The Ins and Outs of Dietary Supplement Regulation and Product Liability Litigation

Wednesday, October 23, 2013
Presented By the IADC Product Liability Committee

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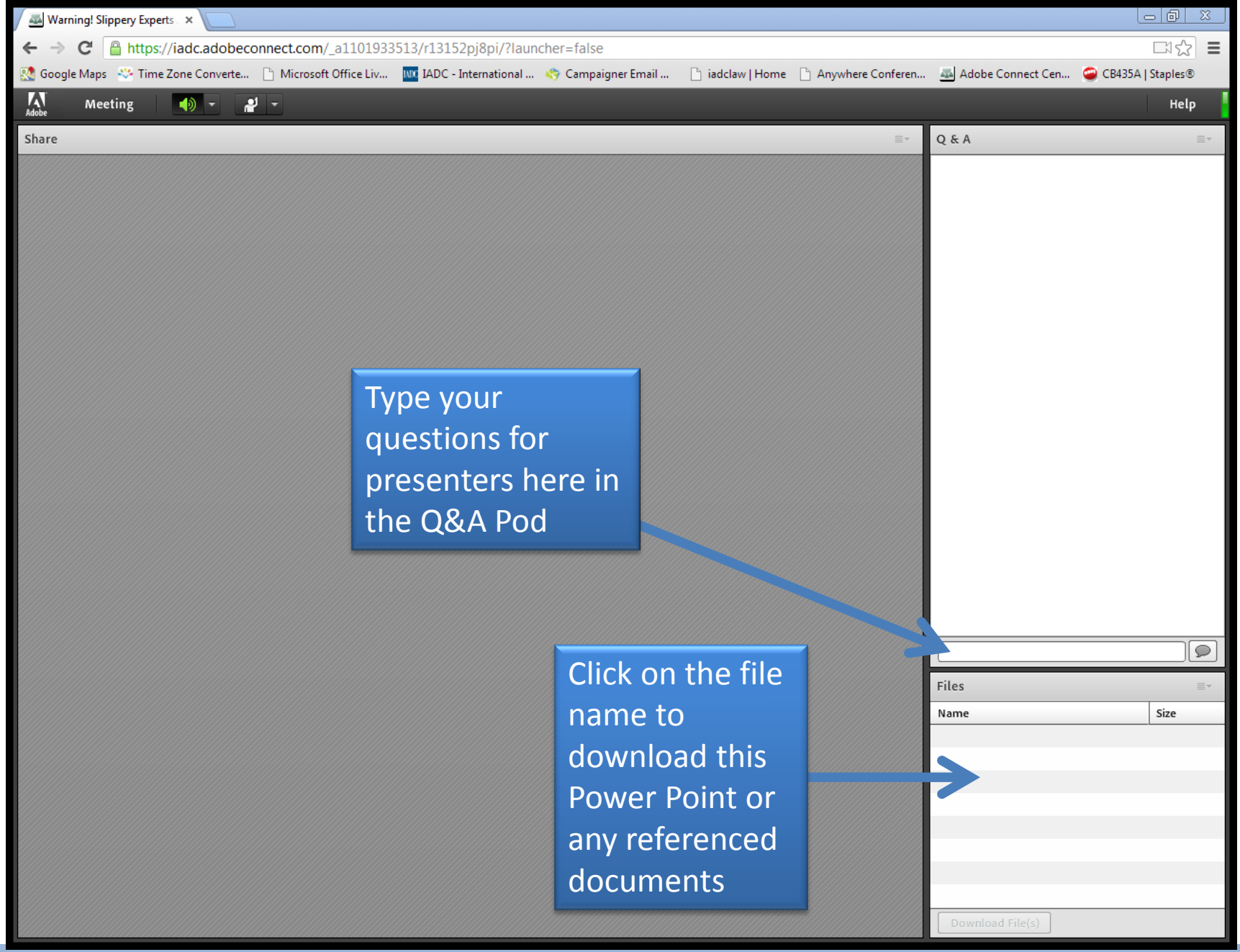
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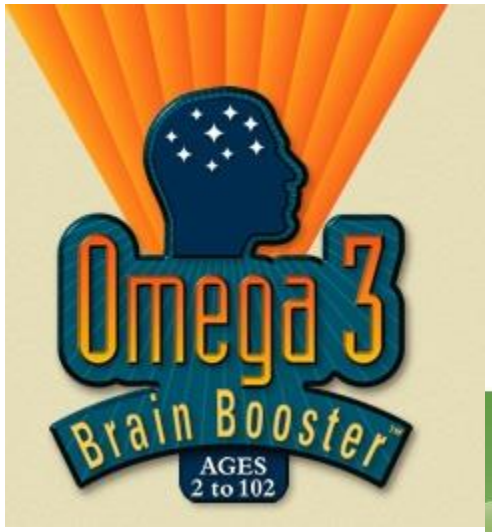
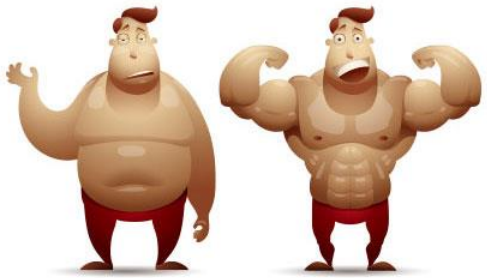
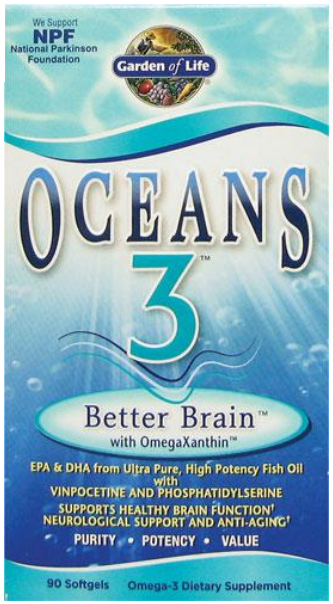
Lose weight! Get smarter! Boost energy! Live longer smarter stronger everything HOORAY!







