u>

30. Rx Drug labeling
a. 860-64, 866-75 (labeling review, *Bradley v. Weinberger*)
b. §§ 502(f), skim 502(e), 503(b), 502(a), 201(n), 505(k), 505(o) [incl 505(o)(4)]
c. 21 CFR 201.100(b)-(d), skim 21 CFR 201.56

31. Misbranding in Labeling and Advertising, Off-label
a. 814-20 incl. note 8 (physician prescribing)
b. Preview off-label DTC 907-915, 925-928 (other off-label promotion), [934-938] 938 (notes 5 and 6)-957 *WLF v. Henney, Franklin v. Parke-Davis, Caronia* (promotion, commercial speech)

c. 21 CFR 314.81(b)(3)(i), 21 CFR 312.2(d), 21 CFR 312.7(a), 21 CFR 202.1 (l)(2), 21 CFR 201.100(c)-(d), 21 CFR 201.5
d. DISTRIBUTE SECOND ASSIGNMENT

32. Direct-to-Consumer Advertising
a. 907-915, 915-25 (DTC)
b. §§502(n), §§ 301(kk), 503B, 503C
c. 21 CFR 202.1(e), 21 CFR 202.1(l)(2),

33-4. Patient Labeling, Preemption
d. 802-807 (Rx/OTC distinction, *El-O-Pathic*)
e. 980-983 incl. note 2 (monograph approach) [TBD]
f. 876-79, 882-88 (patient labeling) [TBD]
g. 888-907 (learned intermediary and labeling, duty to warn, preemption *MacDonald v. Ortho, Wyeth v. Levine, Pliva v. Mensing*)
h. §§503(b), 502(f)
i. 21 CFR 330.1 *et seq*, 21 C.F.R. 314.70(c)
j. SECOND ASSIGNMENT DUE

<u>Exclusivities</u>

35-6. Generics
k. 775-78, 780-83 (history, *Hoffman-LaRoche*)
l. 996-1016 (*Generix*)
m. FTC v. Actavis
n. Review orphan and pediatric, new antibiotics in Assignments 13-4 and 16-7 above (§§525-528, 505A and B, 505E).
o. §§301(j), 505(b)(2), 505(j) [incl. 505(j)(2)(A), 505(j)(2)(A)(vii)(IV), 505(j)(4), 505(j)(8), 505(j)(5)(B) and (D through F)]
p. 21 CFR 320.1

IV DEVICES

37-39. Devices
- 1194-6 (history)
- 1200-1207, 1212-1218 (history, drug v. device, need for device classification)
- 1218-1229 (routes to market and intro to 510(k))
- 1236-43 (Class III and PMA)
- 1247-8, 1251 (classif/reclass)
- 1251-54 (Class II and special controls)
- 1254-64, 1271-77 (Class I and general controls,)
- 1264-68 (restricted device)
- 1211, 1243-5 (diagnostics)
- 1280-1292 (preemption)
- §§510(k), 510(l) & (m), 513, 514, 515, 518(b), 519, 520(e) 520(f), 520(g), 520(h)(4), 520(l)(2), 520 (l)(5), 522, 523

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