Morales v. Kraft Foods Group, Inc.

Laurie J. Beyranevand
Senior Faculty Fellow and Professor of Law
Vermont Law School

"Here, the court need not inquire whether defendant made true statements that had the capacity to deceive because the undisputed facts demonstrate Kraft's advertising was literally false."

"We've got a class-action suit if ever I saw one."

Court certified the class in June 2015, but narrowed it to:

All persons who, between May 2010 through the present, purchased the Product in the State of California for personal use and not for resale and who did so because the Product was described as "natural cheese" which meant it contained no artificial ingredients.

Kraft's motion to stay pending FDA's determination regarding the definition of "natural" denied.

FDA's regulations are not determinative of the issue in this case, which is "whether the 'natural cheese' label is deceptive to the reasonable consumer. Moreover, compliance with the regulations does not "'automatically shield' Kraft from a claim under the relevant statutes."

What's the latest?

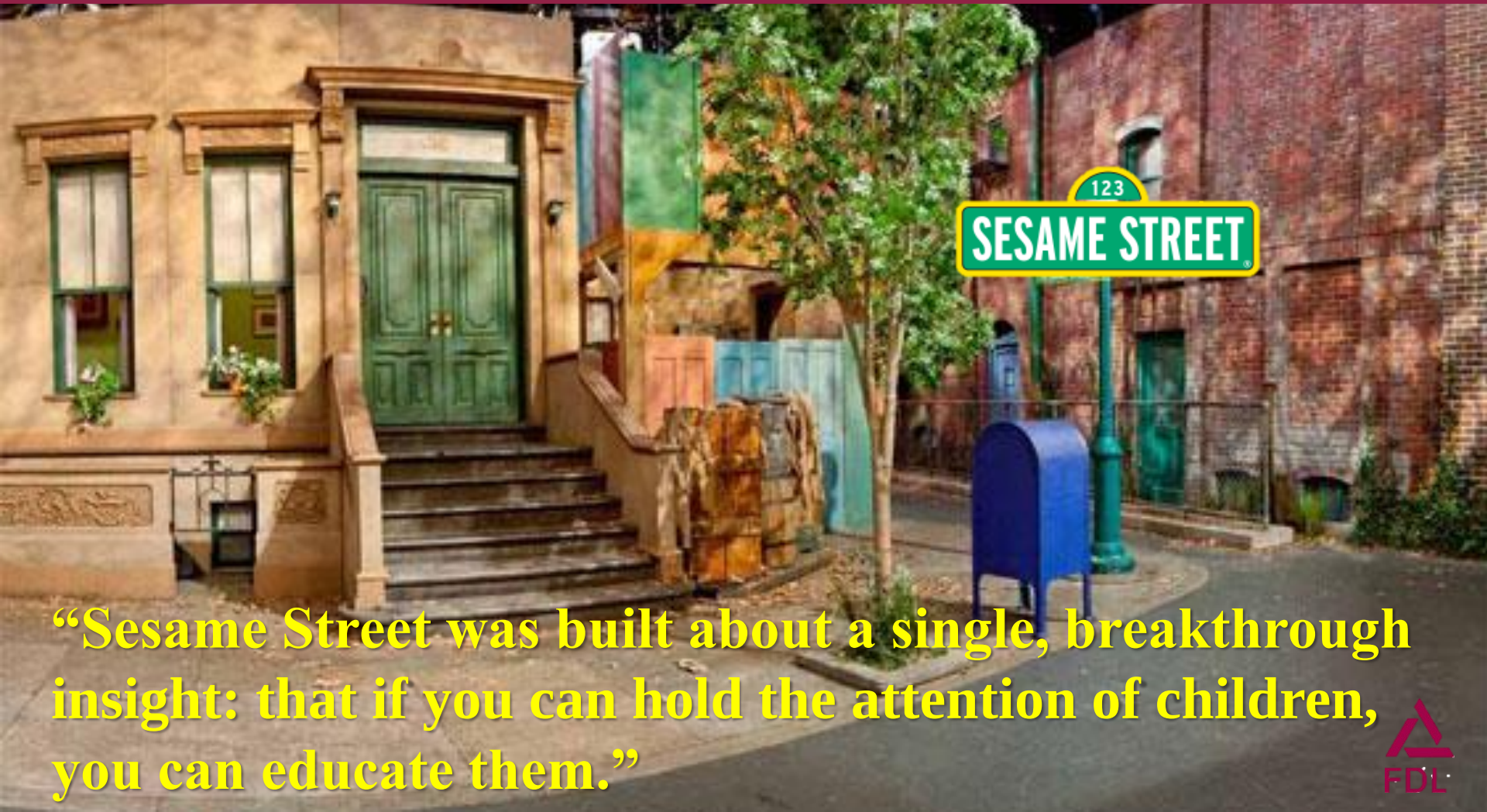
In March, the Court declined to decide on Kraft's motions for partial summary judgment, to decertify the class, and to exclude the plaintiffs' damages expert suggesting the need for an evidentiary hearing.

