ASSIGNED STUDENT PRESENTATIONS (DEBATES)

FOOD AND DRUG LAW

HARVARD LAW SCHOOL
WINTER TERM 2018

Peter Barton Hutt

January 9, 2018

Assigned Student Presentations (Debates)
(Three to five minutes per student)

Student presentations should briefly summarize all pertinent points and should be given from outlines rather than read. All presentations should be made from the podium. You may use information from any source, including the internet.

The date assigned for each presentation (debate) is coordinated with the reading material assigned for that date. If the course falls behind the projected schedule (as may happen), the presentations will similarly slip to the next day. If a student is unavoidably absent, Mr. Hutt will make the presentation.

II. Jurisdiction and Enforcement

January 3:

1. The FD&C Act should be amended to apply to intrastate as well as interstate commerce.
   For: Atkins Against: Nam

2. The FD&C Act should be amended to give FDA increased administrative enforcement authority (e.g., administrative detention, recall, and subpoena power) for all products it regulates.
   For: Harding Against: Hutt

III. Regulation of Human Food

January 4: No class.

January 5:

1. The FD&C Act should be amended to require that FDA approve all food labeling prior to use (just like USDA approves all meat labels prior to use).
   For: Maurer Against: Zietman

2. FDA should define what is a "natural" food.
   For: Roesser Against: Hutt

January 8:

1. FDA should strictly control the fortification of food with nutrients.
   For: Romero Against: Hutt

2. The Dietary Supplement Health and Education Act of 1994 should be repealed.
   For: Hofman Against:Mordi

January 9:

1. All food should be labeled with the filth content.
   For: Siegel Against:Ebert

2. The FD&C Act should be amended to delete the GRAS exemption from premarket approval of food additives.
   For: Chan Against:Guo

IV. Regulation of Human Drugs

January 10: Morning

1. Oral contraceptives should be switched from prescription to nonprescription status.
   For: Jeong Against: Daisy Joo

   All students participate in establishing a venture capital-financed biotechnology company.

January 10: Afternoon

All students participate in establishing a venture capital-financed biotechnology company.

January 11:

All students participate in establishing a venture capital-financed biotechnology company.

V. Regulation of Animal Feed and Drugs

January 12:

1. FDA should not spend its scarce resources on regulating animal feed and pet food.
   For: Eric Joo Against:Ren

2. As long as there is any uncertainty about human safety, antibiotics should be banned from animal feed.
   For: Ehlert Against:Young

VI. Regulation of Human Biological Drugs and Biotechnology

January 16:

1. FDA should exercise regulatory control over all organs and tissues used for human replantation or transplantation.
   For: Kumar Against:Deak

2. FDA approval of a human vaccine should preclude tort liability for the manufacturer for all injury to consumers.
   For: Cordes Against: Spichtin

VII. Regulation of Human Medical Devices

January 17:

1. The FD&C Act should be amended to delete the Section 510(k) "substantial equivalence" exception to the requirement of premarket approval of medical devices.
   For: Against:

2. The premarket approval requirements for medical devices should be applied by FDA as stringently as the premarket approval requirements are applied for new drugs.
   For: Against:

January 18:

1, Sun tanning booths should be banned by FDA.
For: Noonan Against:

2. Technology assessment should be undertaken by FDA for every new medical device to determine whether the societal benefits outweigh the costs and risks.
For: Against:

VIII. Regulation of Human Cosmetics and Carcinogens

January 19:

1. The FD&C Act should be amended to impose more stringent regulatory requirements for cosmetics.
For: Against:

2. The FD&C Act should be amended to permit FDA to make a benefit-risk decision, or to use quantitative risk assessment, when determining whether to approve a carcinogenic food additive or color additive.
For: Against: