Multiple Documents

Part	Description
1	20 pages
2	Affidavit Declaration of Adam R. Salvas In Support of Defendant Sulzer Orthopedi
3	Exhibit Exhibit A to Salvas' Declaration
4	Exhibit Exhibit B to Salvas' Declaration
5	Exhibit Exhibit C to Salvas' Declaration
6	Exhibit Exhibit D to Salvas' Declaration
7	Exhibit Exhibit E to Salvas' Declaration
8	Affidavit Declaration of Larry Beeman in Support of Defendant Sulzer Orthopedics
9	Affidavit Declaration of Brian J. Devine in Support of Defendant Sulzer Orthoped
10	Affidavit Declaration of Richard J. May in Support of Defendant Sulzer Orthopedi
11	Appendix Certificate of Service

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re	MDL Docket No. 01-CV-9000
INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	ALL CASES
	(JUDGE KATHLEEN O'MALLEY)

DEFENDANT SULZER ORTHOPEDICS INC.'S MOTION FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT

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Defendant Sulzer Orthopedics Inc., through its counsel of record, hereby moves this Court for an order conditionally certifying a settlement class under Rule 23(b)(3) and preliminarily approving a proposed settlement under Rule 23(e).

I

PRELIMINARY STATEMENT

This proposed class settlement was designed to provide the greatest good to the greatest number of patients affected by Sulzer Orthopedics Inc.'s ("SOI's") recent hip device recall. In essence, the settlement forces SOI and its affiliates to pay everything they can today, and then operate over the next seven years under financial conditions that are barely tolerable so they can make further payments to class members. The alternative is piecemeal litigation, which if allowed to persist, will likely mark the end of SOI and leave most affected patients with no compensation for their alleged injuries.

SOI voluntarily recalled certain of its Inter-Op™ acetabular shells on December 5, 2000 and voluntarily withdrew a second product the Natural Knee II™ tibial baseplate in March 2001. Those products have now generated more than 1,300 civil actions nationwide. About 200 of the cases are in federal court and are in the process of being transferred to this Court for pretrial proceedings under MDL No. 1401. The litigation is complex, costly, and extensive, and it represents a significant drain on SOI's resources. Indeed, if the litigation continues at its present pace on a piecemeal basis, SOI's liabilities will exceed its resources in short order.

The parties have designed this proposed settlement to handle this reality. It provides, among other things, for medical expenses for affected patients and substantial cash payments for those who need to have a recalled device replaced. Further, to fund the settlement, SOI and its parent and affiliate companies are contributing and/or pledging all their assets and net income for the next seven years. That includes every remaining penny of the approximately $235 million policy limits and every asset of the companies in the United States and Europe.

Nevertheless, there will be opposition to this settlement. Personal injury lawyers from California, Texas, and elsewhere will argue that they should be allowed to take their individual cases to trial and "take their shot" at SOI while the getting is still good. It is an understandable position for zealous lawyers to take in light of their duties to their individual clients. But such a myopic view of this litigation would benefit only the relative few at the great expense of the many. Put another way, by placing their individual interests above those of the patient group as a whole, the objecting lawyers are not only threatening the viability of SOI, but are trying to thwart efforts to compensate affected patients in a fair and even-handed way.

In short, by dividing the companies' limited resources equitably among those affected by these products, this settlement is a fair resolution of the claims against SOI. The alternative is to litigate these claims separately until the money runs out, at which point defendants may or may not be able to go on. Accordingly, SOI urges this Court to grant preliminary approval to the settlement. In addition, to help achieve the benefits of the settlement, SOI has requested, in a

separately captioned motion, an order enjoining all related litigation in federal and state court.

II

THE INTER-OP™ RECALL HAS RESULTED IN A FLOOD OF COSTLY LITIGATION THAT IS THREATENING SULZER ORTHOPEDICS INC'S VIABILITY AND CREATES THE NEED FOR A COMPROMISE TO AVOID PIECEMEAL LITIGATION

SOI is a Texas-based manufacturer of orthopedic devices, such as knee, hip, and shoulder replacement systems. (Declaration of Larry Beeman ¶ 2) It is one of a number of medical device companies owned directly or indirectly by Sulzer Medica Ltd., a Swiss medical technology company that is publicly traded on the New York Stock Exchange.[1] (Declaration of Richard May ¶¶ 2, 4)

The device at issue in the Settlement Agreement is SOI's Inter-Op™ acetabular shell, a hip replacement component. On December 5, 2000, after investigating reports that some Inter-Op™ shells were not staying tightly implanted into the patients' hip bones, SOI voluntarily recalled certain manufacturing lots, a total of about 40,000 devices. Before and after the recall, SOI reviewed all its manufacturing processes, to see if other products could experience problems, especially those products manufactured in a fashion similar to the Inter-Op™ acetabular shells. The Natural Knee II™ tibial baseplate, a knee replacement component, is the only other product made in the same way. Thus, in March

[1] Until recently, Sulzer Medica Ltd.'s majority shareholder was a Swiss industrial company called Sulzer AG, which owned 74 percent of Sulzer Medica Ltd.'s outstanding stock. However, on July 10, 2001, Sulzer AG divested itself of virtually all its shareholding in Sulzer Medica Ltd. (May Decl. ¶ 3)

2001, SOI decided voluntarily to withdraw that product from the market as well. SOI has publicly acknowledged responsibility for patient needs in connection with the recalled and withdrawn products. (Beeman Decl. ¶¶ 3-5)

Within weeks of the Inter-Op™ recall, affected patients started filing lawsuits across the country, especially in the South and West. There are currently more than 1,300 hip and knee lawsuit pending against SOI. About 200 lawsuits are in federal court and are being transferred to this Court under the MDL statute. The remainder are in state court — 329 in California (as of the beginning of August, 2001), 237 in Texas, 295 in Florida, 93 in New York, and the remainder scattered in other states. A few are pending in Canada. There are about 50 class actions. (Declaration of Adam R. Salvas ¶ 3)[2]

Discovery has been extensive. SOI has responded to thousands of interrogatories and requests for admissions, and the parties are currently working through a master deposition schedule that includes more than 20 defense witnesses. SOI also has done a master production of documents, having produced approximately 85,000 pages in four different machine readable formats on compact discs. Further discovery is ongoing. (Salvas Decl. ¶ 6)

[2] In addition to suing SOI, plaintiffs have sued a number of other Sulzer companies — mostly notably Sulzer AG, Sulzer Medica Ltd., Sulzer Orthopedics Ltd., Sulzer Medica USA Holding Co., and Sulzer Medica USA Inc. (Salvas Decl. ¶ 4) None of these companies made or sold the Inter-Op™ acetabular shell or the Natural Knee II™ tibial baseplate, so liability claims against them are slim, based only on strained theories of alter ego or agency. (Beeman Decl. ¶ 2) In addition, Sulzer AG, Sulzer Medica Ltd., and Sulzer Orthopedics Ltd. are Swiss companies, making it virtually impossible to establish jurisdiction over them in U.S. courts or to enforce U.S. judgments against them.

The litigation has been distracting and costly. With national counsel in California and local counsel throughout the United States and in Canada handling the more than 1,300 civil actions, SOI's legal expenses related to the Inter-Op™ recall this year have totaled $8.5 million, currently about $2.0 million per month. (Declaration of Brian Devine ¶ 6) And with trials commencing shortly, the expenses from this point forward will be substantially higher. This is on top of the expense caused by diverting SOI's employees from their regular duties to litigation-related duties, such as responding to discovery and appearing for depositions.

All of the litigation costs are being paid from the same insurance proceeds that will compensate patients. SOI has liability coverage totaling 400 million Swiss francs (about $235 million). (Devine Decl. ¶ 4-5) But it is now clear that SOI's potential liability and defense costs will exhaust the policy limits. As of the beginning of August, there had been 2,371 hip revisions and 280 knee revisions reported to SOI. The average age of these patients is 63. The number of hip revision surgeries has tailed off dramatically since the peak in February, but there will be some number of revisions in the future, particularly knee revisions. (Beeman Decl. ¶¶ 8-9)

For several months, SOI has been in negotiations with a group of plaintiffs over a possible settlement. These plaintiffs have been ably represented by experienced and accomplished plaintiffs' tort lawyers, and counsel have had the benefit of voluminous discovery materials, as well as additional information provided informally during the talks. Because of the scope of SOI's potential liabilities and the limited resources that exist to meet them, discussions eventually focused on a class settlement.

III

THE PROPOSED CLASS SETTLEMENT DEDICATES VIRTUALLY ALL THE RESOURCES OF SULZER ORTHOPEDICS INC. AND ITS AFFILIATES TO EQUITABLE COMPENSATION FOR AFFECTED PATIENTS AND IS A FAIR AND REASONABLE RESOLUTION OF PENDING AND FUTURE CLAIMS

On August 2, 2001, the parties agreed on the material terms of a class settlement, the details of which have since been memorialized in the Settlement Agreement. (Salvas Decl., Exh. E) The essential provisions are as follow:

A. Compensation For The Putative Class

The putative class consists of all recipients of recalled Inter-Op™ acetabular shells, including shells that were "reprocessed" and sold following the recall (the "Affected Products"), in the U.S. and their spouses and beneficiaries. The class members will be paid in five subclasses as follows:

- Group I consists of class members who have undergone or will undergo replacement of *one* Affected Product before December 31, 2008. Defendants will pay reasonable and necessary medical expenses to replace the Affected Product. In addition, each Group I member will receive $37,500 in cash and 3,922 American Depository Receipts ("ADRs") of Sulzer Medica Ltd., publicly

traded on the New York Stock Exchange (NYSE:SM). The agreement assumes an ADR price of $5.10,[3] which makes the combined cash and stock worth $57,500.

- Group II consists of class members who have undergone or will undergo replacement of *more than one* Affected Product before December 31, 2008. Members of Group II will receive medical expenses, plus $63,500 in cash and 6,667 ADRs. The combined cash and stock is worth $97,500, which again is on top of medical expenses.

- Group III consists of class members who do not have their Affected Products replaced before December 31, 2008. Each Group III member will receive $750 in cash and 392 ADRs, a total value of $2,750. If Group III members undergo revision surgery before December 31, 2008 — and thus change Groups — their compensation as members of Group I or Group II will be reduced by the amounts they already received.

- Group IV consists of spouses of members of Group I and Group II, class members who have undergone revision surgery. These spouses will receive $5,000.

- Group V consists of spouses of Group III members, non-revised members. Those spouses will receive $500.

[3] In fact, Sulzer Medica Ltd. ADR's were trading at $8.38 on the morning of August 15, 2001, a substantial premium over the figure used in negotiating the settlement. At that price, class members stand to receive much more in equity than the agreement contemplates on its face.

B. Funding By Sulzer Orthopedics Inc. And Its Affiliates

To provide for these payments, and others described below, SOI and its affiliates and parents will create four separate funds:

- The General Fund: Upon final settlement approval, SOI and its affiliates and parents will pay into a General Fund all amounts immediately owing to all class members. SOI will contribute all but $10 million of its available insurance proceeds to the General Fund. It will also contribute *all* the cash and liquid cash equivalents currently available to it *and* its parents and affiliates, retaining only 30-days worth of working capital. Further, in *each* of the next seven years, SOI will contribute the *greater* of (a) $25 million or (b) one-half of the consolidated net income for the prior fiscal year of Sulzer Medica Ltd. and all of its subsidiaries. All payments due to class members, including revision surgery expenses, will be paid from the General Fund, except payments that are to be paid from the Medical Monitoring Fund or the Extraordinary Fund, explained below.

- The Extraordinary Fund: Upon final settlement approval, SOI will contribute the remaining $10 million in insurance proceeds to a fund established for class members eligible to receive additional compensation under a predetermined matrix. Such additional compensation will be awarded by a court-appointed Special Master, with applicants retaining a right to appeal to this Court. SOI will make additional contributions to the Extraordinary Fund on an ongoing basis, such that the Fund's balance does not fall beneath $10 million; *except* that SOI will not have to contribute more than $10 million within in the first year following final settlement approval or more than $20 million within the first two

years. SOI's aggregate payment to the Extraordinary Fund shall not exceed $30 million.

- The Medical Monitoring Fund: SOI will create a fund to provide medical monitoring services for class members who have not already undergone revision surgery. Each such member will be entitled to periodic x-rays, which is the best method to detect loosening. SOI will contribute $2 million to the fund upon final settlement approval and will contribute additional sums on an ongoing basis for five years, such that the Fund's balance does not fall beneath $1 million. SOI's aggregate payment to the Medical Monitoring Fund shall not exceed $20 million.

- The Research Fund: SOI will create a $4 million fund to finance medical research relating to reconstructive orthopedic implants, specifically hip and knee implants.

C. Securing The Funding

To secure the obligations that SOI is undertaking, Sulzer Medica Ltd. has granted the class members a security interest in *all* its assets until June 30, 2009. That means that *all* the assets of Sulzer Orthopedics Inc., Sulzer Medica Ltd., Sulzer Orthopedics Ltd., Sulzer Medica USA Holding Co., and all of Sulzer Medica USA Holding Co.'s operating subsidiaries have been fully encumbered for the next eight years for the purposes of securing the funding for the class settlement.

D. Attorneys' Fees

The Settlement Agreement provides for contingency attorneys' fees. An attorney representing a class member under a written agreement as of August 2, 2001 will receive a fee equal to one-third of the total payments made to the represented class member. Attorneys will be paid two-thirds in cash and one-third in ADRs.

E. Release

In consideration for the relief described above, the class representatives, on behalf of the entire class, have agreed to release each class member's "Settled Claims" against SOI and others. Under the Settlement Agreement, the "Settled Claims" are:

> any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the Affected Products. . . .

(Settlement Agreement § 1.1(ccc), attached to the Salvas Decl. as Exh. E) Such claims are released against the "Released Parties," which are :

> [Sulzer Orthopedics Inc.] and each of its affiliates, including [Sulzer Medica Ltd.] and each of [Sulzer Medica Ltd.'s] other past, present and future parent companies and direct or indirect subsidiaries, including without limitation those U.S. entities listed on Annex III, together with each of their respective past, present and future directors, officers, affiliates, insurers and agents, including without

> limitation, sales agents; Sulzer AG, a limited company organized under the laws of Switzerland, and all of its past, present and future parent companies and direct or indirect subsidiaries, its and their respective past, present and future directors, officers, affiliates, insurers and agents; Winterthur [an insurer] and all of its past, present and future parent companies and direct or indirect subsidiaries, its and their respective past, present and future directors, officers, affiliates, insurers and agents; all surgeons who performed primary and/or Revision Surgery with respect to Affected Products and affiliated physicians or physician groups, organized medical specialty organizations, raw material or other suppliers of Sulzer of materials used in the manufacture of the Affected Products, distributors of the Affected Products; and any other person or entity involved in the design, manufacture, distribution, implant or explant of an Affected Product.

Settlement Agreement § 1.1(tt). The parties would like to give notice to the class members and set a date for a final approval in this Court.

IV

PRELIMINARY APPROVAL OF THE SETTLEMENT IS APPROPRIATE BECAUSE IT WAS NEGOTIATED AT ARM'S LENGTH AND IS WITHIN THE RANGE OF POSSIBLE FINAL APPROVAL

Before the parties can give notice to the class and set a fairness hearing date, the Court must grant preliminary approval. The scope of this Court's preliminary review is defined as follows:

> First, counsel [must] submit the proposed terms of settlement and the court makes a preliminary fairness evaluation. . . . [¶] . . . If the preliminary evaluation of the proposed settlement does not disclose grounds to doubt its fairness, such as unduly preferential treatment of class representatives of segments of the class, or

> excessive compensation for attorneys, and ***appears to fall within the range of possible approval***, the court should direct that notice under Ruled 23(e) be given to the class members of a formal fairness hearing, at which arguments and evidence may be presented in support of and in opposition to the settlement.

Manual for Complex Litigation (Third) § 30.41 (3d ed. 1997) (emphasis added); *see also In re NASDAC Market-Makers Antitrust Litig.*, 176 F.R.D. 99, 102 (S.D.N.Y. 1997).

Thus, a settlement should be approved preliminarily if it "appears to fall within the range of possible approval." In evaluating whether the settlement falls within the range of possible approval, courts examine the settlement's terms to determine that "the agreement is not the product of fraud or overreaching by, or collusion between, the negotiating parties, and that the settlement, taken as a whole, is fair, reasonable and adequate to all concerned." *See Officers for Justice v. Civil Serv. Comm'n*, 688 F.2d 615, 625 (9th Cir. 1982). As part of this evaluation, courts also do not second guess the settlement terms and do not reach ultimate conclusions on contested issues of fact and law. *Id.*; *see also Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1027 (9th Cir. 1998). Moreover, where a settlement is the result of extensive negotiations, there is a presumption that it is fair. *See Duhaime v. John Hancock Mut. Life Ins. Co.*, 177 F.R.D. 54, 68 (D. Mass. 1997) ("In general, a settlement arrived at after genuine arm's length bargaining may be presumed to be fair); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 176 F.R.D. 158, 184 (E.D. Pa. 1997) ("Significant weight should be attributed 'to the belief of experienced counsel that settlement is in the best interest of the class'") (internal citations omitted).

In further considering what is fair and reasonable, district courts also evaluate various additional factors, including: (1) the strength of the plaintiff's case on the merits balanced against the amount offered in settlement; (2) the ability of the defendant or defendants to withstand a greater judgment; (3) reaction of members of the class to the settlement; (4) the complexity of the litigation, the stage of the proceedings, and the amount of discovery completed; and (5) the opinions of counsel for the class and the defendants. *See, e.g.*, *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 962 F. Supp. 450, 534 (D.N.J. 1997) (enumerating similar factors); *Manchaca v. Chater*, 927 F. Supp. 962, 966 (E.D. Tex. 1996) (same).

Given the relevant standard and factors considered, the proposed settlement here is well within the range of possible approval.

First, the class, as a settlement class, meets the requirements of Rule 23. Plaintiffs have pleaded or will plead that their class action satisfies Rule 23, and their memorandum in support of preliminary approval of this settlement explains why they believe the factors are met. From SOI's perspective, it only would add that the settlement avoids the sort of conflicts of interest highlighted in *Amchem Products., Inc. v. Windsor*, 521 U.S. 591, 610-20 (1997). The proposed settlement divides the current and future claimants into separate subclasses and provides that future claimaints will receive the same compensation as those who have already undergone revision surgery. In addition, the agreement is structured to ensure that resources will be available to meet those future obligations.

Second, the proposed settlement was negotiated at arm's length over several months by experienced and informed counsel. These attorneys examined the costs and benefits of piecemeal litigation versus compromise. They had the best information available on the strengths and weaknesses of the parties' cases and the economic resources available to resolve these cases.

Third, the proposed settlement provides significant compensation for all. The Settlement Agreement provides for all necessary revision-related medical expenses, plus medical monitoring costs above and beyond normal follow-up. The agreement also provides for additional payments, which are substantial — $57,500 for one revision, $97,500 for more than one. Any class member who has a revision *for any reason* in the next seven years (which is at the lower end of the normal life for a perfectly good hip implant) also becomes eligible for payment, *i.e.*, similarly situated class members are treated the same. There is also a $30 million Extraordinary Fund to provide further compensation for extraordinary cases.

Fourth, the proposed settlement accounts for the limited resources available to SOI and its likely inability to satisfy judgments. There are more than 1,300 civil actions pending, and there have been more than 2,300 revision surgeries involving recalled Inter-Op™ shells. SOI's potential liability therefore is enormous, ranging from a conservative $500 million to potentially over $1 billion.[4] (Salvas Decl. ¶¶ 7-9; Devine Decl. ¶¶ 7-8; Beeman Decl. ¶¶ 7-9) Available insurance benefits are about $217 million — the $235 million policy limits less

[4] The estimated range depends on variables such as the estimated total number of revision surgeries required through December 31, 2008 and on potential recoveries, including the potential for punitive damages.

what SOI has already spent on defense costs and to resolve individual Inter-Op™ cases. (Devine Decl. ¶¶ 5-7) Even adding the liquidation value of the entire Sulzer Medica group of companies (about $120 million), it is clear that there currently is not enough money to go around. (May Decl. ¶ 9)

The Settlement Agreement deals with this limited-resource situation in several ways. To begin with, SOI is contributing all available insurance coverage and all available liquid assets for the purpose of paying the class. In every way, SOI is putting in everything it has. Moreover, the agreement augments the amount of available resources by pledging not only SOI's insurance and liquid assets, but also those of its affiliates and parents, including Sulzer Medica Ltd. Indeed, under the agreement, Sulzer Medica Ltd. is contributing all available cash and cash equivalents, saving only one month's operating capital. Rather than force insolvency, the agreement allows SOI and Sulzer Medica Ltd. to keep doing business, which protects a future income stream to pay the class members. Finally, to secure their performance, the companies' have granted the class a security interest in *all* their assets. So if liquid assets are not sufficient to meet the obligations under the Settlement Agreement, class members have recourse against additional assets.

Fifth, settlement at this stage in the litigation is of great benefit. This litigation's current posture lends itself to a class settlement. It has progressed far enough for the parties to assess their positions and make informed decisions, yet it has not gone beyond the point of manageability. There have been no trials (although several are set to start soon), and although there are about 50 class actions, no class has been certified. The parties are currently in a "settlement

window" that will provide the maximum benefit to all concerned if a settlement can be finalized promptly. Further, to ensure that the "window" does not close, SOI has requested in a separate motion that this Court enjoin all related litigation nationwide pending completion of the settlement approval process.

Sixth, plaintiffs' class counsel and defendants believe the settlement is fair. The proposed settlement is the most intelligent way to resolve this litigation. It takes into account the available funds and the class members' needs, and it provides immediate compensation while allowing SOI to continue doing business. It is far preferable to the alternative, which is to litigate individual cases until the money is gone.

V

CONCLUSION

This proposed settlement meets the requirements of the law and represents a fair and equitable way to resolve this litigation. For the reasons explained above, SOI requests that this court conditionally certify the proposed

settlement class, preliminarily approve the settlement, approve the proposed class notice and set a final fairness hearing date for December 2001.

DATED: August 15, 2001.

CROSBY, HEAFEY, ROACH & MAY
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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re	MDL Docket No. 01-CV-9000
INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	ALL CASES
	(JUDGE KATHLEEN O'MALLEY)

DECLARATION OF ADAM R. SALVAS IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION

I, Adam R. Salvas, declare:

1. I am an attorney at law and an associate with the law firm of CROSBY, HEAFEY, ROACH & MAY, Professional Corporation, attorneys of record for Sulzer Orthopedics Inc. I make this Declaration in support of Defendant Sulzer Orthopedics Inc.'s Motions for Preliminary Approval of Class Settlement, Approval of Class Notice and Enjoining All Related Litigation. I have personal knowledge of the matters set forth in this Declaration. If called as a witness, I could and would competently testify to these matters.

2. Crosby, Heafey, Roach & May, Professional Corporation has been retained as national counsel for Sulzer Orthopedics Inc. ("SOI") for all litigation regarding Sulzer Orthopedics Inc.'s InterOp™ hip and Natural Knee II™ knee prostheses.

3. As of August 2001, approximately 1,310 lawsuits have been filed against SOI nationwide, including 196 in federal court. Approximately 97% of the state court actions have been filed in either California (390 lawsuits), Florida (319 lawsuits), Texas (243 lawsuits) or New York (129 lawsuits). Of the 1,310 lawsuits filed in the United States, at least 53 are pleaded as a class actions, 19 of which are filed in state court. In addition, SOI has been named as a defendant in several lawsuits in Canada.

4. In addition to suing SOI, plaintiffs have also sued a number of other Sulzer companies - most notably Sulzer AG, Sulzer Orthopedics Ltd., Sulzer Medica USA Holding Co. and Sulzer Medica USA Inc. At least 307 of the suits have specifically named Sulzer Medica Ltd. as a defendant, 573 have named an

agent or distributor of SOI, and 51 have named a doctor or other medical provider as a defendant. Approximately 470 of the lawsuits seek punitive damages. Of the approximately 1,966 named plaintiffs who have filed suit, approximately 450 allege to be a spouse or otherwise related to a patient who received an allegedly defective Inter-Op™ shell or tibial baseplate manufactured by SOI.

5. Currently at least 41 lawsuits are scheduled for trial before December 31, 2001: Rupp et al. v. Sulzer Orthopedics Inc., Case No. 01-60581-4 (Nueces County, Texas), August 20, 2001; Black v. Sulzer Orthopedics Inc., Case No. GN100174 (Travis County, Texas), September 10, 2001; Nations v. Sulzer Orthopedics Inc., Case No. 2001-22036 (Harris County, Texas), September 10, 2001; Spellman v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), September 17, 2001; Drummer v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), September 17, 2001; Linde v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), September 17, 2001; Dryden v. Sulzer Orthopedics Inc., Case No. GN100073 (Travis County, Texas), October 1, 2001; Gross v. Sulzer Orthopedics Inc., Case No. 018876 CA24 (Miami-Dade County, Florida), October 1, 2001; Kirkpatrick v. Sulzer Orthopedics Inc., Case No. 2001-06346 (Harris County, Texas), October 8, 2001; Adkins v. Sulzer Orthopedics Inc., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Annuzzi v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Berrie v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Bochman v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination

Proceedings, California), October 15, 2001; Bruington v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Elhardt v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Elms v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; French v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Friedman v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Granum v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Howland v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Jozwiak v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; McConnell v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Morse v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Oril v. Sulzer Orthopedics Inc., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Reck v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Schmitz v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001; Loeffler v. Sulzer Orthopedics Inc. et al., Case No. 01-0266 (Harrison County, Texas), October 15, 2001; Tobin v. Sulzer Orthopedics Inc. et al., Case No. JCCP 4165 (In re Hip Replacement Coordination Proceedings, California), October 15, 2001;

Martin v. Sulzer Orthopedics Inc. et al., Case No. 01CVS517 (County of Wayne, North Carolina), October 15, 2001; Blankenship v. Sulzer Orthopedics Inc., Case No. 2001-04539 (Harris County, Texas), November 5, 2001; Fort v. Sulzer Orthopedics Inc., Case No. GN100278 (Travis County, Texas), November 5, 2001; King v. Sulzer Orthopedics Inc. et al., Case No. 01CVS518 (County of Wayne, North Carolina), November 5, 2001; Smith v. Sulzer Orthopedics Inc., Case No. 01CVS152 (County of Wayne, North Carolina), November 5, 2001; Irving v. Sulzer Orthopedics Inc., Case No. 2001-18439 (Harris County, Texas), November 12, 2001; McCain v. Sulzer Orthopedics Inc., Case No. 2001-17955 (Harris County, Texas), November 12, 2001; Pitchfod v. Sulzer Orthopedics Inc. et al., Case No. 2001-19259 (Harris County, Texas), November 12, 2001; Adams v. Sulzer Orthopedics Inc., Case No. 01003637 (Hillsborough County, Florida), November 26, 2001; DiFonzo v. Sulzer Orthopedics Inc., Case No. 01003902 (Hillsborough County, Florida), December 3, 2001; Romero v. Sulzer Orthopedics Inc. et al., Case No. D0101 CV 200100741 (County of Santa Fe, New Mexico), December 3, 2001; Dalness v. Sulzer Orthopedics Inc. et al., Case No. D0101 CV 200100740 (County of Sante Fe, New Mexico), December 3, 2001; Berge v. Sulzer Orthopedics Inc. et al., Case No. D0101CV2001-00968, (County of Santa Fe, New Mexico), December 3, 2001.

6. As a result of the litigation arising from the Inter-Op™ recall, Sulzer Orthopedics Inc. has had to respond to thousands of interrogatories and requests for admissions. The parties are currently working through a master deposition schedule that has included more than 21 defense witnesses scheduled for over 37 days of testimony. Several third party witnesses have also been subpoenaed. In addition, defendants have produced approximately 85,000 pages of documents in four different computer-readable databases on compact discs.

Thousands of additional pages were subsequently produced at various depositions. Further discovery is ongoing.

7. I conducted an on-line computer search for judicial opinions discussing jury verdicts against manufacturers of either hip or knee implants. My research revealed the following jury awards:

(a) $525,000 [Vossler v. Richards Manufacturing Co. Inc., 143 Cal. App. 3d 952 (1983)] (knee implant);

(b) $196,775 (Elbert v. Howmedica, Inc., 59 F.3d 174 (9th Cir. 1995) (knee implant);

(c) $1,686,988.70 [Haudrich v. Howmedica, Inc., 169 Ill. 2d 525 (1996)] (knee implant);

(d) $1,793,842 [Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997)] (hip implant);

(e) $256,000 (Thompson v. Goetzmann, 2001 WL 771012 (N.D. Tex, 2001) (hip settlement).

True and correct copies of these opinions are attached hereto as Exhibit A. I also found the following opinions containing a discussion of jury verdicts awarded against tortfeasors who caused injuries necessitating either a hip or knee implant surgery:

(f) $150,000 [Florida's Patient's Compensation Fund v. Tillman et al., 453 So.2d 1376 (Fla. App. 1984)] (knee implant);

(g) $150,000 "for future pain and suffering associated with knee replacement" [Randolph v. Budget Rent-A-Car, 878 F.Supp. 162 (C.D. Cal. 1995)] (knee);

(h) $130,000 [Wilson v. National Union Fire Ins. Co. of Lousiana, 665 So.2d 1252 (Ct. App. La. 1995)] (hip).

True and correct copies of these opinions are attached as Exhibit B.

8. In addition, my research has also revealed the following cases in which damages were awarded or settlements reached either (a) with a hip or knee implant manufacturer or (b) other tortfeasor where a plaintiff was forced to undergo a surgical hip or knee implant procedure:

(a) $100,000 [Pletcher v. Depuy, Inc. (Circuit County, Virgina 1994)] (settlement, hip);

(b) $352,000 [Monnes v. Zimmer et al. (Middlesex County, Conn. 1991)] (hip);

(c) $216,000 including $16,000 loss of consortium [Mulligan v. Howmedica (Hamilton County, Ohio 1994)] (knee)

(d) $36,000 [Pesovic v. Barnett Bank of Pinellas County (Pinellas County Circuit Court, Florida 1994)] (hip);

(e) $50,000 [Lisker v. Lewis Rossi (Dade County Circuit Court, Florida 1987)] (hip);

(f) $131,400 [Elam v. Harris Methodist Hosp. (Tarrant County, Texas 1991)] (hip);

(g) $473,000 [Selger v. Stevens Nursery & Hardware (California 1989)] (hip).

True and correct copies of the Westlaw or Lexis report describing these these verdicts are attached hereto as Exhibit C.

9. I have personally reviewed the medical records for approximately 7 patients who have had hip revision surgery and 20 who had a knee revision surgery after receiving an implant from Sulzer Orthopedics Inc. These twenty-seven patients claimed to have incurred approximately $2,351,523.17, or $87,093.45 on average, in medical expenses and to have suffered $234,609.88 in economic harm as the result of receiving an allegedly faulty implant manufactured by Sulzer Orthopedics Inc. The average age of these patient is 66 years old and the claimed medical and economic damages range from $ 31,879.19 to $196,174.81.

10. An additional 30 patients' medical records were reviewed by others under my direction. All of these patients claimed to have received a

defective hip implant manufactured by Sulzer Orthopedics. These patients claimed to have incurred medical expenses of approximately $801,580.26, or $26,719 on average.

11. Attached as Exhibit D is a draft of Defendant Sulzer Orthopedics Inc.'s proposed class notice.

12. Attached as Exhibit E is a true and correct copy of the Class Action Settlement Agreement with some annexes to be provided after Court approval.

I declare under penalty of perjury under the laws of United States that the foregoing is true.

DATED: August 14, 2001.

Adam R. Salvas

LEVEL 1 - 22 OF 53 CASES

NELLIE VOSSLER, Plaintiff and Respondent, v RICHARDS MANUFACTURING COMPANY INC., Defendant and Appellant

Civ No. 6436

Court of Appeal of California, Fifth Appellate District

143 Cal. App. 3d 952; 1983 Cal. App. LEXIS 1832; 192 Cal. Rptr 219; CCH Prod. Liab. Rep. P9707

June 15, 1983

SUBSEQUENT HISTORY: [**1]

Appellant's petition for a hearing by the Supreme Court was denied September 7, 1983.

PRIOR HISTORY:

Superior Court of Tulare County, No. 82827, William Silveira, Jr., Judge.

DISPOSITION: The judgment is affirmed.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant manufacturer appealed from a judgment of the Superior Court of Tulare County (California), awarding compensatory and punitive damages in favor of plaintiff patient in a products liability case arising out of a defective modular knee which was manufactured by defendant and implanted into plaintiff.

OVERVIEW: A modular knee manufactured by defendant manufacturer was implanted in the right knee of plaintiff patient. A defect in the product necessitated eventual removal of plaintiff's kneecap, and other damages. Plaintiff brought a products liability action against defendant. The jury awarded plaintiff compensatory damages of $ 25,000 and punitive damages of $ 500,000. On appeal, defendant contended that punitive damages could not be awarded unless plaintiff introduced evidence of defendant's wealth or profit from wrongdoing; the trial court erred in instructing the jury regarding the relationship between actual and punitive damages; plaintiff's counsel made an improper argument, and the ratio between punitive and compensatory damages was disproportionate. The court held that the plaintiff had no obligation to introduce evidence of the defendant's financial condition when seeking punitive damages; the jury was properly instructed on the relationship between punitive and compensatory damages; the jury's award of punitive damages was fully justified; there was no prejudicial misconduct in plaintiff's argument; and the ratio between punitive and compensatory damages was not too high.

OUTCOME: The court affirmed the trial court's judgment in favor of plaintiff because the trial court did not err in admitting evidence or instructing the jury on punitive damages, there was no prejudicial misconduct in plaintiff's closing argument, the jury's award of punitive damages was fully justified, and the ratio between punitive and compensatory damages was not disproportionate.

CORE TERMS: punitive damages, wealth, knee, medium, modular, compensatory damages, template, ratio, introduce evidence, net worth, gross sales, excessive, punitive, surgery, metal, defense counsel, actual damages, manufacturing, cross-examination, manufactured, financial condition, exemplary damages, wrongdoer, favorable, mandated, implantation, manufacturer, subsidiary, introduce, kneecap

CORE CONCEPTS -

Civil Procedure: Jury Trials: Province of Court & Jury
It is within the discretion of the trial court to preclude cumulative and time-consuming duplication of inquiry.

Civil Procedure: Jury Trials: Province of Court & Jury
The trial court has very broad discretion in admitting or excluding evidence.

Civil Procedure: Appeals: Standards of Review: General Rules
Both case law and constitutional authority provide that prejudice is not presumed and must be affirmatively shown. A judgment will not be reversed unless it can be said that a different result would have occurred had asserted error not been made.

Torts: Damages: Punitive Damages
In determining the amount of punitive damages necessary to impose the appropriate punitive effect, the court is entitled to consider the wealth of the defendant. The object is to make an example as well as a punishment to fit the offense and in determining the amount necessary

to impose a punitive effect, the jury may consider the wealth of the defendant. Thus, no review of a defendant's wealth is mandated before an award of punitive damages can be made.

Torts: Damages: Punitive Damages
The plaintiff has no obligation to introduce evidence of the defendant's financial condition when seeking punitive damages.

Civil Procedure: Jury Trials: Jury Instructions
It cannot be presumed on appeal that the jury ignored a proper instruction on damages.

Torts: Damages: Punitive Damages
In assessing the propriety of a punitive damage award, as in assessing the propriety of any other judicial ruling based upon factual determinations, the evidence must be viewed in the light most favorable to the judgment.

Torts: Damages: Punitive Damages
Net, not gross, sales figures are the best yardstick to be used in determining punitive damages in a product liability case.

Torts: Damages: Punitive Damages
Evidence of gross sales figures are relevant in determining punitive damages in a product liability case, even if they are entitled to less weight than net profit.

Torts: Products Liability: Plaintiff's Conduct
The definition of proscribed conduct in a product liability case is malice, which may be established if the defendant acted with a conscious disregard for the safety of others.

Torts: Damages: Punitive Damages
Torts: Products Liability
A factor that may affect the amount of punitive damages is the existence of multiple claims by numerous persons affected by the wrongdoer's conduct. It is appropriate to take into consideration both the punitive damages that have been awarded in prior suits and those that may be granted in the future, with greater weight being given to the prior awards.