Niedner *v.* Ortho-McNeil Pharmaceutical, Inc.

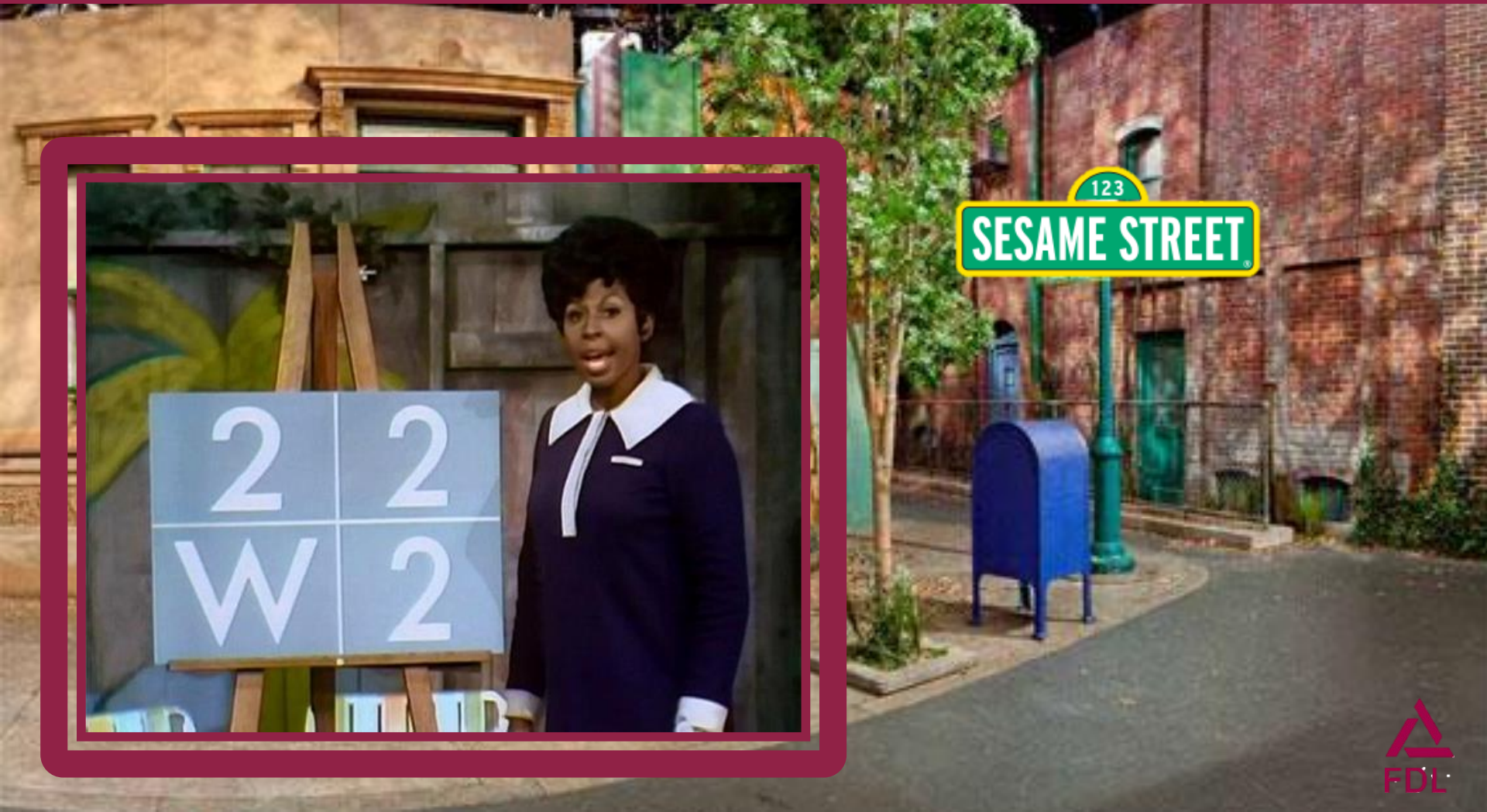
Massachusetts Appeals Court – Suffolk County
Decided: September 2016