IF ONLY IT WERE THAT EASY…

Who keeps track?
FDA and FTC

FDA: Food and Drug Administration

FTC: Federal Trade Commission

The FDA and the FTC work together whereby the FDA has primary responsibility over product labeling and the FTC has primary responsibility for claims in advertising.

* The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, medical devices, most of our nation's food supply, all cosmetics, dietary supplements, and products that give off radiation

The FDCA and DSHEA

FDCA: Food Drug and Cosmetic Act of 1938: "To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes."

DSHEA: Dietary Supplement Health and Education Act of 1994, an amendment to the FDCA.

What did DSHEA do?

With this amendment, the government created a framework to regulate dietary supplements. DSHEA imposes the responsibility on manufacturers and distributors to:

1. **Make sure the product is safe**
2. **Assure representations or claims made about the product are substantiated by adequate evidence and that they are not false or misleading**
3. **Mandate that companies alert the FDA of adverse events**

DSHEA put on the FDA the responsibility to prove a product is "unsafe" before forcing the company to remove it from the market.

What is a Dietary Supplement?

- FDCA Definition - 21 U.S.C. 321 (ff) –
  - A product that's not marketed as a conventional food or a sole item of a meal or diet, and that contains one or more "dietary ingredients." Things like - vitamins; minerals; herbs and other botanicals; amino acids; concentrates, metabolites, constituents, and extracts

Spotlight on: Caffeine

- Energy drinks: dietary supplement or a beverage? Depends.
  - Different labeling requirements.
  - FDA draft guidance – December 2009
- GRAS status of caffeine – 200 ppm
- May 2013 announcement by FDA re: investigation of added caffeine (marshmallows, gum?!)

Dietary Supplements vs. Drugs

- PEDs and HGH - commonly misbranded as dietary supplements
- July 28, 2009 FDA Public Health Advisory - FDA recommends that consumers should not use body building products marketed as containing steroids or steroid-like substances

Growth of Dietary Supplement Industry

- Linus Pauling & Vitamin C – the beginning of an era
- Michael Pollan and the “real food” movement
- 1994: DSHEA, dietary supplements no longer require FDA’s pre-market approval
- Online vs. brick-and-mortar dietary supplements
- Dietary supplement industry – massive growth
  - $32 billion in revenue for dietary supplements in 2012
  - Projected to top $60 billion in 2021

What are the Regulations and What do they Mean?

- FDA Regulations vs . FTC Regulation – but all largely in context of a self-regulated industry
- Labeling regulations
- New Dietary Ingredients
- Current Good Manufacturing Practices
- Adverse Event Reporting

Labeling

→Must be labeled “DIETARY SUPPLEMENTS”

→Certain types of claims are authorized: for example, those that describe “the role of a nutrient or dietary ingredient intended to affect the structure or function in humans” or “characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.”