COUNSEL: Tuttle & Taylor C. Stephen Howard, Jeffrey M. Hamerling and Alan D. Smith for Defendant and Appellant.

Richard R. Clifford and Arthur E. Schwimmer for Plaintiff and Respondent.

JUDGES: Opinion by Andreen, J., with Zenovich, Acting P. J., and Hamlin, J., concurring.

OPINIONBY: ANDREEN

OPINION: [*957] [***221] (See fn. 1.) Defendant Richards Manufacturing Company Inc. (Richards) appeals from a judgment following jury trial in a products liability case. n1 No attack is made on the sufficiency of evidence except as to the matter of punitive damages. The judgment was for compensatory damages of $25,000 and punitive damages of $500,000. We affirm.

n1 Richards also appealed from an order denying a motion for a directed verdict. This is not an appealable order (Code Civ. Proc., § 904.1; 4 Cal.Jur.3d, Appellate Review, § 45, p. 83.)

[**2]

Facts

We state the record in a light most favorable to the judgment. (*Neal v. Farmers Ins. Exchange (1978) 21 Cal.3d 910, 922 [148 Cal.Rptr. 389, 582 P.2d 980].)*

In the period from 1970 through 1972, Dr. Leonard Marmor an orthopedic surgeon working with the defendant corporation, developed a prosthetic device known as the Marmor Modular Knee, which permitted treatment of certain diseases of the knee by inserting specially crafted pieces of metal and plastic onto the surfaces of the bones that make up the knee joint. The metal components of the modular knee were originally produced in three sizes -- small, medium and large -- and each size included three elements (a template, a trial and a final component), each perfectly matched within a size for implantation. When implanting a metal component, the surgeon used the template to mark and prepare the bone, the trial component to insure that preparation of the bone was accurate, and then cemented the final component permanently in place. An important [*958] part of the surgical technique involved placing the final component so that it did not protrude forward of its proper location and impinge upon the kneecap when [**3] the knee was flexed.

During 1973 defendant, through engineering error, began manufacturing final metal components of the medium category which were larger than originally designed and which therefore did not match the medium template and trial components. It was thus possible that a surgeon could prepare a bone for insertion of the medium

metal component using properly sized medium template and trial components (which were reused from surgery to surgery) and then cement into place a too-large medium final component.

Defendant had no procedure for insuring that the final components it produced were of the proper size, and so it manufactured and sold the larger-than-proper medium final components for some time without discovering the error. In January of 1974, defendant discovered its error but in order to prevent its competitors from gaining a larger share of the market for such devices, concealed it from the medical profession, from its own sales personnel and from Dr Marmor Defendant attempted to replace, on a pretext, all of the properly sized medium [***222]template and trial components with newly manufactured larger components, and later attempted to resell the originally[**4] designed medium components as a supposedly new "small-medium" size, all without informing anyone outside the defendant corporation of the reason for its actions.

On October 15, 1974, a Marmor Modular Knee was implanted in the right knee of the then 67-year-old plaintiff. One of the metal components used by the surgeon was a medium, and in the subsequent complications and treatment thereof it was revealed that the discrepancy between the older, smaller template and trial components and the larger final component had resulted in improper positioning of the final component, causing impingement on the plaintiff's kneecap which necessitated eventual removal of the kneecap, and other damages.

On the issue of punitive damages, plaintiff proved that the components of the modular knee were actually manufactured by a subsidiary of the defendant and "sold" to defendant for approximately $ 23 per component, of which 10 percent reflected profit to the subsidiary. Defendant sold the modular knee components to the medical profession for prices ranging during the relevant period from $ 108 to $ 140 per component. From January 10, 1973, through April 2, 1973, 4,042 of the medium trial and final[**5] components were manufactured. The modular knee components comprised about one-third of the output of the subsidiary that manufactured it. Defendant's sales revenues were approximately $ 50 million in 1979, and the modular knee was one of 7,000 different products sold by defendant during the relevant period. (Evidence regarding the number [*959] of modular knee instrument sets [the template and trial components which were reused from surgery to surgery] in use and the number of implant surgeries performed using medium components was also introduced.)

Defendant sought to introduce testimony relating to the amount of royalties paid to Dr Marmor in connection with the sales of the modular knee, and an objection on relevancy grounds was sustained. During cross-examination of Dr Marmor following his rebuttal testimony defense counsel sought to examine him concerning his alleged bias against the defendant, but the trial court would not permit such questions.

During plaintiff's closing argument, defense counsel objected to the statement of plaintiff's counsel that defendant was " . . . doing over fifty million dollars a year in sales ," on the grounds that it was unsupported [**6]by evidence, irrelevant and prejudicial. The objection was overruled on all grounds.

In the course of deliberations, the jury requested by note an interpretation of certain instructions relating to punitive damages. The court answered the jury's question as follows: "The Court: And what I want to tell you about this, is something that's rather simple, but I want you to listen to it carefully And that is that there is no fixed relationship prescribed in the law between actual damages and punitive damages.

"That is a matter that's left to your sound discretion, but you should consider it in light of the whole instruction given, 14.71, pages one, and two, including the last two lines of page 29 that you asked me about.

"I can tell you nothing further"

Evidentiary Rulings

Dr Marmor testified at length in plaintiff's case-in-chief Direct and cross-examination during plaintiff's case established that Dr Marmor had demanded that Richards notify doctors about the change in the configuration of the medium component and indemnify him against any loss due to any malpractice action brought against him due to the mismatch, and that there was serious disagreement between Marmor and[**7] Richards as to what should be done to remedy the situation. In addition, there was testimony about litigation brought by Dr Marmor against Richards because of the manufactuting error, and by way of attempted impeachment of Marmor, Richards read portions of the transcript of that litigation. [***223] It was further shown that Dr Marmor and plaintiff's treating physician, Dr Williams, were colleagues and had socialized, and that when Dr Williams experienced problems in surgery with plaintiff's knee, he called Dr Marmor The same day that Dr Williams phoned, Dr Marmor [*960] and his attorney traveled from Los Angeles to Tulare to meet with Dr Williams

in order to gather evidence for Marmor's case against Richards. It was established that Dr Marmor had sought the testimony of other surgeons for use in his litigation against Richards. The jury also learned that Dr Marmor would not permit Richards' salesmen to attend his seminars, and that he insisted that his name be removed from the product.

After the defense case, Dr. Marmor was recalled by plaintiff in rebuttal and examined concerning the nature of the fracture of plaintiff's femur following implantation of[**8] the modular knee, the size of the template and final components used in implantation, and the cause of certain damage to plaintiff's kneecap, all as revealed by previously introduced evidence. On cross-examination, after questioning relating to the rebuttal testimony, defense counsel proposed to question Dr Marmor concerning his general bias against defendant. Following a nonreported conference at the bench, defense counsel announced the ruling of the court in a reported conference at the bench. n2

n2 "[Defense counsel]: Your Honor, I will indicate that I have no further questions of Dr. Marmor at this time. I did have -- did intend to go into some of the questions that were raised off the record in [sic] during the examination, such as general questions relating to bias of the witness, and you had indicated at that time that as far as rebuttal was concerned, you didn't think I had a right to go into that. I will state that that was a large part of what I intended to do from this point on, and I'd make an offer of proof that this witness is biased against Richards, and it colors his judgment, his medical judgment. And I intend to go into that. But based on the ruling off the record, I have no further questions regarding specifically to the testimony of this afternoon. And if I accurately stated your ruling, I have no further questions.

"The Court: You're accurately stating my ruling."

[***9]

It was well within the discretion of the trial court to preclude such cumulative and time-consuming duplication of inquiry. (*People v. La Macchia (1953) 41 Cal 2d 738, 743-744 [264 P.2d 15];* People ex rel. Dept. *Pub. Wks. v. Miller (1964) 231 Cal.App.2d 130, 134 [41 Cal.Rptr. 645], People v. Flores (1977) 71 Cal.App.3d 559, 565-566 [139 Cal Rptr 546].)* In a trial that had already consumed 13 court days and would last for another 5, no abuse of discretion appears from a limitation of cross-examination on a subject previously well covered by the defense. n3

n3 The defendant's contention that the trial court failed to exercise its discretion because it believed that cross-examination for bias was not permitted as a matter of law is simply not supported by the record. To presume that a reasonable and legally proper ruling was founded upon an erroneous understanding of the law, as revealed only by the paraphrasing of the trial court's ruling by defense counsel, would be unnecessarily speculative.

[**10]

The second evidentiary error claimed by defendant relates to the exclusion of testimony which would have shown the amount of royalties paid by defendant to Dr Marmor After establishing that such royalties were paid, an objection to the question as to amount was sustained on the grounds that it was [*961] irrelevant. Defendant's attempt to characterize this evidence as rehabilitative towards its expert, Dr Bechtol, is disingenuous. It had already been shown that both Drs. Marmor and Bechtol received royalty payments from defendant. The notion that the jury would (or should) have compared the amounts paid to each expert (by the same party) in weighing their credibility is more a product of defendant's disappointment with the result of the trial than any reasoned analysis of its processes.

The trial court has very broad discretion in admitting or excluding evidence. (*Continental Dairy Equip. Co. v. Lawrence (1971) 17 Cal.App.3d 378, 384 [94 Cal.Rptr. 887].)* Both case law and constitutional authority provide that prejudice is not presumed and must be affirmatively shown. (Ibid.) A judgment will not be reversed unless it can be said that a different result[**11] would have occurred had asserted error not [***224] been made. (Ibid.) It is a tribute to the skill and diligence of the trial court that so lengthy and complex a trial produced such improbable assertions of error

Necessity of Introducing Evidence of Defendant's Wealth as Prerequisite for Punitive Damages

Citing *Neal v. Farmers Ins Exchange, supra, 21 Cal.3d 910,* Richards contends that punitive damages may not be awarded unless a plaintiff introduces evidence of defendant's wealth or profit from wrongdoing. However, Neal holds only that in determining whether a

punitive damages award was excessive as a matter of law, the court should consider the wealth of the defendant. Neal did not hold that a punitive damages claim would fall if plaintiff did not introduce evidence of defendant's wealth.

Defendant also relies on *Alhino v Starr (1980) 112 Cal.App 3d 158 [169 Cal.Rptr. 136]*, which reversed a conditional order for new trial on the grounds of excessive damages. The reversal was mandated by the trial court's failure to provide the requisite written specification of reasons. (Code Civ. Proc., § 657.) There was no evidence in the record of the[**12] net worth of the defendant. In order to assure that the punitive damages award was not excessive, the ease was remanded for a redetermination of the appropriate amount. The appellate panel stated at page 179:

"However, the record here provides no evidence of the net worth of the . . . defendanta. Further the instant award has not been approved by tbe trial court though, by reason of its failure to make an adequate statement of reasons, the order granting a new trial cannot stand . . .

". . . The trial court may take additional evidence on the net worth of the . . . defendants, if necessary.

[*962] " . . . The judgment . . . against the . . defendants is . . . remanded for s redetermination of the punitive damages in light of the net worth of the defendants." (*Alhino v Starr, supra, 112 Cal.App 3d at p. 179*)

The appellate panel's disposition is opaque. The judgment was reinstated, but the court took action " . . to assure thst the punitive damage award is not excessive ." This language sounds as if the matter were remanded to the trial court for consideration of the new trial motion. Such action would imply that the verdict would stand, even though[**13] there was no evidence of net worth, but that the trial court should consider net wotth on a new trial motion. However, in the same psragraph the court stated: "Accordingly, we remand for a redetermination of the appropriste amount of punitive damages in light of the principles stated above. The trial court may take additional evidence on the net worth of the . . defendants, if necessary " (*Id, at p. 179.*) This language suggests that the remand mandsted a jury trial on the issue of punitive damages. We admit to some puzzlement as to the true holding in Alhino. Albino was a decision of the First District, Division Two. Presiding Justice Taylor authored the opinion and it was concurred in by Justices Miller and Smith.

Justice Taylor also wrote *Nelson v Gaunt (1981) 125 Cal.App.3d 623 [178 Cal Rptr 167]*, in which Justices Miller and Smith concurred. It was a tort action for damages resulting from implantation of silicone in the breasts of plaintiff Her special damages were $ 25,000. The verdict was for $ 450,000 in compensatory damages and $ 1.5 million in punitive damages. The court addressed the issue at page 643: "Equally without merit is Gaunt's contention[**14] that Civil Code section 3294 requires that an inquiry be made of his wealth before punitive damages can be awarded. The courts of this state have consistently held that in determining the amount necessary to impose the appropriate punitive effect, the court is entitled to consider the wealth of the defendant (*MacDonald v Joslyn (1969) 275 Cal.App. 2d 282* .). The object is to make an example as well as a punishment to lit the offense and in determining [***225] the amount necessary to impose a punitive effect, the jury may consider the wealth of the defendant (*Roemer v. Retail Credit Co. (1975) 44 Cal.App.3d 926* .). Thus, no review of a defendant's wealth is mandsted before an award of punitive damages can be made."

In view of the fact that the identical justices served on the psnels in the earlier case of Alhino and the later case of Nelson v Gaunt and that the latter addressed the lssue directly and unequivocally, it cannot be maintained that Alhino stands for the proposition that plaintiff is required to introduce evidence of defendant's wealth before an award of punitive damages can stand.

Richards also relies on *Forte [**15] v. Nolfi (1972) 25 Cal App.3d 656 [102 Cal Rptr. 455]* There, a defendant who secured and caused to be recorded [*963]what was in effect a forged instrument was assessed damages of $ 20,000. The maximum compensatory damages would have been $ 2,800. Against s claim that the damages were excessive, the plaintiff contended that the damages were justified as an award for punitive damages. The judgment was reversed with directions to reassess the compensatory and exemplary damages. The appellate panel concluded " . that the award made was the result of passion or prejudice engendered by a failure to properly determine the compensatory damages awardable, and to appraise the wealth of the wrongdoer " *(Id, at p 689.)*

Standing against *Forte v. Nolfi, supra*, is a considerable body of authority

In *Zimmer v. Dykstra (1974) 39 Cal.App 3d 422 [114 Cal Rptr 380]*, the Second District Court of Appeal upheld an award of $ 10 compensatory and $ 1,500 puni-

tive damages to landowners whose access easement had been encroached upon. The Court of Appeal refused to follow *Forte v. Nolfi, supra, 25 Cal.App.3d 656,* and held that there was no necessity[**16] to introduce evidence of the wealth of a defendant to support an award of exemplary damages. (*Zimmer v. Dykstra, supra, 39 Cal.App.3d, at pp. 438-439.)*

Zimmer relied upon *Hanley v. Lund (1963) 218 Cal.App.2d 633 [32 Cal.Rptr. 733],* a Second Appellate District case which affirmed an award of $ 15,000 compensatory and $ 5,000 punitive damages in a slander action. The appellate court stated that it had discovered no authority requiring introduction of evidence of a defendant's wealth to support punitive damages, and further said: "The parties were content to go to the jury on the implied basis that defendant's ability to pay was consistent with his occupation. He did not contend, either in the trial court or here, that in fact the award made was excessive in the light of his financial status. Since no authority anywhere, expressly directs that the plaintiff must introduce evidence of defendant's wealth when seeking exemplary damages, we find no merit in defendant's contention in this regard." (*Id., at p. 646,* italics added.)

Fletcher v. Western National Life Ins. Co. (1970) 10 Cal.App.3d 376 [89 Cal.Rptr. 78, 47 A.L.R.3d 286], in which an[**17] insurer was assessed $ 640,000 in punitive damages (reduced on remittitur to $ 180,000) based upon $ 60,000 in compensatory damages in connection with a claim of intentional infliction of emotional distress, also expressly held that there was no necessity that a plaintiff introduce evidence of a defendant's wealth in support of an award of punitive damages, citing *Hanley v. Lund, supra.* (Id., at p. 404.) The opinion noted the Supreme Court's expressions of the desirability of such evidence, but ruled that it was not "absolutely essential." (Ibid.)

The trend of modern decisions in other jurisdictions is to place the burden of producing evidence of wealth on the wrongdoer permitting the defendant to establish its financial inability to pay punitive damages.

[*964] For instance, in *Rinaldi v. Aaron (Fla. 1975) 314 So.2d 762,* the Supreme Court of Florida reversed a trial court's order removing consideration of punitive damages from the jury where the plaintiff had not introduced any evidence of the defendant's financial ability to pay. The court noted that such evidence of ability to pay was always admissible, but held that it was not a requisite [***226] [**18] to such an award, following the decisions of many other jurisdictions, including California. n4 (*Id., at p. 764.)*

n4 The Florida case cited *Fletcher v. Western National Ins. Co., supra, 10 Cal.App.3d 376 [89 Cal.Rptr. 78, 47 A.L.R.3d 286]* as exemplary of California law *(Rinaldi v. Aaron, supra, 314 So.2d at p. 764.)*

Similarly in *Zarcone v. Perry (2d Cir. 1978) 572 F.2d 52,* the United States Court of Appeals for the Second Circuit rejected the claim of a defendant in a civil rights action that punitive damages awarded against him were improper because no evidence of his net worth was introduced at trial. The federal appeals court ruled that, " . . . decided cases and sound principle require that a defendant carry the burden of showing his modest means -- facts peculiarly within his power -- if he wants this considered in mitigation of damages. [Citations.]" (*Id., at p. 56.)*

We recognize that since the purpose of punitive damages is to punish and deter wrongdoing by fashioning[**19] a monetary penalty tailored to the wealth of the defendant and to the reprehensibility of his conduct, absence of any evidence about the defendant's wealth significantly impairs a rational effectuation of this purpose. However, in view of direct California authority for the principle that the plaintiff need not introduce evidence of the defendant's wealth in order to be awarded punitive damages (*Nelson v. Gaunt, supra, Zimmer v. Dykstra, supra; Fletcher, supra; Hanley, supra),* it is consonant with stare decisis and consistent with the modern trend to require the wrongdoer to demonstrate at the trial level that a particular award of punitive damages will exact too great a penalty because of his financial condition. Presumably, in the great majority of cases it will be to the plaintiff's advantage to show that the defendant is capable of absorbing a substantial penalty, and in those situations where it is otherwise, the defendant will be motivated to show its penury. The defendant is in the best position to provide the most accurate data concerning its financial condition, and need not decide whether to introduce such information until after the plaintiff has presented [**20]a sufficient case for the punitive damages issue to go to the trier of fact. If the defendant wishes to challenge an award of exemplary damages on appeal, its production of financial data will provide the basis for appellate review as mandated by the Supreme Court in Neal and other cases.

Richards contends that " . . . to require a defendant to present 'mitigating' financial condition evidence

would be, for all intents and purposes, requiring the defendant to make a tscit admission that some award of punitive damages is [*965] appropriate . The unfairness of placing such a burdan on the defendant is manifest." Although not directly analogons because such evidence almost invariably follows expert evidence produced by the ptaintiff, we note that defendants in personal injury cases where liability is disputed regularly introduce evidence tending to show that plaintiff's injuries are less than claimed. Defendants have developed techniques which permit them to introduce mitigating evidence without diminishing the force of their contest as to liability

For all these reasons, we hold that the plaintiff has no obligation to introduce evidence of the defendant's financial[**21] condition when seeking punitive damages.

Instructions to the Jury

In the course of instructing the jury, the trial court stated as follows:

"The law provides no fixed standard as to the amount of such punitive damages, but leaves the amount to the jury's sound discretion, exercised without passion or prejudice.

"Any amount awarded for punitive damages should bear a reasonable relation to the scnal damages, although no fixed ratio exists." n5

n5 BAJI No. 14.71 (1980 rev).

The jury was provided with written copies of all instructions orally given by the trial court. In response to a note requesting interpretation of the instruction regarding the relationship of punitive and actual [***227] damages the court reinstructed the jury as set forth in the statement of facts, above. Defendant argues on appeal that the court's response to the jury request eliminated the requirement that punitive damages bear a reasonable relationship to compensatory damages because the trial court did not expressly repeat this [**22]admonition.

"It cannot be presumed on appeal that the jury ignored a proper instruction on damages. [Citation.]" (*Agarwal v. Johnson (1979) 25 Cal 3d 932, 953 [160 Cal.Rptr 141, 603 P.2d 58.)* In responding to the jury's request, the trial court specifically drew the jury's attention to the previously given instruction which expressly stated that punitive damages must bear a reasonable relationship to actual damages. The trial court's additional comment that there is no fixed relationship preseribed in the law between actual and punitive damages was a correct statement of the law (*Nelson v. Gaunt, supra, 125 Cal App.3d at p. 644*) The trial court's response did not etiminate the requirement that punitive aud compensatory damages be reasonably related, and therefore was not error.

[*966] Defendant's Conduct as Justifying an Award of Punitive Damages

Defendant's attempt on appeal to suggest that its conduct exhibited a concern for the safety of the public via careful monitoring of its manufacture and sale of the modular knee is patently ludicrous. Itwas undisputed at trial that defendant purposely concealed the discrepancy in size between the medium final [**23]component as originally designed and as later produced by defendant from the medical profession, from Dr Marmor – the inventor of the modular knee – and from its own sales personnel solely lo protect its market position. The jury evidently disbelieved the self-serving testimony of defendant's corporate officers regarding their purported tests as to the medical significance of the larger-than-proper medium final component. Defendant further attempted to capitalize on its concealment of its manufacturing error hy marketing the originally designed medium components ss a purportedly "new" size. The comments of the Court of Appeal in *Grimshaw v. Ford Motor Co. (1981) 119 Cal.App 3d 757 [174 Cal Rptr 348]* are particularly appropriate here: "In assessing the propriety of a punitive damage award, as in assessing the propriety of any other judicial ruling based upon factual determinations, the evidence must be viewed in the light most favorable to the judgment. [Citation.] Viewing the record thusly in the instant case, the conduct of Ford's management was reprehensible in the extreme. It exhibited a conscious and callous disregard of public safety in order to maximize corporate[**24] profits. Ford's self-evalustion of its conduct is based on a review of the evidence most favorable to it instead of on the basis of the evidence most favorable to the judgment. Unlike malicious conduct directed toward a single specific individuall, Ford's tortious conduct endangered the lives of thousands of Pinto purchasers. Weighed against the factor of reprehensibility, the punitive damage award as reduced by the trial judge was not excessive." (*Id , at pp. 819-820*)

Defendant's conduct in the present case was marginally less monstrously inhumane than the conduct of the defendant in Grimshaw, since concealment

of Richards' manufacturing error for the sole purpose of protecting its profits merely threatened excruciating pain and crippling immobility to thousands of arthritic patients and anguish to their physicians and their families, not the fiery death that the auto manufacturer visited upon its customers. However, insofar as reprehensibility of conduct was concerned, the jury's award of punitive damages was fully justified.

Plaintiff's Closing Argument

Richards contends that the court should not have permitted plaintiff's counsel to argue the amount of Richards' [**25] gross sales and a calculation of Richards' profit from its manufacture of the mismatched modular knee.

[*967] Counsel established the cost of the knee to Richards from its subsidiary and the sales [***228] price to its customers. From this he calculated an alleged profit margin and, using the number of operations of Dr Jennings, constructed an argument of how much profit Richards had made from the sale of the mismatched knee.

The first question which must be addressed is whether Richards preserved the issue on appeal. There was an off-the-record conference which is the subject of a settled statement. The settled statement establishes that the sole defense objection was that there was no evidence in the record that the defendant was doing over $ 50 million a year in sales. And that, if supported by the evidence, such was irrelevant and prejudicial. This was the extent of the objection.

Net, not gross, figures are the best yardstick to be used in determining punitive damages. (*Little v Stuyvesant Life Ins. Co. (1977) 67 CalApp.3d 451, 469, fn. 5 [136 Cal.Rptr. 653]*) Plaintiff's counsel purported to argue net income from the sales of the medium-sized components. [**26] Although the argument was superficial, there was no objection as to that portion of it. The issue is waived. (*Sabella v Southern Pac Co (1969) 70 Cal.2d 311, 318 [74 Cal.Rptr 534, 449 P.2d 750].)*

As to the objection as to the amount of gross sales, that figure was in evidence. Read in context, the gross sales amount was used in part to demonstrate to the jury that Richards was a sophisticated company and that when it made its marketing decision to conceal its product defect from its salesmen and the physicians who were to implant it, it should be held responsible for its actions. The gross sales figure was also used to bolster the amount of punitive damages claimed. However, there was no objection to this line of argument; the only objection made was to the use of the gross sales amount in the first context.

Evidence of gross sales figures are relevant, even if entitled to less weight than net profit. See, for example, *Neal v Farmers Ins. Exchange, supra, 21 Cal.3d 910* which stated at page 929: "Finally, we note that the amount of punitive damages represented by the reduced judgment (i.e., approximately $ 740,000) represents less than one-tenth of 1[**27] percent of defendant's gross assets . . ." (Italics added.) And see *Wyatt v Union Mortgage Co. (1979) 24 Cal.3d 773 [157 Cal.Rptr 392, 598 P.2d 45]* which referred to the amount of late charge income of the defendants, without mention of what net income such charges generated.

Even in cases in which other evidence of net wealth appeared in the record, courts have indicated that figures on gross sales, gross income, or gross wealth are at least relevant to the issue of punitive damages. (See, e.g., *Pistorius v Prudential Insurance Co. (1981) 123 CalApp.3d 541, 554-555 [176 Cal.Rptr 660]* [gross assets]; *Schomer v Smidt (1980) 113 Cal.App.3d 828, 836 [170 [*968] Cal.Rptr 662]* [affirming award of about 25 percent of the defendant's gross salary]; *Toole v Richardson-Merrell Inc (1967) 251 Cal App 2d 689, 700, 701 [60 Cal Rptr 398, 29 A.L.R.3d 988]* [biggest drug in the defendant's history; gross sales]; *Armstrong v Republic Rity Mtg Corp. (8th Cir. 1980) 631 F2d 1344, 1353* [gross annual income]; *Sturm, Ruger & Co., Inc v Day (Alaska 1979) 594 P.2d 38, 47, fn. 15* [gross wealth].)

We conclude that[**28] to the extent the issue was preserved for appeal, there was no prejudicial misconduct.

Ratio Between Punitive and Compensatory Damages

The jury's award of $ 500,000 in punitive damages represents a ratio of 20:1 between punitive and compensatory damages. Richards does not argue that such a ratio is disproportionate in punitive damage cases generally -- indeed it cannot. It limits its argument to products liability actions, and contends that in the special circumstances of such litigation, the ratio is too high. It states that no punitive/compensatory ratio in a products case has ever exceeded 2:1 in California or 7:1 in any jurisdiction.

Products liability cases may be distinguished from typical punitive damage cases in several respects. The definition of proscribed conduct is malice, which may be established if the defendant acted with a [***229] "conscious disregard for the safety of others." A manufac-

143 Cal. App. 3d 952, *968; 1983 Cal. App. LEXIS 1832, **28;
192 Cal. Rptr. 219, ***229; CCH Prod. Liab. Rep. P9707

turer designing a product must take trade-offs in terms of product safety against cost and utility A design engineer necessarily makes cost-benefit analyses many times in the production of a complex product. Such a definition of malice may operate unfairly in some cases, [**29] and may tend to discourage product development. However that consideration is of no moment here. Richards was not punished for a design decision; it had a well-designed product. Due to a manufacturing error the product did not fit the template for which it was made. Richards knew of this defect, but in order to protect its competitive position against other manufacturers of prosthetic devices, decided to continue to market the defective product anyway The public policy in favor of product development is unaffected by the award of punitive damages in this case.

Next it is argued that high ratios are improper in product cases because they run the risk of punishing the manufacturer several times for the same conduct. The argument is answered in *Grimshaw v. Ford Motor Co., supra, 119 Cal.App.3d 757, 812:* "We recognize the fact that multiplicity of awards may present a problem, but the mere possibility of a future award in a different case is not a ground for setting aside the award in this case . . . . If Ford should be confronted with the possibility of an award in another case for the same conduct, it may raise the issue in that case."

[*969] The suggestion in [**30] Grimshaw is similarly made in Restatement of Torts Second, section 908, comment e: "Another factor that may affect the amount of punitive damages is the existence of multiple claims by numerous persons affected by the wrongdoer's conduct. It seems appropriate to take into consideration both the punitive damages that have been awarded in prior suits and those that may be granted in the future, with greater weight being given to the prior awards."

We leave the problem to a court in which the problem is raised by proof of other litigation.

The requirement of a reasonable relationship between compensatory and punitive damages is a useful tool in guarding against juror excess. So applied in this case, the ratio of 20:1 is not too high. The actual damages were limited; Richards' conduct was egregious. A ratio of 20:1 would be excessive in a case like Grimshaw. It is appropriate here because the jury could logically determine that any less would not sufficiently punish and deter

Conclusion

The judgment is affirmed.

(Cite as: 59 F.3d 174, 1995 WL 383409 (9th Cir.(Hawai'i)))

NOTICE: THIS IS AN UNPUBLISHED OPINION.

(The Court's decision is referenced in a "Table of Decisions Without Reported Opinions" appearing in the Federal Reporter. Use FI CTA9 Rule 36-3 for rules regarding the citation of unpublished opinions.)

United States Court of Appeals, Ninth Circuit.

George ELBERT, Plaintiff-Appellant,
v.
HOWMEDICA, INC., A DIVISION OF PFIZER HOSPITAL PRODUCTS GROUP, INC.,
Defendant-
Appellee.

No. 94-15683.

Argued and Submitted May 3, 1995.
Decided June 28, 1995.

Appeal from the United States District Court, for the District of Hawaii, D.C. No. CV-91-00616-HMK; Barry M. Kurren, Magistrate Judge, Presiding.

D.Hawai'i

AFFIRMED IN PART, REVERSED IN PART, REMANDED.

Before: PREGERSON, KOZINSKI, and HAWKINS, Circuit Judges.

MEMORANDUM [FN*]

FN* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

**1 Following a jury verdict, the district court entered judgment of $196,775 for George Elbert against Howmedica, Inc. for damages caused by an allegedly defective prosthetic knee ("PCA knee") manufactured by Howmedica. We have jurisdiction under 28 U.S.C. § 1332 and 28 U.S.C. § 1291.

We affirm the decisions denying preemption, reconciling the jury's verdicts and protecting Howmedica's confidential documents. We conclude that the court erred in admitting certain expert testimony, and on that basis we reverse and remand.

The jury found that Howmedica was negligent and breached an implied warranty in its manufacture and sale of the PCA knee. But the jury found no strict liability.

Howmedica appeals the district court's verdict on three grounds. (1) the district court erred in admitting Kenneth Kayser's testimony regarding the PCA knee deterioration (delamination) and Howmedica's breach of due care in the manufacture and testing of the PCA knee; (2) Elbert's state law claims alleging negligence and breach of implied warranty were preempted by the Medical Device Amendments ("MDA") to the Food and Drug Administration regulations; and (3) the jury's findings of negligence and breach of implied warranty are not reconcilable with its finding against strict liability.

Elbert appeals the district court's denial of his motion to lift the pre-trial stipulated order protecting Howmedica's confidential documents. Elbert does not appeal the finding of no strict liability. The issue of strict liability, therefore, is not before the Court.

I

Elbert's expert in this case, Kenneth Kayser, was an electrical engineer who admitted to having no training or familiarity with prosthetic knee joints or their components prior to his enlistment as an expert witness. Having never before seen a PCA knee, Kayser drew his conclusions regarding Howmedica's manufacturing process and duty to test only from reviewing extracts of articles others had published. Kayser presented no evidence of his experience or qualifications regarding the specific subject areas in which he offered testimony. Yet Kayser's testimony was crucial to the issue of delamination, the critical flaw alleged in the PCA knee. Kayser was the only witness who offered testimony asserting that Howmedica could have known and should have

known its PCA knee would delaminate and thereby produce Eibert's injury.

The jury's award against Howmedica for negligence and breach of warranty, despite its finding of no strict liability, is strong evidence that Kayser's testimony was prejudicial. We find that the district court abused its discretion under Fed. R. Evid. 702 in permitting the jury to hear Kayser's opinions as to subject areas which were unequivocally outside any area of expertise he might have.

Accordingly, we reverse the district court's admission of Kayser's expert testimony.

II

**2 The district court properly considered the scope of the MDA's preemption clause in determining that Elbert's state law claims were not preempted by the MDA. 21 U.S.C. § 360k. The FDA clarified the MDA's preemption clause in its regulations: "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d) (1992). The FDA did not establish specific standards or requirements as to the class II device PCA knee implanted into Elbert with bone cement in 1986. See 21 C.F.R. § 888.3560. Thus we affirm the district court's finding that neither the MDA nor FDA regulations preempted Elbert's state tort actions.

III

The jury's verdicts were neither unreasonable nor irreconcilable. Negligent failure to warn and breach of implied warranty are causes of action distinct from an action for strict product liability.

The jury had a number of reasons to not find Howmedica strictly liable for the PCA knee failure. First, Howmedica's product was not abnormally hazardous, since it functioned well for Eibert over a period of years. Second, the PCA knee was unavoidably imperfect, as are all man-made joints. Third, the need for the PCA knee replacement outweighed the harm from the replacement's failure. Finally, Mr. Elbert was held to be partially at fault for pushing his joint beyond its mechanical endurance.

IV

Howmedica reasonably relied on the integrity of the court's protective order when it disclosed information under the initial discovery agreements. The district court did not abuse its discretion in refusing Elbert's request to modify a stipulated protective order for the apparent purpose of facilitating future actions against Howmedica.

We affirm the district court's denial of Elbert's motion to lift the protective order.

V

The judgment of the district court is AFFIRMED in part and REVERSED in part. We remand this case for further proceedings consistent with the views set forth above.

END OF DOCUMENT

662 N.E.2d 1248
Prod.Liab.Rep. (CCH) P 14,513
(Cite as: 169 Ill.2d 525, 662 N.E.2d 1248, 215 Ill.Dec. 108)

Supreme Court of Illinois.

Marilyn HAUDRICH, Ex'r and Sole Legatee of Donald Haudrich, Deceased, Appellee,
v
HOWMEDICA, INC., et al., Appellants.

No. 78319.

Jan. 18, 1996.
Rehearing Denied April 1, 1996.

Patient who had received implant of knee prosthesis which had failed and was replaced less than three years after implantation brought products liability action against manufacturer of device and its sales representative. The Circuit Court, St. Clair County, Robert L. Craig, J., entered judgment on jury verdict awarding patient $1,686,988.70 in damages. Manufacturer appealed, and the Appellate Court, 267 Ill.App.3d 630, 204 Ill.Dec. 744, 642 N.E.2d 206, affirmed. After appeal was allowed, the Supreme Court, Bilandic, C.J., held that: (1) issue of preemption of action under Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA) was in nature of affirmative defense and had been waived; (2) finding that prosthesis was unreasonably dangerous was supported by evidence; and (3) damages awarded did not constitute abuse of discretion.

Affirmed

Miller, J., concurred in part and dissented in part and filed opinion.

Heiple, J., dissented and filed opinion.

West Headnotes

[1] Appeal and Error ⚿169
30k169

Issues not raised in trial court are deemed waived and may not be raised for first time on appeal.

[2] Appeal and Error ⚿171(1)
30k171(1)

Theory upon which case is tried in lower court cannot be changed on review, and issue not presented to or considered by trial court cannot be raised for first time on review.

[3] Appeal and Error ⚿173(2)
30k173(2)

Issue of whether products liability action against manufacturer of knee prosthesis was preempted by Medical Device Amendments to MDA was waived, and could not be raised on appeal, where manufacturer did not raise issue in trial court; issue of preemption was not jurisdictional issue which could be considered at any time, but was in nature of affirmative defense which involved not choice of forum but rather whether state tort or federal statutory law was controlling, and was subject to traditional rules of appellate adjudication. Federal Food, Drug, and Cosmetic Act, § 521, as amended, 21 U.S.C.A. § 360k

[4] Products Liability ⚿10
313Ak10

[4] Products Liability ⚿11
313Ak11

Manufacturer has duty to use reasonable care in design and manufacture of its product, bearing in mind intended and actual uses of product.

[5] Products Liability ⚿8
313Ak8

In order for plaintiff to recover in strict liability, his injury must be shown to result from condition of product, condition must be unreasonably dangerous, and condition must have existed at time product left manufacturer's control.