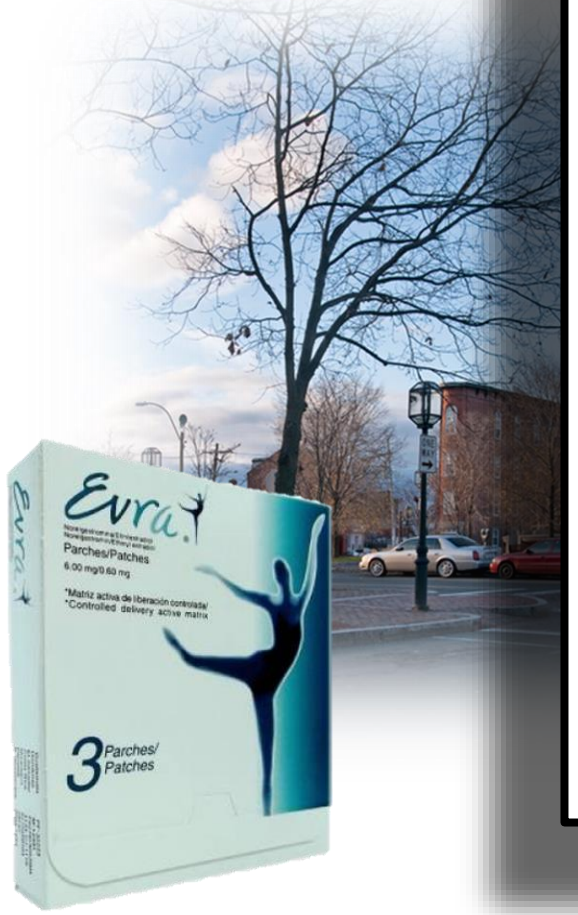
PROF. WILLIAM M. JANSSEN
CHARLESTON SCHOOL OF LAW

FDLI



“Sesame Street was built about a single, breakthrough insight: that if you can hold the attention of children, you can educate them.”


123
SESAME STREET
2 2
W 2



Niedner Admx v Ortho-McNeil Pharmaceutical Inc et al, Docket No. SUCV2010-03736 (Mass. Super.

Current on Bloomberg Law as of Dec. 09, 2010 12:19:48

Massachusetts Superior Court
Suffolk County
Docket for Case #: SUCV2010-03736

Niedner Admx v Ortho-McNeil Pharmaceutical

Date Filed:	Sept 21, 2010
Status:	Needs review for service
Jury demand:	Yes
Case location:	Civil F, 3 Pemberton Sq, Boston
Case Type:	Products liability
Status Date:	Sep 21, 2010

Parties and Attorneys

Plaintiff	Leslie Niedner Admx	
Representation	Michael S Appel , Niedner Admx, Leslie 101 Merrimac Street 9th Floor Boston, MA 02114 Phone: 617-227-3030 Fax: 617-523-4001	
Defendant	Ortho-McNeil Pharmaceutical Inc	
Representation	David L Ferrera , Ortho-McNeil Pharmaceutical Inc, Seaport West 155 Seaport Boulevard Boston, MA 02210 Phone: 617-439-2247 Fax: 617-310-9247	Robyn S Maguire , Ortho-McNeil Pharmaceutical Inc, World Trade Cent 155 Seaport Boule Boston, MA 0221 Phone: 617-439-2 Fax: 617-310-900
Defendant	Dr Sara M Nelson	
Defendant	Johnson & Johnson Pharmaceutical Research & Development LLC fk	
Representation	David L Ferrera , Johnson & Johnson Pharmaceutical Research & Development LLC fka, Seaport West 155 Seaport Boulevard Boston, MA 02210 Phone: 617-439-2247 Fax: 617-310-9247	Robyn S Maguire , Pharmaceutical R fka, World Trade Cent 155 Seaport Boul Boston, MA 0221 Phone: 617-439-2 Fax: 617-310-900

- Manufacturing Defect
- Warning Defect
- Design Defect
- Breach of Express Warranty
- Fraudulent Concealment
- Negligence
- Mass. Consumer Protection Act

Manufacturing Defe

Warning Defect

Design Defect

Breach of Express Warr

Fraudulent Concealm

Negligence

Mass. Consumer Protecti t

FDLI

Manufacturing Defect

Warning Defect

Design Defect

Breach of Express Warranty

Fraudulent Concealment

Negligence

Mass. Consumer Protection Act

FDLI

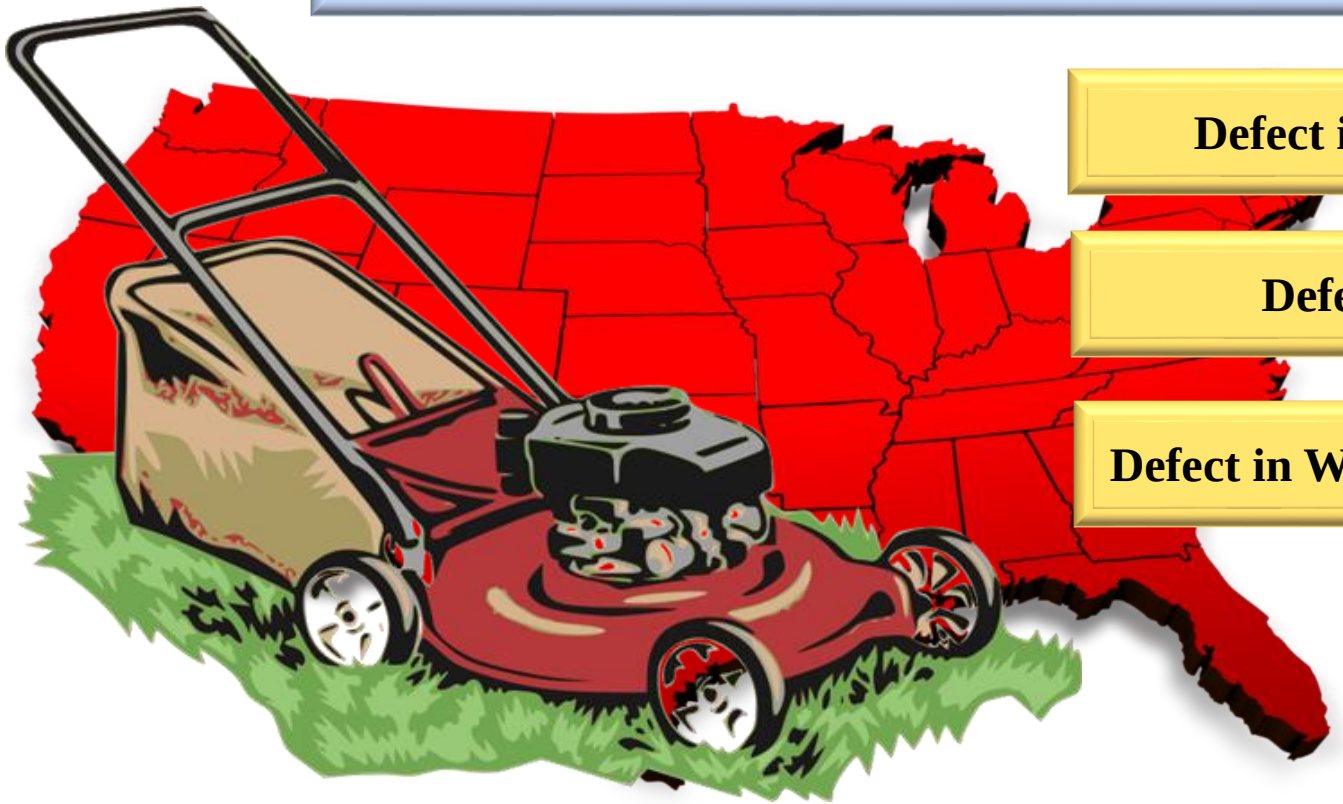
“As such, one cannot serve as a safer alternative for the other.”

Design Defect

“While both products are hormonal contraceptives that prevent pregnancy, the difference in the drug delivery method, each of which has its own advantages and disadvantages, makes the pill fundamentally different from the patch.”

FDLI

Core Product Liability Theory



- Defect in Manufacture
- Defect in Design
- Defect in Warning / Instruction

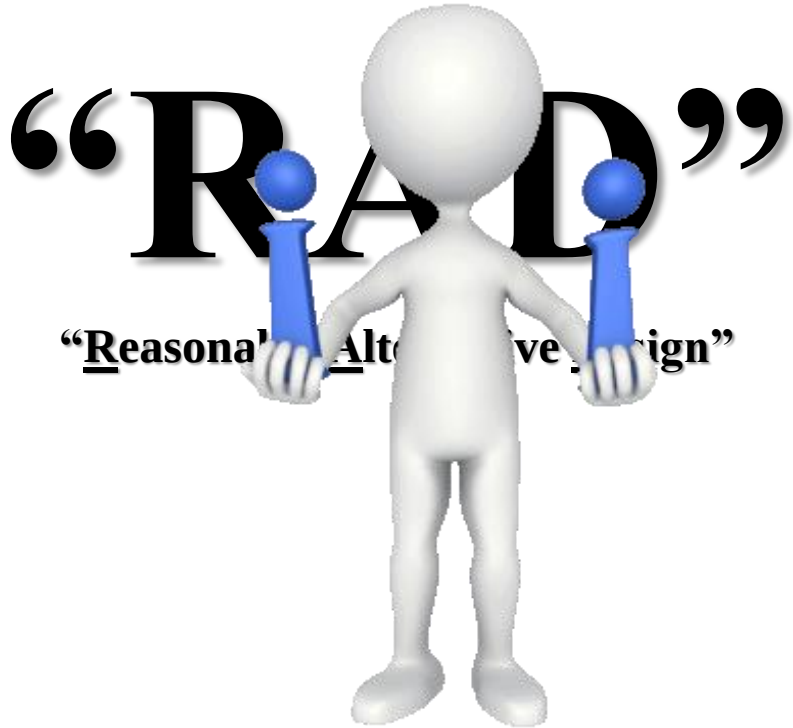
FDLI

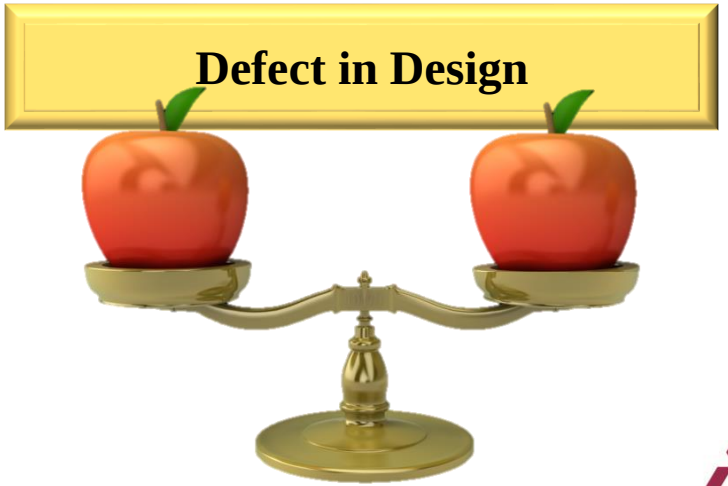
Core Product Liability Theory

- Defect in Manufacture
- Defect in Design
- Defect in Warning / Instruction

FDLI

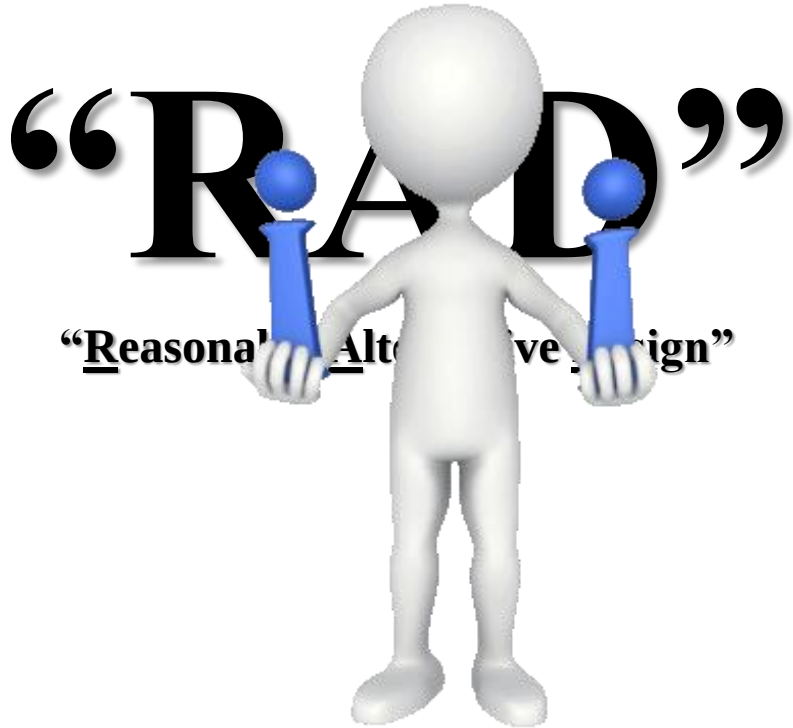
Core Product Liability Theory





FDLI

Core Product Liability Theory



FDLI

Core Product Liability Theory

"RAD"

"Reasonable Alternative Design"

Defect in Design

[8th Circuit - 1990]	[Texas - 1995]	[Texas - 2011]	[Alabama - 2016]
Police Vests	**Loaders**	**Helicopters**	**Smoke Alarms**

FDLI

Core Product Liability Theory

"RAD"

"Reasonable Alternative Design"

Core Product Liability Theory

"RAD"

"Reasonable Alternative Design"

Pedicle Screws	Prempro	Children's Motrin	Pelvic Mesh	Raptiva Farxiga Propulsid

FDLI

Core Product Liability Theory

"RAD"

Contraceptive Patch v. Contraceptive Pill

Niedner v. Ortho-McNeil Pharmaceutical, Inc.

Pedicle Screws	**Prempro**	**Children's Motrin**	**Pelvic Mesh**	**Raptiva Farxiga Propulsid**

FDLI

FDLI

Has Plaintiff offered a creditable "RAD"?

- May be a **Jury Question**, *unless* your jurisdiction has the "**different-product**" rule (and it applies!), *and*
- Plaintiff's RAD is an "***entirely*** different product," considering:
  - Chemical composition
  - Pharmacodynamics properties
  - Pharmacokinetic properties
  - Indications
  - Efficacy properties
  - Safety profile
  - Tolerability

Defect in Design

FDLI

Eagles Pharmaceuticals, Inc. v. Burwell

U.S. District Court – District of Columbia

The Orphan Drug Act *and* "Serial Exclusivity"

FDLI

United States v. Vascular Solutions, Inc. 181 F. Supp 3d 342

Francis B. Palumbo, PhD, JD
University of Maryland
School of Pharmacy
Center on Drugs and Public Policy

- Defendants filed a Motion in Limine to set ground rules for trial regarding the First Amendment.
- Defendants also moved to exclude evidence of the company's subjective intent to market the Vari-Lase device.

- The Court Denied both motions.

- Defendants sell, under the brand name Vari-Lase, a medical device which permanently closes poorly-performing veins (often known as varicose veins) by use of a laser.

- Human legs have two major vein networks
  - The deep venous system, closer to the bone and
  - The superficial venous system, closer to the skin
- Veins connecting the two systems are called perforator veins.
- The government's position is that FDA approved the device for treating superficial veins only.