The label does NOT have to be pre-approved by the FDA – the company only has to provide the FDA with notice within 30 days of first use of any claim and must include a disclaimer on the label stating the FDA has not evaluated the claim, and that the product is not intended to “diagnose, treat, cure or prevent any disease.”

Example:


First Elements™ is a high-energy compound with antioxidant properties and a unique colloidal carrier system. First Elements™ has been synthesized to replicate the characteristics of Hunza water known for both energy and health-sustaining attributes.
Negative Ions have been injected into organized structures made of silica nano-particles boosting both physical capacity and mental clarity.*
Recommended Dosage: As a dietary supplement, one capsule is recommended for the morning with a second capsule taken in the later afternoon always with at least eight ounces of non-carbonated water.
Keep out of reach of children. Persons with known medical conditions or who are pregnant should consult a medical professional prior to taking this compound.
*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.
First Elements™
60 Vegetarian Capsules (500 mg)
Nanotronic Nutrients™
Supplement Facts
Serving Size: 1 Capsule
Servings Per Container 60
Amount Per Serving
% Daily Value
First Elements™
Proprietary Blend, Silica Hydride 500 mg †
Ingredients: Potassium Citrate, Magnesium Citrate, Potassium Silicate, Boron, Silica.
† Daily values have not been established.
7.83 Hz
Made in USA
Manufactured by:
Earthpulse Nanotronic Technologies, Inc.
P.O. Box 201393
Anchorage, Alaska
USA 99520
Phone: 1-907-249-9111
Fax: 1-907-696-1277
www.earthpulse.com
0 94922 61691 3

New Dietary Ingredients

A new dietary ingredient ("NDI") includes any ingredient not sold in the U.S. as a dietary supplement before October 15, 1994. If your product includes an NDI, you have to submit information to the FDA prior to market. The information must include evidence that the ingredient can be reasonably expected to be safe.

But, even then the FDA doesn't have to do anything. The FDA has 75 days to respond to the safety information submission; if it does not, the product can go to market.

Current Good Manufacturing Practices

Focus on ensuring identity, purity, quality, strength and composition of dietary supplements. There is a focus on sanitation and proper implementation of a system of production and process / quality controls.

Why is it important to follow cGMP?

Risk (and litigation) prevention:

- dietary supplements that contain ingredients in amounts that are less or worse, greater than those listed on the label
- wrong ingredient!
- other contaminant (e.g., bacteria, pesticide, glass, lead)
- foreign material in a dietary supplement container
- improper or mislabeled packaging

Adverse Event Reporting Requirements

- 21 USC § 379aa
- Adverse Event: “any health-related event associated with the use of a dietary supplement that is adverse”
- Serious Adverse Event: event that results in
  - death;
  - a life-threatening experience;
  - inpatient hospitalization;
  - a persistent or significant disability or incapacity;
  - a congenital anomaly or birth defect
- OR – “requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described [above].”
- Must submit serious adverse event reports to FDA within 15 business days after the report received by “responsible person”

Recent Regulatory Activities: New Developments in Adverse Event Reporting

- From 2008 through 2011, the FDA received 6,307 reports of adverse event reports for dietary supplements.
  - 71% came from industry, as serious adverse events required by law
  - May be more adverse events out there. Consumers and others may be reporting to poison control centers.

- Potential for increased regulation
  - January 29, 2009 GAO Report: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding
  - March 18, 2013 GAO Report: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products

- Increased reporting in recent years –
  - Between 2008 and 2011, FDA received an average of 2100 dietary supplement adverse event reports, compared to less than 400 in 2008

Product Liability Actions: The lessons of Ephedra

When considering the product liability implications of dietary supplements, it helps to recall a major litigation battle: Ephedra

Supplement makers included ephedra in products in the 1980s, often combined with guarana (for caffeine). Immensely popular.

In the late 1990s, allegations surfaced that the compound caused cardiac trouble, strokes, seizures, and other serious adverse events.

After years of back and forth with the FDA, and a rising tide of allegations, the lawsuits came. Ephedra product manufacturers, distributors, and retailers were sucked into the maelstrom.

In the end, the manufacturers stopped making the products and the largest manufacturers, including Twinlab and Metabolife, filed for bankruptcy. Clever ADR techniques grounded in a global settlement and fair allocations approved by plaintiffs' counsels resolved all claims.

Product Liability Actions – Defining the Defects

Design Defect:

- A product in a condition not reasonably contemplated by the ultimate consumer, unreasonably dangerous for its intended use; whose utility does not outweigh the danger inherent in its introduction into the stream of commerce

Design: Use of dangerous substances and compounds

Examples:

- Usnic Acid (Maria B.)
- DMAA (Oxy Elite Pro and Jack3D)
- Ephedra

Product Liability Actions – Defining the Defects

Manufacturing defect:

- A product not made as intended.
- A consumer may reasonably expect a product to be made in accordance with the manufacturer's standards.

Manufacture: Trouble at the plant, trouble in the pipeline

- What is Adulteration?
  - 21 U.S.C. § 342
  - "significant or unreasonable risk of illness or injury"
- Deliberate adulteration: e.g., DMMA presence in GNC dietary supplements
  - July 23, 2013 – 1,500 Cases of Adulterated Dietary Supplements Destroyed In Seizure Action brought by U.S. Attorney's Office in W.D. Pa.
  - Government proceeded under 21 U.S.C. 324(f)
- Accidental adulteration: e.g., Sunland, Inc.'s peanut butter (salmonella)
  - Government proceeded under 21 USC § 350d (registration of food facilities) and § 415(b) (suspension/revocation)
  - November 26, 2012 letter from FDA to Sunland

Product Liability Actions – Defining the Defects

Failure to Warn:

- A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known.
- A manufacturer also has a duty to warn of the danger of unintended uses of a product provided these uses are reasonably foreseeable.

Failure to Warn

- Warning requirements are loosely regulated
- When do you need to say more?
- When have you said too much?

Nature of Issue

- Is it really a labeling issue?
- Did you fail to warn of specific substances in the product? Or did you fail to warn of dangerous side effects?

Design Defect + Failure to Warn

Example: CRAZE. USA Today reported over the summer that the popular supplement - that contends to only contain dendrobium - actually contains amphetamine and amphetamine-related compounds. CRAZE had already run into trouble with the FDA based on AERs and on whether dendrobium was an NDI.

Just this past week, a study found other meth-like substances in Craze…

Design Defect + Failure to Warn

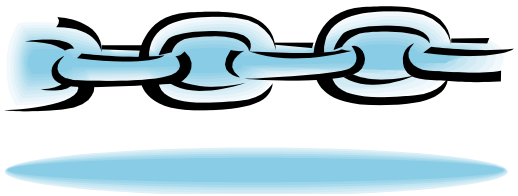
CRAZE: combines a design defect and a failure to warn scenario.

Allegation #1: By [secret] design, the supplement contains meth and is much more dangerous than any consumer could appreciate

Allegation #2: Your label said “natural” and made no mention of these secret dangerous ingredients

Chain of Distribution and Liability

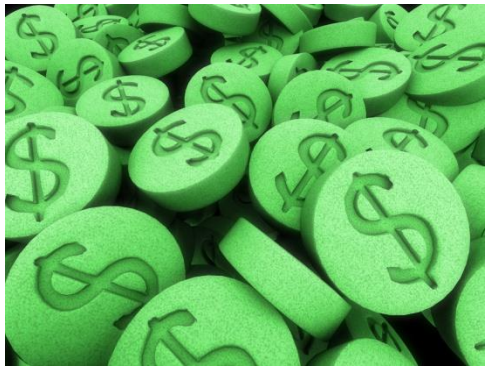
- *Godoy* and the rule in certain jurisdictions
  - *Godoy v. Abamaster*, NY
  - *Covell v. Bell Sports, Inc.*, 3d Cir.
  - *Thermo King Corp. v. Strick Corp.*, W.D. Pa.
  - "innocent retailer" standards in other jurisdictions
- Foreign manufacturers and distributors

