

**Food & Drug Law**  
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**Text:** Katharine Van Tassel, **Food and Drug Law: Problems, Cases and Materials**

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I. Introduction

A. History and Overview

1. Peter Hutt, *The Transformation of United States Food and Drug Law*

B. Product Categories and Intended Use

1. Drugs

- a. Handouts

- b. *United States v. An Article of Drug . . . Bacto-Unidisk*

- c. *United States v. Article of Drug . . . Ova II*

- d. Example: Complaint for Forfeiture, *In Rem: United States v. Undetermined Quantities of Boxes*

- e. Problem #1: *The Battle Against Bad Breath*

2. Role of “Intended Use” in Regulation

- a. Problem #2: *Toothbrush Gum Disease Claims*

- b. Problem #3: *Lollipops With Licorice to Prevent Tooth Decay, handouts*

- c. Problem #4: *Genetically Modified Bacteria to Prevent Tooth Decay, handouts*

3. Cosmetics

- a. U.S. Food and Drug Administration, Center for Applied Nutrition, *Is It A Cosmetic, A Drug, Or Both?*

- b. Lecture: Chemical Components of Cosmetics and Lack of Premarket Testing
    - c. Problem #5: *Age Intervention Eyelash*, by Jan Marini, handouts
  - 4. Nanotechnology and Cosmetics
    - a. Products Liability Overview Lecture
    - b. Problem #6: *Chanel Precision Calming Emulsion*, handouts
    - c. Problem #7: *Product Liability for New Technologies: What about the Canaries?*
  - 5. Dietary Supplements
    - a. Nutritional Labeling and Education Act, handouts; Dietary Supplements Health Education Act Overview, handouts
    - b. *Whitaker v. Thompson*
    - c. *United States v. Lane Labs-USA, Inc.*
    - d. *Nutraceutical Corp. v. Von Eschenbach*
    - e. Problem #8: *Orexus: Dietary Supplement Marketing Exercise*
    - f. Problem #9: Caffeine
    - g. FDA Warning Letters, handouts
  - 6. Medical Devices
    - a. *Alabama Tissue Center v. Sullivan*
    - b. *United States v. Bowen*
    - c. *United States v. An Undetermined Number of Unlabeled Cases*
  - 7. New Drugs
    - a. *United States v. 50 Boxes More or Less*
- C. Adulteration, Misbranding, and the Practice of Medicine
  - 1. *United States v. An Article . . . Acu-dot*

2. *United States v. Evers*

3. *Retkwa v. Orentreich*

D. Food

1. Food

2. Food Additives

a. Handouts

b. *United States v. Two Plastic Drums*

3. Genetically Modified Foods

a. What are GM Foods?

b. Product Liability for GM Foods:

(A) The Introduction of Biotech Foods to the Tort System,  
pp. 1668-1705 (available at  
<http://papers.ssrn.com/abstract/1268908>)

(B) What About the Canaries: Part II

E. FDA Practice and Procedures

Peter Barton Hutt, *The Transformation of United States Food & Drug Law*

1. Adjudication

a. *United States v. Alcon Laboratories*

b. *United States v. Superpharm Corp.*

c. *United States v. Universal Management Services, Inc.*

d. *United States v. Dotterweich*

2. Rulemaking

a. *National Association of Pharmaceutical Mfrs. v. FDA*

3. Informal Mechanisms

- a. *United States v. Bioclinical Systems, Inc.*
- b. *Washington Legal Foundation v. Kessler*

F. Other Actors

1. Federal Agencies

- a. *American Pharmaceutical Association v. Weinberger*

2. State Regulators

- a. *Rayford v. Texas*
- b. *Dowhal v. SmithKline Beecham Consumer Healthcare*
- c. *Committee of Dental Amalgam Mfrs. v. Stratton*
- d. *Whalen v. Roe*