[6] Products Liability ⚿8
313Ak8

Condition or defect in product is "unreasonably dangerous," and recovery based on strict liability may be permitted, if as result those exposed to product are as result subjected to unreasonable risk of harm beyond that which would be contemplated by ordinary person with ordinary knowledge common to community as to product's

characteristics.

[7] Evidence ⚿571(9)
157k571(9)

[7] Products Liability ⚿83
313Ak83

Finding that injuries of patient who received knee prosthesis were caused by unreasonably dangerous condition of prosthesis, allowing recovery based on strict liability in action against manufacturer, was supported by testimony of physician who performed implant that he believed prosthesis would last 10 years, by expert testimony that minimum life expectancy of prosthesis was 10 to 12 years, by evidence that prosthesis failed less than three years after it was implanted, and by testimony of both physician and expert that prosthesis failed to live up to intended function.

[8] Appeal and Error ⚿1013
30k1013

Rule that findings of trial court sitting without jury will not be disturbed unless manifestly erroneous is equally applicable to assessment of damages.

[9] Damages ⚿20
115k20

General rule of damages in tort action is that wrongdoer is liable for all injuries resulting directly from wrongful acts, provided that particular damages are legal and natural consequences of wrongful act imputed to defendant and are such as might reasonably have been anticipated; remote, contingent, or speculative damages do not fall within general rule.

[10] Damages ⚿191
115k191

Trial court did not abuse its discretion in awarding of $21,000 in medical expenses attributable to revision surgery, in which defective knee prosthesis was replaced, to recipient of prosthesis in products liability action against manufacturer; expert witness testified that had initial knee device lasted as long as anticipated, only one revision surgery would have been necessary in recipient's lifetime, and evidence indicated that multiple revision surgeries could have been required as initial prosthesis had failed in less than three years.

[11] Damages ⚿134(3)
115k134(3)

Trial court did not abuse its discretion in awarding lost wages of approximately $400,000 to patient who had received implant of defective knee prosthesis, which failed in less than three years and required additional surgery, in products liability action against manufacturer of prosthesis; patient at time of initial surgery was 46 years old and had been consistently employed in same job for almost 20 years, patient at time of surgery was earning $25,000 per year, and evidence indicated that nondefective knee prosthesis could last as long as 18 years.

[12] Damages ⚿132(6.1)
115k132(6.1)

[12] Damages ⚿135
115k135

Trial court did not abuse its discretion in awarding over $1.2 million in damages for pain and suffering, disability and disfigurement, and future medical expenses to patient who had received implant of defective knee prosthesis which failed in under three years and as result was required to undergo revision surgery; while failed device did not cause original knee injury, device was responsible for substantial portion of pain, suffering, disability, and disfigurement experienced by patient, patient endured significant degree of physical and mental suffering, and due to failure patient was more likely to have to undergo third surgery in his lifetime.

[13] Appeal and Error ⚿711
30k711

Contention by sales representative for manufacturer of knee prosthesis that Appellate Court erred in finding that argument that trial court's judgment against agent should be reversed based on insufficient evidence had been waived, based on contention that representative had sufficiently raised issue in brief to Appellate Court, was not considered by Supreme Court where record before Supreme Court did not contain representative's initial brief filed in Appellate Court

[14] Appeal and Error ⚖497(1)
30k497(1)

[14] Appeal and Error ⚖907(1)
30k907(1)

On review, appellant has burden of presenting court with adequate record regarding claimed error, and any doubts which may arise from incompleteness of record will be resolved against appellant.

**1250 ***110 *525 James V. O'Brien, Thomas L. Caradonna, Lewis, Rice & Fingersh, L.C., St. Louis, MO, for Howmedica Inc.

Thomas Q. Keefe, Jr., P.C., and Harriet Homsher Hamilton, of Cook, Shevlin, Ysursa, Brauer & Bartholomew, Ltd., Belleville, for appellee.

Stephanie A. Scharf and Deirdre A. Fox of Kirkland & Ellis, Chicago, for amici curiae Health Industry Manufacturers Association, Abbott Laboratories, and Baxter International Inc.

*529 Donnellda Rice, Washington, DC, for amicus curiae Health Industry Manufacturers Association.

Mark E. Barnak and Eric S. Palles, Abbott Park, for amicus curiae Abbott Laboratories.

F. Samuel Eberts III, Deerfield, for amicus curiae Baxter International Inc.

Chief Justice BILANDIC delivered the opinion of the court:

The plaintiff, Donald Haudrich, brought this action for strict products liability in the circuit court of St. Clair County against defendant Howmedica, Inc., and for negligence against codefendant, Michael Lukens, a Howmedica sales representative. The plaintiff sought damages for injuries allegedly caused by a defective prosthetic device that had been surgically inserted into his knee. The plaintiff alleged that Howmedica designed, manufactured and sold the device that, at the time it left Howmedica's possession and control, was defective and unreasonably dangerous. He further alleged that Lukens negligently and carelessly sold the defective device and negligently and carelessly failed to warn of the device's defective and unreasonably dangerous condition. Following a bench trial, the trial court entered a judgment against the defendants and awarded the plaintiff damages of $1,686,988.70. The appellate court affirmed. (267 Ill.App.3d 630, 204 Ill.Dec. 744, 642 N.E.2d 206.) We allowed the defendants' petition for leave to appeal. 145 Ill.2d R. 315. [FN1]

FN1. The plaintiff died during the pendency of this appeal, and his wife, Marilyn, was substituted as the plaintiff in this action. For simplicity's sake, all references to "the plaintiff" herein should be understood to mean the decedent.

The primary issue presented in this appeal is whether provisions of the United States Food, Drug, *530 and Cosmetic Act of 1938 (Act) (21 U.S.C. § 301 *et seq.* (1970)) preempt the plaintiff's State-law tort claims. Specifically, the defendants point to the Medical Device Amendments of 1976 (21 U.S.C. §§ 351 through 360 (1994)) as barring the plaintiff's claims. The appellate court rejected this contention, holding instead that the United States Congress did not intend to preempt common law tort actions by passing the Medical Device Amendments. The appellate court declined to address the plaintiff's argument that the defendants waived the issue of preemption by failing to raise it in the trial court.

The defendants also contend that the evidence was insufficient to prove that the plaintiff was injured by an unreasonably dangerous condition of the knee device, that the award of damages was excessive, and that **1251 ***111 the appellate court erred in finding that they waived the issue of whether Lukens' negligence had been sufficiently proved.

FACTS

In 1983, the plaintiff sustained a work-related injury to his left knee and subsequently underwent a series of treatments to improve his condition. When these treatments failed, the plaintiff opted for a total knee replacement. The plaintiff's treating physician, Dr. William Simmons, selected the "PCA Total Knee System" manufactured by Howmedica. This device received premarket approval by the Federal Food and Drug Administration in September 1988, three years after the plaintiff's surgery.

The surgery was performed in November 1985. The plaintiff was allowed to return to work one year later. Approximately 2 1/2 years after the surgery, the plaintiff complained to Dr. Simmons of

"popping" inside his knee joint. In May 1988, the plaintiff began complaining of pain, swelling and instability in his knee. A few months *531 later, the plaintiff felt something snap inside the back of his knee, and shortly thereafter, the decision was made to replace the prosthetic knee device. At the time the initial surgery was performed, Dr. Simmons had informed the plaintiff that the knee prosthesis would last approximately 10 years, give or take two years, and that it would eventually need to be replaced. Charles Lawyer, Howmedica's director of quality assurance, testified that he was unable to say how long the knee device should last, since its longevity depended on numerous factors. The prosthetic device implanted in the plaintiff's knee failed in less than three years.

The PCA Total Knee System is comprised of three components. The component at issue is comprised in part of a piece of polyethylene plastic which rests inside a metal tray and is situated on top of the shin bone. While performing the "revision" surgery in January 1989, Dr. Simmons discovered that the polyethylene piece attached to the first knee implant had "almost completely worn away," and he found "multiple shavings of this particular plastic" behind the plaintiff's knee joint. Dr. Simmons determined that the plastic piece had slipped from its original position, which explained the plaintiff's statement that something in the knee had "popped." At a deposition, Dr. Simmons testified that when he implanted the first device, he did not expect the plastic failure to occur. He had used the device in the past and had been satisfied with its performance. Based on his findings during the second surgery, Dr. Simmons opined that the first knee prosthesis failed to perform as reasonably intended, based on a reasonable degree of medical and scientific certainty. He could not identify anything in his surgical technique or in the plaintiff's physical makeup that could explain the device's failure. Although the plaintiff had a deformity in his legs which caused bowleggedness, this condition *532 did not contribute to the premature wear of the polyethylene piece. Dr. Simmons found no evidence that the plaintiff had abused the prosthesis.

The second knee replacement differed from the first in that the thickness of the polyethylene piece was nine millimeters as opposed to seven. Bone cement was also used to hold the second device in place whereas a cementless process was used to secure the first one. Dr. Simmons explained that the nine-millimeter model was available at the time of the initial surgery, but he opted for the thinner model because it required less of the plaintiff's bone to be removed, and Howmedica representatives advised that the thinner model be used to preserve bone mass. At that time, Howmedica had not yet recommended that doctors discontinue using the seven-millimeter model. Sometime after the initial surgery, Howmedica began advising doctors to use the thicker model because the other model was "perhaps a little too thin." Dr. Simmons criticized the seven-millimeter polyethylene as being too thin.

After the second surgery, the plaintiff was unable to return to work, and it was not anticipated that he would ever be able to do so. According to Dr. Simmons, the plaintiff continued to complain of pain in his knee even after the second surgery. At the time of trial in July 1992, the plaintiff complained of pain, stiffness, swelling and some instability of the knee. Dr. Simmons stated, however, **1252 ***112 that the plaintiff was "much better off" having had the second surgery.

Dr. Simmons explained, however, that with every successive knee replacement, the knee becomes more and more unstable. He stated that after a certain number of revisions, it becomes necessary to insert a prosthesis which locks together. After a third or fourth revision, the insertion of that type of prosthesis may have become necessary for the plaintiff. However, it *533 would not have become necessary if the plaintiff had needed only two surgeries in his lifetime, as Dr. Simmons had contemplated, given the plaintiff's age and the anticipated lifespan of the device. Dr. Simmons also noted that subsequent revision surgeries increase the risk of infections, nerve damage, and vessel injury and make rehabilitation more difficult. He added that the expected life of a revision implant tends to decrease as the number of revisions increases. At the time of trial in 1992, the cost of a revision surgery, according to Dr. Simmons, was between $25,000 and $30,000.

The plaintiff's expert witness, Roy D. Bloebaum, Ph.D., testified as to his expertise in the analysis of prosthetic devices. In the course of his research, he investigated a problem with respect to the premature wear of polyethylene in various prosthetic devices and co-authored numerous articles on the subject

Dr. Bloebaum testified that the minimum life expectancy of the PCA Total Knee System was 10 to 12 years, with 18 to 20 years not being unreasonable. Dr. Bloebaum cited one study which reported that 65% of knee devices which predated the PCA device survived 17 years. Dr. Bloebaum agreed that the survivability of a device depended on many factors, including the manner of use and the patient's weight. He saw nothing in the plaintiff's physical makeup that would have adversely affected the lifespan of the knee device. He did not criticize Howmedica's use of the polyethylene material since that was all that was available at the time the device was manufactured, but he did criticize the fact that the polyethylene was processed using heat, which made it susceptible to certain defects like pitting, scratching and "delamination," whereby the polyethylene breaks apart in layers. The specific design errors he noted in addition to the heat processing were concentrated stresses on the femoral component of the device which *534 fits over the polyethylene and the use of a polyethylene plastic piece that had an inadequate thickness. According to Dr. Bloebaum, these design characteristics lead to premature wear and failure of the device. He opined to a reasonable degree of scientific certainty that these characteristics caused the product to be unreasonably dangerous and defective. He eliminated misalignment in the plaintiff's case as a cause of the device's failure.

Defendants' expert, Dr. John Lyons, a specialist in total joint reconstruction, testified that the prosthesis was implanted at an excessive angle, which was the cause of the premature wear of the polyethylene plastic. He based this opinion on a review of post-operative X rays and on an analysis of the knee device that was removed from the plaintiff's body. In Dr. Lyons' opinion, neither the thickness of the polyethylene insert nor the heat processing played any role in the failure of the plastic.

Stephen Hirsch, Howmedica's director of sales and formerly its director of marketing for reconstructive products, testified concerning a Howmedica publication entitled the "Polyethylene Awareness Series." The publication was undertaken because orthopedic surgeons were becoming "quite concerned" about premature wear of the polyethylene piece used in the knee device and about the increasing number of revision surgeries having to be performed. A Howmedica bulletin acknowledged that questions were being asked by orthopedic surgeons about implant design, insert thickness, contact stresses and material composition as they related to polyethylene wear. Through the "Awareness Series," Howmedica sought to determine if premature wear could result from a design which subjected the polyethylene plastic to contact stresses, from an insert that was too thin, or from the heat processing method Howmedica used. Hirsch concluded they were all factors but added *535 that there were other factors which could also explain the premature wear of the polyethylene piece. Howmedica ultimately determined, at some point after the plaintiff's first surgery, that a **1253 ***113 seven-millimeter plastic piece was too thin and eventually advised doctors to stop using it. Hirsch agreed that if premature failure resulted from contact stresses, the use of heat to process the piece, and inadequate polyethylene thickness, the product would be considered unsafe.

Howmedica's vice president of product development, Peter Van Syckle, testified for the defendants that the design of the PCA Total Knee System was not defective. He acknowledged that the particular device implanted in the plaintiff's knee could have been defective and agreed that the polyethylene plastic failed. However, he stated that other factors besides those claimed by the plaintiff could have caused the failure. Van Syckle defined a defective product as one that does not perform in a "reasonably anticipated way" and acknowledged the testimony of Dr. Simmons, as the user of the device, that the product did not perform as reasonably anticipated.

ANALYSIS

A. Preemption

The defendants contend that section 360k of the Medical Device Amendments to the Act (21 U.S.C. § 360k (1994)) expressly preempts the plaintiff's State-law tort claims. As previously stated, the appellate court rejected this contention, concluding instead that Congress did not intend to preempt common law tort actions by enacting the Medical Device Amendments. The appellate court declined to address the plaintiff's claim that the defendants waived the issue of preemption by failing to raise it in the trial court. We, however, have decided to address the issue. For the reasons which follow, *536 we hold that the waiver doctrine should apply to the situation presented here.

[1][2] It is well settled that issues not raised in the trial court are deemed waived and may not be raised for the first time on appeal. (See *Daniels v. Anderson* (1994), 162 Ill.2d 47, 58-59, 204 Ill.Dec. 666, 642 N.E.2d 128; *Geise v. Phoenix Co. of Chicago, Inc.* (1994), 159 Ill.2d 507, 514-15, 203 Ill.Dec. 454, 639 N.E.2d 1273; *Lannom v. Kosco* (1994), 158 Ill.2d 535, 539-40, 199 Ill.Dec. 743, 634 N.E.2d 1097; *Mittelman v. Witous* (1989), 135 Ill.2d 220, 230, 142 Ill.Dec. 232, 552 N.E.2d 973.) In *Daniels*, this court reiterated that " 'the theory upon which a case is tried in the lower court cannot be changed on review, and * * * an issue not presented to or considered by the trial court cannot be raised for the first time on review.' " (*Daniels*, 162 Ill.2d at 58, 204 Ill.Dec. 666, 642 N.E.2d 128, quoting *Kravis v. Smith Marine, Inc.* (1975), 60 Ill.2d 141, 147, 324 N.E.2d 417.) We concluded that allowing the defendant to change his theory of defense on appeal would "not only weaken the adversarial process and our system of appellate jurisdiction" (*Daniels*, 162 Ill.2d at 59, 204 Ill.Dec. 666, 642 N.E.2d 128), but would likely prejudice the plaintiff, since he may have been able to present evidence to discredit the theory had it been raised in the evidence presentation stage, that is to say, in the trial court. *Daniels*, 162 Ill.2d at 59, 204 Ill.Dec. 666, 642 N.E.2d 128.

Similarly, in *Geise* this court concluded that the theory the defendant attempted to raise for the first time on appeal, which was based on a State statutory provision, was in the nature of an affirmative defense and, as such, was waived by not being presented initially in the trial court. (*Geise*, 159 Ill.2d at 514, 203 Ill.Dec. 454, 639 N.E.2d 1273.) In finding waiver, the court in *Geise* determined that the situation presented was not one in which "some basic legal impediment exist[ed] to a claim or defense on which the judgment [was] based," nor was it "a situation where a party need[ed] to be rescued from some inadvertent blunder it or its attorney made at trial." (*Geise*, 159 Ill.2d at 514, 203 Ill.Dec. 454, 639 N.E.2d 1273.) This court determined, rather, that the defendant *537 had made a purely strategic decision not to raise the statute-based theory at trial in the hope that the plaintiff's common law negligence claim would fail and it would escape liability entirely. The court emphasized that "our responsibilities as a court of review do not extend to protecting a party from its own failed trial strategy." *Geise*, 159 Ill.2d at 514-15, 203 Ill.Dec. 454, 639 N.E.2d 1273.

The defendants in this case argue, however, that the claim of preemption is not in the **1254 ***114 nature of an affirmative defense but is a jurisdictional matter which cannot be waived and which may be raised at any time. Specifically, they argue that section 360k of the Medical Device Amendments deprives State courts of jurisdiction to render judgments for damages based on State tort law for defective or unreasonably dangerous medical devices which have received premarket approval by the Food and Drug Administration. We reject this argument. Initially, we note that on at least one occasion, this court has recognized that a party's failure to invoke the Federal preemption doctrine in the trial court may preclude him from raising it on appeal. (See *Beckman v. Freeman United Coal Mining Co.* (1988), 123 Ill.2d 281, 286, 122 Ill.Dec. 805, 527 N.E.2d 303.) Moreover, we find the Supreme Court's decision in *International Longshoremen's Association v. Davis* (1986), 476 U.S. 380, 106 S.Ct. 1904, 90 L.Ed.2d 389, upon which the defendants primarily rely in support of their claim that the issue of Federal preemption is jurisdictional, to be inapposite to the case at bar.

Davis involved the application of the National Labor Relations Act (NLRA). There, the Supreme Court held that the appellant's preemption claim was not a waivable affirmative defense because the claim went to the trial court's power to adjudicate the case. In so ruling, the Court found that Congress had deprived courts of jurisdiction to decide cases involving conduct that is or may likely be protected by the NLRA, and it did so by *538 "vesting exclusive jurisdiction over [the] controversy in another body," namely, the National Labor Relations Board. (*Davis*, 476 U.S. at 388, 106 S.Ct. at 1910, 90 L.Ed.2d at 398.) The Court noted:

" 'Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. It went on to confide primary interpretation and application of its rules to *a specific and specially constituted tribunal* and prescribed a particular procedure for investigation, complaint and notice, and hearing and decision, including judicial relief pending a final administrative order.' " (Emphasis added.) (*Davis*, 476 U.S. at 389, 106 S.Ct. at 1911, 90 L.Ed.2d at 399, quoting *Garner v.*

Teamsters, Chauffeurs & Helpers Local Union No. 776 (1953), 346 U.S. 485, 490, 74 S.Ct. 161, 165-66, 98 L.Ed. 228, 239.)

The Court emphasized that it was "essential" to the administration of the NLRA that determinations with respect to activities within the purview of that statute " 'be left in the first instance to the National Labor Relations Board.' " *Davis*, 476 U.S. at 390, 106 S.Ct. at 1911, 90 L.Ed.2d at 400, quoting *San Diego Building Trades Council v. Garmon*, (1959), 359 U.S. 236, 244-45, 79 S.Ct. 773, 779, 3 L.Ed.2d 775, 783.

In short, the *Davis* Court determined that the issue on review was not whether the State court erroneously decided a matter of Federal law in a case within its jurisdiction or whether Federal or State law governed a case properly before the State's courts. Rather, the situation involved a State court " 'finally and erroneously asserting its jurisdiction to deal with a controversy which [was] beyond its power and instead [was] within the exclusive domain of the National Labor Relations Board.' " (*Davis*, 476 U.S. at 390-91, 106 S.Ct. at 1912, 90 L.Ed.2d at 400, quoting *Local No. 438 v. Curry* (1963), 371 U.S. 542, 548, 83 S.Ct. 531, 536, 9 L.Ed.2d 514, 519.) In other words, the Court noted, the issue was a choice-of-forum rather than a choice- of-law question. *Davis*, 476 U.S. at 391, 106 S.Ct. at 1912, 90 L.Ed.2d at 401.

[3] *539 In the present case, however, unlike in *Davis*, Congress has not designated another forum for the resolution of disputes concerning medical devices. Although Congress has enacted a body of substantive law dealing with such devices, it has not " 'confide[d] primary interpretation and application of its rules to a specific and specially constituted tribunal.' " (*Davis*, 476 U.S. at 389, 106 S.Ct. at 1911, 90 L.Ed.2d at 399, quoting *Garner v. Teamsters* (1953), 346 U.S. 485, 490, 74 S.Ct. 161, 165-66, 98 L.Ed. 228, 239.) Thus, the issue here does not involve a choice of forum but instead concerns whether State tort or Federal statutory law controls. Under these circumstances, the issue of preemption is not jurisdictional but is in the nature of an affirmative defense, subject to the traditional **1255 ***114 rules of appellate adjudication, including timely presentment of issues and waiver.

Under circumstances virtually identical to those presented here, the First Circuit Court of Appeals, in *Violette v. Smith & Nephew Dyonics, Inc.* (1st Cir.1995), 62 F.3d 8, applied the waiver rule where the defendant failed to argue at trial the issue of preemption over State products liability claims pursuant to the Medical Device Amendments. The court held that the defendant would not be permitted to " 'evade the scrutiny of the [trial] court * * * on appeal with a new claim in order to create essentially a new trial.' " (*Violette*, 62 F.3d at 11, quoting *G.D. v. Westmoreland School District* (1st Cir.1991), 930 F.2d 942, 950.) We concur in this view. Moreover, we have found several appellate court decisions of this State and numerous Federal court decisions to be in accord with this approach as well. (See, *e.g., Zook v. Norfolk & Western Ry. Co.* (1994), 268 Ill.App.3d 157, 164, 205 Ill.Dec. 231, 642 N.E.2d 1348; *Yates v. Doctor's Associates, Inc.* (1990), 193 Ill.App.3d 431, 438, 140 Ill.Dec. 359, 549 N.E.2d 1010. See also *Piekarski v. Home Owners Savings, F.S.B.* (8th Cir.1992), 956 F.2d 1484, 1489. *Sweeney v. Westvaco Co.* (1st Cir.1991), 926 F.2d 29, 36-41; *Dueringer v. General American Life Insurance Co.* (5th Cir.1988), 842 F.2d 127, 130. *Johnson v. Armored Transport of California, Inc.* (9th Cir.1987), 813 F.2d 1041, 1043-44. *Gilchrist v. Jim Stemons Imports, Inc.* (9th Cir.1986), 803 F.2d 1488, 1496-97.) *540 Neither the plaintiff nor the trial judge in this case had his "rightful opportunity to address the question in the first instance" (*Violette*, 62 F.3d at 11), and for this reason we hold that the issue of preemption is waived. We thus save for another day the question of whether the Medical Device Amendments to the Act, and specifically section 360k, preempt the sort of State-law tort claims raised by the plaintiff here.

We turn now to the remaining issues the defendants raise on appeal.

B. Sufficiency of the Evidence

The defendants first contend that there was insufficient evidence to support a finding that the plaintiff was injured by an unreasonably dangerous condition of the knee device.

[4][5][6] It is axiomatic that a manufacturer has a duty to use reasonable care in the design and manufacture of its product, bearing in mind the intended and actual uses of the product. (*Buehler v.*

Whalen (1977), 70 Ill.2d 51, 60-61, 15 Ill.Dec. 852, 374 N.E.2d 460.) In order for a plaintiff to recover in strict liability, his injury must be shown to result from a condition of the product, the condition must be unreasonably dangerous, and the condition must have existed at the time the product left the manufacturer's control. (*Hunt v. Blasius* (1978), 74 Ill.2d 203, 210, 23 Ill.Dec. 574, 384 N.E.2d 368.) In an attempt to once again define the term "unreasonably dangerous condition," the court in *Hunt* agreed that " 'those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected *541 in light of their nature and intended function.' " (*Hunt*, 74 Ill.2d at 211, 23 Ill.Dec. 574, 384 N.E.2d 368, quoting *Dunham v. Vaughan & Bushnell Manufacturing Co.* (1969), 42 Ill.2d 339, 342, 247 N.E.2d 401.) The court went on to find that a condition or defect in a product is unreasonably dangerous if it subjects those exposed to the product to an unreasonable risk of harm beyond that which would be contemplated by the ordinary person with ordinary knowledge common to the community as to the product's characteristics. *Hunt*, 74 Ill.2d at 211-12, 23 Ill.Dec. 574, 384 N.E.2d 368, citing Restatement (Second) of Torts § 402A, Comment i (1965). See also *West v. Deere & Co.* (1991), 145 Ill.2d 177, 180, 164 Ill.Dec. 122, 582 N.E.2d 685.

[7] Applying the foregoing principles to the present case, we hold that sufficient evidence was presented at trial to find Howmedica strictly liable for the plaintiff's injuries.

Dr. Simmons testified that, based on information he received from Howmedica representatives at seminars and based on his background and experience, he believed the plaintiff's knee replacement would last 10 years, give or take two years. The plaintiff's expert witness, Dr. Bloebaum, testified at trial that the minimum life expectancy of the Howmedica device was 10 to 12 years, and **1256 ***116 that it was not unreasonable to expect it to last 18 to 20 years. Although both doctors agreed that numerous factors dictated the survivability of the device, neither found that the plaintiff's physical makeup, his physical activities or the placement of the device in the plaintiff's body was a factor leading to the premature failure of the polyethylene insert after less than three years. Both doctors opined that the device failed to live up to its intended function, based on a reasonable degree of medical and scientific certainty, primarily because of the inadequate thickness of the polyethylene insert, which Howmedica itself later recognized.

Dr. Bloebaum's examination of the device at issue *542 revealed delamination, or separation of the polyethylene, as well as pitting and scratching, which he testified were consistent with a design that uses a heat-pressing technique. While he had no quarrel with Howmedica's use of the polyethylene material, he testified that the defects apparent in the device were magnified by the combination of heat pressing, the inadequacy of the plastic's thickness, and contact stresses. Dr. Bloebaum opined that the device was defective and unreasonably dangerous on these bases.

Although Howmedica's vice president of product development, Van Syckle, testified that the design of the knee device was not defective, he acknowledged that the polyethylene insert failed and agreed that the device implanted in the plaintiff's knee could have been defective. He also agreed that the company's manufacturing technique using heat may have contributed to accelerated wear of the polyethylene but disagreed that the thickness of the plastic was a factor. Howmedica's expert, Dr. Lyons, opined that Dr. Simmons' misalignment of the device in the plaintiff's body and the plaintiff's activities after surgery were the causes of the device's failure. Dr. Lyons agreed that all of the radiologist's reports indicated that the device was in excellent alignment, but he nevertheless concluded that Dr. Simmons' failure to comply with appropriate medical standards led to its premature failure.

Despite the testimony of Howmedica's experts to the contrary, sufficient evidence was presented to support a finding that the device failed to perform in a manner reasonably expected in light of its nature and intended function and subjected the plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person. We conclude that the plaintiff met his burden of proving that his injuries resulted from an unreasonably dangerous condition of the Howmedica knee device.

*543 C. Damages

The defendants also contend that the damages

award totaling $1,686,988.70 was excessive.

[8][9] The rule that findings of a trial court sitting without a jury will not be disturbed unless manifestly erroneous is equally applicable to an assessment of damages. (*Lynch v. Precision Machine Shop, Ltd.* (1982), 93 Ill.2d 266, 278, 66 Ill.Dec. 643, 443 N.E.2d 569.) The general rule of damages in a tort action is that "the wrongdoer is liable for all injuries resulting directly from the wrongful acts * * *, provided the particular damages are the legal and natural consequences of the wrongful act imputed to the defendant, and are such as might reasonably have been anticipated. Remote, contingent, or speculative damages do not fall within this general rule." *Siemieniec v. Lutheran General Hospital* (1987), 117 Ill.2d 230, 259, 111 Ill.Dec. 302, 512 N.E.2d 691.

[10] Regarding medical expenses, Howmedica argues that the $21,000 attributable to the revision surgery was nonrecoverable because the evidence undisputedly reveals that the plaintiff would have had to undergo another revision surgery at some point. Dr. Simmons testified, however, that, had the initial knee device lasted as long as anticipated--approximately 10 years according to Simmons and as long as 18 years according to Dr. Blochaum--only one revision surgery would have been necessary in the plaintiff's lifetime. Because the first device failed in less than three years, the evidence reveals that multiple revision surgeries might have been necessary. The trial court was well within its discretion to compensate the plaintiff for the expense of an additional **1257 ***117 revision he would not otherwise have had to face had the initial device not failed.

[11] We likewise conclude that it was within the trial court's discretion to award the plaintiff lost wages of approximately $400,000. The evidence indicates that, at the time of the initial surgery, the plaintiff was 46 years old and had been consistently employed in the same job *544 for nearly 20 years prior to that. There was no evidence presented that the plaintiff would not have worked to retirement age had he been able to do so. At the time of the surgery, the plaintiff was earning $25,000 per year. As previously stated, the plaintiff presented evidence demonstrating that a nondefective knee device could last as long as 18 years. In light of this evidence, the trial court could well have concluded that the plaintiff lost 16 years of income by having to undergo revision surgery several years sooner than anticipated. We do not believe an award of $400,000 for lost wages was manifestly erroneous.

[12] The remainder of the damages award was for the plaintiff's pain and suffering, disability and disfigurement, and future medical expenses. The dissent contends that the amounts awarded for pain and suffering and for disability and disfigurement are "grossly excessive" and should be reduced. While it is unclear from the record precisely how much of the $1.69 million award the trial court allocated to these two categories of damages, the dissent estimates that it was between $1 million and $1.2 million. Even if that is the case, we do not agree that such an award is "grossly excessive." To the contrary, we believe the damages awarded are amply supported by the evidence.

While we are cognizant of the fact that the failed device did not *cause* the plaintiff's original knee injury, we nevertheless find that it was responsible for a substantial portion of the pain, suffering, disability and disfigurement the plaintiff experienced from the spring of 1988, when the device failed, onward. As the evidence reveals, both the plaintiff and his doctor fully anticipated that the plaintiff would be able to return to work following the initial knee surgery. He, in fact, did so one year later. After the device failed, however, the plaintiff was unable ever to return to the job he had performed for *545 nearly 20 years or to any other job, and his activity level outside of work was also severely curtailed. Had the device functioned as intended, the plaintiff could have lived at least five and as many as 15 or 16 years longer, according to Dr. Simunacis, without the disability and disfigurement which flowed from the device's failure. We hold that the trial court did not manifestly err in awarding the damages it did for the plaintiff's disability and disfigurement.

Moreover, ample evidence was presented at trial showing that the plaintiff endured a significant degree of physical and mental suffering beginning as early as 2 1/2 years after the initial surgery, when his knee began to pop and swell and become unstable. To alleviate these symptoms, the premature revision surgery had to be performed. However, that surgery was unsuccessful in eliminating the physical problems which occurred

when the first device failed. In fact, at the time of trial, which followed four years after the second surgery, the plaintiff still complained of pain, stiffness, swelling and instability in his knee. While we agree with defendants that pain, swelling and other physical signs leading to the necessity for revision knee surgery occur regardless of *when* a device wears out, the fact is that the revision surgery in this case was forced to occur several years earlier than it should have been, causing the plaintiff to experience unanticipated suffering during a time in which the initial knee device should have improved his condition. Moreover, while we acknowledge Dr. Simmons' testimony that the plaintiff was better off having had the second surgery, it is difficult to imagine how he would not have been, given that the failure of the first device led to popping and snapping inside his knee joint and caused a significant amount of pain, swelling, and instability in his knee.

Moreover, the evidence shows that, because of the *546 premature failure of the knee device, the plaintiff in all likelihood would have had to undergo an additional surgery in his lifetime that would have been avoided had the initial knee device functioned for as long as expected. Apart from the physical pain another surgery would bring, Dr. Simmons **1258 ***118 testified, a third surgery would have caused the plaintiff's knee to become even more unstable and would have exposed the plaintiff to further risks of infections, nerve damage, and vessel injury.

This court has held in the past that a damages award for pain and suffering is proper where there is evidence of a physical injury. (See *Ballweg v. City of Springfield* (1986), 114 Ill.2d 107, 116, 102 Ill.Dec. 360, 499 N.E.2d 1373.) In light of the consequences flowing from the premature failure of the Howmedica knee device, as discussed above, we uphold the award of damages for the plaintiff's pain and suffering.

D. Lukens' Liability

[13][14] Finally, the defendants contend that the appellate court erred in finding that they waived their argument that the trial court's judgment against Lukens should be reversed based on insufficient evidence. The appellate court applied the waiver rule after determining that the defendants failed to raise the issue regarding Lukens' liability in its initial brief. The defendants maintain that the issue was sufficiently raised in their brief. We are unable to determine the propriety of the appellate court's ruling on this issue, however, because the defendants have failed to support their argument with adequate proof. Specifically, the record before us does not contain the defendants' initial brief filed in the appellate court. On review the appellant has the burden of presenting the court with an adequate record regarding the claimed error (*Holston v. Sisters of the Third Order of St. Francis* (1995), 165 Ill.2d 150, 163, 209 Ill.Dec. 12, 650 N.E.2d 985), and any doubts which may arise from the incompleteness of the *547 record will be resolved against the appellant (*Foutch v. O'Bryant* (1984), 99 Ill.2d 389, 391-92, 76 Ill.Dec. 823, 459 N.E.2d 958). In the absence of the proof necessary to resolve the issue, we must presume that the appellate court's determination was proper.

CONCLUSION

For the foregoing reasons, the judgment of the appellate court is affirmed.

Affirmed.

HARRISON, J., took no part in the consideration or decision of this case.

Justice MILLER, concurring in part and dissenting in part:

I agree with the majority's holdings that defendant Howmedica, Inc., waived its preemption defense and, further, that there was sufficient evidence to find Howmedica strictly liable for the plaintiff's injuries. I do not agree, however, with the majority's conclusion that the amount of damages awarded in this case is supported by the record.

In closing argument, plaintiff's counsel requested a damage award ranging between $1.6 million and $1.8 million, divided among the following: $200,000 for past and future medical expenses, $400,000 for past and future lost wages, $500,000 to $600,000 for pain and suffering, and $500,000 to $600,000 for disability and disfigurement. The trial judge apparently agreed with counsel's itemization, for, in a bench proceeding without a jury, the Judge awarded nearly $1,690,000 in damages, a sum that approximates plaintiff's request.

I believe that the amount of damages awarded by the trial judge is against the manifest weight of the evidence. In upholding the present award, the appellate court concluded, from the testimony of the plaintiff's *548 own doctor, that the plaintiff might have lost seven years of employment as a consequence of the premature failure of the prosthesis at issue here. The plaintiff earned approximately $25,000 a year from his employment as a truck driver and laborer, so the amount of lost income according to his best estimate, even without discounting it to present value, would have been about $175,000, far less than the $400,000 urged by counsel.

An award of $200,000 for past and future medical expenses similarly lacks support in the record. The estimated expenses of a revision surgery are about $30,000. Although the premature failure of the plaintiff's prosthesis could necessitate earlier replacements in future years, a sum as large as $200,000 for medical expenses is at best speculative under the facts in this case.

Finally, one must question an award totaling more than $1 million for pain and suffering **1259 ***119 and disability and disfigurement. Plaintiff is entitled to be compensated only for the injuries attributable to the premature failure of the prosthesis involved here. Even if one allows that the failure of the device would accelerate the normal replacement schedule, I fail to see how the pain and discomfort, or disability and disfigurement, from the added procedures caused by that can justify an award of more than $1 million, the amount apparently determined here. For these reasons, I believe that the award of damages in this case is not supported by the record, and I would remand the action to the circuit court for further proceedings on this issue.

