PRODUCT LIABILITY FOR DEFECTIVE MEDICAL DEVICES

PETER J. FLOWERS
MEYERS & FLOWERS, L.L.C.
CHICAGO, ILLINOIS

Defective Medical Device Litigation

Legally Complicated

Very Expensive

Time consuming

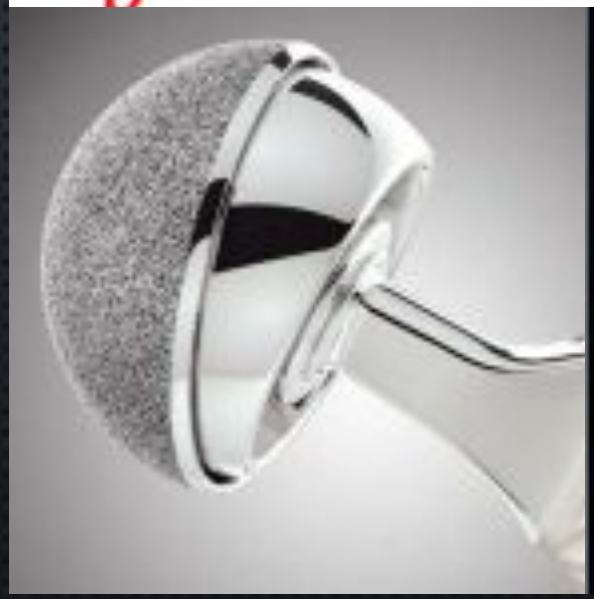
But….interesting

Hip Replacements

- In Re DePuy ASR Hip Litigation (Cook County IL 10 L 10506)
- IN RE: DePuy ORTHOPAEDICS, INC ASR HIP IMPLANT PRODUCTS (N.D. Ohio MDL Docket No. 2197)
- In re: STRYKER REJUVENATE AND ABG II HIP IMPLANT PRODUCTS LIABILITY LITIGATION (D. Minn. MDL docket No. MDL No. 2441)
- IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY Litigation (N.D. Ind MDL Docket No. 2391)
- In Re: Zimmer Durom Hip Cup Products Liability Litigation (D.N.J. MDL Docket No. 2158)

DePuy

a Johnson & Johnson company



stryker®

BIOMET®

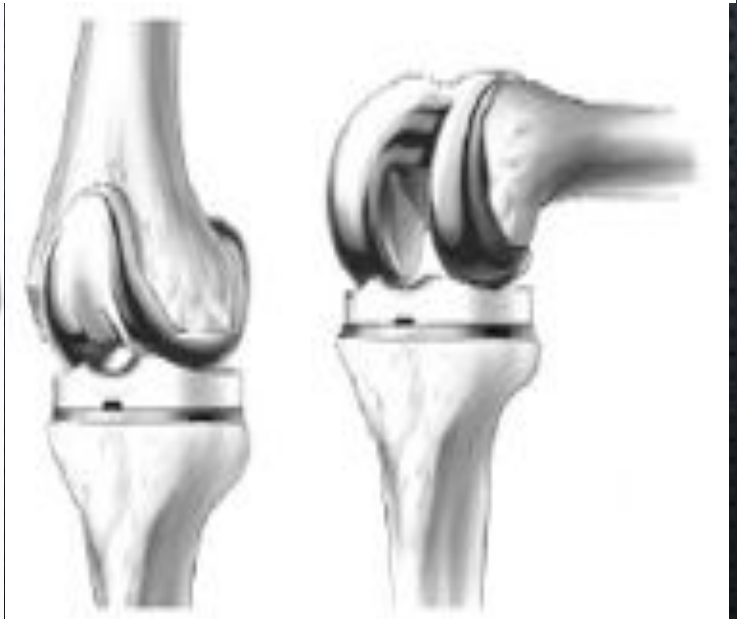
ORTHOPEDICS

zimmer

KNEE REPLACEMENTS

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION (N.D. ILL MDL DOCKET NO. 2272)