Superceding Indictment
Counts 2-5 address misbranding

- Defendants caused the introduction into interstate commerce of misbranded Vari-Lase devices
  - Vascular Solutions failed to provide FDA with required notification of a new intended use, namely with perforator veins
  - The labeling lacked adequate directions for that new intended use

Superceding Indictment
Count 1 Conspiracy

- Count one alleges a conspiracy to commit the above substantive offenses, and to defraud the United States by concealing the sale of these devices for the unapproved use.

Defendants presented two arguments

- First-
- Noting that U.S. v Caronia does not “criminalize” mere truthful promotion of off label uses…., defendants assert that the government’s case risks violating the First Amendment …

Defendants presented two arguments

- Second

- The intended use of Vari-Lase may only be determined by examining communications & representations they made to the market place because….21 CFR 801.4 says the “intended use” of a device is determined by the objective intent of the persons legally responsible for the devices, and objective intent cannot be demonstrated by internal deliberation or communication.

Defendant's Proposed Remedies

- First, the Court should hold that speech is constitutionally protected if "it is either true or only potentially misleading" Byrum v Landreth (5th Cir, 2009) and that it loses protection only if the government proves beyond a reasonable doubt that it is actually or inherently misleading."
- Second, the Court should hold that speech about an off label use of a medical device is not misleading merely because FDA has not approved that off label use or reviewed or approved the speech.

Defendant's Proposed Remedies

- Third, the Court should hold that for the government to prove a communication actually misleading, it must show that the communication misled a substantial subset of its intended audience.
- Fourth, the Court should hold that speech does not lose its constitutional protection merely because it fails to tell the whole truth about a product.

Defendant's Proposed Remedies

- Finally the Court should exercise its discretion to order the government to disclose the speech on which it intends to rely and should then determine whether a jury could find beyond a reasonable doubt that each communication was false or misleading.

Other defense contention- repeated from above

- The intended use of Vari-Lase may only be determined by examining communications & representations they made to the market place because….21 CFR 801.4 says the “intended use” of a device is determined by the objective intent of the persons legally responsible for the devices, and objective intent cannot be demonstrated by internal deliberation or communication.

Legal Standards

- The Court noted that the Supreme Court, in Wisconsin v Mitchell, 508 U.S. 476, 489 (1993), unanimously held that the First Amendment does not prohibit the evidentiary use of speech to establish the elements of a crime to prove motive or intent.

The Court Defines Intended Use

The words intended uses or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent (emphasis added) of the persons legally responsible for the labeling of devices.

That intent is determined by such person' expressions or may be shown by the circumstances surrounding the distribution of the article

Examples

- Labeling claims, advertising matter or oral or written statements by such persons or their representatives
- It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

Use of promotional speech

- The government does not plan to use promotional speech to doctors to prove the intended use of the devices for perforator ablation.
- It will rely on conduct alone.
  - Its purpose is to eliminate any possibility that the misbranding offenses criminalize commercial speech.

- It does plan to rely on statements to doctors for the purpose of proving the conspiracy charge and notes that a lawful act may serve as the overt act in furtherance of a conspiracy.
- The Court rejected defendants response that truthful speech is not an act taken to effect the object of the conspiracy and sees no First Amendment threat from reliance on the statements to doctors.

Lanham Act Analogy?

- Defendants also asked the Court to hold that "to prove that a communication was actually misleading, the government must prove that the communication misled a substantial subset of its intended audience." The Court noted that Defendants correctly observe that such proof is required in false advertising cases brought under the Lanham Act.
- But this requirement is explicit in the Lanham Act and absent from the Food Drug and Cosmetic Act.

Defendants motion to exclude evidence of subjective intent

"…defendants neglected to cite *Reeves v. Acromed Corp.*, in which this Circuit observed that "FDA regulations require manufacturers to provide appropriate labeling if the manufacturer *has reason to believe* that its medical device might be used for purposes different from the purposes for which the device is approved." *44 F.3d 300 (5th Cir. 1995)* (citing *21 C.F.R. § 801.4*) (emphasis added)."

Both Motions Were Denied