Justice HEIPLE, dissenting:

"Little Jack Horner

Sat in the corner,
Eating a Christmas pie;
He put in his thumb, And he took out a plum,
And said, 'What a good boy am I!' "

*549 Plaintiff sought damages against defendants, Howmedica and its sales representative, for injuries caused by the premature failure of the artificial knee manufactured by Howmedica. Defendants argued that provisions of the United States Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. § 301 *et seq.* (1970)) preempted plaintiff's State-law tort claim. The majority determined, and I concur, that defendants waived their preemption argument by failing to raise it in the trial court.

I disagree, however, with the court's affirmance of the damage award. In truth, the damages awarded to plaintiff by the trial court are grossly excessive and should be reduced.

Plaintiff, then age 45, injured his knee at work in 1983. After other treatment options failed, plaintiff decided to undergo total knee replacement. In 1985, Howmedica's artificial knee was implanted and plaintiff's doctor related his hope that it would last 8 to 12 years. About three years later, however, plaintiff's Howmedica knee failed and it was successfully replaced with another Howmedica artificial knee. Plaintiff then brought a products liability suit against Howmedica and a negligence suit against Howmedica's sales representative. After a bench trial, plaintiff was awarded damages of $1,686,988.70.

To award such an excessive sum, the trial court either forgot or did not care that plaintiff's knee was not injured by defendants' device, but had been damaged years earlier in a work-related injury. The only valid complaint against defendants is that the artificial knee wore out sooner than the parties had hoped.

In closing argument, plaintiff argued that a proper damage award was $1.6 to 1.8 million, apportioned as: $200,000 for past and future medical expenses; $400,000 for past and future lost wages; $500,000 to $600,000 for *550 pain and suffering; and $500,000 to $600,000 for disability and disfigurement. Since the trial court awarded almost $1.69 million, an amount in the range suggested by plaintiff, it may be assumed that the individual awards were broken down as plaintiff suggested.

PAIN AND SUFFERING

The trial court awarded plaintiff over $500,000 for pain and suffering. Since defendant's device did not cause plaintiff's original knee injury, plaintiff is

entitled to pain and suffering damages only for affliction caused by the premature failure of defendant's device. At the time of trial, plaintiff's knee revision was doing fine and he was on no prescription pain medication. In addition, he had not seen the doctor in the 18 months prior to trial, other than during a routine yearly check-up. Such evidence does not support a damage award in excess of half a million dollars for pain and suffering.

DISABILITY AND DISFIGUREMENT

Plaintiff received more than $500,000 for disability and disfigurement. As stated above, plaintiff is entitled to damages only for the disability and disfigurement that resulted from the premature failure of defendant's device.

After plaintiff's initial knee injury at work, he was disabled from many activities. Once his knee was replaced by the Howmedica knee, plaintiff was able to be more active, but was still restricted from heavy lifting. At **1260 that time, plaintiff's doctor rated him as having a 50% disability for purposes of worker's compensation.

Following failure of the Howmedica knee and the necessary revision surgery, plaintiff suffered from various disabilities, including limitations on boating, golf, and gardening. However, plaintiff is not entitled to damages for these restrictions because they existed prior to the implantation of the Howmedica knee and were not *551 caused by its premature failure. Indeed, plaintiff's doctor testified that plaintiff was better off after surgery than if he had never had knee replacement surgery.

Once again, this court refuses to rein in the riverboat gambling atmosphere that characterizes the Illinois tort system. See *Lee v. Chicago Transit Authority* (1992), 152 Ill.2d 432, 480, 178 Ill.Dec. 699, 605 N.E.2d 493 (Heiple, J., dissenting) ("While the courts could order remittitur in an appropriate case such as [this], they have shown no willingness to do so").

Justice demands that plaintiff's damages should be subject to a substantial remittitur. Accordingly, I respectfully dissent.

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65 USLW 2760, Prod Liab.Rep. (CCH) P 14,912,97 CJ C.A.R. 560
(Cite as: 111 F.3d 782)

United States Court of Appeals,
Tenth Circuit.

Maureen G. OJA, Plaintiff--Appellee/ Cross--Appellant,
v.
HOWMEDICA, INC., a Delaware corporation, Defendant--Appellant/ Cross--Appellee.
Product Liability Advisory Council, Inc.; Health Industry Manufacturers Association; Association of Trial Lawyers of America, Amici Curiae.

Nos. 95-1085, 95-1104, 95-1123.

April 16, 1997.

Recipient of hip prosthesis brought products liability action against manufacturer, in which negligence, negligent failure to warn, and strict liability claims were asserted. After motion for summary judgment based on preemption was denied, the United States District Court for the District of Colorado, Jim R. Carrigan, J., 848 F. Supp. 905, granted motion for directed verdict on strict liability manufacturing defect claim, and entered judgment on jury verdict for manufacturer on remaining strict liability claims and for recipient on negligent failure to warn claim. Appeals were taken, and the Court of Appeals, Tacha, Circuit Judge, held that: (1) negligent failure to warn claim was not preempted by Medical Device Amendments (MDA); (2) jury verdicts on strict liability and negligent failure to warn claims were facially inconsistent; and (3) issue of whether prosthesis contained manufacturing defect for which manufacturer could be held strictly liable was for jury.

Affirmed in part, vacated in part, reversed in part, and remanded.

West Headnotes

[1] Drugs and Narcotics ⇨ 11
138k11

[1] States ⇨ 18.65
360k18.65

Two-prong inquiry is applied in determining preemptive scope of Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA); first, federal requirement must be applicable to device in question, or other words, federal requirement will preempt state law only if specific to particular device, and second, state requirement must be with respect to medical device and must be different from, or in addition to federal requirement; accordingly, state regulations of general applicability are not preempted except where they have effect of establishing substantive requirement of specific device. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a); 21 C.F.R. § 808.1.

[2] Products Liability ⇨ 46
313Ak46

[2] States ⇨ 18.65
360k18.65

Food and Drug Administration (FDA) did not impose specific warning requirements applicable to prosthetic hip in connection with its approval of hip, and thus, state law negligent failure to warn claim against hip manufacturer was not preempted under Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA); general labeling requirement imposed by FDA did not establish substantive requirement for specific device, as required for preemption to occur. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a).

[3] Products Liability ⇨ 46
313Ak46

[3] States ⇨ 18.65
360k18.65

Duties imposed by state law negligent failure to warn claim asserted against manufacturer of prosthetic hip were not positive enactments

of law sufficient to constitute state requirement developed with respect to medical device, as would allow preemption to occur under Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA), and thus, even assuming that letter voluntarily sent to physicians by manufacturer of prosthetic hip constituted requirement imposed by Food and Drug Administration (FDA), letter did not preempt action. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k(a).

[4] Federal Courts ⇐ **635**
170Bk635

Party's failure to object to general jury verdict on ground of inconsistency before jury is discharged constitutes waiver, unless verdict is inconsistent on its face such that entry of judgment upon verdict is plain error.

[5] Federal Courts ⇐ **635**
170Bk635

Defendant had meaningful opportunity to object to general jury verdict on ground of inconsistency before jury was discharged, and thus, defendant's failure to do so constituted waiver of objection to verdict unless verdict was facially inconsistent, even though verdict had been returned at 5:00 P.M. on night before Thanksgiving and court had then read verdict, polled jury, entered judgment, and excused jurors; defendant was given opportunity to object to any inconsistencies, and had objected to at least one aspect of verdict before leaving courtroom.

[6] Federal Civil Procedure ⇐ **2197**
170Ak2197

Verdict that resolves separate and distinct causes of action in favor of both parties is not inconsistent on its face.

[7] Federal Civil Procedure ⇐ **2197**
170Ak2197

When several causes of action are identical and defended on same ground, verdict for plaintiff on one cause of action and for defendant on another is inconsistent.

[8] Products Liability ⇐ **14**
313Ak14

Under Colorado law, negligence theory requires plaintiff to prove that manufacturer's failure to warn of risk fell below acceptable standard of care, but under strict liability theory, focus of inquiry is whether defendant failed to warn of particular risks that were known or knowable in light of generally recognized and prevailing scientific and technical knowledge available at time of manufacture and distribution.

[9] Products Liability ⇐ **14**
313Ak14

Under Colorado law, rigid distinction is not drawn between negligence and strict liability failure to warn concepts; as with all tort claims, plaintiff must prove elements of causation and damages, and critical area of overlap is that regardless of whether action is grounded in negligence or strict liability, plaintiff must prove that product was defective at time of sale.

[10] Products Liability ⇐ **71**
313Ak71

Under Colorado law, jury verdicts in favor of manufacturer of prosthetic hip on strict liability claim asserted by recipient of hip, and in favor of recipient on negligent failure to warn claim, were facially inconsistent and warranted new trial; to find for recipient on negligent failure to warn claim, jury was required to find that hip was defective at time of sale and caused injuries, but to find for manufacturer on strict liability claim, jury had to find that hip was either not defective or did not cause injuries.

[11] Federal Courts ⇐ **776**
170Bk776

Court of appeals reviews district court's grant of directed verdict de novo, applying same standard used by district court.

[12] Federal Civil Procedure ⇨ 2127
170Ak2127

Directed verdict is appropriate only if evidence, viewed in the light most favorable to nonmoving party, points but one way and is susceptible to no reasonable inferences supporting nonmoving party; however, mere scintilla of evidence is insufficient to create jury question and defeat motion for directed verdict.

[13] Federal Courts ⇨ 416
170Bk416

[13] Federal Courts ⇨ 420
170Bk420

While federal law dictates whether directed verdict is appropriate, in diversity action court examines evidence in terms of underlying burden of proof as dictated by state law.

[14] Products Liability ⇨ 87.1
313Ak87.1

To avoid a directed verdict in strict liability action brought under Colorado law, plaintiff must offer proof of each element set forth in Restatement (Second) of Torts sufficient to create issue of fact; in particular, plaintiff must offer sufficient evidence that product at issue was in defective condition unreasonably dangerous at time the product was sold to plaintiff. Restatement (Second) of Torts § 402A.

[15] Products Liability ⇨ 5
313Ak5

Under Colorado law, claim of defect in strict liability action brought under Restatement (Second) of Torts can be premised on manufacturing, design, or warning defect. Restatement (Second) of Torts § 402A.

[16] Products Liability ⇨ 8
313Ak8

Under Colorado law, question in manufacturing defect cases brought under strict liability provision of Restatement (Second) of Torts is whether product as produced conformed with manufacturer's specifications. Restatement (Second) of Torts § 402A.

[17] Products Liability ⇨ 82.1
313Ak82.1

Under Colorado law, plaintiff may prove manufacturing defect, for purposes of strict liability claim under Restatement (Second) of Torts, by direct or circumstantial evidence. Restatement (Second) of Torts § 402A.

[18] Products Liability ⇨ 88
313Ak88

Issue of whether prosthetic hip implant which patient received suffered from manufacturing defect was for jury in strict liability action brought under Colorado law against implant's manufacturer; staking peg in implant was completely missing after implant was removed, and manufacturer had received product experience reports indicating that problems with inadequate staking were not infrequent during early production of implant and that problems could have been caused by inadequate testing and inspection in manufacturing process. Restatement (Second) of Torts § 402A.

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Manufacturers Association, Washington, DC, for amicus curiae Health Industry Manufacturers Association.

Pamela A. Liapakis, President, Association of Trial Lawyers of America, Washington, DC and Jeffrey Robert White, Washington, DC, for amicus curiae Association of Trial Lawyers of America.

Before TACHA, BRISCOE, and MURPHY, Circuit Judges.

TACHA, Circuit Judge.

Maureen Oja brought a products liability action against Howmedica, Inc., the manufacturer of a prosthetic hip replacement system, asserting three claims relevant to this appeal: (1) negligence, (2) negligent failure to warn, and (3) strict liability. At the close of the plaintiff's case, the district court granted *785 Howmedica's motion for a directed verdict on Oja's strict liability manufacturing defect claim. The court, however, permitted Oja to proceed with her strict liability claims based on design and warning defects.

The jury returned a general verdict for Howmedica on the negligence and remaining strict liability claims. The jury, however, found for Oja on her negligent failure to warn claim. The jury awarded Oja $896,921 in compensatory and $896,921 in punitive damages. The district court reduced the damage award to $448,460.50 and $612,535.96, respectively, and awarded Oja prejudgment interest from the date the action accrued.

On appeal, Howmedica argues that: (1) the Medical Device Amendments of 1976 ("MDA") preempts Oja's negligent failure to warn claim; (2) the jury's finding of negligent failure to warn is inconsistent with its verdict for Howmedica on the strict liability and negligence claims; (3) the district court erred in submitting both a "negligence" and "negligent failure to warn" claim to the jury without properly instructing the jury about the elements and burdens of proof on each claim; and (4) punitive damages cannot be awarded as a matter of law because the evidence was insufficient to show that Howmedica acted wantonly or recklessly.

In her cross-appeal, Oja raises two issues. Oja argues that the district court erred in (1) dismissing her strict liability claim based on a manufacturing defect and (2) awarding her prejudgment interest from the date that her action "accrued" as defined by the relevant statute of limitations rather than the date of her injury.

We exercise jurisdiction pursuant to 28 U.S.C. § 1291. For the reasons set forth below, we affirm the district court's ruling that the MDA does not preempt Oja's negligent failure to warn claim. We reverse and remand for a new trial, however, because we conclude that the jury's finding of negligent failure to warn is irreconcilably inconsistent with its verdict for Howmedica on the strict liability claim. We also reverse the district court's order granting a directed verdict for Howmedica on the strict liability manufacturing defect claim. Because we remand for a new trial, we do not address the remaining issues on appeal.

BACKGROUND

The Porous-Coated Anatomic One-Piece Acetabular Component hip ("PCA hip") consists of three components: (1) a metal stem that is inserted into the central canal of the patient's large upper leg bone, (2) a cup that is inserted into the patient's hip socket, and (3) a rounded metal femoral head that is rigidly attached to the top of the metal stem and is fitted into the cup. The cup is composed of an outer metal shell and an inner polyethylene liner. The liner attaches to the metal shell by an integral staking peg projecting from the back of the liner through a hole in the metal shell. An "anti-rotation lug" prevents the liner from rotating in the metal shell. Unless the liner is prevented from rotating, the liner will wear and shed microscopic debris. Such debris may cause a patient to suffer from severe bone dissolution or "osteolysis."

On July 2, 1984, Oja underwent surgery to replace her existing artificial hip with a PCA

hip. Her orthopedic surgeon, Dr. McElhinney, implanted the PCA hip without using cement because he had concluded that Oja's existing bone structure provided little area for cement fixation.

By early 1992, Oja began experiencing severe pain in her hip in the area of her PCA hip implant. Dr. Richard Evans, an orthopedic surgeon, recommended immediate surgery. On July 29, 1992, he removed the PCA hip. The surgery revealed that the staking peg was missing, that the polyethylene liner had completely disengaged from the metal cup, and that debris had spread into Oja's hip joint. Moreover, osteolysis had left large defects in Oja's hip, especially in the area of the hole in the cup. On April 21, 1993, Oja filed this products liability suit against Howmedica.

DISCUSSION

I. PREEMPTION OF OJA'S NEGLIGENT FAILURE TO WARN CLAIM

a. Overview of the Medical Device Amendments

Howmedica argues that the MDA preempts Oja's negligent failure to warn *786 claim. [FN1] Because Congress's intent is the "ultimate touchstone" in every preemption case, *see Retail Clerks Int'l Ass'n v. Schermerhorn*, 375 U.S. 96, 103, 84 S.Ct. 219, 223, 11 L.Ed.2d 179 (1963), we begin our preemption analysis by outlining the purposes and statutory framework of the MDA.

FN1. Prior to trial, Howmedica moved for summary judgment, claiming that *all* of Oja's state law claims were preempted by the MDA. The district court denied Howmedica's motion and its motion for reconsideration. At the close of the evidence, Howmedica moved for a directed verdict on *all* of Oja's state law claims based on MDA preemption. The district court denied the motion.
After the jury returned its verdict, Howmedica renewed its motion for judgment as a matter of law, arguing *only* that the MDA preempted Oja's negligent failure to warn claim. The district court denied the motion. On appeal, Howmedica again argues *only* that the MDA preempts Oja's negligent failure to warn claim. Thus, we do not address whether the MDA preempts any of Oja's other state law claims. *See State Farm Fire & Cas. Co. v. Mhoon*, 31 F.3d 979, 984 n. 7 (10th Cir.1994) (holding that the failure to raise an issue in the opening brief waives the issue).

In 1976, Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Pub.L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA classifies medical devices into three categories (classes I, II and III) based on the amount of risk they pose to the public. Class I devices are subject only to "general controls" because they pose little threat to public health and safety. 21 U.S.C. § 360c(a)(1)(A). Class II devices are subject to special controls because "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(B). Class III devices are subject to the most stringent MDA controls because they present "a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

The MDA automatically classifies a device as a class III device unless the device fits within one of three exceptions listed. First, a device placed in commercial distribution prior to May 28, 1976, avoids class III status through a grandfathering provision. 21 U.S.C. § 360c(f)(1)(A)(i)(I). Second, a post-1976 device may escape classification as a class III device if the FDA has reclassified the device as a class I or II device. 21 U.S.C. § 360c(f)(1)(A)(i)(II); 21 U.S.C. § 360c(f)(1)(B). Finally, a device may avoid class III device status if it is "substantially equivalent" to a grandfathered device or a post-1976 device that the FDA has classified as a class I or II device. 21 U.S.C. § 360c(f)(1)(A)(ii).

Manufacturers intending to market any new medical device must submit a premarket notification to the FDA. 21 U.S.C. § 360(k). In addition to the premarket notification (also known as the "§ 510(k) process"), Class III devices must undergo a comprehensive premarket approval ("PMA") process before marketing. 21 U.S.C. § 360e. The purpose of the PMA is to provide the FDA with

"reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2).

While the MDA contemplates that most Class III devices will reach the market only through the PMA process, a manufacturer may obtain market approval through any of three alternative processes. First, the MDA contains a grandfathering provision which allows pre-1976 devices to remain on the market without FDA approval until the FDA completes the PMA. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Second, the MDA contains an investigational device exemption ("IDE") for new devices under clinical investigation to determine their safety or effectiveness. *See* 21 U.S.C. § 360i(g). In order to foster the development of useful devices, IDE procedures allow manufacturers to begin limited marketing of new devices without undergoing the rigorous PMA process. 21 U.S.C. § 360j(g)(1). Finally, a Class III device may reach the market without undergoing the PMA procedures if the FDA determines, on the basis of the § 510 process, that the device is "substantially equivalent" to a device already on the market. 21 U.S.C. § 360e(b)(1)(B).

b. Regulation of the PCA Hip Under the MDA

On April 25, 1983, Howmedica filed a premarket notification submission with the *787 FDA, seeking permission to market the PCA hip under the § 510(k) process. The application included sample labels, a description of the intended use, a description of the product (dimensions, materials, processing, and sterilization procedures), photographs of the components, engineering drawings, and a description of test results. During the next few months, the FDA requested that Howmedica submit additional testing information and certification that the PCA hip would be used only with cement. Howmedica complied with each of these requests.

On August 10, 1983, the FDA granted Howmedica permission to market the PCA hip for use with bone cement pursuant to the § 510(k) process "subject to the general controls provision of the Federal Food, Drug & Cosmetic Act." The FDA also imposed several specific limitations on Howmedica: (1) the PCA hip could not be labeled or promoted for non-cemented use, (2) the PCA hip could only be used with low-viscosity cement, and (3) fixation of the PCA hip without cement would be considered an investigational procedure requiring an IDE.

On October 18, 1983, Howmedica submitted an IDE application in order to conduct a clinical study of the PCA hip when used without cement. [FN2] Over the course of the next year, Howmedica submitted annual studies, comparative control groups, and other information to the FDA. On December 12, 1984, the FDA authorized Howmedica to conduct the clinical investigation. After that date, the PCA could be used without cement in an experimental context, with a patient's full informed consent

FN2. Oja underwent her PCA hip surgery on July 2, 1984, when Howmedica's IDE application was pending. Thus, at the time of Oja's surgery, Howmedica had not yet received an IDE for cementless use. This distinguishes our case from *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir.1997) and *Berish v. Richards Med Co.*, 937 F.Supp. 181 (N.D.N.Y.1996).

On September 4, 1987, the FDA issued its final rule classifying the PCA hip as a class II medical device when used with cement. 52 Fed.Reg. 33686, 33707 (codified at 21 C.F.R. § 888.3350). At that time, the FDA had determined that classification as a class III device was "not necessary to provide reasonable assurance of the safety and effectiveness of the device." 21 C.F.R. § 860.93.

On October 26, 1989, following the clinical investigation of the PCA hip, Howmedica filed a request for a PMA to market the PCA hip when used without cement. The FDA issued a conditional approval letter on April 2, 1991. The FDA conditioned final approval upon: (1) deleting one word from the proposed labeling, (2) providing an update of the clinical

database, and (3) complying with future requirements, such as the summation of long-term survivorship data.

In 1991, the FDA inspected and cited Howmedica for several regulatory violations, including the failure to report information that the PCA hip had caused serious injury in patients. In response, Howmedica informed the FDA that it would "voluntarily" issue a "Dear Doctor" letter to surgeons using the device, instructing them on the proper surgical techniques to avoid damage to the polyethylene liner of the cup. The FDA indicated that it had "no adverse comments" about the content of the letter.

On February 21, 1992, the FDA reclassified the PCA hip when used without cement from a class III device to a class II device. *See* 58 Fed.Reg. 3227 (Jan. 8, 1993). Howmedica therefore invoked the § 510(k) process (rather than the more rigorous PMA) to obtain authorization to market the PCA hip without cement. On June 10, 1992, the FDA granted Howmedica permission to market the PCA hip when used without cement under the premarket notification procedure. On January 8, 1993, the FDA published its final rule classifying the PCA hip as a class II medical device when used without cement. 58 Fed.Reg. 3227, 3228 (codified at 21 C.F.R. § 888.3358)

c. MDA Preemption Analysis in *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the Supreme Court addressed whether the MDA's general labeling regulations preempted a state law negligent failure to warn claim for injuries suffered by the recipient of a *788 pacemaker, a class III device. [FN3] *Id.* at----, 116 S.Ct. at 2256-58. The regulations require manufacturers of every medical device, with a few limited exceptions, to label the device with "information for use, ... any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c).

FN3 In a five to four decision, the Court held that the MDA did not preempt any of the plaintiffs' common law claims. Justice Stevens authored the plurality opinion, which Justices Kennedy, Souter, and Ginsburg joined in its entirety. Justice Breyer, who concurred in the judgment, joined in Parts I, II, III, V, and VII of the plurality opinion. Thus, only those five sections constitute the opinion of the Court.

The Court began its preemption analysis by looking to the text of the MDA's preemption provision (21 U.S.C. § 360k) and the FDA's regulation interpreting that provision (21 C.F.R. § 808.1(d)):

§ 360k State and local requirements respecting devices
(a) General Rule
Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
§ 808.1 Scope
(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act, thereby making any existing divergent state or local requirements applicable to the device different from or in addition to, the specific Food and Drug Administration requirements.

Medtronic 518 U.S. at ---- - ----, 116 S.Ct. at 2256-58. The Court concluded that the statute and regulation evinced "an overarching concern that pre-emption occurs only where a particular state requirement threatens to interfere with a particular federal interest." *Id* at----, 116 S.Ct. at 2257.

[1] Based on the MDA's statutory language and the FDA's regulation, the Court

developed a two-prong inquiry to determine the preemptive scope of the MDA. *Id.* First, a federal requirement must be "applicable to the device" in question. *Id.* at ----, 116 S.Ct. at 2257 (quoting 21 U.S.C. § 360k). In other words, a federal requirement will preempt state law only if "specific" to a "particular device." *Id.* (quoting 21 C.F.R. § 808.1(d)). Second, a state requirement must be "with respect to" a medical device and must be "different from, or in addition to" a federal requirement. *Id.* (quoting 21 U.S.C. § 360k). Accordingly, "[s]tate regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.' *Id.* (quoting 21 C.F.R. § 808.1(d)(1)).

Applying the two-prong test, the Court concluded that the MDA's labeling regulations did not preempt the plaintiffs' negligent failure to warn claim. First, the Court found no preemption because the federal labeling regulations reflected "important but entirely generic concerns about device regulation generally." *Id.* at ----, 116 S.Ct. at 2258. Second, the Court concluded that the negligent failure to warn claim also escaped preemption because its "generality leaves [it] outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Id.*

d. Application of *Medtronic*

[2] In its supplemental brief Howmedica argues that the FDA imposed two warning requirements sufficient to preempt Oja's negligent failure to warn claim. [FN4] Howmedica *789 points to the FDA's regulation of the PCA hip in 1983 and in 1991. With respect to Howmedica's dealings with the FDA in 1983, Howmedica alleges:

> FN4. Prior to the Supreme Court's decision in *Medtronic*, Howmedica argued that several FDA "requirements" would preempt Oja's negligent failure to warn claim. The Supreme Court rejected most of these grounds in *Medtronic*. Accordingly, in Howmedica's supplemental brief filed after *Medtronic*, Howmedica limited its preemption argument to the only viable grounds remaining, namely the FDA's dealings with Howmedica in 1983 and 1991. Thus, we address only these grounds.

> In 1983, when first deciding whether to allow Howmedica to begin marketing the PCA hip, the FDA four times required Howmedica to submit more testing, information, and certifications ... and then required Howmedica to add, to all labeling and promotional materials for that specific device, specific warning statements that the device be used only with bone cement, not cementless.... The warnings specifically required by the FDA did not include any of the warnings that Oja asked the jury to impose under Colorado tort law.
>
> Appl't. Supp. Brief at 4 (citations omitted).

Under the *Medtronic* two-pronged preemption test, we must first determine whether the FDA imposed any specific federal warning requirement applicable to the PCA hip in its 1983 dealings with Howmedica. The record indicates that the FDA imposed only one labeling requirement on Howmedica: the FDA stated that Howmedica could not label or promote the PCA hip for non-cemented use. This mandate constitutes a specific federal requirement applicable to the PCA hip, but that does not end our preemption inquiry. Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. *Medtronic*, 518 U.S. at ----, 116 S.Ct. at 2258. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Id.* Moreover, Howmedica's general duty to warn users of potential dangers in this case does not have "the effect of establishing a substantive requirement for a specific device." *Id.* at ----, 116 S.Ct. at 2257. Thus, the standard of care governing Oja's negligent failure to warn claim is not the type of device-specific requirement that would threaten the MDA's federal interests. *See id.* at ----, 116 S.Ct. at 2258. Accordingly, we find no preemption

based on Howmedica's dealings with the FDA in 1983.

[3] Similarly, we find no preemption based on the FDA's regulation of the PCA hip in 1991. Howmedica alleges:

> In 1991 the FDA specifically scrutinized Howmedica's internal documents regarding reported problems with the PCA hip, reexamined Howmedica's medical device reports pertaining to the PCA hip (including reports relied on by Oja at trial as evidence of the need for additional warnings), reexamined Howmedica's labeling and warning materials, and imposed device-specific requirements for specific additional labeling and warnings. The warnings required by the FDA did not include any of the warnings that Oja asked the jury to require under Colorado tort law...

Applt. Supp. Brief at 3-4 (citations omitted). First, we note that any FDA requirement imposed in 1991 would have no preemptive effect as to Howmedica's pre-1991 post-sale duty to warn. Second, the record is not clear that the 1991 "voluntary" Dear Doctor letter even constituted an MDA "requirement" at all. We need not resolve this question, however, because assuming *arguendo* that the warnings contained in the letter were specific federal requirements, we find no preemption under the second prong of the analysis employed in *Medtronic*. As with the 1983 claims, the duties imposed by Oja's negligent failure to warn claim do not constitute positive enactments of state law sufficient to constitute a state requirement developed "with respect to" a medical device. The Court in *Medtronic* made clear that the general duty to warn of foreseeable dangers is "not the kind[ ] of requirement[ ] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Medtronic*, 518 U.S. at ----, 116 S.Ct. at 2258. Accordingly, we affirm the district court's ruling that the MDA does not preempt Oja's negligent failure to warn claim.

*790 II. INCONSISTENT JURY VERDICTS

a. Waiver

[4] Howmedica next contends that we should vacate the judgment entered on the jury verdict in favor of Oja on her negligent failure to warn claim because it is irreconcilably inconsistent with the jury verdict in favor of Howmedica on Oja's strict liability claims. As a preliminary matter, we must determine whether we may review this issue. A party's failure to object to a general jury verdict on the ground of inconsistency before the jury is discharged constitutes waiver, unless the verdict is inconsistent on its face such that entry of judgment upon the verdict is plain error *Hinds v General Motors Corp.*, 988 F.2d 1039, 1047 (10th Cir.1993) (citing *Diamond Shamrock Corp. v. Zinke & Trumbo, Ltd.*, 791 F.2d 1416, 1424 (10th Cir.1986)).

[5] In this case, the parties do not dispute that the verdict forms required the jury to return a general verdict. The jury reached a verdict at 5:00 pm on the night before Thanksgiving. The court then read the verdict, polled the jury, entered judgment, and excused the jurors. Howmedica relies on *Jarvis v. Commercial Union Assurance Cos.*, 823 F.2d 392, 393 (10th Cir.1987), to support its position that under these circumstances, Howmedica had no "meaningful opportunity" to object to the verdict and therefore its failure to object should not constitute waiver. In *Jarvis*, the jury returned a verdict and special interrogatory answers that the trial judge recognized as arguably inconsistent. *Id.* at 394. In open court, the judge asked the jury to review its verdict and answers to determine if the jury marked the forms as intended. *Id* After further deliberations, the jury sent the judge a note stating that the forms were correctly marked and that "if there is a conflict with the Special Interrogatory form and the Verdict Forms, we will need a description of this conflict." *Id* at 395. The court informed the parties of the jury's note and explained:

> I wanted to inquire if there was an inconsistency in the jury's mind. They are saying that there is none, so I am going to bring them in and publish the verdict.

Id. at 394. Accordingly, the judge read the verdict, polled the jury, entered judgment, and discharged the jury. *Id.* We held that "it would be a perverse default of justice to say that under the circumstances present here, counsel had waived the right to correct an onerous inconsistency in the jury's resolution of his client's case only because he did not raise an objection." *Id.* at 396.

We find Howmedica's reliance on *Jarvis* misplaced. In *Jarvis*, "the court summarily declared the conflict resolved and proceeded with entry of the verdict." *Id.* Under such circumstances, an objection to the verdict as inconsistent would have been frivolous in light of the trial court's disposition of the issue. In contrast to *Jarvis*, the trial court in this case did not raise and decide the issue *sua sponte* before discharging the jury. Instead, the record indicates that Howmedica had the opportunity to object to any inconsistencies in the verdict prior to the jury's discharge or immediately thereafter. In fact, Howmedica's counsel objected to at least one aspect of the verdict before leaving the courtroom. The attorney stated, "I think there are some problems with the verdict in that there are--seems to me the punitive damages are above the compensatory." Howmedica could have made similar objection to the verdict being inconsistent or complained that the trial court discharged the jury before Howmedica could make such an objection. Howmedica did not do this. Under such circumstances, we hold that Howmedica has waived its right to object to the verdict unless it is "inconsistent on its face such that entry of judgment upon the verdict is plain error." *Hinds*, 988 F.2d at 1047.

b. Facial Inconsistency

[6][7] "A verdict that resolves separate and distinct causes of action in favor of both parties is not inconsistent on its face." *Harris Mkt. Research v. Marshall Mktg. & Communications, Inc.*, 948 F.2d 1518, 1522 (10th Cir.1991). In contrast, when "several causes of action are identical and defended on the same ground, a verdict for the plaintiff on one cause of action and for the defendant on *791 another is inconsistent." *Diamond Shamrock Corp.*, 791 F.2d at 1425.

[8][9] To determine whether the verdicts in this case are irreconcilably inconsistent, we must examine the relationship between strict liability and negligence under Colorado law. In *Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1174 (Colo.1993) (en banc), the Supreme Court of Colorado stated:

> Under a negligence theory a plaintiff is required to prove that a manufacturer's failure to warn of a risk fell below an acceptable standard of care. Under a strict liability theory, however, the focus of the inquiry is whether the defendant failed to warn of particular risks that were known or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution.

Despite the theoretical differences noted in *Fibreboard Corp.*, we have recognized that Colorado has not drawn a "rigid distinction between negligence and strict liability failure to warn concepts." *Romero v. International Harvester Co.*, 979 F.2d 1444, 1452 (10th Cir.1992). For example, as with all tort claims, the plaintiff must prove the elements of causation and damages. More importantly, "[o]ne critical area of overlap is that, '[r]egardless of whether a product liability action is grounded in negligence or strict liability, a plaintiff must prove that the product was defective.' " *Perlmutter v. United States Gypsum Co.*, 54 F.3d 659, 663 (10th Cir.1995) (quoting *Mile Hi Concrete Inc. v. Matz*, 842 P.2d 198, 205 (Colo.1992)). Under either theory, the product must have been defective at the time of sale. *See Perlmutter v. United States Gypsum Co.*, 4 F.3d 864, 869 (10th Cir.1993) (holding that in a negligence claim, there is "no post-sale duty to warn or remedy when the product was non-defective under standards existing at the time of manufacture"); *Fibreboard Corp.*, 845 P.2d at 1175 (stating that "[i]n [strict liability] failure-to-warn cases, a product is not defective and unreasonably dangerous if a particular risk is not known or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time

of manufacture and distribution").

[10] In this case, the elements of defectiveness and causation were common to all of Oja's claims. The record on appeal reveals that these two elements were essentially the only elements disputed at trial. To find for Oja on her negligent failure to warn claim, the jury had to find that the PCA hip was defective at the time of sale and caused her injuries. [FN5] To find for Howmedica on Oja's strict liability claim, the jury had to find that the PCA hip was either not defective at the time of sale or did not cause her injuries. [FN6] *792 Given these parameters, we hold that the verdict for Oja on her negligent failure to warn claim and the verdict for Howmedica on Oja's strict liability failure to warn claim were facially inconsistent. Accordingly, we vacate the judgment of the district court and order a new trial.

FN5. The jury instruction regarding Oja's negligent failure to warn claim stated:
If a product manufacturer knows, or in the exercise of reasonable care should know, that use of the product may be harmful or injurious to a user, and such risk of harm or injury is not obvious to a reasonable surgeon, then the manufacturer must use reasonable care to warn the surgeon of the risk of harm or injury if, and to the extent, and in the manner, a reasonably careful person would warn under the same or similar circumstances.
The duty to warn may extend beyond the time of sale of a product where a danger concerning the product becomes known to the manufacturer subsequent to the sale and delivery of the product, even though it was not known at the time of the sale.
A manufacturer has no duty to warn surgeons regarding its product after the product is sold unless you find that the product was defective and unreasonably dangerous as originally designed and sold. Where dangerous defects in design come to the manufacturer's attention after the device has been sold, the manufacturer has a duty to either remedy such defects, or, if such a complete remedy is not feasible, to give physicians adequate warnings and instructions concerning methods for minimizing danger and injury. Failure to do so is negligence.
A manufacturer has no duty to warn surgeons using a product about a newly developed safety device if the product was not defective under standards existing at the time the product was manufactured.
Whether or not the PCA hip was defective as originally sold should be determined by the standard set forth in these instructions of the plaintiff's claim for sale of a defective product.
Here, too, if the defendant had a duty to warn, it would be a duty to warn members of the medical profession, including the plaintiff's surgeons.

FN6. With respect to the strict liability for failure to warn claim, the jury instructions stated in relevant part:
For the plaintiff, Ms. Oja, to recover from the defendant, Howmedica, on her claim for sale of a defective product, you must find that all of the following facts have been proved by a preponderance of the evidence:
(1) The PCA hip was defective and, because of one or more defects, it was unreasonably dangerous to a person who might reasonably be expected to use it or be affected by it; (2) The PCA hip was defective at the time it was sold by the defendant or left its control;
(3) Plaintiff incurred injuries, damages or losses, and
(4) The defect in the PCA hip was a cause of the plaintiff's injuries, damages or losses.

III. DIRECTED VERDICT ON THE MANUFACTURING DEFECT CLAIM

In her cross-appeal, Oja argues that the district court erred in directing a verdict for Howmedica on Oja's manufacturing defect claim. The district court concluded that Oja had failed to present any evidence to support a jury finding that the PCA hip contained a manufacturing defect. Instead, the court found that Oja had presented evidence sufficient only to permit a jury to find that the PCA hip suffered from a design defect.

