Pharmaceutical Products Liability

DAY PITNEY LLP

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State Tort Liability for Drug Manufacturers

Product Liability Burden Of Proof

- That the defendant was engaged in the business of selling the product.
- That the product was in a defective condition and unreasonably dangerous to the consumer or user.
- The defect caused the injury or damage.
- The defect existed at the time of the sale.
- The product was expected to and did reach the consumer without substantial change in condition.

What is Unreasonably Dangerous?

- 402A of Restatement (Second) Torts provides that “it is dangerous to the extent beyond which you could be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to the community as to its characteristics.”

Why Pharmaceutical Companies are Different

- Unlike most consumer products, medications are developed for the specific purpose of curing or preventing serious diseases and alleviating suffering.

- Because of their unique characteristics, prescription drugs are not available to consumers on demand.

Why Pharmaceutical Companies are Different

- Regulated by the FDA controlling the process for bringing new prescription medications to the market place through a series of complex federal statutes and regulations.

- The FDA acts as “gatekeeper” to the United States marketplace reviewing documents and data concerning the chemical composition, formulation, manufacturing process, labeling, safety and ethicacy of a particular compound.

Why Pharmaceutical Companies Are Different

- Comment K to Section 402A of the Restatement (Second) Torts bars strict liability claims for design defects against prescription medication manufacturers by recognizing that some consumer products, specifically including prescription medications, are “unavoidably unsafe”.

- Not recognized in all jurisdictions.

Recent Plaintiffs' Verdicts

- Reckis v. Johnson & Johnson, $63,000,000 verdict in Boston, Mass, April 26, 2013.
- Rossitto, et al v. Hoffman-La Roche, Inc., $18,000,000 verdict, Atlantic County, NJ., November 23, 2012.
- Cooper, et al v. Takeda Pharmaceuticals America, Inc., et al, $6,500,000 verdict in Los Angeles, CA., February 13, 2013.
- Davids, et al v. Novartis Pharmaceuticals Corp, $10,500,000 verdict, Eastern District of New York, October 5, 2012.

Highly Dependent on Jurisdiction

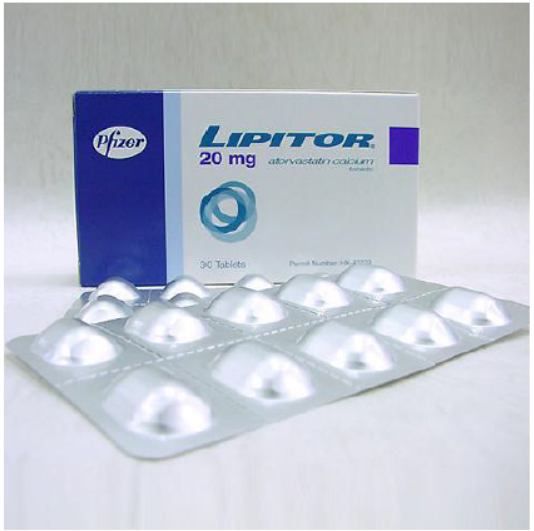
Favorite “magnet court” jurisdictions for plaintiffs:

- Madison County, Illinois;
- Jefferson County, Texas;
- Cook County, Illinois;
- Los Angeles, California;
- Philadelphia, Pennsylvania.

Typical Website "Trolling" For Plaintiffs

Bad Drug

Your Resource for Adverse Reactions and Drug Recalls



Average User Rating:
★ ★ ★ ★ ★
Lipitor, 2.25 / 5 (4 votes)

Home » Bad Drug » Bad Drug List » Lipitor

- Side Effects
- Warnings & Recalls
- What it's for
- Lawsuits & Legal

Author: Partha Choudhury
Posted on Nov 19, 2012

http://www.bad-drug.net/bad-drug/lipitor-2#tab3#tab3

Trolling Continued

3 Things To Do Today

- Sign Up on Bad-Drug.net
- Track Alerts on Your Drug
- Report a Bad Drug

Find Your Bad Drug on the List

Find my Bad Drug... SEARCH

- Bad Drugs List
- Speak with a Lawyer

Sign Up for Bad Drug Newsletter
Email Address

Trolling Continued

Lipitor Treatment and Use

Lipitor | Atorvastatin is a statin medication marketed by Pfizer for lowering blood cholesterol. **Lipitor** also stabilizes plaque and prevents stroke from happening through anti-inflammatory mechanisms. Like other statins, the active ingredients that are in **Lipitor | Atorvastatin** work by inhibiting HMG-CoA reductase, which is an enzyme found in the tissue of the liver that plays a key role in the development of cholesterol in the human body. It comes as a pill to take at least once a day.

Lipitor | Atorvastatin was first synthesized in 1985 by what is now the drug company Pfizer. It is known to be the best-selling drug ever in pharmaceutical history with sales of **Lipitor | Atorvastatin** exceeding $125 billion worldwide.

Adverse Side Effects From Lipitor | Atorvastatin

There are reported adverse side effects from the drug **Lipitor | Atorvastatin** that can be quite serious. These range from dermatological side effects such as dermatomyositis, immunological side effects such as autoimmune diseases and systemic lupus erythematosus and neurological side effects such as hemorrhagic cerebral infarction, which is a kind of stroke.

Contact Us

If you or a loved one have experienced serious adverse side effects as a result of taking this drug, please do not hesitate to contact someone who can help you.

Author: Partha Choudhury
Posted on Nov 19, 2012

Trolling Continued

Lawsuits & Legal Information for Lipitor

Lipitor Lawsuit Updates

Current

Multi-District Litigation (5/2013): Five lawers petitioned to the Judicial Panel on Multidistrict Litigation to consolidate all Lipitor cases into a multidistrict litigation action (MDL).

Future

Far Past

Approved (12/1996): Lipitor was approved by the FDA.

Lawsuits (6/2006): Lawsuits are filed with claims that Pfizer neglected to warn of serious side effects associated with Lipitor, including muscle and nerve problems and memory loss.

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Posted on Nov 19, 2012

http://www.bad-drug.net/bad-drug/lipitor-2#tab3#tab3

Multi-District Litigation

When civil actions involving one or more common questions of fact are pending in different districts such actions may be transferred to one district for coordination and consolidation of pre-trial proceedings.

- This decision is made by the Judicial Panel on Multi-district Litigation based upon considerations of convenience of the parties and witnesses and whether an MDL will promote that just an efficient conduct

- More than 50 pharmaceutical product liability MDLs are pending from **A**ctos to **Z**oloft.

PHARMACY COMPOUNDING

Pharmacy Compounding

- The “practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient.”
- Serves important public interests if a patient cannot be treated with an FDA-approved drug
  - If a patient has an allergy to a particular dye
  - Elderly patient cannot swallow a pill
- Not FDA-approved

Who Regulates Compounding?

- Compounded pharmacies are licensed by each state's board of pharmacy
  - These boards have day-to-day oversight
  - FDA "defer[s] to state authorities regarding less significant violations"
    - FDA's Compliance Policy Guide § 460.200
- FDA's regulatory authority over pharmacies is more limited than its authority over drug manufacturers
  - Not FDA-approved
  - Pharmacies do not have to register with FDA

Statutory Guidance

- 21 U.S.C. § 353a – Pharmacy Compounding
  - Exempts compounding from certain provisions of the Food, Drug and Cosmetic Act
    - Submit a new drug application prior to interstate sale
    - Label drug with adequate directions for use
    - Strictly follow good manufacturing practices
  - Must have a valid prescription from a licensed practitioner
  - Drugs must be compounded by a licensed pharmacist
  - Drugs must be compounded from ingredients that meet certain quality standards

Statutory Guidance (continued…)

- Prior to the enactment of 21 U.S.C. § 353a, then-FDA Commissioner, David Kessler, criticized the new provisions at an agency hearing.
  - Exempting pharmacies from FDA oversight will "encourage large-scale manufacturing under the guise of pharmacy compounding."
  - "A shadow industry of unapproved generic drugs is likely to develop."
  - "[S]terile drugs could be compounded (even on a large scale) without regard to current good manufacturing practices . . . ."

Risks Associated with Compounding

- Unsafe Products
  - Use poor quality compounding practices
  - Contaminated or Adulterated
  - Too potent
- Ineffective Products
  - Compared to FDA-approved drugs, compounded drugs may prove to be unsuccessful
- Unaware Patients
  - May not be able to determine if it is safe
  - Unable to pinpoint which drugs are easier to compound than others

Margrit Long Case

- March 30, 2007 – Long injected with colchicine, to treat back pain
  - Drug normally taken in pill for gout
  - Treated with this drug for years
  - A few hours later, Long died from acute colchicine toxicity
- Investigation
  - Colchicine came from a compounding pharmacy
  - Drug contained 8 times the normal dose

Texas AG Takes (Little) Legal Action

- Pharmacist Gary Osborn and ApotheCure (the compounding pharmacy)
  - Pleaded guilty to federal misdemeanors
  - Probation: 5 years for ApotheCure; 1 year for Osborn
  - Fined: ApotheCure - $200,000; Osborn - $100,000
- Permanent Injunction
  - Essentially defendants cannot compound illegal drugs
    - (1) Before receiving a prescription; (2) Unsafe or ineffective drug; (3) Non-FDA-approved active ingredient; (4) Wholesale distribution; (5) Advertising an FDA-approved drug for other purposes

New England Compounding Center ("NECC")

- Manufactured an injectable steroid known as methylprednisolone acetate
  - Sterile
  - Relieved chronic pain
- Framingham, Massachusetts
- 17,000 vials shipped to over 3,000 hospitals and clinics across 23 states