zimmer

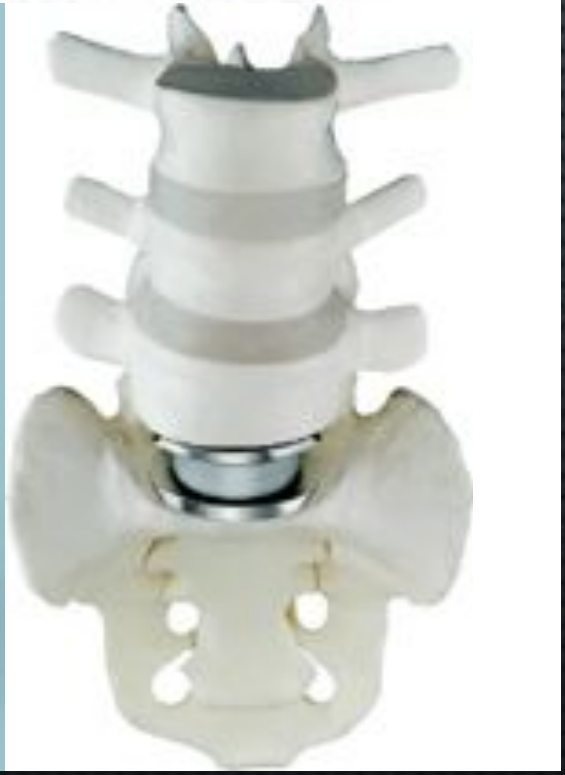


DISC REPLACEMENT

BROWN, ET AL. V. DEPUY SPINE, INC. (MASS STATE COURT)

DePuy

Spine Inc.



Legal complications

How devices are regulated

- Federal Food, Drug, and Cosmetic Act (1938)
- Medical Device Amendments (1976) sponsored by Ted Kennedy

FOOD, DRUG, AND COSMESTIC ACT 1938 (FDCA)

- PROHIBITED THE MOVEMENT IN INTERSTATE COMMERCE OF ADULTERED AND MISBRANDED FOOD, DRUGS, DEVICES, AND COSMETICS.
- AUTHORIZED THE FDA TO DEMAND EVIDENCE OF SAFETY FOR NEW DRUGS, ISSUE STANDARDS FOR FOOD, AND CONDUCT FACTORY INSPECTIONS.

Medical Device Amendments (1976)

MDA included a classification system. The higher the class, the higher the risk. Class III devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Strictly regulating these devices is important to public safety.

Class I

low risk and subject to least regulatory controls. 510(k) exempt and Good Manufacturing Practice (GMP)/Quality System exemption (dental floss, crutches, arm sling).

Class II

higher risk than class I and greater regulatory controls to provide reasonable assurance of device's safety and effectiveness. These devices are NOT exempt from GMP requirements unlike class I devices (condoms, powered wheelchairs).

Class III

highest risk devices and subject to highest regulatory control. Two different regulatory pathways for these devices: 510k and PMA (pacemakers, breast implants, total hip replacements).

Medical Device Amendments of 1976: Regulatory Pathways

510k

- Determination of substantial equivalence to a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from a class III to class II or I (the predicate).
- Substantial equivalence means that the new device is at least as safe and effective as the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

JUL – 2 2008

Re: K080991
Trade/Device Name: DePuy ASR™ XL Modular Acetabular Cup System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: March 17, 2008
Received: April 7, 2008

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Medical Device Amendments of 1976: Regulatory Pathways

PMA

- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of class III medical devices.
- PMA is the most stringent regulatory pathway
- PMA approval is based on the determination that the PMA contains sufficient scientific evidence to assure that the device is safe and effective for its intended uses.
- An approved PMA grants the applicant permission to market the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William Christianson
Vice President, Clinical and Regulatory Affairs
DePuy Spine, Inc.
A Johnson & Johnson Company
325 Paramount Drive
Raynham, MA 02767-0350

OCT 2 6 2004

Re: P040006
CHARITÉ™ Artificial Disc
Filed: February 13, 2004
Amended: March 3, 2004; April 13, 2004; April 19, 2004; April 23, 2004; April 29, 2004; July 15, 2004; July 16, 2004; August 9, 2004; September 20, 2004; September 27, 2004; September 28, 2004; October 14, 2004; October 22, 2004; October 25, 2004
Procode: MJO

Dear Mr. Christianson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

Why is the classification system important?

The ability to litigate a device depends on classification and regulatory pathway.

Class I = viable

Class II = viable

Class III = viable – depends

Supreme Court Medical Device Decisions

Medtronic, Inc. v. Lohr (1996)

Riegel v. Medtronic, Inc. (2008)

Medtronic, Inc. v. Lohr (1996)

- Pacemaker (class III 510k)
- The MDA grandfathered devices on the market before 1976 and permitted devices that are substantially equivalent to pre-existing devices to avoid approval. The device at issue in this case was deemed substantially equivalent (510k)
- When Congress is preempting a law in a field generally governed by the states, the Supreme Court assumes that the powers of the state are not preempted unless that was the clear purpose of congress.
- The scope of the preemption statute must reflect a clear understanding of congressional purpose.

Medtronic, Inc. v. Lohr (1996)

- The legislative history of the MDA in no way supports complete immunity for design defect liability for the entire industry.
- Common law claims are not preempted by the act. These claims are general state common-law requirements that every manufacturer use due care to avoid foreseeable dangers in its products and inform users of potentially dangerous risks involved in their use.

Riegel v. Medtronic, Inc. (2008)

- Balloon Catheter (Class III PMA)
- Section 360k(a) of the MDA contains a preemption provision that provides "no State may establish…any requirement which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and which relates to the safety and effectiveness of the device…"
- The MDA expressly preempts only state requirements "different from, or in addition to, any requirements applicable to the device."

Riegel v. Medtronic, Inc. (2008)

- Section 360k(a) of the MDA contains a preemption provision that provides "no State may establish…any requirement which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and which relates to the safety and effectiveness of the device…"
- The MDA expressly preempts only state requirements "different from, or in addition to, any requirements applicable to the device."

Riegel v. Medtronic, Inc. (2008)

- Premarket approval imposes specific requirements, as the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness.
- The MDA does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations because such duties "parallel" and do not add to federal requirements.

FIRST STEP IN DETERMINING CASE VIABILITY: WHAT PATHWAY ALLOWED THE DEVICE ON THE MARKET?

510K

VIABLE

PMA

LIKELY UNVIABLE

VENUE

State Court

- Great venue if you can get it
- No daubert in best state venues
- Since manufacturer likely not in state, removal to federal court
- If removal is granted, in the MDL you go

Federal Court

- Difficult to get case(s) to trial
- Consolidation with other cases in an MDL
- Possibility of an out of state judge applying plaintiff's home state law

Multidistrict Litigation (MDL)

- Pretrial proceedings in related cases may be consolidated In a single district by the Judicial Panel on Multidistrict Litigation under 28 U.S.C. § 1407
- Plaintiffs steering committee (PSC) is appointed by order of the transferee judge. The PSC has an organization structure consisting of lead counsel and various committee members.
- Transferee judge manages discovery and other pretrial matters
- Transferee judge may preside over the bellwether trial(s)

Discovery Document Production

- Production of electronically stored information (ESI) metadata – format – how and when?
- E-discovery vendor and document review platform (millions of documents)
- Questionable redactions
- Third party discovery issues (surgeon consultants and distributors)
- Design history file, device master record, adverse event reports, clinical data, consultant agreements, product development agreements, patent information, testing, design, etc…

Discovery depositions

- 50 to 100 defendant employees
- Locations around the country and world
- Highly coached deponents

Main theories of liability

Strict liability

&

Negligence

THEORIES OF LIABILITY: STRICT LIABILITY

***SUVADA V. WHITE MOTOR CO.*, 32 ILL.2D 612, 210 N.E.2D 182 (1965)**

RULE: PLAINTIFF MUST DEMONSTRATE THAT THEIR INJURY OR DAMAGE RESULTED FROM A CONDITION OF THE PRODUCT, THAT THE CONDITION WAS AN UNREASONABLY DANGEROUS ONE AND THAT THE CONDITION EXISTED AT THE TIME IT LEFT THE MANUFACTURER'S CONTROL.

THEORIES OF LIABILITY: STRICT LIABILITY

***SUVADA V. WHITE MOTOR CO.*, 32 ILL.2D 612, 210 N.E.2D 182 (1965)**

REASONING: THE PROTECTION OF LIFE AND HEALTH DESERVES FULL PROTECTION UNDER THE LAW. IF A MANUFACTURER SOLICITS THE USE OF ITS PRODUCT AND PROFITS THEREFROM, IT SHOULD ALSO BE LIABLE FOR THE HARM THAT IS CAUSED BY THE PRODUCT.

THEORIES OF LIABILITY: STRICT LIABILITY

SUVADA V. WHITE MOTOR CO., 32 ILL.2D 612, 210 N.E.2D 182 (1965)

ELEMENT 1: ONE WHO SELLS ANY PRODUCT IN A DEFECTIVE CONDITION UNREASONABLY DANGEROUS TO THE USER OR CONSUMER OR TO HIS PROPERTY IS SUBJECT TO LIABILITY FOR PHYSICAL HARM THEREBY CAUSED TO THE ULTIMATE USER OR CONSUMER, OR TO HIS PROPERTY, IF:

A. THE SELLER IS ENGAGED IN THE BUSINESS OF SELLING SUCH A PRODUCT, AND

B. IT IS EXPECTED TO AND DOES REACH THE USER OR CONSUMER WITHOUT SUBSTANTIAL CHANGE IN THE CONDITION IN WHICH IT IS SOLD.

Theories of Liability: Strict Liability

Suvada v. White Motor Co., 32 Ill.2d 612, 210 N.E.2d 182 (1965)

Element 2: The rule stated in Subsection (1) applies although

A. the seller has exercised all possible care in the preparation and sale of his product, and

B. the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Theories of Liability: Negligence

Difference Between Strict Liability and Negligence

In a product liability action involving a claim based upon negligence, a plaintiff must prove the elements of common-law negligence - a duty of care owed by the defendant, a breach of that duty, an injury proximately caused by the breach, and damages. *Calles v. Scripto-Tokai Corp.*, 224 Ill.2d 247, 864 N.E.2d 249, 309 Ill.Dec. 383 (2007).

Theories of Liability: Strict Liability (Three Types)

- Manufacturing defect
- Failure to warn
- Design defect

Theories of Liability: Strict Liability

Manufacturing defect

- Restatement (Third) Torts: A product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.
- An example of a manufacturing defect would be if one device within a produced lot did not conform to the design specifications of the device, and that device failed to perform the intended function of the device.

Theories of Liability: Strict Liability

Failure to warn

"A product can perform as intended yet subject its seller to strict liability if the seller fails to warn of a danger known to the seller but unanticipated by the consumer." *Sollami v. Eaton,* 201 Ill.2d 1, 772 N.E.2d 215, 265 Ill.Dec. 177 (2002).

Theories of Liability: Strict Liability

Failure to warn

Restatement (Third) Torts: A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe

Theories of Liability: Strict Liability

Failure to warn

A manufacturer is held to the degree of knowledge and skill of an expert. *Eaves v. Hyster Co.*, 244 Ill.App.3d 260, 614 N.E.2d 214, 185 Ill.Dec. 80 (1st Dist. 1993)

Theories of Liability: Strict Liability

Failure to warn

Adequacy of warnings under *Collins v. Sunnyside Corp.*, 146 Ill.App.3d 78, 496 N.E.2d 1155, 1157, 100 Ill.Dec. 90 (1st Dist. 1986):

Warnings may be inadequate if warnings:

1. do not specify the risk presented by the product;
2. Are inconsistent with how a product would be used;
3. Do not provide reason for warnings; or
4. Do not reach foreseeable users

Theories of Liability: Strict Liability

Federal preemption in failure to warn cases

"A state law claim will be preempted only if the state law requirement interferes with the federal interest in regulation or when the state law imposes a higher standard with which the device must comply" *Kernats v. Smith Industries Medical Systems, Inc.*, 283 Ill.App.3d 455, 669 N.E.2d 1300, 1305, 218 Ill.Dec. 774 (1st Dist. 1996), relying on *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 135 L.Ed.2d 700, 116 S.Ct. 2240 (1996).

Theories of Liability: Strict Liability

Design Defect

An example of a design defect would be if products are manufactured within design specification, but an inherent flaw in the design of the product causes it to fail to perform its intended function.

Theories of Liability: Strict Liability

Design Defect

Two tests:

1. Consumer-Expectation Test: Does the device perform as an average consumer expects it to perform?
2. Risk-Utility Test: Are there foreseeable risks of harm posed by the product that could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and does the omission of the alternative design render the product as not reasonably safe?

Theories of Liability: Strict Liability

Design Defect

An Illinois plaintiff may choose either method of proof under *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 864 N.E.2d 249, 255 – 56, 309 Ill.Dec. 383 (2007), which indicates that a plaintiff may use the risk-utility test if his claim does not meet the consumer expectation test.

Theories of Liability: Strict Liability

Design Defect

- In *Mikolajczyk v. Ford Motor Co.*, 231 Ill.2d 516, 901 N.E.2d 329, 327 Ill.Dec. 1 (2008), the Court outlined the following factors from RESTATEMENT (THIRD) TORTS to be used in risk-utility analysis:
- "Under section 2(b), the risk-utility balance is to be determined based on consideration of a 'broad range of factors,' including 'the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing,' as well as 'the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products.'"

Theories of Liability: Negligence

Difference Between Strict Liability and Negligence

The focus in a product liability action based on negligence is on the conduct of the defendant and not, as in strict liability, on the product. *Blue v. Environmental Engineering, Inc.*, 215 Ill.2d 78, 828 N.E.2d 1128, 1141, 293 Ill.Dec. 630 (2005) (emphasis added).

Theories of Liability: Negligence

Elements

(1) Duty of care owed by the defendant;

(2) Breach of duty;

(3) Injury proximately caused by breach; and

(4) Damages

Under a theory of negligence, a manufacturer has a duty of care to design and manufacture a product that will be reasonably safe for its intended use and any reasonably foreseeable uses. *Cornstubble v. Ford Motor Co.*, 178 Ill.App.3d 20, 532 N.E.2d 884, 127 Ill.Dec. 55 (5th Dist. 1988).

Theories of Liability: Negligence

To establish a negligence claim for a defective design of a product, a plaintiff must prove that either (1) the defendant deviated from the standard of care that other manufacturers in the industry followed at the time the product was designed, or (2) the defendant knew or should have known, in the exercise of ordinary care, that the product was unreasonably dangerous and the defendant failed to warn of its dangerous propensity. *Blue v. Environmental Engineering, Inc.*, 215 Ill.2d 78, 828 N.E.2d 1128, 1141, 293 Ill.Dec. 630 (2005).

Theories of Liability: Negligence

Duty to Warn in Negligence Cases

A manufacturer, reasonably aware of a dangerous propensity of its product, has a duty to warn foreseeable users when there is unequal knowledge, actual or constructive, and it knows or should know that harm might or could occur if no warning is given. Failure to warn under such circumstances can expose the manufacturer to liability for negligence. *Modelski v. Navistar International Transportation Corp.*, 302 Ill.App.3d 879, 707 N.E.2d 239, 236 Ill.Dec. 394 (1st Dist. 1999).

Theories of Liability: Negligence

Duty to Warn in Negligence Cases

Any warning must adequately inform the user of any unusually dangerous propensity about which the manufacturer knows or should have known. The manufacturer is held to the degree of knowledge and skill of experts. *Peterson v. B/W Controls, Inc.*, 50 Ill.App.3d 1026, 366 N.E.2d 144, 9 Ill.Dec. 30 (3d Dist. 1977).

Theories of Liability: Negligence

Adequacy of Warnings

A warning may be found to be inadequate if it fails to specify the risk presented by the product, if it is inconsistent with how the product is to be used, if it fails to advise of the reason for the warning, or if it does not reach the foreseeable users. The question of whether a product is unreasonably dangerous because a warning is inadequate is a question of fact for the jury. *Byrne v. SCM Corp.*, 182 Ill.App.3d 523, 538 N.E.2d 796, 131 Ill.Dec. 421 (4th Dist. 1989).

THEORIES OF LIABILITY: NEGLIGENCE

PROVING STANDARD OF CARE

A PLAINTIFF MAY ESTABLISH A NEGLIGENCE CLAIM BY PLEADING FACTS THAT SHOW THAT THE DEFENDANT DEVIATED FROM THE STANDARD OF CARE THAT OTHER MANUFACTURERS IN THE INDUSTRY FOLLOWED AT THE TIME THE PRODUCT WAS DESIGNED OR MANUFACTURED OR BY PLEADING FACTS THAT SHOW THE DEFENDANT KNEW OR SHOULD HAVE KNOWN, IN THE EXERCISE OF ORDINARY CARE, THAT ITS PRODUCT WAS UNREASONABLY DANGEROUS AND FAILED TO WARN OF ITS DANGEROUS PROPENSITY. *BLUE V. ENVIRONMENTAL ENGINEERING, INC.*, 215 ILL.2D 78, 828 N.E.2D 1128, 1141, 293 ILL.DEC. 630 (2005).

DAMAGES

COMPENSATORY

&

PUNITIVE

Damages

Pain and suffering:

An award for pain and suffering is intended to compensate a plaintiff for the physical experience associated with his or her injury.

A jury may consider physical pain and mental suffering in determining an award for an injury. *McDaniels v. Terminal Railroad Association of St. Louis,* 302 Ill.App. 332, 23 N.E.2d 785 (4th Dist. 1939).

Damages

Pain and suffering includes that which has already occurred, or that which may be likely to continue into the future. A plaintiff seeking future pain and suffering must be able to demonstrate that future pain and suffering is likely to occur. *Harp v. Illinois Central Gulf R.R.*, 55 Ill.App.3d 822, 370 N.E.2d 826, 12 Ill.Dec. 915 (5th Dist. 1977).

Currently, there is no rule requiring pain and suffering to be proportionally related medical expenses, but the court may find that an award of one without the other is inconsistent. See *Stamp v. Sylvan*, 391 Ill.App.3d 117, 906 N.E.2d 1222, 329 Ill.Dec. 611 (1st Dist. 2009).

Damages

Disability/Loss of a Normal Life:

A disability relates to the inability of the injured party to perform life functions in the manner that he or she was able to do before an injury.

A disability must not necessarily be permanent in order to be compensable. The jury may consider evidence of the plaintiff's lifestyle before and after the injury to determine an award for disability. *Martin v. Cain,* 219 Ill.App.3d 110, 578 N.E.2d 1161, 161 Ill.Dec. 515 (5th Dist. 1991).

Damages

If a plaintiff testifies about the effect that his or her injuries have had on his or her life, the court should give an instruction on loss of a normal life instead of disability. *Hiscott v. Peters,* 324 Ill.App.3d 114, 754 N.E.2d 839, 851, 257 Ill.Dec. 847 (2d Dist. 2001).

DAMAGES

DISFIGUREMENT

An award for disfigurement is intended to compensate a plaintiff for the damage or change in appearance to his or her body as a result of the injury.

The Court has defined disfigurement as that which impairs or injures beauty, symmetry, or appearance of a person, that which renders unsightly or imperfect or deforms in some manner. *Rapp v. Kennedy*, 101 Ill.App.2d 82, 242 N.E.2d 11 (4th Dist. 1968).

DAMAGES

MEDICAL EXPENSES

A plaintiff is entitled to recover as compensatory damages the reasonable expense of necessary medical care resulting from the defendant's negligence or defective product. *Chicago City Ry. v. Henry*, 218 Ill. 92, 75 N.E. 758 (1905).

DAMAGES

LOSS OF EARNINGS

A party injured by a defective product may receive an award of damages to compensate him or her for the earnings lost as a result of the injury. This is the value of the time lost from employment, including sick time. *Cummings v. Jha*, 394 Ill.App.3d 439, 915 N.E. 2d 908, 333 Ill.Dec. 837 (5th Dist. 2009).

Damages

Loss of Earnings

An injured party may recover for future lost earnings as well. This calculation is made by comparing the plaintiff's earning capacity before the injury to the plaintiff's earning capacity after the injury. This may be established without expert testimony, although expert testimony may be allowed. *LaFever v. Kemlite Co.*, 185 Ill.2d 380, 706 N.E.2d 441, 235 Ill.Dec. 886 (1998).

Punitive damages

Punitive damages are those that are intended to punish the defendant for wrongful conduct, and to deter similar conduct from the defendant or other parties in the future.

PUNITIVE DAMAGES

STANDARD

Punitive damages are recoverable in injury cases if there is evidence of willful and wanton conduct on the part of the defendant. *Madison v. Wigal,* 18 Ill.App.2d 564, 153 N.E.2d 90 (2d Dist. 1958)(emphasis added).

PUNITIVE DAMAGES

PLEADING

In Illinois, under 735 ILCS 5/2-604.1, a complaint must not contain a request for punitive damages when it is filed. A plaintiff must make a motion for punitive damages and be granted leave to amend the complaint to include the request. The plaintiff must demonstrate at the time of the motion that he or she has a reasonable likelihood of proving facts at trial to support the award of punitive damages.

PUNITIVE DAMAGES

CORPORATE COMPLICITY

In a product liability action, the plaintiff must demonstrate that the corporate entity which created the product was complicit in the conduct giving rise to the punitive damages claim. This may be demonstrated in the following ways:

(a) the principal authorized the doing and the manner of the act,

(b) the agent was unfit and the principal was reckless in employing him or her,

(c) the agent was employed in a managerial capacity and was acting in the scope of employment, or

(d) the principal or managerial agent of the principal ratified or approved the act. *Mattyasovszky v. West Towns Bus Co.*, 61 Ill.2d 31, 330 N.E.2d 509, 512 (1975).

Punitive Damages

Actual Damages

An award of punitive damages cannot stand alone. There must be an underlying finding of liability for actual damages.

Punitive Damages

Limitations on Punitive Damages

In *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 155 L.Ed.2d 585, 123 S.Ct. 1513 (2003), the Supreme Court indicated that punitive damage awards that exceed a single-digit multiple of the actual damages awarded may indicate a violation of due process.

How do these cases get resolved

- Too many cases to get tried
- Bellwether case(s) may establish value
- Positive working Relationship with defense counsel
- Settlement by law firm case inventory
- Medical records & Bills
- Individual offers
- Lead role in discovery and large case inventory

DEPUY ASR HIP LITIGATION

- 39,000+ devices implanted in the U.S. ~90,000 worldwide.
- Cases filed in federal court (MDL) as well as multiple state courts throughout the country (Illinois, California, New Jersey).
- Cooperation amongst the plaintiffs counsel from the sate and federal litigation.
- Document review – 50 million+ documents
- Coordination of depositions (70+ 2 day deps in and outside the US)
- Millions in costs, expenses & time

Stryker ABG II and Rejuvenate MDL

- Recently consolidated - In Re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation
- Finalizing the PSC
- ~30,000 devices in commerce
- Early investigation indicates mixed metal construct as a contributory mechanism of failure

THANK YOU

Peter J. Flowers
Meyers & Flowers, L.L.C.
Chicago, Illinois