[11][12][13] We review the district court's grant of a directed verdict de novo, applying the same standard used by the district court. *Knight v. Snap-On Tools Corp.*, 3 F.3d 1398, 1401 (10th Cir.1993). "A directed verdict is appropriate only if the evidence, viewed in the light most favorable to the nonmoving party, 'points but one way and is susceptible to no reasonable inferences supporting' the nonmoving party." *Id.* (internal citations

omitted). "However, a mere scintilla of evidence is insufficient to create a jury question." *Honce v. Vigil*, 1 F.3d 1085, 1088 (10th Cir.1993). Although federal law dictates whether a directed verdict is appropriate, in a diversity action we examine the evidence in terms of the underlying burden of proof as dictated by state law. *Mason v. Texaco, Inc.*, 948 F.2d 1546, 1554 (10th Cir.1991).

[14][15][16] In *Hügel v. General Motors Corp.*, 190 Colo. 57, 544 P.2d 983, 988 (1975), the Supreme Court of Colorado expressly adopted the doctrine of strict liability in tort for selling a product in a "defective condition unreasonably dangerous to the user or consumer" as stated in section 402A of the Restatement (Second) of Torts. To avoid a directed verdict in a strict liability action brought under Colorado law, a plaintiff must offer proof of each element set forth in section 402A sufficient to creare an issue of fact. *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 125 n. 12 (Colo.1983). In particular, a plaintiff must offer sufficient evidence that the product at issue was in a "defective condition unreasonably dangerous" at the time the product was sold to the plaintiff. *White v. Caterpillar, Inc.*, 867 P.2d 100, 104-05 (Colo.Ct.App.1993). A claim of defect can be premised on a manufacturing, design, or warning defect. *Id.* at 105. "The question in manufacturing defect cases is whether the product as produced conformed with the manufacturer's specifications." *Camacho v. Honda Motor Co.*, 741 P.2d 1240, 1247 (Colo.1987). A defect in manufacturing usually occurs because of insufficient quality control. *See, e.g.*, LEWIS BASS, PRODUCTS LIABILITY: DESIGN AND MANUFACTURING DEFECTS, § 4.07, at 57 (1986).

[17][18] Under Colorado law, a plaintiff may prove a manufacturing defect by direct or circumstantial evidence. *See Union Ins. Co. v. RCA Corp.*, 724 P.2d 80, 82-83 (Colo.Ct.App.1986). In this case, the staking peg was completely missing when Dr. Evans removed Oja's PCA hip. Under such conditions, direct proof of a defect in the staking peg was impossible *See id.* at 83. Accordingly, Oja relied exclusively on circumstantial evidence to support her manufacturing defect claim.

Oja's surgeon testified that he made only a visual check for improper staking before implanting the PCA hip. Her expert concluded that although the surgeon saw no noticeable defect in the device, the PCA hip could still have suffered from an internal manufacturing defect in the staking peg. To support her claim, Oja introduced evidence that *793 Howmedica received at least two product experience reports ("PERs") describing instances in which surgeons discovered a staking problem only after implanting the PCA hip and performing a trial reduction.

In addition to those two PERs, Oja submitted six other PERs describing inadequate staking in PCA hips manufactured near the time Howmedica manufactured Oja's PCA hip. In particular, Howmedica received a PER on February 1, 1984, that stated:

Nature of Complaint [By Surgeon]: Please replace to my stock--no charge-- while dislocating the hip during a trial reduction in surgery the plastic core came out of metal backing.

Results of Evaluation [By Howmedica Employee]: The assembly staking on above part was inadequate. We have established a push test & careful visual inspection (100%) on PCA acetabular cup assemblies which should preclude such failures.

Similarly, Howmedica received a PER on August 27, 1984, that stated:

Nature of Complaint [By Surgeon]: Customer complains that the HDP is not close enough in the metal part.

Results of Evaluation [By Howmedica Employee]: As received the fit of the insert to the cup was excellent but the stake holding the components together was poor. This part was of very early production (Oct. 1983) and the staking process still required improvement. The process has been improved and we have also added a "push test" to the stake to assure adequate assembly.

Finally, Oja submitted evidence indicating that Howmedica rejected one of the PCA hips from the same lot as Oja's PCA hip because of a staking problem. The remaining devices in her lot underwent a "tightness of plastic insert to cup VISUAL" test. Howmedica did not, however, conduct any other performance tests on the lot of PCA hips containing her hip. Oja claims the absence of adequate inspection and testing procedures increased the likelihood that her PCA hip suffered from a manufacturing defect.

We have carefully reviewed the record and conclude that Oja presented sufficient evidence from which a jury could reasonably conclude that Oja's PCA hip suffered from a manufacturing defect. The staking peg in Oja's PCA hip was completely missing. Within a year of the device's manufacture, Howmedica sent a number of other PCA hips to surgeons that did not "conform to [Howmedica's] specifications" because of inadequate staking. *See Camacho*, 741 P.2d at 1247. The PERs strongly suggest that problems with inadequate staking were not infrequent during early production of the PCA hip. More importantly, the PERs indicate that the problems could have been caused by inadequate testing and inspection in the manufacturing process, in addition to inadequate design. Under such circumstances, we hold that a jury could reasonably conclude that Oja's PCA hip suffered from a manufacturing defect.

CONCLUSION

We AFFIRM the district court's order finding that the MDA does not preempt Oja's negligent failure to warn claim. We VACATE the judgment entered on the jury's verdict and REMAND for a new trial because we hold that the jury's verdict for Howmedica on the strict liability failure to warn claim but against Howmedica on the negligent failure to warn claim are irreconcilably inconsistent. We also REVERSE the directed verdict for Howmedica on Oja's strict liability manufacturing defect claim. Because we remand for a new trial, we do not address the remaining issues presented on appeal.

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United States District Court, N.D. Texas, Dallas Division.

Tommy THOMPSON, Secretary of the United States, Department of Health & Human Services, Plaintiff
v
Stephen GOETZMANN, Bernice Loftin, and Zimmer, Inc., Defendant(s.

No. CIV.A.3:00-CV-2177-L.

July 3, 2001.

MEMORANDUM OPINION AND ORDER

LYNN, District J.

*1 Plaintiff ("the Government") sues the three Defendants for reimbursement of Medicare payments pursuant to 42 U.S.C. § 1395y(b)(2), the Medicare Secondary Payment ("MSP") statute, and also sues Defendant Zimmer, Inc. ("Zimmer") for double damages pursuant to 42 U.S.C. § 1395y(b)(3). Before the Court is Zimmer's Motion to Dismiss Pursuant to Rule 12(b)(6), filed on December 4, 2000, the brief in support of that motion and all responses and replies thereto.

Having considered the record, applicable law, and arguments of counsel presented in their briefs, for the reasons stated below, the Court GRANTS Zimmer's Motion to Dismiss.

I. Background

On June 16, 1993, Bernice Loftin ("Loftin") dislocated her hip while recovering from hip replacement surgery. Loftin underwent a second surgery; however, her hip became infected. Her physicians fought the infection with extensive procedures, the details of which are not relevant to the issues now before this Court. Medicare ultimately paid $143,881.82 for Loftin's medical costs related to the hip surgeries.

At some unspecified time, Loftin filed suit against various defendants, alleging their responsibility for her complications and prolonged treatment. One of these defendants was Zimmer, a pharmaceutical company that manufactures and sells orthopedic medical devices, including prosthetic hip joints.

In October 1997, Loftin's attorney, Stephen Goetzmann ("Goetzmann"), contacted the Health Care Financing Administration ("HCFA"), an agency of the United States Department of Health and Human Services which administers the Medicare program, and requested a waiver of its claim for reimbursement from Loftin. Goetzmann allegedly acknowledged the likelihood that Loftin would satisfy the amount owed to Medicare through any recovery from Zimmer. The HCFA denied Goetzmann's request. After receiving a partial payment from the insurer for one of the other alleged tortfeasors in Loftin's suit, and after negotiation with Goetzmann, the HCFA expected reimbursement for $95,117.17 from a settlement of Loftin's claims against Zimmer. However, the HCFA was not reimbursed, although Goetzmann and Loftin received, in December 1998, a settlement tender from Zimmer of $256,000. This suit was filed in October 2000.

II. Motion to Dismiss Standard

In considering Zimmer's 12(b)(6) Motion to Dismiss, this Court must accept all well-pleaded facts as true and view those facts in the light most favorable to the Government. *Campbell v. City of San Antonio*, 43 F.3d 973, 975 (5th Cir.1995). "[A] claim may not be dismissed unless it appears certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle him to relief." *Leffall v. Dallas Indep. Sch. Dist.*, 28 F.3d 521, 524 (5th Cir.1994). However, " 'the complaint must contain either direct allegations on every material point necessary to sustain a recovery ... or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial.' " *Campbell* 43 F.3d at 975 (citing 3 Wright & Miller, FEDERAL PRACTICE AND PROCEDURE: CIVIL 2d § 1216 at 156-59 (footnote omitted)).

III. Analysis

*2 Medicare, through the HCFA, is entitled to assert a direct action for reimbursement of payments made by it to a Medicare beneficiary, against a

primary payer, which, pursuant to a "primary plan," has paid or should have paid for the medical care in question. 42 U.S.C. § 1395y(b)(2)(B); 42 C.F.R. § 411.24(e). A "primary plan" is defined in the statute to include a "liability insurance policy or plan (including a self-insured plan) or no fault insurance ..." 42 U.S.C. § 1395y(2)(A). The Government here seeks to recover from Zimmer, asserting that Zimmer is a primary payer, responsible under a primary plan for Loftin's medical expenses, and that, therefore, it should have reimbursed Medicare, as a secondary payer, for $95,117.17 in net payments made by Medicare for Loftin.

The central questions here are whether, under any factual scenario, Zimmer is a primary payer, pursuant to a "primary plan," so that the Government is a secondary payer entitled to reimbursement under the MSP. The Government claims that because Zimmer has no liability insurance for products liability suits against it, it is a "self-insured plan." The applicable Regulations define such a plan as an "arrangement, oral or written ... to provide health benefits or medical care or [to] assume legal liability for injury or illness" under which an entity "carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.21 (definition of "plan") and § 411.50(b) (definition of "self insured"). The Government seems to suggest by its analysis that merely because an entity which supplies products does not have liability insurance, and in that sense is "self insured," it is a primary plan under the MSP. This Court disagrees with that analysis. For that status to exist, a more formal plan or arrangement, such as one by which the self insured entity reserves funds for losses and payments, would be required. Here, the Government pleads that Zimmer is self insured, but the details of what that means are not set out, presumably because the Government does not now know the details. The Court does not believe it appropriate to resolve the question of whether Zimmer is "self insured," in the sense that term is used in the MSP, on a Motion to Dismiss under FED. R. CIV. P. 12(b)(6). However, that issue notwithstanding, the Court concludes that Zimmer is not liable under the MSP to reimburse the Government in these circumstances.

Medicare is entitled to make a conditional payment to a Medicare beneficiary and then to seek reimbursement if payment "has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a ... liability insurance policy or plan (including a self insured plan) ..." 42 U.S.C. § 1395y(b)(2)(A)(ii). Such plans are defined as "primary plans." *Id.* In this case, when the Government paid for Loftin's care, Zimmer had not made payment, and such payment could not "reasonably be expected to be made promptly" (emphasis added). "Promptly" is defined by the applicable regulations as 120 days after the earlier of (1) the date a claim is filed with an insurer or a lien is filed against a potential liability settlement or (2) the date the service was furnished or, in the case of inpatient hospital services, the date of discharge. 42 C.F.R. § 411.50. In other words, Medicare is entitled to make a conditional payment, and to seek reimbursement from a self insured plan, if the self-insured plan was reasonably expected to make prompt payment. Given the allegations here, a belief that Zimmer, the supplier of prosthetic hip joints, could be expected to make prompt payment on a disputed claim with multiple defendants, could not be reasonably based. Such a prospect conceivably could be reasonable if liability were wholly uncontested, but no such contention is made here. Although hindsight is not dispositive of the issue, the Court observes that Zimmer's settlement with Loftin occurred more than five years after her injuries arose, and this is not atypical of the extended delay that often precedes resolution of such suits.

*3 To the extent the Government is attempting to use the MSP to obtain reimbursement from companies which have potential and contested products liability to Medicare beneficiaries, the Court is of the view that the MSP does not provide for it. Medicare's payment under such circumstances is not conditional, and the statute does not provide Medicare with a basis for reimbursement. *See Evanston Hosp. v. Hauck*, 1 F.3d 540, 544 (7th Cir.1993); *In re Diet Drugs (Phentermine Fenfluramine, Dexenfluramine) Prods. Liab. Litig.*, No. MDL 1203, Civ. A. 99-20593, 2001 WL 283163, at *10 (E.D.Pa. March 21, 2001).

There is nothing in the MSP that justifies interpreting it to reach contesting, but accused, tortfeasors. In that respect, the statute is to be distinguished from the Medical Care Recovery Act, 42 U.S.C. § 2651-2653, which specifically allows

the Government to recover from a tortfeasor. 42 U.S.C. § 2651(a).

IV. Conclusion

The Court concludes as a matter of law that Zimmer is not a primary payer under a primary plan and that the Government is not a secondary payer with respect to Zimmer under 42 U.S.C. §§ 1395y(b)(2), (3), and that Counts III and IV of the Government's First Amended Complaint thus should be, and hereby are, DISMISSED with prejudice under FED. R. CIV. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

SO ORDERED.

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LEVEL 1 - 29 OF 53 CASES

FLORIDA PATIENT'S COMPENSATION FUND, Appellant, v JOSEPH TILLMAN, HOWMEDICA, INC., et al, Appellees, ST MARY'S HOSPITAL, Appellant, v JOSEPH TILLMAN, BRUCE WAXMAN, M.D., et al., Appellees ST. MARY'S HOSPITAL, Appellant, v JOSEPH TILLMAN, Appellee, BRUCE WAXMAN, M.D., et al., Appellees JOSEPH TILLMAN, Appellant, v ST MARY'S HOSPITAL, etc., et al., Appellees BRUCE WAXMAN, M.D., Appellant, v JOSEPH TILLMAN, Appellee BRUCE WAXMAN, M.D., Appellant, v. JOSEPH TILLMAN, et al., Appellees
No. 82-1197, 82-1199, 82-1370, 82-1433, 82-1527, 82-1823
Court of Appeals of Florida, Fourth District
453 So. 2d 1376; 1984 Fla. App. LEXIS 13945

July 13, 1984

SUBSEQUENT HISTORY: [**1]

Rehearings Denied September 10, 1984.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant surgeon challenged an adverse judgment in plaintiff's medical malpractice action, arguing that the Florida trial court erred in failing to conclude that plaintiff's claim against him was barred by the statute of limitations.

OVERVIEW: Plaintiff filed a medical malpractice suit against defendant hospital and defendant manufacturer after experiencing problems with a prosthetic device. Ten months later after learning that his problems could be attributable to physician negligence, plaintiff added defendant surgeon as a party Defendant surgeon moved for summary judgment on the basis of the statute of limitations and subsequently moved for a directed verdict on that same basis at trial. Defendant appealed an adverse judgment, arguing that the trial court erred in failing to conclude that plaintiff's claim against him was barred by the statute of limitations. In affirming, the appellate court noted that the statute of limitations began to run when plaintiff discovered a malpractice claim, and where there was a question as to notice or discovery, it was for the jury to decide when the statute of limitations began to run. Where there was evidence that plaintiff did not learn of defendant surgeon's negligence until after suit had been commenced, this was sufficient to take the question to the jury and to sustain the jury's conclusion that the cause of action was not barred by the statute of limitations.

OUTCOME: The judgment for plaintiff in his medical malpractice action was affirmed, as plaintiff's claim against defendant surgeon was not barred by the statute of limitations where there was a question as to notice or discovery Where evidence supported the jury's conclusion that plaintiff did not discover defendant's negligence until months after commencing suit, a conclusion that the cause of action was not barred was proper

CORE TERMS: femoral, bone, knee, statute of limitations, mismatched, patient, comparative negligence, prosthesis, surgery, tibial, affirmative defense, stability medical malpractice, summary judgment, doctor, standard of care, directed verdict, smaller, contributory negligeoce, giving rise, reduction, discovery, notice, bed, expert testimony manufactured, responded, withdrew, surgical, plastic

CORE CONCEPTS -

Torts: Malpractice Liability: Physicians & Healthcare Providers
Torts: Procedure: Commencement
Torts: Procedure: Statutes of Limitations
See Fla. Stat. Ch. 95.11(4)(b).

Torts: Malpractiee Liability: Physicians & Healthcare Providers
Torts: Procedure: Statutes of Limitations
Discovery of the incident giving rise to the cause of action is the point when the statute of limitations begins to run. The term "incident" encompasses (1) a medical procedure; (2) tortiously performed (3) which injures (damages) the patient.

Torts: Malpractice Liability: Physicians & Healthcare Providers
Torts: Procedure: Statutes of Limitations
Where there is a question as to notice or discovery in a medical malpractice action, it is for the jury to decide when the statute of limitations begins to run.

Evidence: Witnesses: Expert Testimony
Torts: Malpractice Liability: Physicians & Healthcare Providers

An obvious breach of duty that would be apparent to persons of common knowledge does not require support by expert testimony

Torts; Malpractice Liability: Physicians & Healthcare Providers
Torts: Procedure: Statutes of Limitations
The two-year statute of limitations, *Fla. Stat ch. 95.11(4)(b)*, applies to the health care provider and persons in privity with the provider of health care.

Civil Procedure: Pleading & Practice: Defenses, Objections & Demurrers: Affirmative Defenses
Torts: Procedure: Statutes of Limitations
Where defendant never raises the statute of limitations defense, he cannot later avail himself of an affirmative defense that he failed to properly present.

COUNSEL: Michael B. Davis of Walton Lantaff Schroeder & Carson, West Palm Beach, for Florida Patient's Compensation Fund.

David F. Crow of Paxton, Crow Bragg & Austin, P.A., West Palm Beach, for St. Mary's Hospital.

Edna L. Caruso of Edna L. Caruso, P.A., West Palm Beach, and Kocha & Houston, P.A., West Palm Beach, for Joseph Tillman.

Robert M. Klein and Debra Levy Neimark of Stephens, Lynn, Chernay & Klein, P.A., Miami, for Bruce Waxman, M.D.

JUDGES: Hersey, J. Letts and Beranek, JJ., concur

OPINIONBY: HERSEY

OPINION: [*1378] These consolidated appeals devolve from a medical malpractice action.

Joseph Tillman developed a knee problem which required the surgical implantation of a two-element prosthesis manufactured by Howmedica, Inc. The surgery was performed by Dr. Bruce Waxman at St. Mary's Hospital on April 12, 1978. The prosthetic device obtained by St. Mary's Hospital from another hospital consisted of a tibia component and a fibula component. Each of these components is manufactured in two sizes. The prosthesis inserted in Tillman's knee consisted of mismatched components. Shortly after the surgical procedure Dr. Waxman advised[**2] Tillman that mismatched elements had been implanted in the knee. Some difficulty with the knee was encountered by Tillman almost immediately, and ultimately another surgeon performed corrective surgery which, because of deterioration of bone structure, required that the knee be fused.

On February 29, 1980, plaintiff Tillman filed his initial complaint naming St. Mary's Hospital and Howmedica, Inc., as defendants. On December 2, 1980, Dr. Waxman was added as a defendant. On July 9, 1981, Florida Patient's Compensation Fund was added as a defendant. Subsequently, Waxman and the Fund filed motions for summary judgment based upon the statute of limitations. Both motions were denied and the case proceeded to trial. During trial Dr. Waxman made a motion for directed verdict based upon the statute of limitations. The motion was denied. St. Mary's motion for directed verdict, based on the argument that there was no evidence on the hospital's standard of care or its negligence, was likewise denied. Also during the trial Dr. Waxman withdrew his affirmative defense of comparative negligence.

At the conclusion of the trial the jury found Tillman 12% negligent, St. Mary's Hospital[**3] 8% negligent, and Dr. Waxman 80% negligent. The jury found the total amount of damages to be $150,000. The trial court entered judgment on May 7, 1983, awarding Tillman $132,000 after reducing the damages by 12%, representing Tillman's comparative negligence. The final judgment is the subject of several of the appeals prosecuted by the parties -- Tillman, Dr. Waxman, St. Mary's Hospital and Florida Patient's Compensation Fund. Thereafter, the trial court awarded attorney's fees to Tillman and that order, dated July 30, 1982, is also appealed by Dr. Waxman.

APPEAL OF DR. WAXMAN

Waxman relies upon the medical malpractice statute of limitations in urging that his motions for summary judgment and directed verdict were erroneously denied. The applicable statute, *Section 95.11(4)(b)*, Florida Statutes, as amended in 1975 (thus rendering cases under the former version of the statute relied upon by Waxman of doubtful value as precedent) provides:

An action for medical malpractice shall be commenced within 2 years from the time the incident giving rise to the action occurred or within 2 years from the time the incident is discovered, or should have been discovered with[**4] the exercise of due diligence; however, in no event shall the action be commenced later than 4 years from the date of the incident or occurrence out of which the cause of action accrued. . . . In those actions covered by this paragraph in which it can be shown that fraud, concealment, or intentional misrepresentation of

fact prevented the [*1379] discovery of the injury within the 4-year period, the period of limitations is extended forward 2 years from the time that the injury is discovered or should have been discovered with the exercise of due diligence, but in no event to exceed 7 years from the date the incident giving rise to the injury occurred.

Discovery of the "incident giving rise to the cause of action" is the point when the statute begins to run. In *Swagel v. Goldman, 393 So.2d 65 (Fla. 3d DCA 1981)*, the court equated "incident" with the "now-alleged surgical malpractice." The term "incident," however could not refer solely to the particular medical procedure since that would obviously be "discovered" at the time it was performed, rendering nugatory the additional two year period permitted by the statute for discovering the incident. Thus, the term[**5] must encompass (1) a medical procedure; (2) tortiously performed (3) which injures (damages) the patient. The question, then, is when did Tillman discover the "incident." The testimony presented below was conflicting.

After Dr. Waxman learned about the mismatched knee components he called Howmedica. Waxman testified that an engineer for Howmedica said "that he thought it would work out fine and he thought there was a slight impingement on the tibial spines, but that this would be resolved by cold flow." In support of Dr. Waxman's testimony, Dr. Diaz (who assisted with the operation) testified that after Waxman spoke with Howmedica, "he was assured that it should work very well and that if any problem occurred, that it would probably be what we call cold flow . . . He was advised that it should do quite well." This state of mind of Waxman, that no harm had been done, bears out Tillman's version of subsequent events. According to Tillman, within a few days after the operation Waxman told him that he "thought [he] had implanted the wrong or mismatched sizes" but that he "thought that it would work but [he] wasn't sure." On each of the subsequent office visits, Waxman "told[**6] him [Tillman] he was improving. . . ."

Tillman admitted that he never improved after the operation, but when he told Waxman, Waxman allegedly "didn't pay any attention. He acted like he wasn't paying a bit of attention. . . ." Tillman testified that he learned for the first time that his leg needed another operation when x-rays were taken at Dr. Ennis' office in January or February of 1979. Although Tillman had last seen Dr. Waxman in January of 1979, Waxman never told Tillman he would need another operation.

In addition to the very real possibility that Tillman was never in a position to recognize that an incident had occurred, there exists another factual determination which affects our consideration. If Tillman knew of the mismatched components shortly after the operation, the statute would begin to run only if the subsequent damage was caused by the mismatched components. Although the evidence would support a finding to that effect, there was evidence of other possible causes which were never brought to Tillman's attention.

Dr. Petty performed the corrective operation on Tillman. When Petty opened the knee, he found the prosthesis was "quite unstable." Petty then tried [**7] to replace the prothesis with a larger one but was "unable to get good bone fixation and good stability." He decided to fuse the knee.

When asked for his opinion regarding the instability of the right knee replacement, Petty responded as follows:

> I think there are two or three possibilities. Possibility Number 1 would be for the, at the time of the total knee arthroplasty either excessive bone was removed, or too small a prosthesis was put in place, or a combination of those two, and those two are very closely related, and it is difficult to say either/or
>
> . . . .
>
> Another possibility is that the patient had such sever [sic] instability prior to [*1380] the total knee arthroplasty that with whatever components or with the biggest component available, stability could still not be achieved. I don't believe the latter was the cause in this instance though.

Regarding the first reason, by "too small a prosthesis," Petty meant the tibial and femoral parts were too small in their thickness and size. Petty believed that Tillman needed a thicker tibial component but he also stated that "the femoral component was smaller than what was ideal for the patient." [**8] When asked what led to his belief that the femoral component was smaller than ideal, Petty responded, "the femoral component [was] considerably narrower than the distal femoral bone that it resurfaces." Although the doctor thought the components were too small for Tillman, he did not have an opinion as to whether the two components were, in fact, mismatched.

In addition to Dr. Petty's deposition testimony, the jury saw a video deposition of Dr. Volz. When asked whether he felt Dr. Waxman removed too much bone, Volz stated:

Yes, I believe he did. I believed -- not necessarily did be remove too much bone, but he did not insert a wide enough plastic component part to properly place the ligaments under appropriate tension. . . . That either too much bone was removed, and if so, not enough -- not a thick enough plastic component was inserted.

The doctor further stated that his "criticism [was] not that too much bone was removed, it was that if he had taken that much bone, he should have then used a wider component part."

Dr Volz was then asked whether the stability of the knee would have been better if the components had been matched. He responded as follows: [**9]

My opinion is that if the standard femoral component had been used with the standard tibial component, there would have been some added measure of stability other than what is observed when one mates a small femoral component with the standard tibial. I will concede that there is some degree of stability with that degree of mismatch but there is not as much stability, that is lessened chance for dislocation, with this combination as we can observe using a standard femoral and a standard tibial.

On this same point, he further stated, "I think the issue of the mismatching might not have been a problem at all if he'd used a wider piece of plastic. I think that's the critical deficiency."

Regarding the issue of too much bone being removed, Waxman's counsel conceded that Tillman did not know about that.

Where there is a question as to notice or discovery in a medical malpractice action, it is for the jury to decide when the statute of limitations begins to run. *Weiner v. Savage, 407 So.2d 288 (Fla. 4th DCA 1981); Phillips v. Mease Hospital & Clinic, 445 So.2d 1058 (Fla. 2d DCA 1984).* Here, the jury concluded that the period had not expired at the time[**10] Waxman was brought into the litigation. There was evidence upon which the jury could have concluded either that Tillman did not discover that the mismatched components were causing an injury until early 1979 or that the injury was caused by the removal of too much bone or the use of a prosthesis that was too small. This was sufficient to take the question to the jury and to sustain its ultimate position that the cause of action was not barred by the statute of limitations.

Waxman's point IV is rendered moot by the foregoing determination and his point II is without merit.

Point III suggests that the trial court committed error in awarding attorney's fees to Tillman on the basis that the original complaint was filed prior to the effective date of the medical malpractice attorney's fee statute, *Section 768.56*, Florida Statutes, although Waxman was joined [*1381] as a defendant subsequent to its effective date. We agree this was error *Theodorou v. Burling, 438 So.2d 400 (Fla. 4th DCA 1983).*

APPEAL OF ST. MARY'S HOSPITAL

The only issue raised by St. Mary's is the failure of the trial court to direct a verdict in its favor because the plaintiff having the burden, [**11]failed to establish what standard of care should be applied as to it and failed to offer expert testimony as to its negligence. (We use the term plaintiff throughout this discussion for clarity)

St. Mary's argues that the evidence did not establish any standard of care, relying on *Memorial Hospital v. Doring, 106 So.2d 565 (Fla. 2d DCA 1958)* In that case, the doctor ordered complete bed rest for a patient. The patient was placed in a bed without rails (rails were not ordered by the doctor), and either fell out of the bed or fell after he got up from the bed. The patient admitted that he did not need special nursing care. In addition, the court specifically found that the record failed to disclose what the hospital should have done but failed to do. Therefore, the appellate court held a verdict should have been directed in favor of the hospital.

In the case at bar, the plaintiff clearly alleges that the hospital failed to check the femoral component to make sure it provided the right size to the doctor The manager of surgery at St. Mary's, Harry Wallace, admitted that he had the responsibility to ensure that the proper components were received by the hospital and further[**12] admitted that he failed to check the components used in this operation; further, that it was standard procedure to check the stock numbers to ensure that the proper components had been received. The head nurse also failed to check the size of the femoral component before surgery

These witnesses stated that they failed to check the components because they did not know that Howmedica, Inc., manufactured different sizes. However, the evidence showed that Howmedica, Inc., had been manufacturing different sizes for at least a year before this surgery; that the salesman for Howmedica stated that he had discussed the knee and the various sizes with Wallace

prior to the surgery; and that other hospitals knew there were different size components. Thus the evidence itself established that the hospital deviated from its regular standard of care by not checking the components and that it should have known there were different sizes.

The hospital's failure to check the components used in the operation would appear to constitute an obvious breach of duty which would be apparent to persons of common knowledge. Thus we hold, contrary to St. Mary's position, that expert testimony was not[**13] required. In *Atkins v. Humes, 110 So.2d 663 (Fla. 1959)*, the court stated that "a jury would have the right to conclude that it is negligence . . . to fail to sterilize surgical instruments before performing an operation . . ." *Id. at 666* (citing *Lanier v. Trammell, 207 Ark. 372, 180 S.W.2d 818 (1944)*). See also *Stepien v. Bay Memorial Medical Center 397 So.2d 333* (Fla. 1st DCA), pet. for review dismissed, *402 So. 2d 607 (Fla. 1981)*.

Finally, St. Mary's asserts that even if the hospital failed to notice the femoral component, its failure did not cause any injury to the plaintiff. According to St. Mary's, the plaintiff's expert testimony established that his problem could have been attributed to either too much bone being removed, or the use of too small a prosthesis (including the tibial and femoral components). Although Dr. Petty testified that he did not notice if the components were mismatched, he did state that "the femoral component was smaller than what was ideal for this patient."

Because the fact that the hospital failed to check the components before surgery constituted an obvious breach of duty, and [*1382] because a smaller femoral component[**14] than what was ideal for the patient may have contributed to the ultimate failure of the operation, the trial court did not err in denying St. Mary's motion for a directed verdict.

APPEAL OF DEFENDANT FLORIDA PATIENT'S COMPENSATION FUND

Defendant, Florida Patient's Compensation Fund (Fund), contends that the trial court erred in denying its motion for summary judgment. It is undisputed that Tillman admits he discovered his injury no later than February of 1979. However, he failed to add the Fund as a defendant until July 9, 1981. The Fund asserts that because the two year statute of limitations, *Section 95.11(4)(b)*, Florida Statutes, applies to "the health care provider and persons in privity with the provider of health care," Tillman's failure to add it as a defendant within two years entitled it to summary judgment.

Tillman contends that he was in privity only with the hospital and Dr. Waxman and therefore the two year statute of limitations was not applicable as to the Fund. Further, Tillman argues that the "insurer's exception" to the statute of limitations should be applied and cites *Davis v. Williams, 239 So.2d 593 (Fla. 1st DCA 1970)*, and *Clemons v. Flagler [**15] Hospital, Inc., 385 So.2d 1134 (Fla. 5th DCA 1980)*, for this position.

We disagree that the statute of limitations defense is available to Florida Patient's Compensation Fund in the present case. We, instead, are persuaded by the logic and therefore adopt the rationale of Judge Ferguson's dissent in *Fabal v. Florida Keys Memorial Hospital, 452 So. 2d 946* (Fla. 3d DCA, 1984) [9 F.L.W. 1210]. In so doing we acknowledge that we create a direct and express conflict with the following cases: *Taddiken v. Florida Patients Compensation Fund, 449 So.2d 956 (Fla. 3d DCA, 1984) [9 F.L.W. 1074]; Burr v. Florida Patient's Compensation Fund, 447 So. 2d 349 (Fla. 2d DCA, 1984) [9 F.L.W. 5261]*, *Owens v. Florida Patient's Compensation Fund, 428 So.2d 708* (Fla. 1st DCA), pet. for review denied, *436 So.2d 100 (Fla. 1983)*; *Mercy Hospital, Inc. v. Menendez, 371 So.2d 1077 (Fla. 3d DCA 1979)*, cert. denied & appeal dismissed, *383 So. 2d 1198 (Fla. 1980)*; and *Fabal v. Florida Keys Memorial Hospital, supra*.

St. Mary's argues that if the judgment is reversed as to the Fund, then the judgment against St. Mary's should be limited to $100,000, the maximum liability [**16] of the health care provider under *Section 768.54*, Florida Statutes. However, we held in *Florida Medical Center, Inc. v. Von Stetina, 436 So.2d 1022, 1028 (Fla. 4th DCA 1983)*, that *Section 768.54(2)(b)*, Florida Statutes (1977), "imposes no substantive limitation upon plaintiff's right to judgment in the full amount" and found that section unconstitutional. Therefore, the plaintiff is entitled to recover against St. Mary's without limitation.

APPEAL OF PLAINTIFF, JOSEPH TILLMAN

Tillman argues that since Waxman withdrew his affirmative defense of comparative negligence and the jury was so advised by Waxman's counsel, Waxman was not entitled to the 12% reduction of the judgment (the percentage of negligence attributed to Tillman). Additionally, Tillman argues that a defendant may not benefit from an affirmative defense he fails to present and cites *Searcy v. Godwin, 129 Ga. App. 827, 201 S.E.2d 670 (1973)*, and *Haddock v. Smithson, 30 N.C. App. 228, 226 S.E.2d 411*, review denied, *290 N.C.*

776, 229 S.E 2d 32 (1976). We agree.

In Searcy the defendant never raised the statute of limitations and the court said that the defendant could not "avail himself of[**17] an affirmative defense which he failed to properly present." *Id 201 S E 2d at 671-72.* In Haddock, one of the defendants pled contributory negligence while the other defendant did not. The court found that because the defendants filed separate answers, the defendant who failed to raise contributory negligence in his answer could not take advantage of the other defendant's claim for contributory negligence to support a summary judgment in favor of [*1383] both defendants. In both Searcy and Haddock, the defendants failed to plead an affirmative defense; thus the court did not permit either of them to take advantage of the defense in the proceeding.

In the case at bar, Waxman initially pled the affirmative defense but then withdrew it during trial. The defense of comparative negligence was maintained by St. Mary's Hospital and therefore presented to the jury. Waxman argues that "any defense filed by one defendant, common to a codefendant, inures to the benefit of that codefendant." *Allied Chemical Corp. v. Van Buren School Dist. No. 42, 264 Ark. 810, 575 S W.2d 445, 448 (1979).* Waxman additionally argues that the comparative negligence defense was common[**18] to both himself and St. Mary's and that the jury ultimately found the plaintiff 12% negligent. Since *Section 768 31(3)(a),* Florida Statutes, Uniform Contribution Among Tortfeasors Act (1982), provides that joint tortfeasors are responsible for their pro rata share of the entire liability, if Waxman is liable for the full $150,000, he argues that he will pay more than his pro rata share.

However, having withdrawn his defense of comparative negligence and so informing the jury, Waxman will not be permitted to take advantage of the defense simply because it is now to his benefit to do so. The final judgment should reflect a reduction for St. Mary's Hospital based on the plaintiff's negligence but Waxman should not be afforded the same reduction.

Upon remand the lower tribunal is instructed to make such corrections in its judgment and orders as are necessary to reflect that:

1. Tillman is not entitled to attorney's fees under *Section 768.56,* Florida Statutes;
2. The amount of damages recoverable from Waxman is not to be reduced for comparative negligence.

In all other respects we affirm.

AFFIRMED IN PART; REVERSED IN PART; AND REMANDED WITH INSTRUCTIONS. [**19]

LETTS and BERANEK, JJ., concur.

878 F Supp. 162
(Cite as: 878 F.Supp. 162)
< KeyCite Red Flag>

United States District Court,
C.D. California.

John RANDOLPH; Johanne Randolph, Plaintiffs,
v.
BUDGET RENT-A-CAR; Saudi Arabian Airlines, Defendants.

No. CV 93-5087-AAH(JGx).

March 3, 1995.

Motorcyclist and his wife brought action for personal injuries and loss of consortium against foreign airline and against rental car company, arising from intersection collision. Following nonjury trial, the District Court, Hauk, Senior District Judge, held that: (1) defendant airline was a "foreign state" within meaning of the Foreign Sovereign Immunities Act, but was not immune from jurisdiction in action based on commercial activity in the United States; (2) plaintiff motorcyclist who suffered knee and hand injuries and pelvic injuries resulting in sexual dysfunction expected to last at least one additional year was entitled to $200,000 for past sexual dysfunction, $50,000 for future sexual dysfunction, $300,000 for past pain and suffering, $150,000 for future pain and suffering associated with knee replacement, and $50,000 for other future pain and suffering; (3) wife was entitled to $40,000 for past and future loss of consortium; and (4) rental car company's liability as owner under California statute would be automatically discharged upon satisfaction by the airline, whose employee's negligence caused the accident, of an amount of the judgment against the airline at least equal to the rental company's liability.

Judgment for plaintiffs.

West Headnotes

[1] International Law ⇐ 10.34
221k10.34

Airline corporation formed under the laws of a foreign nation and wholly owned and operated by the government of that nation was a "foreign state" for purposes of the Foreign Sovereign Immunities Act, but was not immune from district court's jurisdiction in action based on a commercial activity carried on in the United States. 28 U.S.C.A. §§ 1602 et seq., 1603(a), 1605(a)(2).

[2] Damages ⇐ 185(1)
115k185(1)

Evidence established that, as result of automobile accident in which plaintiff motorcyclist had suffered, inter alia, fracture of pelvis resulting in separation of pubic rami and severe hematoma, resulting in major rectus muscle injury, plaintiff had suffered traumatic sexual dysfunction for two years and would continue to suffer with diminishing impact for at least one additional yeat.

[3] Damages ⇐ 132(.5)
115k132(.5)

[3] Damages ⇐ 132(7)
115k132(7)

[3] Damages ⇐ 132(8)
115k132(8)

Motorcyclist, who, as result of intersection collision, suffered fracture of knee which would require artificial knee implant, pelvic injury resulting in traumatic sexual dysfunction for two years in the past and at least one year in the future, and fractures of hand was entitled to general damages in amount of $200,000 for past sexual dysfunction, including secondary impotence and orgasmia, $50,000 for future sexual dysfunction, $300,000 for past pain and suffering, $150,000 for future pain and suffering associated with knee replacement, and $50,000 for other future pain and suffering.

[4] Damages ⇐ 133
115k133

Wife of motorcyclist, who, as result of

intersection collision, had suffered traumatic sexual dysfunction for past two years and would continue to suffer with diminishing impact for at least one additional year was entitled to $30,000 for past loss of consortium and $10,000 for future loss of consortium.

[5] Damages ⇐ 63
115k63

Statutory liability of rental car company as owner of vehicle under California law would automatically be discharged upon satisfaction by employer of negligent operator of vehicle of at least as much of the judgment against employer as equalled rental company's liability. West's Ann.Cal.Vehicle Code §§ 17150, 17151(a).

[6] Damages ⇐ 127
115k127

For purposes of California statutes imposing limited amount of liability based on ownership of automobile involved in accident, loss of consortium is an independent injury wholly separate and distinct from physical injury suffered by spouse, so that the limit applies separately. West's Ann.Cal.Vehicle Code §§ 17150, 17151(a).

*163 Douglas G. McKanas, Law Offices of McKanas & Wabby, Encino, CA, for plaintiffs.

Stephen T. Swanson, Arter & Hadden, Jay T. Rubin, Brumer, Rubin & Weston, Los Angeles, CA, for defendants.

DECISION AFTER COURT TRIAL, FIXING DAMAGES FOR PERSONAL INJURIES, INCLUDING SEXUAL DYSFUNCTION AND LOSS OF CONSORTIUM

HAUK, Senior District Judge.

This matter came on regularly for Court Trial on January 17, 1995, and continued daily until January 20, 1995, before the Honorable A. Andrew Hauk, United States District Judge. Upon conclusion of this non-jury trial the case was taken under submission for decision.

The Court has heard the testimony, carefully examined all the evidence offered by the respective parties, considered all legal points and authorities, and now, being fully advised in the premises, makes and enters its Decision.

The Trial was a mandatory non-jury trial pursuant to 28 U.S.C. § 1441(d). [FN1] This *164 Court has jurisdiction over this action pursuant to Article III § 2 of the United States Constitution [FN2] as implemented by 28 U.S.C. § 1330(a). [FN3]

FN1. 28 U.S.C. § 1441(d) provides:
Any civil action brought in a State court against a foreign state as defined in section 1603(a) of this title may be removed by the foreign state to the district court of the United States for the district and division embracing the place where such action is pending. Upon removal the action shall be tried by the court *without jury*.
28 U.S.C. § 1441(d) (1994) (emphasis added).

FN2. Article 3, Section 2 provides:
The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States ... to Controversies ... between a State, or the Citizens thereof, and foreign States, Citizens or Subjects. U.S. CONST. art. 3, § 2.

FN3. 28 U.S.C. § 1330(a) provides:
The district courts shall have original jurisdiction without regard to amount in controversy of any nonjury civil action against a foreign state as defined in section 1603(a) of this title as to any claim for relief in personam with respect to which the foreign state is not entitled to immunity either under sections 1605-1607 of this title or under any applicable international agreement.
28 U.S.C. § 1330(a) (1994).

[1] Under the Foreign Sovereign Immunities Act "foreign states" are immune from the jurisdiction of the United States courts insofar as their non-commercial activities are concerned. 28 U.S.C. § 1602 *et seq.* Defendant Saudi Arabian Airlines ("Saudia") is a corporation formed under the laws of Saudia Arabia and is wholly owned and operated by the Government of Saudi Arabia. As such it is a "foreign state" as defined in 28

U.S.C. § 1603(a). [FN4] However, since the action was based upon a commercial activity carried on in the United States by the foreign state, Saudia is not immune from the Court's jurisdiction. 28 U.S.C. § 1605(a)(2). [FN5]

FN4. 28 U.S.C. § 1603 provides:
(a) A "foreign state", except as used in section 1608 of this title, includes a political subdivision of a foreign state or an agency or instrumentality of a foreign state as defined in subsection (b).
(b) An "agency or instrumentality of a foreign state" means any entity--
(1) which is a separate legal person, corporate or otherwise, and
(2) which is an organ of a foreign state or political subdivision thereof, or a majority of whose shares or other ownership interest is owned by a foreign state or political subdivision thereof, and
(3) which is neither a citizen of a State of the United States as defined in section 1332(c) and (d) of this title, nor created under the laws of any third country.

28 U.S.C. § 1603 (1994).

FN5. 28 U.S.C. § 1605(a)(2) provides:
A foreign state shall not be immune from the jurisdiction of courts of the United States or of the States in any case ...
in which the action is based upon a commercial activity carried on in the United States by the foreign state; or upon an act performed in the United States in connection with a commercial activity of the foreign state elsewhere; or upon an act outside the territory of the United States in connection with a commercial activity of the foreign state elsewhere and that act causes a direct effect in the United States....
28 U.S.C. § 1605(a)(2) (1994).

On January 26, 1993, Plaintiff John Randolph was driving his motorcycle westbound on the Pacific Coast Highway ("PCH") in the right-hand lane. Fahad Abdullah Maghrabi ("Maghrabi"), an employee of Saudia acting in the scope of his employment, was stopped on Corral Canyon waiting to turn left onto the PCH to go eastbound. According to the police report, Maghrabi, while driving a rental car obtained from Automated Transportation, Inc., dba Budget Rent-A-Car, LAX ("Budget"), did not see John Randolph coming, and proceeded into the highway, thereby proximately causing a collision between himself and Randolph. The police report added that Maghrabi was at fault due to failure to yield to traffic. Defendants have admitted that Fahad Abdullah Maghrabi was negligent and that Plaintiff, John Randolph, was not contributorily negligent. Additionally, Defendants have admitted that Maghrabi was the permissive user of the car rented from Budget. Based upon these facts the Court ruled prior to trial that as a matter of law Maghrabi was on a permissive mission for his employer Saudia. Further, the Court ruled as a matter of law that Saudia is liable for the injuries and damages proximately caused by Maghrabi's negligence.

As a proximate result of the accident John Randolph has suffered extensive orthopedic injuries. His left knee has a fractured tibial plateau and a tear of its anterior cruciate ligament; his pelvis was fractured resulting in the separation of his *pubic rami;* his pelvic region suffered a severe hematoma, resulting in a major *rectus* muscle injury; and the third and fourth metacarpals of his *165 left hand were also fractured. In an effort to alleviate some of the pain John Randolph has been suffering, he must undergo two future surgeries. The first is to remove metal fragments from his left knee; the second is to replace the left knee with an artificial knee implant. Further, it is quite possible that a second knee replacement operation will be needed if the first replacement does not work.

[2] The expert medical evidence was stipulated by both sides to consist of their respective doctors' reports as direct testimony; and both sides waived their right to cross examination. Upon analysis of these reports, standing as they do uncontradicted by any cross examination, the court necessarily finds that the preponderance of the evidence weighs in favor of the plaintiff John Randolph, who has provided the Court with psychiatric and neurological reports that are more compelling than those of defendant's doctors. For instance, Dr. Daniel Asimus, plaintiff's psychiatrist/neurologist, has served as plaintiff's doctor for over ten years and makes

his medical conclusions that plaintiff has secondary impotence and orgasmia directly related to the accident, based upon his personal examinations of the plaintiff both before and after the accident. By comparison, the defense's psychiatrist/neurologist, Dr. Irwin Ruben, based his evaluation of plaintiff solely upon one visit with the plaintiff and a review of other doctors' medical records.

As such, the Court finds that plaintiff has provided the Court with stronger testimony than that offered by the defendants, thereby enabling the Court to reach the reasoned conclusion, based upon the preponderance of the evidence, that John Randolph has suffered for the past two years, and will continue to suffer with diminishing impact but for at least one additional year, traumatic sexual dysfunction, as a direct and proximate result of the accident of January 26, 1993. This sexual dysfunction constitutes a major injury to him in that he is unable to obtain the normal erection or orgasm which he was able to achieve prior to the accident. Further, he and his wife have been unable to engage in normal marital relations for the nearly two years that he has suffered from the sexual dysfunction. Finally, it is clear that they may never be able to resume a mutually satisfying sexual relationship involving fully normal male erection and penetration.

Obviously, John Randolph's inability to perform and enjoy normal sexual intercourse, effects a palpable and tangible injury upon his wife, Johanne Randolph, which has prohibited her from enjoying conjugal fellowship and relationship with him for the past two years and will prohibit such fellowship for at least one additional year.

[3] Now, having found the facts of the traumatic sexual dysfunction syndrome and injury suffered by John Randolph, and having concluded that as a matter of law Plaintiff John Randolph has indeed suffered from the injury of sexual dysfunction, including secondary impotence and orgasmia, it becomes the duty of this trial court to fix and determine the extent of these injuries in terms of dollar damages.

The Court has considered, in this connection, all of the evidence offered by Plaintiffs and Defendants, and the expert as well as non-expert testimony in making the findings of fact and the Court's conclusions as to the amount of damages set forth hereafter.

Moreover, the Court has conducted a determined and diligent search of the law, particularly decisions and judgments rendered in the courts both state and federal, where these courts have evaluated and fixed the monetary damages of traumatic sexual dysfunction and injury. As might be expected, this issue is shrouded in natural reticence and modesty which apparently have affected not only the medical literature--physiological as well as psychological--but also the judicial literature, particularly the decisional literature--trial as well as appellate.

Nevertheless, the Court should not be deterred or derailed by such difficulties, but must do the best it can here to arrive at reasonable and fair conclusions. In this connection, the Court has conducted an on-line computer search of judicial precedents and has come up with the following non-jury decisions and jury verdicts in cases where damages *166 have been awarded, in whole or in part, for sexual dysfunction:

Non-Jury Decisions

District of Idaho

Phillips v. United States, 801 F.Supp. 337, 349 (D.Idaho 1992) (in awarding $3 million for "pain and suffering, mental anguish, and loss of enjoyment of life," the court in its non-jury decision listed sexual dysfunction as one of many ailments of the plaintiff who was left paraplegic from the accident.)

Eastern District of Louisiana

Bourg v. Hebert Marine, Inc., 1988 WL 2690, at *11, 1988 U.S.Dist. LEXIS 128, at *12 (E.D.La. Jan. 13, 1988) (in awarding $15,000 for "urological problems" and $100,000 for future pain and suffering, the court in its non-jury decision cited injuries as "neurological

problems ... incontinence and sexual dysfunction.")

Louisiana

James v. State 154 So.2d 497, 502 (La.Ct.App.1963) (in awarding $75,000 for pain and suffering, the court in its non-jury decision specified that damages covered "his life in a wheelchair, sexual impotence, anxieties, loss of social life ... and dependency on others for his every movement" after plaintiff was left paraplegic from the accident.)

New York

Ogle v. State. 191 A.D.2d 878, 594 N.Y.S.2d 824 (N.Y.App.Div.1993) (in awarding $320,000 total damages, the court in its non-jury decision listed permanent paresthesia, spastic gait and sexual dysfunction among plaintiff's ailments when prison hospital failed to timely diagnose and treat plaintiff's spirall ruberculosis.)

Jury Verdicts

California

Rosh v. Cave Imaging Systems, Inc., 26 CalApp.4th 1225, 32 Cal.Rptr.2d 136 (1994) (in awarding $2,990,000 non-economic damages to plaintiff and $895,000 to his wife, the jury found that plaintiff's gun-related injury inflicted permanent partial paralysis below the waist, sexual dysfunction, bowel and bladder control problems and wife's loss of consortium.)

Northern District of Illinois

Love v. Lerch, 1993 WL 8200, 1993 U.S.Dist. LEXIS 185 (N.D.Ill. Jan. 13, 1993) (finding that plaintiff was injured in an auto accident causing him severe headaches and sexual dysfunction the jury awarded him $25,000 and $25,000 to his wife for loss of consortium.)

Illinois

Mayol v. Summers, Watson & Kimpel. 223 Ill.App.3d 794, 166 Ill.Dec. 154, 585 N.E.2d 1176 (1992) (in awarding $700,000 total damages in a legal malpractice action, the jury found plaintiff's back pain worsened as a result of visiting defendant chiropractors, causing loss of control over bowels and bladder and sexual dysfunction.)

Pennsylvania

Walsh v. Kubiak 27 Phila. 239, 1994 Phila.Cty.Rptr. LEXIS 35 (Com.Pl.Ct.Phila.Cty. Jan. 6, 1994) (in awarding $2.6 million total damages in medicall malpractice claim, the jury found unnecessary back surgery to plaintiff resulted in "a myriad of neurological damages," loss of control of bowels and bladder and sexual dysfunction.)

We note that four of the above cases were non-jury decisions, ranging from $75,000 to $3 million. Four of the cases were jury verdicts, ranging from $25,000 to nearly $4 million. They obviously cannot and do not mandate our decision, but they do give us a context in which to consider our conclusions.

As a direct consequence of this accident John Randolph has suffered and will in the future suffer chronic pain and suffering. Assigning a dollar value to these injuries, the Court finds that plaintiff John Randolph is entitled to special damages fixed as follows:

a)	Past medical expenses	$115,645.83
b)	Past loss of earnings	8,858.00
c)	Future medical expenses	33,750.00
d)	Future loss of earnings	6,000.00
	Total Special Damages	$164,253.83

Further, Plaintiff John Randolph is entitled to general damages as follows:

a)	Past sexual dysfunction including secondary impotence and orgasmia	$200,000.00
b)	Future sexual dysfunction including secondary impotence and orgasmia	50,000.00
c)	Past pain and suffering	300,000.00
d)	Future pain and suffering associated with the knee replacement	150,000.00
e)	Other future pain and suffering	50,000.00
	Total General Damages	$750,000.00

***167** [4] Now we turn to the wife, Plaintiff Johanne Randolph, and the cause of action for loss of consortium which comes under the rubric of general damages. Plaintiff Johanne Randolph is entitled to general damages as follows:

a)	past loss of consortium	$30,000.00
b)	Future loss of consortium	10,000.00
	Total General Damages	$40,000.00

As a result of the foregoing the Court concludes that the liability of the defendants should be apportioned.

[5] Saudia is liable for $914,253.83 to Plaintiff John Randolph. The maximum liability as against defendant Budget is $15,000.00 to Plaintiff John Randolph. Further, Budget's liability is automatically discharged upon the satisfaction by Defendant Saudi Arabian Airlines of at least $15,000.00 of the judgment entered in favor of Plaintiff John Randolph. *See Fenley v Kristoffersen*, 94 Cal.App 3d 139, 156 Cal.Rptr. 187 (1979)

[6] The liability of defendant Budget is controlled by California Vehicle Code §§ 17150, 17151(a). Loss of consortium is an independent injury to Johanne Randolph, wholly separate and distinct from that of the physical injuries suffered by her husband, John Randolph. Saudia is liable for $40,000.00 to Plaintiff Johanne Randolph. The maximum liability of defendant Budget is $15,000.00 to Plaintiff Johanne Randolph. Further, Budget's liability is automatically discharged upon the satisfaction by Defendant Saudi Arabian Airlines of at least $15,000.00 of the judgment entered in favor of Plaintiff Johanne Randolph. *Id.*

The foregoing Decision shall constitute the

Findings of Fact and Conclusions of Law of this Court pursuant to Rule 52 of the Federal Rules of Civil Procedure.

JUDGMENT FIXING DAMAGES FOR PERSONAL INJURIES, INCLUDING SEXUAL DYSFUNCTION AND LOSS OF CONSORTIUM

The Court having made and entered its decision, including finding of facts and conclusions of law herein, based thereon, and good cause appearing;

It is hereby ORDERED, ADJUDGED and DECREED as follows:

1. That John Randolph shall have and recover from Defendant Saudi Arabian Airlines the sum of $914,253.83 and shall have and recover from Defendant Automated Transportation, Inc., dba Budget Rent a Car, Lax, the sum of $15,000.00.

2. That Plaintiff Johanne Randolph shall have and recover from Defendant Saudi Arabian Airlines the sum of $40,000.00 and shall have and recover from Defendant Automated Transportation, Inc, dba Budget Rent a Car, Lax, the sum of $15,000.00.

3. That these judgments against Budget shall be automatically discharged upon the satisfaction by Defendant Sandi Arabian Airlines in an amount exceeding $15,000.00 of the judgment entered for Plaintiff John Randolph and in an amount exceeding $15,000.00 of the judgment entered for Plaintiff Johanne Randolph.

END OF DOCUMENT

Court of Appeal of Louisiana, Second Circuit.

James WILSON and Sherry Wilson, Plaintiffs-Appellees,
v.
NATIONAL UNION FIRE INSURANCE COMPANY OF LOUISIANA and Hardee's Food Systems, Inc., Defendant-Appellant.

No. 27702-CA.

Dec. 6, 1995.

Customer sued restaurant corporation for injuries he sustained when he slipped on restaurant floor. The First Judicial District Court, Parish of Caddo, No. 389,413-C, Leon L. Emanuel, III, J., accepted jury's allocation of fault that customer was comparatively negligent to extent of 50% and accepted award of $50,000 for general damages, but reduced jury's award of medical damages to $72,709.07, awarded $10,000 to customer for future medical treatment, awarded $20,000 for customer's disability and loss of enjoyment of life, and awarded $3,000 for loss of consortium for customer's wife. Parties appealed. The Court of Appeal, Norris, J., held that: (1) erroneous jury instructions did not require reversal; (2) finding that customer was 50% comparatively negligent was not manifestly erroneous; (3) evidence of corporation's accident reporting procedure was admissible for impeachment purposes; (4) erroneous admission of evidence of subsequent remedial measures was not prejudicial; (5) customer was entitled to award of $80,000 for general damages; (6) customer was not entitled to awards for future medical expenses and disability; and (7) wife was entitled to award of $2,000 for loss of consortium.

Affirmed in part, reversed in part, and rendered.

West Headnotes

[1] Negligence ⇨ 1595
272k1595
(Formerly 272k121.1(8))

Presence of foreign substance on floor on premises of merchant does not create presumption of negligence. LSA-R.S. 9:2800.6

[2] Trial ⇨ 233(1)
388k233(1)

[2] Trial ⇨ 238
388k238

Adequate jury instructions are those that fairly and reasonably point up issues and provide correct principles of law for jury to apply to those issues. LSA-C.C.P. art. 1792.

[3] Appeal and Error ⇨ 930(1)
30k930(1)

[3] Appeal and Error ⇨ 999(1)
30k999(1)

Generally, factual findings of jury are accorded great weight and may not be disturbed by appellate court in absence of manifest error; however, when verdict is based on jury instructions that are faulty in a critical regard, verdict is tainted and not entitled to presumption of regularity

[4] Appeal and Error ⇨ 1064.1(1)
30k1064.1(1)

Appellate courts exercise great restraint before overturning jury verdict on suggestion that instructions were so erroneous as to be prejudicial.

[5] Trial ⇨ 295(1)
388k295(1)

Standard of review for appellate court in determining whether erroneous jury instruction tainted verdict involves comparison of degree of error with instructions as a whole and circumstances of the case.

[6] Appeal and Error ⇨ 1064.1(1)
30k1064.1(1)

Pertinent inquiry in determining whether erroneous jury instruction warrants reversal is whether instruction misled jury to such an extent that jury was prevented from doing justice.

[7] Judgment ⇐ 199(3.5)
228k199(3.5)

JNOV is warranted when facts and inferences point so strongly and overwhelmingly in favor of one party that court believes that reasonable men could not arrive at contrary verdict. LSA-C.C.P. art. 1811.

[8] Judgment ⇐ 199(3.5)
228k199(3.5)

Motion for JNOV should be granted only when evidence points so strongly in favor of moving party that reasonable men could not reach different conclusions, not merely when there is preponderance of evidence for movant. LSA-C.C.P. art. 1811.

[9] Judgment ⇐ 199(3.6)
228k199(3.6)

If there is evidence opposed to motion for JNOV which is of such quality and weight that reasonable and fair-minded men in exercise of impartial judgment might reach different conclusions, motion should be denied. LSA-C.C.P. art. 1811.

[10] Judgment ⇐ 199(3.2)
228k199(3.2)

[10] Judgment ⇐ 199(3.3)
228k199(3.3)

In ruling on motion for JNOV, court should not evaluate credibility of witnesses, and all reasonable inferences or factual questions should be resolved in favor of nonmoving party. LSA-C.C.P. art. 1811.

[11] Appeal and Error ⇐ 863
30k863

On review of trial court's grant of JNOV, appellate court must first determine if trial court erred in granting JNOV: such determination is made by same criteria as trial judge used in granting the motion. LSA-C.C.P. art. 1811.

[12] Appeal and Error ⇐ 999(1)
30k999(1)

Under manifest error rule, appellate court reviews record not to determine whether jury's findings were right or wrong, but whether its conclusion was reasonable.

[13] Appeal and Error ⇐ 996
30k996

[13] Appeal and Error ⇐ 1002
30k1002

Even when reviewing court feels its own evaluations and inferences are more reasonable than fact finder's, reasonable evaluations of credibility and reasonable inferences of fact should not be disturbed where conflict exists in the testimony.

[14] Appeal and Error ⇐ 1002
30k1002

Only when documents or objective evidence so contradict witness' story, or story itself is so internally inconsistent or implausible on its face that reasonable fact finder would not credit witness' story, may appellate court find manifest error.

[15] Appeal and Error ⇐ 1004(7)
30k1004(7)

[15] Appeal and Error ⇐ 1004(8)
30k1004(8)

Finding of abuse of "much discretion" in jury's award of general damages for pain, suffering, and mental distress must be based on particular injuries sustained and their effects under particular circumstances on particular injured person. LSA-C.C. art. 1999.

[16] Appeal and Error ⇐ 1151(2)
30k1151(2)

[16] Appeal and Error ⇐ 1151(3)
30k1151(3)

After appellate court determines that jury has abused its "much discretion" by its award of general damages for pain, suffering, and mental distress, appellate court may raise or lower award to lowest or highest amount reasonably within fact finder's discretion. LSA-C.C. art. 1999.

[17] Appeal and Error ⇐ 1064.1(9)
30k1064.1(9)

[17] Appeal and Error ⇐ 1068(1)
30k1068(1)

In negligence suit arising from customer's slip on restaurant floor, trial court's erroneous instruction that inference of negligence arose against restaurant did not require reversal; incorrect instruction came after two correct statements of applicable law, verdict form contained no mention of presumption, and jury allocated significant degree of comparative fault to customer, showing that jury was not misled into overburdening restaurant with presumption of negligence. LSA-R.S. 9:2800.6

[18] Negligence ⇐ 1025
272k1025
(Formerly 272k31)

Statute governing negligence claims against merchants for injury, death, or loss sustained because of fall, also applies to cases in which plaintiff slips but does not actually fall. LSA-R.S. 9:2800.6.

[19] Negligence ⇐ 1745
272k1745
(Formerly 272k139(7))

In negligence action brought by customer who slipped on restaurant floor, trial court was required to instruct jury that customer in grocery store or fast-food restaurant has diminished duty to inspect floor before him.

[20] Appeal and Error ⇐ 1067
30k1067

In negligence action brought by customer who slipped on restaurant floor while carrying tray to trash bin, trial court's erroneous failure to instruct jury that customer had diminished duty to inspect floor before him did not require reversal; customer was not required to return his tray to trash bin, doctor had instructed customer to be extremely careful when walking because of his hip replacement, hazard was fairly large damp area well ahead of him as he started toward trash bin, and customer saw another customer slip just a few paces ahead of him.

[21] Damages ⇐ 33
115k33

Defendant takes his victim as he finds him and is responsible for all natural and probable consequences of his tortious conduct.

[22] Damages ⇐ 163(1)
115k163(1)

Plaintiff bears burden of proving causal relationship between accident and injuries complained of.

[23] Damages ⇐ 33
115k33

When defendant's tortious conduct aggravates preexisting condition, defendant must compensate victim for full extent of the aggravation.

[24] Damages ⇐ 213
115k213

Instruction that defendants were responsible "only for the consequences of their negligence or fault" but that defendant had to compensate plaintiff for full extent of aggravation of preexisting condition was not so irregular as to prevent jury from doing justice.

[25] Evidence ⇐ 571(3)
157k571(3)

[25] Negligence ⇐ 1289
272k1289

(Formerly 272k67)

Customer's failure to see "Caution: Wet Floor" sign before slipping on restaurant floor was comparative fault; sign was within 15 feet of where customer had been sitting, and experts testified that sign should have been visible from where customer was sitting, even though it was on opposite side of wet spot.

[26] Negligence ⇐ 1683
272k1683
(Formerly 272k135(4))

Jury had reasonable basis to find that customer who slipped in restaurant had disregarded oral warning about wet spot, based on employee's testimony that she had advised customer she was about to mop, even though nobody at customer's table recalled hearing such warning.

[27] Negligence ⇐ 1289
272k1289
(Formerly 272k68)

Restaurant's violation of its clean-up procedure by bringing mop bucket into customer area during operating hours and sweeping while customers were present did not absolve customer of his own duty of reasonable care and duty to see what could be seen.

[28] Negligence ⇐ 1684
272k1684
(Formerly 272k135(9))

In negligence suit brought by customer who slipped on restaurant floor, verdict that customer was 50% negligent was not manifestly erroneous; faced with conflicting evidence, jury could reasonably have found that restaurant's floor was wet and posed unreasonable risk of harm but that customer was not sufficiently attentive, or could have found that floor was only moderately slippery and that restaurant had partially satisfied its duty of reasonable care by installing relatively slip-resistant tile.

[29] Witnesses ⇐ 331.5
410k331.5

In negligence suit brought by customer who slipped on restaurant floor, evidence that restaurant corporation threw away written accident report within 24 hours after it was phoned to home office was admissible to impeach credibility of restaurant employees, who had no writings with which to refresh their memories prior to trial. LSA-C.E. art. 612, subd. C.

[30] Evidence ⇐ 219.25(1)
157k219.25(1)
(Formerly 272k131)

Evidence that restaurant corporation dropped its policy of using general purpose soap for daily mopping and recommended use of hot water following accident in which customer slipped on restaurant floor that was being mopped, was inadmissible as evidence of subsequent remedial measures. LSA-C.E. art. 407.

[31] Appeal and Error ⇐ 1050.1(7)
30k1050.1(7)

Trial court's erroneous admission of evidence that restaurant corporation had dropped its requirement for using general purpose soap for daily mopping and instead recommended hot water, following accident in which customer slipped on restaurant floor, was not prejudicial; restaurant at which customer fell was already using hot water at time of accident rather than general purpose soap. LSA-C.E. art. 407.

[32] Judgment ⇐ 199(3.5)
228k199(3.5)

JNOV is warranted only when district court finds that reasonable men must reach verdict different from jury's.

[33] Appeal and Error ⇐ 949
30k949

[33] Judgment ⇐ 199(3.5)
228k199(3.5)

Denial of motion for JNOV is discretionary and should not be disturbed absent abuse of discretion.

[34] Damages ⇐ 130.2
115k130.2

Customer who slipped on restaurant floor was entitled to general damages for pain, suffering, and mental anguish of $80,000; injuries required customer to undergo one unsuccessful nerve decompression surgery, accelerated necessity for two hip implants, caused several months of serious pain in both hips, made customer "cranky" with his family, interrupted his marital relations for approximately 11 months, and made customer more susceptible to period of enhanced mental anguish because of his history of health problems.

[35] Damages ⇐ 43
115k43

Customer who slipped on restaurant floor was not entitled to future medical expenses for hip replacement surgery; customer had already had hip replacement surgery prior to accident, and expert testified that implants often need revision but did not testify that revision in customer's hip would be result of customer's slip.

[36] Damages ⇐ 38
115k38

Customer who slipped on restaurant floor was not entitled to special damages for disability; injury from slip did not cause customer any greater permanent disability than he was destined to have from three prior back surgeries, previous automobile accident, and previous collision with shopping cart.

[37] Husband and Wife ⇐ 209(3)
205k209(3)

[37] Husband and Wife ⇐ 209(4)
205k209(4)

Elements of loss of consortium include loss of love and affection, society and companionship, sexual relations, right of performance of material services, right of support, aid and assistance, and loss of felicity, but not spouse's loss of income.

[38] Damages ⇐ 133
115k133

Wife of customer who was injured in slip in restaurant was entitled to $2,000 for loss of consortium; customer's hip pain made him "snappy" with wife and children, marital relations ceased for 11 months, there was some tension in the marriage, and wife's sleep was interrupted.

**1256 Blackman Law Firm by Gordon N. Blackman, Jr., Shreveport, for appellant.

Peters, Ward, Bright & Hennessy by J. Patrick Hennessy, Shreveport, for appellee.

Before NORRIS and STEWART, JJ., and SAVOIE, J. Pro Tem.

*1 NORRIS, Judge.

Both the plaintiffs, James and Sherry Wilson, and the defendant, Hardee's Food Systems Inc., appeal a judgment based on a jury verdict and the district court's grant of JNOV in this case arising from James Wilson's slip on the floor of a Hardee's restaurant. For the reasons expressed, we affirm in part, reverse in part and render.

Factual background

In October 1992 James Wilson, his wife Sherry, and several family members went for lunch at the Hardee's restaurant on Line Avenue in Shreveport. Wilson was at the time 36 years old and had been on total disability since sustaining work-related back injuries in 1983 and 1984. When he and his family were ready to leave the restaurant, Wilson picked up his tray and carried it toward the trash bin. He was walking behind his sister-in-law, Charlotte Lagrone. Neither Wilson, Ms. Lagrone, nor anyone else in his group noticed that the floor was damp or that a Hardee's employee was performing an after-lunch damp- mop in the area. Wilson

testified that when he got near the trash bin, his left foot slipped perhaps 10-12", but he was able to avert a complete fall by catching himself with his right foot, which also slipped about 10-12". Ms. Lagrone testified that walking just a few steps in front of Wilson she also slipped without falling, but did not have time to warn him that the floor was wet. After the incident Wilson and his family noticed a "Caution: Wet Floor" sign on the floor near the front of the dining area, but it was actually located beyond the wet spot from Wilson's vantage point. An eyewitness, Mary Sims, verified that the sign was on the other side of the wet spot from where Wilson was walking. Ms. Sims also testified that after Wilson slipped, she saw the floor was not "wet, wet," but damp and drying; Wilson's family members corroborated this.

*2 A Hardee's employee, Debra Barham, testified that last thing before she got off shift at 2:00 p.m. she swept and damp-mopped the dining area. She remembered Wilson's family; although they were rather loud she interrupted their conversation to tell them she was about to mop (no one in Wilson's group recalled this warning). She further testified that she damp-mopped with clear, hot water; this detail was verified by the store manager, Bob Burgoyne. Mr. Burgoyne added that it was actually company policy at the time to use a general purpose soap called Kadet (R) for daily cleaning, but he felt this created a buildup so he instructed his staff to use clear, hot water. There was considerable testimony about the quality of tile used in the restaurant, the preferred placement of warning signs, and accident reporting procedures; these will be addressed later in the opinion.

Immediately after the incident Wilson walked to his truck to leave Hardee's, but realized his right hip was starting to hurt. His father-in-law, Rev. Adams, advised him to go back and file an accident report, which he did. Mary Fobbs, the store's assistant manager, took the information from Wilson and apparently advised him to go to Physicians and Surgeons Hospital for an examination. [FN1] Wilson did so, and when the pain and tingling in his right hip did not subside, he went to his orthopedic surgeon, Dr. Garrett. **1257 Dr. Garrett, it turns out, had previously diagnosed Wilson with avascular necrosis in the femoral heads of both hips. In March 1990 he had operated on Wilson, replacing his right hip; he released him three months later with a slight limp. A few days after the slip, Dr. Garrett thought Wilson had damaged a small nerve in the front of his thigh, and treated it conservatively, but when after six weeks Wilson began complaining of "popping" when he moved his thigh, Dr. Garrett suspected *3 a partial dislocation of the implant. He performed two operations, ultimately removing Wilson's damaged right hip implant and putting in a new one (a "revision"). He testified that "the fall Mr. Wilson told me about" was probably the cause of the damage to the implant. While his right thigh was recovering, Wilson's left thigh began to give him problems; Dr. Garrett felt this was an acceleration of a pre-existing condition owing to the increased demands on his left hip while the right hip was healing from the revision. Dr. Garrett replaced Wilson's left hip in January 1994. Wilson testified that this operation was not completely successful and he expected having to replace the left hip again; Dr. Garrett, however, did not specifically project a revision.

FN1. Wilson and his witnesses were unclear as to which employee actually suggested this.

Dr. Garrett testified that as a result of the implants Wilson is restricted against heavy lifting, jogging and repetitive, stressful activity to his hips. Wilson admitted he had been on total disability since 1984, having undergone two fusions and one decompression that left him in constant pain; however, he testified that his residual back pain was not as bad as the new pain in his hips. He added that the problems resulting from his slip at Hardee's have affected his marriage and made him "snappy" with his children and wife for small things.

Action of the trial court

The Wilsons filed the instant petition in April

1993, James seeking general and special damages, and Sherry claiming loss of consortium. [FN2] At trial in July 1994 the Wilsons introduced medical bills totaling $72,709.07, reflecting treatment and replacement of both hips after the accident. The parties vigorously discussed the proposed jury charge, which forms the basis of several of the assignments of error. In response to special interrogatories, the jury found that *4 the condition of the floor posed an unreasonable risk of harm to Wilson, that Hardee's caused the condition, that Hardee's failed to exercise reasonable care, and that this conduct caused Wilson's damages. The jury also found Wilson comparatively negligent to the extent of 50%. The jury awarded past medical and hospital expenses of $80,000 but denied all future medicals. The jury further awarded $40,000 for past pain and suffering and $10,000 for past mental anguish, but denied all future general damages, loss of enjoyment of life and disability. The jury finally also denied Mrs. Wilson's claim for past lost wages and loss of consortium.

FN2 Hardee's insurer, National Union Fire Insurance Company of Pittsburgh, Pa. (misnamed in the original petition and in the caption of the case) was also named as defendant. It was dismissed in the judgment because of the policy's $1 million deductible. Ex. D-2.

Wilson moved for a new trial or JNOV, urging three grounds: (1) the allocation of fault was improper; (2) general damages should have been at least $225,000; and (3) loss of consorrium should have been awarded in the amount of at least $25,000. Hardee's also moved for JNOV, urging only that the special damages of $80,000 should be reduced to the $72,709.07 proved at trial.

After argument on the motions, the district court declined to change the allocation of fault, noting that reasonable jurors could have differed on that issue. The court then granted Hardee's motion for JNOV, reducing the past medical damages from $80,000 to $72,709.07. Turning to Wilson's motion, the court stated that any reasonable person would have found that he was going to need future medical treatment for his left hip; the court granted JNOV in the amount of $10,000 for this. Stating that "as a result of his injury Mr. Wilson was going to suffer a permanent disability, and it was something different and new from what he already had," the court added $20,000 for Wilson's disability and loss of enjoyment of life. The court finally added an award of $3,000 for Mrs. Wilson's loss of consortium, representing **1258 three months' time she missed working as a private-duty nurse while she tended her husband. Hardee's has *5 appealed suspensively, and the Wilsons have answered the appeal.

Applicable law

Tort claims against merchants for slips and falls on their premises are regulated by statute, La.R.S. 9:2800.6. As amended in 1990 it provides in pertinent par: [FN3]:

FN3 Amended by La.Acts 1990, No. 1025, § 1, effective September 1, 1990.

A. A merchant owes a duty to persons who use his premises to exercise reasonable care to keep his aisles, passageways, and floors in a reasonably safe condition. This duty includes a reasonable effort to keep the premises free of any hazardous conditions which reasonably might give rise to damage.
B. In a negligence claim brought against a merchant by a person lawfully on the merchant's premises for damages as a result of an injury, death, or loss sustained because of a fall due to a condition in or on a merchant's premises, the claimant shall have the burden of proving, and in addition to all other elements of his cause of action, that:
(1) The condition presented an unreasonable risk of harm to the claimant and that risk of harm was reasonably foreseeable;
(2) The merchant either created or had actual or constructive knowledge of the condition which caused the damage, prior to the occurrence; and
(3) The merchant failed to exercise reasonable care.

[1] Under this statute, the presence of a

Foreign substance on the floor does not create a presumption of negligence *Welch v. Winn-Dixie La. Inc.*, 94-2331 (La. 5/22/95), 655 So.2d 309, *Perez v. Wal-Mart Stores Inc.*, 608 So.2d 1006 (La.1992). However, prior formulations of the law of slip-and-fall did indeed establish a presumption of negligence upon proof of a foreign substance on the store's floor and that it caused the plaintiff to fall and sustain injury. *Kavlich v. Kramer* 315 So.2d 282 (La.1975); *McCardle v. Wal-Mart Stores Inc.*, 511 So.2d 1134 (La.1987); La.R.S. 9:2800.6 *prior to the 1990 amendment.* [FN4]

FN4. Prior to amendment, § 2800.6 provided that in a suit for damages by a person who has suffered damages as a result of a hazardous condition while on the merchant's premises, the person must prove that the accident was caused by a hazardous condition. "The burden of proof then shifts to the merchant to prove that he acted in a reasonably prudent manner in exercising the duty of care he owed to the person to keep the premises free of any hazardous conditions."

*6 The statute has been strictly construed not to apply ro falling merchandise cases or to non-merchant defendants. See, e.g., *Edwards v K & B Inc.*, 26,002 (La.App. 2d Cir. 8/17/94), 641 So.2d 1040; *Retif v. Doe* 93-1104 (La.App. 4th Cir. 2/11/94), 632 So.2d 405; *Reynold* v St. *Francis Medical Center* 597 So.2d 1121 (La.App. 2d Cir.1992). However, the statute has been applied where the plaintiff *slipped* but did not actually *fall to the floor Bishop v. Jack Eckerd Corp.*, 93-1043 (La.App. 5th Cir. 5/11/94), 638 So.2d 280, writ denied 94-1406 (La. 9/16/94), 642 So.2d 198; *Cobb v. Wal-Mart Stores Inc*, 93-49 (La.App. 5th Cir. 8/26/93), 624 So.2d 5

[2] Adequate jury instructions are those that fairly and reasonably point up the issues and provide correct principles of law for the jury to apply to those issues. *Fuller v. United States Aircraft Ins. Group*, 530 So.2d 1282 (La.App. 2d Cir.), writ denied 534 So.2d 444 (La.1988), cert denied 490 U.S. 1046, 109 S.Ct. 1954, 104 L.Ed.2d 424 (1989); *Lincecum v. Missouri Pacific R. Co.*, 452 So.2d 1182 (La.App. 1st Cir.), writ denied 458 So.2d 476 (1984). The trial court is not required to give the precise instructions submitted by the litigants: it need only give instructions that properly reflect the applicable law and adequately convey the issues to the jury. La.C.C.P. art. 1792; *Fuller v. United States Aircraft* supra.

[3][4][5][6] Usually the factual findings of the jury are accorded great weight and may not be disturbed by the appellate court in the absence of manifest error. *Rosell v. ESCO*, 549 So.2d 840 (La.1989). However, when the verdict is based on jury instructions that are **1259 faulty in a critical regard, the verdict is tainted and not entitled to a presumption of regularity. *Gonzales v. Xerox Corp.*, 320 So.2d 163 (La.1975); *Fuller v. United States Aircraft* supra. Not every deficient jury *7 instruction will mandate a de novo review. *Ragas v. Argonaut Southwest Ins. Co.*, 388 So.2d 707 (La.1980). Appellate courts exercise great restraint before overturning a jury verdict on the suggestion that the instructions were so erroneous as to be prejudicial. *Doyle v. Picadilly Cafeterias* 576 So.2d 1143 (La.App. 3d Cir.1991). The standard of review for the appellate court in determining whether an erroneous jury instruction tainted the verdict involves a comparison of the degree of the error with the instructions as a whole and the circumstances of the case. *Gunn v Amica Mut. Ins. Co.*, 611 So.2d 805 (La.App. 3d Cir.1992), writ denied 613 So.2d 999 (La.1993). The pertinent inquiry is whether the erroneous jury instruction misled the jury to such an extent that the jury was prevented from doing justice. *Kessler v. Southmark Corp.*, 25,941 (La.App. 2d Cir. 9/21/94), 643 So.2d 345.

[7][8][9][10] The JNOV is provided for in La.C.C.P. art. 1811. The criteria for granting JNOV are set forth in *Anderson v. NOPSI* 583 So.2d 829 (La.1991):

> A JNOV is warranted when the facts and inferences point so strongly and overwhelmingly in favor of one party that the court believes that reasonable men could not arrive at a contrary verdict. The motion should be granted only when the evidence points so strongly in favor of the moving party that reasonable men could not reach different conclusions, not merely when there is a preponderance of evidence for the mover. If there is evidence opposed to the motion

which is of such quality and weight that reasonable and fair-minded men in the exercise of impartial judgment might reach different conclusions, the motion should be denied[.] In making this determination, the court should not evaluate the credibility of the witnesses, and all reasonable inferences or factual questions should be resolved in favor of the non-moving party.

[11] On review, the appellate court must first determine if the trial court erred in granting the JNOV; such determination is made by the same criteria as the trial judge used in granting the motion. *Id.; Drury v American Honda Motor Co.*, 93 1414 (La.App. 1st Cir. 12/22/94), 659 So.2d 738.

[12][13][14] Under the manifest error rule, the appellate court reviews the record not *8 to determine whether the jury's findings were right or wrong, but whether its conclusion was reasonable. *Stobart v. State, through DOTD*, 617 So.2d 880 (La.1993). Even when the reviewing court feels its own evaluations and inferences are more reasonable than the factfinder's, reasonable evaluations of credibility and reasonable inferences of fact should not be disturbed where conflict exists in the testimony. *Rosell v. ESCO*, supra. Only when documents or objective evidence so contradict a witness's story, or the story itself is so internally inconsistent or implausible on its face that a reasonable factfinder would not credit the witness's story, may the appellate court find manifest error. *Id.* The factfinder also has broad discretion in fixing damages which are "insusceptible of precise measurement." La.C.C. art. 1999; *Hae Woo Youn v. Maritime Overseas Corp.*, 623 So.2d 1257 (La.1993).

[15][16] The jury's award of general damages for pain, suffering and mental distress is also subject to the "much discretion" rule. La.C.C. art. 1999; *Hae Woo Youn v. Maritime Overseas Corp.*, supra. The finding of abuse of much discretion must be based on the particular injuries sustained and their effects under the particular circumstances on the particular injured person. *Reck v. Stevens*, 373 So.2d 498 (La.1979). After such determination is made, the appellate court may raise (or lower) the award to the lowest (or highest) amount reasonably within the fact finder's discretion. *Coco v. Winston Industries Inc.*, 341 So.2d 332 (La.1976).

Discussion: The 9:2800.6 instruction

By its first assignment Hardee's urges the district court erred in instructing the jury to presume negligence, as set out in *McCardle v Wal-Mart*, supra, and in the prior version of R.S. 9:2800.6, but contrary to the amended **1260 version. Hardee's correctly argues that any slip or fall after September 1, 1990 is regulated *9 by the 1990 amendment, which does not create a presumption of negligence. *Perez v. Wal-Mart*, supra. Hardee's concedes that the instructions were partially correct in that they begin by quoting the statute; however, it argues the court erred by following the correct charge with this erroneous instruction derived from *McCardle*:

In proving this case, plaintiffs are required to show the following facts:
(1) That a foreign substance created a hazardous condition on Hardee's floor;
(2) That James Wilson slipped on, or onto the foreign substance;
(3) That the foreign substance caused James Wilson to slip and suffer injury.
After plaintiffs have esttablished the occurrence of the above-mentioned facts, an inference of negligence arises and the burden shifts to the defendants to free themselves from the presumption that they were negligent. Defendants may free themselves from the presumption of negligence.

Hardee's concludes that aided by the presumption of negligence, the jury found Hardee's responsible for 50% of Wilson's injuries; absent the presumption, the juty would not have found Hardee's negligent.

Hardee's legal contention is correct: the 1990 version of 9:2800.6 applies to this case, the plaintiffs are required to prove the elements listed in the statute, and there is no presumption of negligence on the defendant's part. *Welch v. Winn-Dixie La.*, supra; *Perez v. Wal-Mart*, supra. For the district court to

include an instruction based on superseded law is legally wrong.

[17] Not every error of jury instructions, however, will require the appellate court to vacate the verdict and reconsider the evidence de novo. *Ragas v. Argonaut Southwest Ins.*, supra. In fact, the appellate court will exercise great restraint before disregarding the verdict on the basis that the jury instructions *10 were prejudicially erroneous. *Doyle v. Picadilly Cafeterias*, supra. We look to the instructions as a whole and to the totality of the circumstances to determine whether the faulty instruction tainted the verdict. *Gunn v. Amica*, supra. This is not a situation where the district court completely omitted a necessary instruction or gave a completely wrong charge; such cases usually result in de novo review. Cf. *McDonough v. Royal Sonesta* 626 So.2d 438 (La.App. 4th Cir.1993); *Walker v. Babcock Industries Inc.*, 582 So.2d 258 (La.App. 1st Cir.1991). Before using the contested instruction, the district court quoted from 9:2800.6, omitting only the reference to "actual or constructive notice," and including "the merchant created the condition," which is pertinent to the facts presented. The court then reiterated the substance of the statute in outline form:

> In order for plaintiffs to receive a favorable verdict from this jury, they must prove by a preponderance of the evidence, each of the following elements:
> (1) That the condition at defendant's, Hardee's Food Systems Inc.'s, presented an unreasonable risk of harm to the plaintiff, James Wilson, and that risk of harm was reasonably foreseeable.
> (2) That the defendant, Hardee's Food Systems Inc., created the condition which caused the damage to plaintiff, James Wilson, prior to the occurrence.
> (3) That the defendant, Hardee's Food Systems Inc., failed to exercise reasonable care; and
> (4) That the damage to plaintiff, James Wilson, was caused by defendant's, Hardee's Food Systems Inc.'s, failure to exercise reasonable care. R. p. 683.

The incorrect instruction follows, but it comes after *two* correct statements of the applicable law. The verdict form also correctly tracks 9:2800.6, containing no mention of the presumption of negligence. R. pp. 110-111. These factors, we feel, minimize the chance of confusing or misleading the jury. Further, it is significant that the jury allocated a significant degree of fault to Wilson; despite the alleged prejudicial effect of the contested instruction, the *11 jury was obviously not misled into overburdening Hardee's with a presumption of negligence.

**1261 In sum, the inclusion of pre-1990 law in this instruction was legally wrong and, in another case, might well mandate overturning the verdict and reviewing the evidence de novo. However, the special circumstances noted above preclude us from finding that the jury was misled to the extent of preventing it from doing justice on the issue of fault. *Kessler v. Southmark Corp.*, supra. Hardee's first assignment does not present reversible error.

[18] Wilson has also contested the same instruction; by his first assignment he urges the district court erred in applying 9:2800.6 at all because Wilson only slipped and did not fall to the floor. In support he urges that the statute is narrowly construed. See, e.g., *Hickman v. Albertson's Inc.*, 598 So.2d 1128 (La.App. 2d Cir.), writ denied 600 So.2d 618 (La.1992). We are aware of no case, however, that distinguishes between a fall to the floor and a slip that does not result in a fall to the floor; in fact, two courts have explicitly applied the statute to mere "slips." *Bishop v. Jack Eckerd Corp.*, supra; *Cobb v. Wal-Mart Stores Inc.*, supra. This court has stated in dictum that the statute applies to slips and falls. *Edwards v. K & B Inc.*, 26,006 at p. 8, 641 So.2d at 1045. At trial, the district court stated that "a slip is the closest thing I know to a fall," and rejected Wilson's proposed instruction because the distinction was too tenuous. R. pp. 612-612. This is not plainly wrong; the district court properly refused to exclude the 9:2800.6 charge. This assignment does not present reversible error.

Other jury instructions

[19] By his second and fifth assignments, Wilson urges the district court erred in refusing two of his requested jury instructions. The first was the proposed *12 charge that a customer in a grocery store or a fast-food restaurant has a diminished duty to inspect the floor before him. In support he cites *Kavlich v. Kramer* supra, and argues that even after the enactment of 9:2800.6 a patron in a self-service store "reasonably assumes that the aisles are clear for passage and focuses on the displayed merchandise and not the pathway." *Perez v. Wal-Mart*, supra. He further argues that this rule applies to fast-food restaurants where the customer is required to carry his own tray, thus preventing him from seeing the floor. *Thompson v. Stalnaker's Restaurant Inc*, 93-1447 (La.App. 3d Cir. 6/1/94), 640 So.2d 733, writ denied 94-1799 (La. 10/14/94), 643 So.2d 165. Wilson concludes that this omission was of such a magnitude as to deprive the verdict of its presumption of correctness and mandate a de novo review of the evidence. *Gonzales v. Xerox Corp.*, supra.

The requested jury charge was derived from *Marshall v. A & P Food Co. of Tallulah*, 587 So.2d 103, 110 (La.App. 2d Cir.1991):

> It is incumbent on the defendant to affirmatively show that the plaintiff was comparatively negligent. The law does not require a * * * customer to devote his attention meticulously to the floor in front of him as he walks. In a self-service store, a patron has a diminished duty to see that which should be seen because his attention is presumed to be attracted to the advertised goods on the shelves.

The instruction actually given included a general statement that the burden was on Hardee's to allege the defense of comparative negligence and establish, by a preponderance of the evidence, that Wilson was negligent and that such negligence was one of the causes of any injuries and subsequent damages he sustained. R. p. 685. This general statement is correct. *Wilkinson v. Hartford Acc. & Indem Co.*, 411 So.2d 22 (La.1982); *Smith v. Jack Dyer & Asso. Inc.* 633 So.2d 694 (La.App 1st Cir.1993). However, we find that the district court erred in not including the special "diminished duty" charge, as it was *13 obviously applicable to this case.

[20] Despite this legal error, the jury had before it certain facts which, in our view, minimized the risk of being misled and impeded from doing justice. Wilson was admittedly carrying a tray when he slipped, and thus could not see the floor immediately ahead of him, but there is no evidence that he was *required* to return his tray to the trash bin. Also, he testified that because of his first hip replacement his doctor had instructed him to be extremely careful when **1262 walking. R. p 432. Further, the hazard was a fairly large damp area and well ahead of him as he started toward the trash bin, not a small spill or a particle of food requiring "meticulous" attention; seeing Ms. Lagrone slip just a few paces ahead probably also did not require close scrutiny. Because it was given these facts and a proper general charge, we do not find the omission of the requested charge to be reversible error. *Kessler v. Southmark Corp.*, supra

By his fifth assignment Wilson urges the court erred in failing to instruct the jury properly as to the defendant's liability for aggravating a pre-existing condition. Wilson contests the following instruction:

> Defendants take the plaintiff as they find him and the defendants are responsible *only for the consequences of their negligence or fault* although injury may be greater because of a prior condition of the plaintiff. The defendants are not responsible for conditions that are not the consequence of their negligence or fault. When the defendants' negligent actions aggravate a pre-existing condition, defendants must compensate the plaintiff for the full extent of the aggravation. R. pp. 685-686 (emphasis added)

[21][22][23] The law is very well settled that the defendant takes his victim as he finds him and is responsible for all natural and probable consequences of his tortious conduct. *Lasha v. Olin Corp.*, 625 So.2d 1002 (La.1993); *Perniciaro v. Brinch*, 384 So.2d 392. It is equally well settled that the plaintiff bears

the burden of proving a causal relationship between the accident and the injuries complained of. *American Motorist Ins. Co. v. American Rent-All*, 579 So.2d *14 429 (La.1991). When a defendant's tortious conduct aggravates a pre-existing condition, the defendant must compensate the victim for the full extent of the aggravation. *Id.*; *Lasha v. Olin Corp.*, 625 So.2d at 1006.

[24] The instant jury instruction is admittedly not a verbatim recital of the language from *Lasha* and *Perniciaro*, supra. However, those cases make it clear that the defendant is liable for the *aggravation* of the plaintiff's condition, not *all* pain, suffering or disability the plaintiff may suffer after the tortious act. The district court's formulation combines the concept of "extent of aggravation" with that of "all natural and probable consequences" which appear in the cases. On at least one occasion, the Fourth Circuit has similarly combined the notions by stated the plaintiff "is only entitled to be compensated for the aggravation of her pre-existing condition [.]" *Pilet v. Schwegmann Giant Supermarkets*, 559 So.2d 894, 898 (La.App. 4th Cir.1990). Under the circumstances, we do not consider this jury charge so irregular as to prevent the jury from doing justice. *Kessler v. Southmark Corp.*, supra.

In sum, none of the challenges to the jury instructions are such as would deprive the verdict of its presumption of regularity. The jury's findings will therefore be regulated by the manifest error rule. *Rosell v. ESCO* supra.

Allocation of fault

By his third assignment Wilson urges that, even assuming he was negligent at all, the jury assigned him too much comparative negligence. The thrust of the argument, based on *McCardie v. Wal-Mart* supra, is that once Wilson proved that he slipped on a wet, damp, slippery floor, the defendants had the burden to exculpate themselves from the presumption of negligence. Br., 9. For reasons already discussed, the law of *McCardie* does not apply to this case. The appropriate analysis follows R.S. 9:2800.6, and the jury's findings are *15 regulated by the manifest error rule. Wilson cites several facts which, he contends, absolve him of liability.

[25] First he cites the testimony of his own family members and of Ms. Sims to the effect that they did not see the "Caution: Wet Floor" sign until after Wilson slipped. The evidence is somewhat conflicting but it tends to show that a sign was present, yet placed on the opposite side of the wet spot from where Wilson and his family were sitting. Wilson's safety expert, Michael Prenzel, testified that for the sign to be effective, it had to be proximate to the hazard, preferably in front of the wet spot. R. pp. 311-313. Mr. Prenzel also admitted, however, that he could see a sign some 10 to 15 feet ahead, **1263 and this sign, even though it was past the wet spot, was within 15 feet. R. p. 340. Hardee's expert, Mark Pinson, testified that the sign should have been visible from where Wilson was sitting. R. p. 548. In short, there was sufficient evidence to permit a finding that the sign was in place, Wilson should have seen it, and his failure to do so was comparative fault.

[26] Wilson next argues the failure of any Hardee's employees to verbally warn him about the wet floor should absolve him from comparative fault. The testimony is in direct conflict. Nobody at Wilson's table recalled anyone giving them such a warning; but Debra Barham, the Hardee's hostess, testified that she interrupted their loud conversation to advise them she was about to mop. R. p. 440. On this record the jury had a reasonable basis to find that Wilson disregarded an oral warning.

[27] Wilson next argues that Hardee's violated its clean-up procedure by bringing a mop bucket into the customer area during operating hours and sweeping while customers were present. Mr. Burgoyne, the store manager, concedes this. R. p. 477. These points serve to establish Hardee's liability for *16 failure to exercise reasonable care under 9:2800.6B(3). However, Wilson does not show how these deficiencies absolved him of his own duty of reasonable care and to see what could be seen. [FN5]

FN5. Wilson does not contest the jury charge to this effect. R. p. 685.

[28] Finally, Wilson argues that the tile on Hardee's floor was unreasonably dangerous when wet. The experts discussed the coefficient of friction of clean and dirty Dal-Tile (R) at great length. Although there is no national standard for slip resistance, both experts testified that the industry standard among safety experts is that a coefficient of friction (represented by *e*) of .5 is the limit of safety; lower than .5 is dangerous, but higher is safe. [FN6] Mr. Pinson visited the store and used an articulated strut testing device to measure the floor's slip resistance. He found that immediately after mopping with clear water, the floor's *e* = .45, or dangerous. However, after five minutes he found *e* = .575, relatively safe, and after 15 minutes, the floor was completely dry and *e* = .8, safe. Ms. Barham testified that the accident occurred some *20 minutes* after she warned Wilson that she was about to mop; it is not clear, however, how much time had elapsed between the actual mopping and the accident. Wilson's expert, Mr. Frenzel, testified that because Hardee's used only clear water for spot cleaning, there was likely a grease buildup which clogged the pores in the tile and made it more slippery. R. pp. 314-317. However, when he visited the store some five months after the accident and examined the floor by scraping it with his fingernails, he picked up no greasy residue. R. p. 346.

FN6. Mr. Frenzel quoted an internal Hardee's report, Ex. P-43, which adopted the following standard of slip resistance: *e* = .6 or higher is very safe; *e* = .5 to .59, relatively safe, *e* = .4 to .49, dangerous; *e* = .35 to .39, very dangerous; and *e* < .35, unusually dangerous. R. p. 303-304.

Faced with this conflicting evidence, the jury could reasonably have found that Hardee's floor was wet and posed an unreasonable risk of harm, but that Wilson was not attentive enough to the "Caution: Wet Floor" sign, the oral *17 warning, the employee who was mopping nearby, and to his sister-in-law who slipped just seconds before him, thus justifying the imposition of comparative fault. The jury could also have found that the floor, though wet, was only moderately slippery and that despite its breach of company cleaning policy, Hardee's had partially satisfied its duty of reasonable care by installing relatively slip-resistant tile. Although as a factfinder we may well have assigned less fault to Wilson, we are simply unable to declare manifestly erroneous a verdict that found him 50% comparatively negligent. This assignment of error lacks merit.

Evidentiary questions

[29] By its second assignment, Hardee's contests the admission of certain testimony at trial. At oral argument counsel for Hardee's conceded that these issues are advanced to aid the court in the event of de novo review or to instruct the district court in the event of a remand. Since the jury **1264 instructions were not found to mandate either of these remedies and review is for manifest error, we will address these arguments only briefly. First Hardee's contends that evidence of the company's accident reporting procedure was irrelevant under La.C.Ev. art. 402, and served only to prejudice Hardee's in the jury's mind. We agree that Hardee's procedure of throwing away the written accident report within 24 hours after it was phoned to the home office tends neither to prove nor disprove either party's negligence in this accident. C.Ev. art. 401. Nevertheless it may have served to impeach the credibility of Hardee's employees, who had no writings with which to refresh their memories prior to trial. C.Ev. art. 612C. The district court's action was not reversible error.

[30][31] Hardee's next urges that testimony about subsequent remedial measures was inadmissible under La.C.Ev. art. 407, and that testimony to this effect was prejudicial. The argument is valid; however, the substance of the "remedial" *18 measure was that shortly after this accident, Hardee's home office dropped the requirement for using Kadet (R) for daily damp-mopping, and now recommends clear, hot water. R. p. 506. Since the change in company policy vindicates Mr. Burgoyne's prior conduct, we perceive no prejudicial error

m admitting this testimony.

General damages

By his fourth assignment Wilson urges that after properly granting his motion for JNOV on certain issues, the district court erred in failing to reassess independently Wilson's general damages and perform a de novo review. Wilson suggests that for his medical treatmem, pain, agony and disability, all resulting from the accident, an award of at least $225,000 would be appropriate. Under the appropriate standard of appellate review, we conclude that the court's award of general damages is abusively low and must be raised to the lowest affirmable amount.

[32][33] Wilson's first contemion is that once the district court granted JNOV on the issues of future medical expenses, disability and loss of consortium, the court erred in not also granting JNOV on general damages. In *Chambers v. Graybiel* 25,840 (La.App. 2d Cir. 6/22/94), 639 So.2d 361, writ denied 94-1948 (La. 10/28/94), 644 So.2d 377, this court held that an inconsistent jury verdict must be read as a whole, to produce a judgment that is just, legal and proper on the record. In *Chambers*, the jury answered interrogatories by stating that neither defendant's conduct caused the plaintiff's damages; however, the jury also allocated fault between the defendants, awarded special damages and denied general damages. We held that the inconsistent responses--rejecting causation but awarding damages--would have to be construed as actually finding causation. We also held that it was inconsistem to award special damages hut completely *19 deny generals. *Sumrall v. Sumrall*, 612 So.2d 1010 (La. App. 2d Cir.1993); *Odendahl v. Wild*, 418 So.2d 36 (La.App. 4th Cir.1982); see also *Brantley v. General Motors Corp.*, 573 So.2d 1288 (La.App. 2d Cir.), writ denied 577 So.2d 17 (La.1991). [FN7] We further held that JNOV was the proper procedural device to correct these inconsistencies. We did not, however, hold that Just because the district court finds a jury error that reqmres JNOV as to one element of damage, the cour: must grant JNOV as to any or all other elements of damage. Rather, JNOV is warranted only when the district cour: finds that reasonable men must reach a verdict different from the jury's. *Anderson v NOPSI*, supra. Denial of the motion is discretionary and should not be disturbed absent an abuse of discretion. *Gibson v. Bossier City Gen l Hosp.*, 594 So.2d 1332 (La.App. 2d Cir.1991).

FN7. *Brantley* actually holds that it is error for the jury to award general damages hut completely deny "clearly proven" special damages.

[34] We have closely examined the instant record and are constrained to find that the jury abused its discretion in the award of general damages. Despite his prior disability and pain, this record is abundantly clear that Wilson sustained a significant period of very serious pain as a result of this accidem, **1265 and continues to endure a more pain than before.

The nature and extent of Wilson's post-accident pain is not really contested. He began to hurt immediately after he slipped; by the time he saw Dr. Garrett on October 29, he had severe pain in his artificial right hip and tingling in the front of his right thigh. Although there was no obvious fracture, Dr. Garrett suspected nerve damage, which he treated conservatively. By December 1, the hip was "popping," suggesting a partial dislocation. A special X-ray showed the artificial hip's femoral component was loose. After excluding Wilson's prior back condition as a canse of the hip pain, Dr. Garrett scheduled *20 him for a nerve decompression surgery in February 1993; this yielded relief for about three weeks. In April Dr. Garrett removed the old implant and put in a new one. Within five months Wilson reached maximum improvement; he testified that he has no more pain in the right hip. However, after he recuperated he began to notice pain in his left hip. He denied any prior problems in the left hip, although Dr. Garrett testified he had complained of pain there in 1990, when avascular necrosis was diagnosed. Dr. Garrett felt that the problem with the right hip probably accelerated the condition in the left. After replacing the left hip in January

1994, Dr. Garrett was still noting residual pain when he gave his deposition in March 1994. At trial in July 1994 Wilson was more graphic, describing his left hip pain as "the worst pain I've ever experienced in my life." R. p. 408.

Admittedly, Dr. Garrett felt that with the 1990 diagnosis of avascular necrosis Wilson was eventually going to need hip replacements anyway, and that young patients such as Wilson often required a revision. Dep., 45. Nevertheless, but for this accident Wilson would not have undergone one unsuccessful neural operation, and two hip implants as soon as he did, with some 11 months of serious pain for the right hip and several more for the left. Although the testimony is not expansive, it easily shows that the leg pain, on top of the back pain, made him cranky with his family and interrupted his marital relations for about 11 months. Moreover, Wilson was more susceptible to a period of enhanced mental anguish because of his history of health problems. On the special facts presented, we find the jury abused its discretion. The lowest amount it could have reasonably awarded was $80,000. Cf. *McGee v. Mears*, 516 So.2d 1241 (La.App. 2d Cir.1987); *Liner v. Terrebonne Parish Cons. Govt.*, 612 So.2d 168 (La.App. 1st Cir.1992); *Lee v. Missouri Pacific R. Co.*, *21 540 So.2d 287 (La.1989). The judgment will be amended accordingly.

Special damages JNOV

By its third assignment Hardee's urges the district court erred in granting Wilson's motion for JNOV with respect to three items of special damages: future medicals, disability, and Mrs. Wilson's loss of consortium. Hardee's argues that reasonable minds could indeed reasonably differ on these issues and thus the court improperly substituted its own judgment for that of the jury. *Anderson v. NOPSI*, supra; *Roland v. Tedesco*, 616 So.2d 780 (La.App. 2d Cir.), writ denied 619 So.2d 579 (La.1993).

By his sixth assignment Wilson challenges as inadequate the JNOV's award of $3,000 to Mrs. Wilson for loss of consortium. He cites Mrs. Wilson's testimony that she lost $3,300 from nursing fees while she stayed at home to care for her husband, and urges this is sufficient proof of her claim. In support he cites *Austin v. Pascarelli*, 612 So.2d 201 (La.App. 4th Cir.1992), writ denied 614 So.2d 1256, 1257 (La.1993). He also urges that his health problems caused him to cease marital relations with his wife for several months and made him "snappy" with her and the children, thus entitling Mrs. Wilson to general damages of $25,000.

[35] *Future medical expenses.* The record shows that two and a half years before this accident, Wilson was diagnosed with avascular necrosis in both hips. This condition had already necessitated the replacement of his right hip in March 1990, and Dr. Garrett indicated that the left hip would need replacement in time. Dr. Garrett did not, however, testify that this revision would be the result of the slip; he only stated that in young patients, implants often need revision **1266 anyway. On this evidence, we cannot say the "facts and inferences point * * * strongly and overwhelmingly" in favor of a finding that Wilson would incur an additional *22 $10,000 of medical expenses *as a result of this accident*. *Anderson v. NOPSI*, supra. The district court erred in granting JNOV to award this item of damages; the judgment will be amended.

[36] *Disability.* Wilson testified that since a work-related back injury in 1984 he has been on disability, neither working, seeking work nor taking vocational rehab. R. pp. 411-412. His wife and children draw his disability. R. p. 432. His medical history of three back surgeries in the mid-1980s and three epidural blocks for back pain in 1989 further support his status as totally disabled. He also described an auto accident in 1990 and a collision with a shopping cart at a discount store in May 1992 (five months before the instant slip). In support of this claim, Wilson testified that he had learned to live with his constant back pain, and that the new pain in his right hip after this accident was worse than anything he had experienced before. Mrs. Wilson was unaware of whether her husband still had any residual back pain from

the work-related injury, and was not even certain that he was on disability. R. pp. 393-394. On this evidence, there is indeed a "valid line of reasoning and permissible inferences which could possibly lead rational men and women to the conclusion reached by the Jury," namely that *this injury* did not cause Wilson any greater permanent disability than he was destined to have. *Roland v. Tedesco*, supra. Simply put, there is significant evidence that the disability predated the accident. The judgment will be amended to delete this award.

[37] *Mrs. Wilson's loss of consortium.* Mrs. Wilson testified, somewhat inconsistently, as to the wages she allegedly lost while she tended her husband during his recuperation. [FN8] The elements of loss of consortium, however, include *23 loss of love and affection, society and companionship, sexual relations, the right of performance of material services, right of support, aid and assistance, and loss of felicity. *Finley v. Bass*, 478 So.2d 608 (La.App. 2d Cir. 1985). The claimant's loss of income is not an element. Thus the award of $3,000 for Mrs. Wilson's loss of income must be reversed.

FN8. In answers to interrogatories three months before trial she set these losses at $600 to $700. At trial, she calculated her loss of income for the same period at $3,480. R. pp. 384-386. Even though this would have yielded an annual income of about $10,000, she testified that she filed no income tax returns from 1990 through 1993. R. p. 394. She also testified that all her work was on a cash basis for which she had absolutely no records.

[38] However, the record supports a finding that Mrs. Wilson did sustain some damage, albeit minimal, for lost felicity and society. Wilson's hip pain made him "snappy" with her and his children; marital relations ceased for 11 months; there was some tension in the marriage; and her sleep was interrupted. R. p. 387. For these inconveniences, the lowest affirmable award is $2,000, which the judgment will be amended to include. Cf *Odom v. Claiborne Electric Co-Op Inc.*, 623 So.2d 217 (La.App. 2d Cir.), writ denied 629 So.2d 1171 (La.1993); *Daigle v. Johnson*, 633 So.2d 268 (La.App. 1st Cir. 1993).

Conclusion

For the reasons expressed, the Judgment is affirmed with respect to the liability of the parties and their comparative fault of 50% each. The JNOV is also affirmed insofar as it fixed past medical expenses at $72,709.07. The judgment is amended to increase Wilson's total general damages for pain, suffering and mental anguish from $50,000 to $80,000. The judgment is also amended to decrease the award for loss of consortium from $3,000 to $2,000. Finally, the judgment is reversed insofar as it awarded future medical expenses and disability; these items are deleted. Judgment is therefore rendered in favor of the plaintiff, James Wilson, and against the defendant, Hardee's Food Systems Inc., in the amount of Seventy-six thousand, three hundred fifty-four and 54/100 ($76,354.54) dollars; and in favor of the plaintiff, Sherry Wilson, against the defendant, Hardee's Food Systems Inc., in the amount of One **1267 *24 thousand ($1,000.00) dollars, both amounts bearing legal interest from date of judicial demand, April 29, 1993. Costs of appeal are assessed equally to each side.

AFFIRMED IN PART, REVERSED IN PART AND RENDERED.