October 2012 Fungal Meningitis Outbreak

- As of July 1, 2013:
  - 749 cases of fungal meningitis
  - 61 deaths
  - 20 states
- FDA Investigation
  - Mold and bacteria in clean rooms
  - Greenish-yellowish residues on equipment
  - Discoloration on equipment used in sterilization
  - Leaky boiler and wet floor near medicine room

Brand Name Manufacturer
vs.
Generic Manufacturer

Wyeth v. Levine, 555 U.S. 555 (2009)

- Levine intravenously injected with Phernergan
  - Drug used to prevent allergies and motion sickness
  - Injected in her arm
- Levine's arm had to be amputated after doctors injected into an artery rather than a vein
- Levine's Arguments:
  - Wyeth failed to include appropriate warning label
- Wyeth's Arguments
  - Because their warning label was FDA-approved, any state regulation making the label insufficient was preempted

Wyeth v. Levine continued…

- Holding:
  - Federal law did not preempt Levine's state-law claim that Wyeth failed to warn of the dangers of the injection
- Reasoning:
  - Brand-name manufacturers are able to unilaterally strengthen their warning labels using the FDA's "changes being effected" ("CBE") process
  - Federal regulations are the floor, not the ceiling
- Manufacturer, not the FDA, is responsible for labeling correctly.

PLIVA v. Mensing, 132 S. Ct. 2567 (Mar. 30, 2011)

- Mensing was prescribed Reglan
  - Pharmacists filled prescription with generic
- She developed a severe neurological disorder
- Allegations
  - The generic manufacturers failed to include warning labels concerning the risk
  - The manufacturers could have used the FDA's CBE regulation that allows manufacturers to unilaterally add warnings before receiving FDA approval.

PLIVA v. Mensing continued…

- Defense:
  - PLIVA, the generic manufacturer argued that federal regulations required the same label to be used as is on Reglan, which didn't have a warning
- Holding:
  - The plaintiff's "failure to warn" claim was pre-empted by federal law
  - Generic manufacturers are prohibited from changing their labeling.

PLIVA v. Mensing continued…

- Reasoning
  - CBE process unavailable to generic manufacturers. Otherwise, the manufacturers would violate the requirement that the generic products' warnings match those of the brand-name
  - The manufacturers had no way to independently comply with both state and federal regulations.
- Implications
  - Generic manufacturers are essentially immunized from state law failure to warn causes of action.

Mutual Pharmaceutical v. Bartlett

- Bartlett injured her shoulder and was prescribed Sulindac, a generic form of Clinoril.
  - Sulindac caused Stevens-Johnson Syndrome
    - Burned over 65% of Bartlett's body
    - Disfigured and legally blind
    - 3 months in the hospital
- Bartlett sued under state law for design defects
  - Not a failure-to-warn claim
- New Hampshire Law
  - Duty for manufacturers to ensure their products are not "unreasonably dangerous."

Mutual Pharm. v. Bartlett continued…

- Holding: (See 133 S. Ct. 2466 (June 24, 2013))
  - Since the "design-defect" claim ultimately imposed a duty to strengthen the label, the "warning-based" design-defect cause of action is similar to the "failure-to-warn" claim from *Mensing*.
    - Since Mutual Pharmaceutical could not change the drug's design, the New Hampshire law that imposed a duty not to produce drugs that are "unreasonably dangerous" essentially required the generic manufacturer to strengthen the label.
  - Bartlett's claim is preempted
    - New Hampshire effectively imposed a duty that federal law restricts.

Off-Label Marketing

What is Off-Label Marketing?

- FDA approves drugs for specified uses
  - Pharmaceutical company must identify each intended use of a drug in its application to the FDA
  - Promotional activities must be limited to the intended uses
  - Promotion of “off-label” uses = product misbranding
- FDA has no authority over physicians
  - Physicians may prescribe a drug off-label
- It is legal for a physician to prescribe a drug off-label, but illegal for a company to market it as such

Abbott Labs. Settlement - $1.5 Billion

- Unlawful promotion of the drug Depakote
  - Intended Use
    - Epileptic seizures
    - Bipolar Mania
    - Prevention of Migraines
  - Abbott's Marketed Uses
    - Control agitation and aggression in dementia patients
    - Treat schizophrenia
- Pleaded Guilty
  - Criminal Fine and Forfeiture - $700 Million
  - Civil Settlement - $800 Million

Wyeth Settles Claims for $490.9 Million

- Complaint filed by 2 whistleblowers
- Unlawful promotion of the drug Rapamune
  - Intended use
    - Help kidney patients accept transplanted organs
  - Wyeth's Marketed Use
    - Promote the drug for unapproved use in transplants of organs other than kidneys and in place of other immunosuppressants
- Pleaded Guilty
  - Criminal fine and forfeiture – $233.58 Million
  - Civil Settlement - $257.4 million