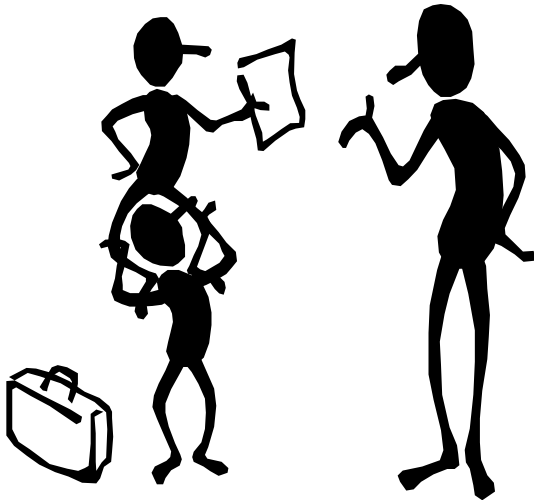


Chain of Distribution and Liability

Jurisdiction over foreign manufacturers and distributors: fallout (or not) of *McIntyre v. Nicastro* and *Goodyear v. Brown*

Chain of Distribution and Liability





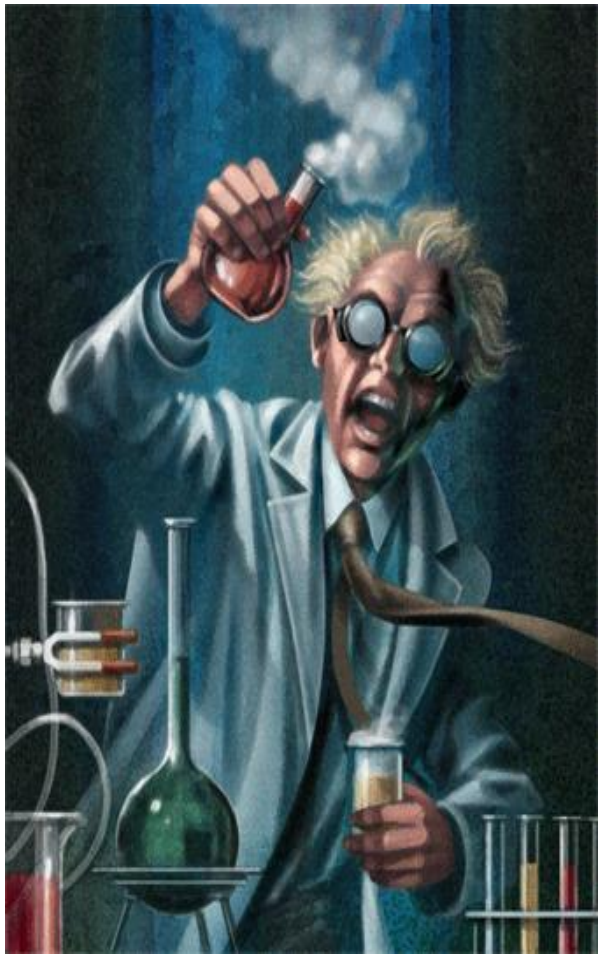
As the retailer:

Get a vendor's endorsement with an insurance policy!

Experts & Medical Evidence

How do you handle the science?

- Know the product
- Know the effects and the side effects
- Know the experts – both yours and your adversary's



Recent Regulatory Activities: Another push for stronger legislation

- August 1, 2013: Senators Durbin and Blumenthal reintroduced the Dietary Supplement Labeling Act
  - Increased coordination between DHHS and Institute of Medicine re: adverse event reporting
  - "Conventional food" definition
  - Require manufacturers to provide more info and warnings to FDA, and on labels
  - Prompted by investigations and adverse events re: Jack3d, Craze, Superdrol

FDA Regulatory Mechanisms to "Crack Down" on Adulteration

- Traditional route: 21 U.S.C. § 342(f)
  - "Significant or unreasonable risk of illness or injury"
  - Court determination of adulteration
  - Proof standard – government bears the burden
- New route: 21 U.S.C. § 415(b) and § 350d
  - "Reasonable probability" of causing serious adverse health consequences
  - FDA essentially has unilateral authority to determine adulteration/order suspension
  - Proof standard – manufacturer must show FDA's decision was "arbitrary and capricious"

Recent Developments

Dramatic increase in AERs

- Are there really more problems?
- Are manufacturers and distributors just getting more proactive?
  - FDA has increased inspections of supplement firms and taken actions against noncompliant firms, which may be prompting increased reporting.

cGMP

- More attention on companies' manufacturing practices means:

→More FDA records

→Dangerous "treasure troves" of damaging information on manufacturing facilities

Increased attention from the press and plaintiffs' lawyers

How does the recent groundswell for more regulation affect product liability actions?

- Energy drinks
- False claims cases (including class actions)
- Serious, serious adverse events
- Performance-enhancing drugs
- Overall wider use of dietary substances
- "A few bad apples"

Questions for Presenters?

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