END OF DOCUMENT

Citation Found Document Rank 1 of 1 Database
JVR No. 127390 LRP-JV
(Cite as: 1994 WL 180628 (LRP Jury))

*1 TITLE: PLETCHER v. DEPUY, INC.
DOCKET-NUMBER:
COURT: Circuit
STATE: County, Virginia
DATE:
Incident:
Filing:
Settlement: January, 1994
APPEAL:
Was Appeal Filed:
Name of Person(s) Filing:
RANGE AMOUNT: $100,000 - $199,999
OUTCOME: Settlement
NON VERDICT AWARD: $110,000
SETTLEMENT TIME: Before Trial
TOTAL VERDICT: $110,000
JUDGE REDUCED AWARD TO:
VENUE CHANGE:
PRIMARY INJURY: Hip Replacement
SECONDARY INJURY:
PERMANENT PAIN:
PERMANENT SCARRING:
LIMITED MOTION:
BODILY IMPAIRMENT:
PERMANENT WEAKNESS:
INJURY TO DOMINANT HAND / ARM:
INTERNAL FIXATION:
NUMBER OF DAYS OF TREATMENT:
LIABILITY:
General: Products liability
Specific: Prosthesis
PLAINTIFF:
Sex: Female
Age: 40
Race:
General Occupation:
Occupational Field:
DECEDENT:
Sex:
Age:
Race:
Occupation:
Married:
Number of Minor Children:

JVR No. 127390
(Cite as: 1994 WL 180628, *1 (LRP Jury))

Number of Adult Children:
Days of Conscious Survival:
Days of Unconscious Survival:
Funeral Expense:
Other Expenses:
DEFENDANT:
Type: Single Organization
Sex: Organization
Organization Type: Manufacturing-Rubber and Plastics
Race:
General Occupation:
Occupational Field:
Insurance:
Policy Limit:
EXPERT-WITNESSES:
Plaintiff:

FINAL DEMAND:
FINAL OFFER:
HIGH / LOW AGREEMENT:
HIGH AMOUNT:
LOW AMOUNT:
CLAIMED PAST MEDICAL: $20,000
CLAIMED FUTURE MEDICAL:
CLAIMED PAST WAGE EXPENSE:
CLAIMED FUTURE WAGE EXPENSE:
FUTURE WAGE LOSS CLAIMED BY ECONOMIST:
Plaintiff's Economist:
Defendant's Economist:
DAMAGES:
Compensatory:
Past Medical:
Future Medical:
Past Wage:
Future Wage:
Pain and Suffering:
Other: $110,000
Total: $110,000
Punitive:
Hedonic:
Property:
Other:
Interest:
Loss of Services:
Loss of Services By:
INTRAFAMILY SUIT:
RES IPSA LOQUITUR:

JVR No. 127390
(Cite as: 1994 WL 180628, *1 (LRP Jury))

DEFENDANT CONTENDED PLAINTIFF ASSUMED RISK:
DEFENDANT ADMITTED LIABILITY:
COMPARATIVE NEGLIGENCE PERCENTAGE:
SMOKER:
ATTORNEY:
  Plaintiff:
  Defendant:
JUDGE:

TEXT:
  A 40-year-old female suffered a total hip replacement when a hip prosthesis, manufactured by the defendant company, failed three years following implantation.
FLETCHER v. DEPUY, INC.
JVR No. 127390, 1994 WL 180628 (LRP Jury)
END OF DOCUMENT

Citation Found Document Rank 1 of 1 Database
JVR No. 76466 LRP-JV
(Cite as: 1991 WL 451273 (LRP Jury))

*1 TITLE: MONNES v. ZIMMER, ET AL.
DOCKET-NUMBER:
COURT: Superior
STATE: Middlesex County, Connecticut
DATE:
Incident:
Filing:
Trial: July, 1991
APPEAL:
Was Appeal Filed:
Name of Person(s) Filing:
RANGE AMOUNT: $200,000 - $499,999
OUTCOME: Plaintiff Verdict
NON VERDICT AWARD: $352,000
TOTAL VERDICT: $352,000
JUDGE REDUCED AWARD TO:
VENUE CHANGE:
PRIMARY INJURY: Aggravated Hip Injury
SECONDARY INJURY:
PERMANENT PAIN:
PERMANENT SCARRING:
LIMITED MOTION:
BODILY IMPAIRMENT:
PERMANENT WEAKNESS:
INJURY TO DOMINANT HAND / ARM:
INTERNAL FIXATION:
NUMBER OF DAYS OF TREATMENT:
LIABILITY:
General: Products Liability
Specific: Prosthesis
PLAINTIFF:
Sex: Male
Age: 58
Race:
General Occupation:
Occupational Field:
DECEDENT:
Sex:
Age:
Race:
Occupation:
Married:
Number of Minor Children:
Number of Adult Children:

JVR No. 76466
(Cite as: 1991 WL 451273, *1 (LRP Jury))

Days of Conscious Survival:
Days of Unconscious Survival:
Funeral Expense:
Other Expenses:
DEFENDANT:
Type: Single Organization
Sex: Organization
Organization Type:
Race:
General Occupation:
Occupational Field:
Insurance:
Policy Limit:
EXPERT-WITNESSES:
Plaintiff:

FINAL DEMAND:
FINAL OFFER:
HIGH / LOW AGREEMENT:
HIGH AMOUNT:
LOW AMOUNT:
CLAIMED PAST MEDICAL:
CLAIMED FUTURE MEDICAL:
CLAIMED PAST WAGE EXPENSE:
CLAIMED FUTURE WAGE EXPENSE:
FUTURE WAGE LOSS CLAIMED BY ECONOMIST:
Plaintiff's Economist:
Defendant's Economist:
DAMAGES:
Compensatory:
Past Medical:
Future Medical:
Past Wage:
Future Wage:
Pain and Suffering:
Other: $352,000
Total: $352,000
Punitive:
Hedonic:
Property:
Other:
Interest:
Loss of Services:
Loss of Services By:
INTRAFAMILY SUIT:
RES IPSA LOQUITUR:
DEFENDANT CONTENDED PLAINTIFF ASSUMED RISK:

JVR No. 76466
(Cite as: 1991 WL 451273, *1 (LRP Jury))

DEFENDANT ADMITTED LIABILITY:
COMPARATIVE NEGLIGENCE PERCENTAGE:
SMOKER:
ATTORNEY:
Plaintiff:
Defendant:
JUDGE:

TEXT:
A 58-year-old male suffered an increased loss of function to the right hip as a result of the attempted implant of the defendant manufacturer's product. The plaintiff contended that he experienced a continuing sensation that the prosthesis was coming out and that his continuing problems with the hip had taken away his ability to enjoy and participate in his usual physical activities. The plaintiff had suffered from osteoarthritis requiring bilateral hip replacement. The left side was completed successfully, but complications arose during the surgery for the right side. The plaintiff contended that the prosthesis was bowed posteriorly when in fact it should have bowed anteriorly. The plaintiff maintained that while attempting to insert the prosthesis into place, the co-defendant surgeon fractured the plaintiff's femur, requiring that the femur be reamed, or dug out from the inside. The plaintiff also contended that the co-defendant made repeated attempts to insert the prosthesis and then had to cement a different prosthesis into the plaintiff's leg, wiring the plaintiff's femur into place. The plaintiff then underwent a complete replacement of the prosthesis after the wiring broke down and the cement came loose. The defendant did not dispute the plaintiff's claim of the defective prosthesis but contended that the co-defendant was negligent in failing to note the defect and in attempting to force the prosthesis into place. The co-defendant denied negligence and maintained that he assumed that the prosthesis was properly manufactured. The jury found no negligence on the part of the co-defendant.
***2** MONNES v. ZIMMER, ET AL.
JVR No. 76466, 1991 WL 451273 (LRP Jury)
END OF DOCUMENT

Citation Found Document Rank 1 of 1 Database
JAS OH Ref. No. 13462WL JASOH-JV
(Cite as: 1994 WL 1723817 (JAS.Ohio Jury))

***1** TITLE: JAMES AND ELOISE MULLIGAN v. HOWMEDICA, A SUBSIDIARY OF PHIZER
DOCKET-NUMBER: C-1-92-671
VENUE:
Court: United States District Court
COUNTY: Hamilton County
STATE: Ohio
YEAR:
Verdict/Settlement: April 21, 1994
TOPIC: Products Liability Product Liability - Artificial Knee Implant - Delamination Consortium
SUMMARY:
Alleged Injury: Permanent knee injury requiring revision surgery. Plaintiff claimed $45,000 in medical specials and $100,000 to $200,000 in lost income. Plaintiff's wife claimed loss of consortium.
Plaintiff Information:
Age: 60; 60
Sex: M
Occupation: Teacher/athletic director
Marital Status: Married
Insurance Carrier:
Result: Verdict: $216,000 Breakdown: $200,000 to James and $16,000 loss of consortium.
Jury Deliberations: 1 day
Settlement Efforts:
Last Demand: $125,000
Last Offer: $50,000
RANGE AMOUNT: $200,000-499,999
ATTORNEY:
Plaintiff's: Janet G. Abaray, Cincinnati
Defendant's: Michael E. Eagen, Cincinnati Nancy K. Griffiths, Cincinnati
JUDGE: S. Arthur Spiegel
EXPERT WITNESSES:
Plaintiff's: John Sauer - Engineer - Cincinnati OH; Harvey Rosen, Ph.D. - Economist - Cleveland OH; Mark Siegel, M.D. - Orthopedic - Cincinnati OH
Defendant's: John Lyons, M.D. - Orthopedic - Erie PA; S. Cook, M.D. - Orthopedic - New Orleans LA; Thomas Bender, M.D. - Orthopedic - Cincinnati OH
FACTS:
Plaintiff received an artificial knee implant, the PCA Total Knee Implant manufactured by Defendant Howmedica, a subsidiary of Phizer. The implant allegedly failed due to delamination of the polyethylene tibial component. Plaintiff suffered bone resorption due to plastic fragments and subsequently underwent revision knee surgery.

Plaintiff alleged that: (1) defendant used a heat pressing technique to

manufacture the polyethylene component which created a stratified surface layer in the plastic, leading to delamination of the outer surface layer; (2) defendant was negligent in failing to test the material properties of the plastic after heat pressing; and (3) defendant knew testing was necessary based upon written warnings of engineers.

Defendant contended that plaintiff misused the product and that all knee implants ultimately fail.

EDITOR'S NOTE:
PUBLISHED IN: Vol. 8, No. 8

D.Ohio
END OF DOCUMENT

Citation Search Result Rank(R) 1 of 4 Database
94 FJVR 9-79 JV-ALL
1994 WL 865304 (FJVR)
(Publication page references are not available for this document.)

TITLE: VERA PESOVIC vs. BARNETT BANK OF PINELLAS COUNTY
DOCKET-NUMBER: 92-4823 CI
VENUE:
Court: Florida Circuit Courts
COUNTY: Pinellas
STATE: **Florida**
YEAR: May 11, 1994 (Verdict/Settlement Date)
TOPIC: Slip/Fall/Bank.
SUMMARY:
Nature of Injury: Injury to right **hip** requiring a surgical **implant.**

Verdict: $36,000 for Plaintiff on May 11, 1994 ($26,000 - past medical expenses; $10,000 - past pain and suffering)
Plaintiff's Negligence: 75%
Defendant's Negligence: 25%

Judgment: $9,000 for Plaintiff.

Plaintiff Information:
Age: 40
Sex: F
Occupation: n/a
RANGE AMOUNT: $1-$49,999
ATTORNEY(S):
Plaintiff's: Dennis E. Dabroski of Boydstun, Dabroski & Lyle, St. Petersburg
Defendant's: William T. Atchley, Jr. of Fowler, White, et al., St. Petersburg
JUDGE: Fred L. Bryson
EXPERT-WITNESSES: N/A
TEXT:
Cause of Injury: On August 4, 1992, Plaintiff was attempting to enter one of Defendant's branch banking offices in St. Petersburg. As Plaintiff stepped onto the wheelchair ramp at the front entrance, she slipped and fell. Plaintiff contended that the worn paint on the surface of the ramp comprised uneven areas of traction, causing the ramp to become more slippery than the parking lot and sidewalk adjoining the ramp. Plaintiff contended that the improper maintenance of the wheelchair ramp was in violation of F.S. Ch. 553, which requires all wheelchair ramps to have a slip-resistant surface. Defendant denied negligence.

Fla.Cir.
94 FJVR 9-79, 1994 WL 865304 (FJVR)
END OF DOCUMENT

Citation Search Result Rank(R) 4 of 4 Database
87 FJVR 8-8 JV-ALL
1987 WL 356066 (FJVR)
(Publication page references are not available for this document.)

TITLE: SALLY LISKER vs. LEWIS ROSSI
DOCKET-NUMBER: 86-53783-CA (23)
VENUE:
Court: Florida Circuit Courts
COUNTY: DADE
STATE: **Florida**
YEAR: August 1987 (Publication Month/Year)
TOPIC: Slip/Fall/Wet Stairway.
SUMMARY:
Nature of Injury: Surgery was performed to repair a broken **hip** and to **implant** a prosthesis.

Verdict: $50,000 for the Plaintiff.
Plaintiff's Negligence: 52%
Defendant's Negligence: 48%

Judgment: $24,000 for the Plaintiff.

Plaintiff Information:
Age: 81
Sex: N/A
Occupation: Unemployed
RANGE AMOUNT: $50,000-99,999
ATTORNEY(S):
Plaintiff's: Robert L. Switkes and Paul D. Novak of Rosen & Switkes, Miami Beach
Defendant's: R. Pierce Kelley, Jr. of Lanza & O'Connor, Coral Gables
JUDGE: Joseph P. Farina
EXPERT-WITNESSES:
Plaintiff's: Hymie Mitrani, Building Inspector, Miami Beach
Oswald Ferro, Building Inspector, Miami Beach
Abraham Bichachi, M.D., Internal Medicine, Miami Beach
Bernard Tarr, M.D., Orthopedic Surgery, Miami Beach
Joseph Kalbac, M.D., Orthopedic Surgery, Miami
David Lehrman, M.D., Orthopedic Surgery, Miami Beach
Todd Kim, M.D., Orthopedic Surgery, Miami Beach
Lewis Dan, M.D., Ophthalmology, Miami

TEXT:
Cause of Injury: On September 15, 1986, after being away temporarily, Plaintiff returned to her apartment which is owned by Defendant. Shortly after a rainfall Plaintiff attempted to climb the three stairs ascending to her apartment. The stairs were not equipped with a handrail and were exposed to the elements. Plaintiff slipped and fell on the stairs. Plaintiff alleged that the Defendant negligently maintained the premises and that the slip and fall was the result of such negligently maintained conditions.

Defendant argued that the Plaintiff failed to establish that the Defendant

87 FJVR 8-8
(Publication page references are not available for this document.)

breached his duty to maintain the premises. Defendant claimed that he had no notice of the dangerous condition and also contended that Plaintiff testified that the injury was her own fault.

NOTES:
Editor's Note: Plaintiff made statements in depositions relating to her fault and negligence.

Fla.Cir.
87 FJVR 8-8, 1987 WL 356066 (FJVR)
END OF DOCUMENT

FOCUS - 3 OF 9 DOCUMENTS

JOAN ELAM vs. HARRIS METHODIST HOSPITALS, FORT WORTH

Case No. 348-120918-89

July 1991

TOPIC: PREMISE LIABILITY - Hospital visitor sustains injury from a slip and fall - Fractured hip

RESULT: $131,400.00 Cash (Settlement)

INJURY: Impacted fracture (R) hip - operated - Bipolar hip prosthesis implant

SPECIALS: Past Medical: $30,000.00; Future Medical: $22,000.00; Lost Earnings: Not Disclosed; Lost Future: Not Disclosed

STATE: Texas

COUNTY: Tarrant

COURT: 348th

PLAINTIFF PROFILE:
Age: 59
Marital Status: Divorced
Job: Unemployed Lab Technician
Current Salary: $10,000.00

PLAINTIFF ATTORNEY: Steve Laird (817-531-3000)

DEFENDANT ATTORNEY: Steve Madsen (817-877-2800)

FACTS: On or about the 29th day of April, 1989, Plaintiff, in the company of her son, was visiting her daughter-in-law, who had just given birth at Defendant hospital. On this occasion, upon approaching the elevator area and noticing a "wet floor" sign nearby, Ms. Elam asked and was granted permission by a hospital maintenance employee to enter a certain elevator. Subsequently, upon exiting the elevator, Ms. Elam was caused to suffer injury when she slipped and fell on the hallway due to the soles of her shoes having become wet from the carpet in the elevator.

Counsel for Plaintiff, taking the position that the maintenance worker had just cleaned the carpet in the elevator without properly drying same, brought action contending Defendant had been negligent in failing to warn of an unreasonably dangerous condition.

Counsel for Defendant denied the Plaintiff's allegations, taking the position that the carpet in the elevator had not been cleaned. In the alternative, if same had been the case, he claimed that unknown third parties had prematurely put the elevator back into service.

PLAINTIFF EXPERTS:
Dr. Fred Sanders, Ortho - Surgeom, Fort Worth
Bill Richardsom, Ph.D., Vocational Rehab., Denton

Published in 07/91 page PI-106

LEVEL 1 - 5 OF 6 DOCUMENTS

SELGER vs. STEVENS NURSERY & HARDWARE

Case No. NWC-035373 Verdictum Juris No. 89-88C

Verdict Date: April 13, 1989

TOPIC: Premises Liability

RESULT: $473,000 Gross (verdict)

Pltf. found 15% negligent Net to Pltf. $402,050

INJURY: Fractured left leg requiring a new hip and femoral stem implant.

SPECIALS: $33,000 Medical; $120,000 Fut. Med; $20,000 Household help.

STATE: California

ARRA: Van Nuys

JUDGE: Hon. Robert Letteau - Dept. G

PLAINTIFF ATTORNEY: Richard B. Koskoff, Torrance

DEFENDANT ATTORNEY: Rudolf Schroeter, Los Angeles

POLL: 9-3

TITLE: A "Fertilized" Sidewalk

FACTS: On 5/14/87, the Pltf., age 70 and unemployed, was walking along the sidewalk in front of the Deft.'s nursery. She frequently walked in this area and noticed that quite often there was dog droppings on the sidewalk. The nursery had no guard dogs. The Pltf. slipped and fell on the droppings and fractured her left leg. She had been born with a birth defect dislocated hip. She had surgery at 8-years-old and at 11-years-old. Then 11 years ago a hip prosthesis and femoral stem implant was done. As a result of the fall, she had to have a completely new hip implant.

PLAINTIFF CLAIMED that the Deft. knew or should have known of the dangerous condition and had a duty to keep the sidewalk clean and safe.

DEFENDANT ARGUED the Pltf. should have looked where she was walking and caused her own accident.

PLAINTIFF MEDICAL EXPERTS:
Herbert Huddleston - Orthopedic Surg. - North Hollywood

PLAINTIFF TECHNICAL EXPERTS:
Charles Turnbow - Slip & Fall - Apple Valley

OFFER: Nothing
DEMAND: $300,000

TRIAL TIME: 1 Week

JURY TIME: 3/4 Day

DRAFT

THIS NOTICE MAY AFFECT YOUR RIGHTS

PLEASE READ IT CAREFULLY

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	MDL Docket No. 01-CV-9000 ALL CASES (JUDGE KATHLEEN O'MALLEY)

NOTICE OF PENDENCY OF CLASS ACTION AND PRELIMINARY APPROVAL OF SETTLEMENT REGARDING CERTAIN HIP AND KNEE REPLACEMENT DEVICES MANUFACTURED BY SULZER ORTHOPEDICS INC.

1. Why should I read this Notice?

The purpose of this Notice is to inform you that there is now pending in this Court a class action on behalf of all people residing in the United States who were implanted with certain recall manufacturing lots of Inter-Op™ acetabular shells, hip replacement devices manufactured by Sulzer Orthopedics Inc. On _____, this Court gave preliminary approval to a settlement of the class action. The purpose of this Notice is to describe the settlement to you. You should read this Notice to determine whether you wish to participate in the class action settlement.

2. What is a class action?

A class action is a type of lawsuit in which one or a few named plaintiffs bring suit on behalf of all the members of a similarly situated group to recover damages for all of the group, without the necessity of each member filing an individual lawsuit or appearing as an individual plaintiff. Class actions are used by the courts where the claims raise basic issues of law or fact that are common, making it fair to bind all class members to the orders and the judgment in the case, without the necessity of hearing essentially the same claims over and over again. Use of a class action eliminates the necessity of filing multiple suits, and assures that all class members are bound by the results of the lawsuit.

3. What is this lawsuit about?

Sulzer Orthopedics Inc. makes and sells implantable orthopedic devices, including hip and knee replacement systems. On December 5, 2000, Sulzer Orthopedics Inc. announced a voluntary recall of certain manufacturing lots of its Inter-Op™ acetabular shell after investigating reports that some shells were not staying tightly implanted. (The recalled acetabular shells will hereinafter be referred to as "Affected Products"). A few months later, Sulzer Orthopedics Inc. voluntarily withdrew a second product, a knee replacement component known as the Natural Knee II™ tibial baseplate, from the market. Several patients have filed lawsuits alleging that an Affected Product caused them injury.

This class action lawsuit was brought by the Class Representatives, _____, on behalf of themselves and on behalf of the Class defined below. The Class Representatives are represented by Class Counsel, _____. The Class Representatives allege that the recalled Inter-Op™ shells are defective and that Sulzer Orthopedics Inc. and its affiliates are responsible for injuries allegedly caused by the Affected Products. The seek monetary damages on behalf

of the Class and injunctive relief in the form of a program to monitor the health of patients who received Affected Products, but have experienced no injury or adverse symptoms.

Following the filing of several lawsuits, SOI reached a settlement agreement with the Class Representatives, which has been preliminarily approved by this Court. On _____, this Court issued an order preliminarily certifying this case as a class action for settlement purposes and defining the Settlement Class as follows:

> All persons or entities wherever located, who have or may in the future have any unsatisfied claim (whether filed or unfiled, pending or reduced to judgment, existing of contingent, and specifically including claims for alleged injuries and damages not yet known or manifest), including assigned claims (e.g., subrogation claims by workers compensation insurers, employers and/or health care insurers or providers), against any of all of Sulzer and the other Released Parties and arising out of, based upon, related to, or involving Affected Products, including (a) all Affected Product Recipients (whether or not such Affected Product has been or may be removed), (2) all Derivative Claimants and (3) all Representative Claimants. The Settlement Class specifically includes persons who have or may have claims with respect to injuries not yet manifested. The Settlement Class shall expressly exclude any person or entity that entered into a settlement with Sulzer (which included a release) related to claims arising out of the implantation of an Affected Product.

On the same date, this Court approved the sending of this Notice to all Class Members to allow them the opportunity to indicate whether they want to accept the benefits of the settlement more fully described below. The Court has set the date of _____ to have a hearing in order to approve finally the settlement. You are not required to appear at this hearing in order to accept the benefits of the settlement. If you want to exclude yourself from the settlement, you are required to take the actions more fully described below in paragraph 10.

4. Who is included in this Class Action?

On _____, the Court certified for settlement purposes a preliminary nationwide Settlement Class under Federal Rule of Civil Procedure 23. The Settlement Class is defined as set forth in paragraph 3 of this Notice. The class settlement excludes from participation all persons who, in accordance with the terms of this Notice, execute a timely request for exclusion from the settlement, and thus, voluntarily opt-out of this class action proceeding.

5. What are the terms of the settlement?

Under the terms of the settlement preliminarily approved by the Court on _____, the class members will be paid in five subclasses as follows:

- Group I consists of class members who have undergone or will undergo replacement of *one* Affected Product before December 31, 2008. Defendants will pay reasonable and necessary medical expenses to replace the Affected Product. In addition, each Group I member will receive $37,500 in cash and 3,922 American Depository Receipts ("ADRs") of Sulzer Medica Ltd., publicly traded on the New York Stock Exchange (NYSE:SM). On August 14, 2001, the ADRs traded at $5.20 per ADR.

- Group II consists of class members who have undergone or will undergo replacement of *more than one* Affected Product before December 31, 2008. Members of Group II will receive medical expenses, plus $63,500 in cash and 6,667 ADRs.

- Group III consists of class members who do not have their Affected Products replaced before December 31, 2008. Each Group III member will receive $750 in cash and 392 ADRs, a total value of $2,750. If Group III members undergo revision surgery before December 31, 2008 — and thus change Groups — their compensation as members of Group I or Group II will be reduced by the amounts they already received.

- Group IV consists of spouses of members of Group I and Group II, class members who have undergone revision surgery. These spouses will receive $5,000.

- Group V consists of spouses of Group III members, non-revised members. Those spouses will receive $500.

In addition, Sulzer Orthopedics Inc. will establish an Extraordinary Fund to provide additional compensation in extraordinary cases, a Medical Monitoring Fund to pay for periodic x-rays for class members who have not undergone revision surgery, and a Research Fund to to finance medical research relating to reconstructive orthopedic implants.

The Settlement Agreement also provides for contingency attorneys' fees. If a class member was represented by an attorney in connection with an Affected Product under a written agreement as of August 2, 2001, the attorney will receive a fee equal to one-third of the total payments made to the represented class member. Attorneys will be paid two-thirds in cash and one-third in ADRs.

The benefits described above will hereinafter be referred to as the "Class Benefit."

6. Do I need to do anything in order to participate in the settlement?

No, if you wish to remain a member of the Settlement Class, you do not need to do anything at this time.

7. What information will be needed from me?

If the Court gives final approval to the settlement, Sulzer Orthopedics Inc. will distribute a claim form on which you will need to provide information such as the lot number(s) of the Affected Product(s) that you believe you were treated with and whether you have undergone surgery to have an Affected Product removed and replaced. Sulzer Orthopedics Inc. will also need to know information about your medical expenses.

8. What does class membership mean?

If you remain a member of the Settlement Class, then:

(a) The Class Representative and the Class Counsel, including those listed on this Notice, will act as your representative and counsel for the approval of the settlement. You are not required to pay for these lawyers' services, or for the costs of the lawsuit.

(b) You will be entitled to participate in the Class Benefit resulting from the settlement in favor of the Settlement Class.

(c) You will be bound by the terms and conditions of the settlement and releases, as well as any judgment or dismissal in the lawsuit.

9. Who represents the Class?

(a) The Class Representative. _____

(b) Class Counsel. The Court has appointed the following plaintiffs' Class Counsel to represent your interests and those of the Settlement Class:

_____

10. How can I exclude myself from the Class?

If you do NOT want to participate in the settlement and wish to exclude yourself, that is, to "opt out" of this settlement, then you must submit a letter requesting exclusion to Sulzer Orthopedics Inc. c/o Kenneth M. Seeger, Esq., Crosby, Heafey, Roach & May Professional Corporation, Two Embarcadero Center, Suite 2000, San Francisco, CA 94111, postmarked no later than _____ (the "Opt-Out Request"). The Opt-Out Request must include your full name and must be signed by you. DO NOT WRITE REQUESTING EXCLUSION IF YOU WISH TO SHARE IN THE CLASS BENEFIT.

11. What is the effect of exclusion?

By electing to be excluded from the settlement (a) you will not share in the Class Benefit, (b) you will not be bound by any further orders or judgment entered for or against the Settlement Class, and (c) you may pursue any claims you may have against Zenith by filing your own lawsuit at your own expense.

12. What if I want to object to or comment on the settlement?

If you decide to remain a member of the Settlement Class and you wish to object to the settlement of otherwise comment upon the settlement, you must file such objections or comments with the Court by _____. Any papers filed with the Court must be served on the Class Counsel (set forth in paragraph __) and counsel for Sulzer Orthopedics Inc. (set forth in paragraph __). If you do not file an objection or comment by _____, you will be precluded from appearing at the fairness hearing for final approval of the settlement on _____.

13. What is the effect of the final settlement approval?

The proposed settlement does not constitute an admission of liability on the part of Sulzer Orthopedics Inc. or any other person or entity. If the Court grants final approval of the settlement, the claims of all members of the Settlement Class against Sulzer Orthopedics Inc. and its affiliates and insurers, against any surgeon involved in implanting an Affected Product, and all other persons and entities involved in making and selling Affected Products, including all claims that have been asserted or that could have been asserted against such persons or entities in connection with any Affected Product. No member of the Settlement Class would be permitted to continue to assert any such claim in any litigation against such person or entity.

14. Where do I get additional information?

If you decide to remain a member of the Settlement Class and you wish to communicate with or obtain information from the Class Counsel, you may do so by writing to the Class Counsel at one of the addresses listed in paragraph 9(b). PLEASE DO NOT CONTACT THE COURT.

This Notice provides only a summary of matters relating to the settlement. You may seek the advice and guidance of your own private attorney at you own expense if you wish. For more detailed information, you may review the pleadings, records and other papers on file in this litigation. You may inspect these documents during regular Court hours at the United States District Court for the Northern District of Ohio, Eastern Division, 201 Superior Avenue, Cleveland, Ohio.

15. Summary of important dates.

- YOUR DEADLINE TO FILE ANY OBJECTION WITH THE COURT _____
- YOUR DEADLINE TO OPT OUT OF SETTLEMENT _____
- FINAL FAIRNESS HEARING _____

DATED:

Kathleen M. O'Malley
United States District Judge

Draft 8/15/2001

CLASS ACTION
SETTLEMENT AGREEMENT

Among

SULZER ORTHOPEDICS INC. AND AFFILIATED ENTITIES
INCLUDING
SULZER MEDICA LTD.

and

CLASS COUNSEL ON BEHALF OF CLASS REPRESENTATIVES
IN RE INTER-OP HIP PROSTHESIS PRODUCTS LIABILITY LITIGATION
MDL Docket No. 01-CV-9000 (MDL No. 1401)

dated as of

August 15, 2001

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CLASS ACTION SETTLEMENT AGREEMENT
WITH SULZER ORTHOPEDICS INC., et. al.

This SETTLEMENT AGREEMENT, dated as of August 15, 2001, is entered into by and among Sulzer Orthopedics Inc., a Delaware corporation ("SOUS"), and its affiliated entities (including Sulzer Medica Ltd., a limited company organized under the laws of Switzerland ("SML"), and each of the other SML direct or indirect subsidiaries (such subsidiaries, together SOUS, SML and any other direct or indirect subsidiaries of SML, are referred to collectively herein as "Sulzer"), on behalf of themselves and the other Released Parties hereunder, and the undersigned Class Counsel on behalf of the Class Representatives (in each case, as defined herein). The Class Representatives, together with Sulzer, are sometimes referred to herein as the "Parties".

RECITALS

WHEREAS, Sulzer and the Class Representatives hereby agree to a class action settlement, subject to the approval of the District Court, with respect to Class Members in the United States which would resolve, on the terms set forth in this Settlement Agreement, Settled Claims against Sulzer and other Released Parties arising from the Affected Products, pending in various courts, including but not limited to claims which have been made in the actions that have been or will be transferred for coordinated or consolidated pretrial proceedings to the United States District Court for the Northern District of Ohio, Eastern Division (In Re Inter-Op Hip Prosthesis Product Liability Litigation (MDL No. 1401)), and in numerous other courts.

WHEREAS, this Settlement Agreement shall not be construed as evidence of or as an admission by Sulzer of any liability or wrongdoing whatsoever or as an admission by the Class Representatives or Class Members of any lack of merit in their claims.

NOW, THEREFORE, Sulzer and the Class Representatives hereby agree, subject to Final Judicial Approval, compliance with applicable legal requirements, and other conditions, all as set forth below, that the Patient Benefit Fund, Research Fund, Medical Monitoring Fund and Extraordinary Injury Fund shall be established, from which the benefits described herein will be paid to the Class Members of the proposed Settlement Class, and that the Settled Claims against Sulzer and other Released Parties, as defined herein, will be settled, compromised and released, in accordance with the following terms.

ARTICLE 1. DEFINITIONS

Section 1.1 For purposes of this Settlement Agreement the following terms shall have the meanings set forth in this Article 1. Terms used in the singular shall be deemed to include the plural and vice versa.

(a) "$" shall denote United States dollars.

(b) "ADR Depositary" shall have the meaning set forth in Section 6.1.

(c) "ADRs" shall mean the American Depositary Receipts of Sulzer (NYSE ticker symbol: SM), issued pursuant to that certain Deposit Agreement between SML and Citibank, N.A., as Depositary thereunder.

(d) "Affected Products" shall mean, collectively, (1) InterOp™ Acetabular shells ("InterOp Shells") identified in the SOUS's Safety Alert dated December 5, 2000 and certain other InterOp Shells machined after porous coating, (2) Natural Knee™ Tibial Baseplates identified in SOUS's Special Notification dated May 17, 2001 and (3) Reprocessed Shells sold prior to the date of this Settlement Agreement, in each case as identified by part and lot numbers on an addendum to be submitted to the Court after the date of this Settlement Agreement, approved by the Parties and the Court and attached as Annex II hereto.

(e) "Affected Product Recipients" shall mean persons in whose bodies one or more Affected Products have been or are now implanted in an operation or other surgical procedure, whether or not any such Affected Product has been or may in the future be removed.

(f) "Affected Product Related" shall mean arising out of, based upon, relating to, or involving an Affected Product.

(g) "Annual Payment Amount" shall have the meaning set forth in Section 2.9(d).

(h) "Business Day" shall mean any day other than Saturday, Sunday or any federal holiday.

(i) "CHF" shall denote Swiss francs.

(j) "Change of Control" means (i) the acquisition by any "person" or "group" (as such terms are used in Section 13(d)(3) of the Exchange Act) of ADRs and/or Shares such that such person becomes the ultimate "beneficial owner," as defined in Rule 13d-3 under the Exchange Act, of more than 50% of the total voting power of the Shares on a fully-diluted basis or (ii) any merger, consolidation, amalgamation or other similar transaction involving SML whereby the beneficial holders of Shares immediately prior to such transaction hold less than a majority of the outstanding voting power with respect to SML (or, if SML shall not be the surviving entity following such transaction, such successor entity) immediately following such transaction or (iii) the date on which less than a majority of the members of SML's board of directors ("continuing directors") serving on the date of this Settlement Agreement shall no longer serve on SML's board of directors, provided that any board member whose nomination is approved by continuing directors shall also be deemed to be a continuing director for purposes of this clause (iii); *provided, however*, that a Change of Control shall not be deemed to have occurred if any action contemplated by clauses (i), (ii) or (iii) of this definition is approved by at least a majority of the continuing directors of SML.

(k) "Claims Administrator" shall mean any person or persons to be appointed by mutual agreement of the Parties, subject to approval of the Court, to administer claims for Benefits pursuant to the Settlement Agreement.

(l) "Class Counsel" shall mean those attorneys executing this Settlement Agreement on behalf of the Class Representatives, or such other attorneys as shall be approved by the Court as counsel to the Settlement Class.

(m) "Class Members" shall mean members of the Settlement Class.

(n) "Class Representatives" shall mean, with respect to Subclass I, George Yasanchak and Mary Jane Yasanchack (as Derivative Claimant), with respect to Subclass II, Harlan N. Herman, Brenda K. Herman (as Derivative Claimant) and Linda F. Wells or different persons as shall be designated by the Court as the representatives of the Settlement Class, in the action captioned In Re Inter-Op Hip Prosthesis Product Liability Litigation (MDL Docket No. 01-CV-9000, MDL No. 1401).

(o) "Code" shall mean the Internal Revenue Code of 1986, as amended, or any successor statute.

(p) "Collateral Agent" shall have the meaning set forth in Section 2.8(a).

(q) "Consolidated Net Income" means, with respect to Sulzer for any period, the aggregate of the net income (used to compute earnings per share) of SML and its consolidated subsidiaries for such period, on a basis consistent with past practices, determined in United States dollars in accordance with IAS, as publicly reported in its annual report.

(r) "Court" and/or "Trial Court" and/or "Federal District Court" means the United States District Court for the Northern District of Ohio, Eastern Division.

(s) "Credit Facility" shall have the meaning set forth in Section 2.8(a).

(t) "Derivative Claimant" shall mean any person asserting the right to sue Sulzer independently or derivatively by reason of their personal relationship with a Affected Product Recipient, including without limitation, spouses, parents, children, dependents, other relatives or "significant others".

(u) "Extraordinary Injury Fund" shall have the meaning set forth in Section 2.1(e).

(v) "Extraordinary Injury Fund Amounts" shall have the meaning set forth in Section 3.5(a).

(w) "Fairness Hearing" means the hearing conducted by the Court to determine the fairness, adequacy and reasonableness of this Settlement Agreement under Fed. R. Civ. P. 23(e).

(x) "Fairness Hearing Date" means the date on which the Fairness Hearing takes place.

(y) "Final Approval Funding Amount" shall have the meaning set forth in Section 2.9(c).

(z) "Final Judicial Approval" refers to the approval of the Settlement Agreement by the Federal District Court and such approval becoming final by the exhaustion of all appeals. Final Judicial Approval shall be deemed not to have been obtained in the event that Trial Court Approval is denied, and the period for appealing such denial has expired without any such appeal having been taken.

(aa) "Final Judicial Approval Date" shall mean the date on which Final Judicial Approval occurs.

(bb) "Funds" means, collectively, the Research Fund, Medical Monitoring Fund, Patient Benefit Fund and Extraordinary Injury Fund.

(cc) "IAS" means International Accounting Standards as promulgated by the International Accounting Standards Board.

(dd) "Initial Funding Requirement" shall have the meaning set forth in Section 2.9(d).

(ee) "Initial Funding Shortfall" shall have the meaning set forth in Section 2.9(e).

(ff) "Insurance Proceeds" shall mean the insurance proceeds payable for the benefit of SOUS, SML or any SML subsidiaries and affiliates (up to applicable policy limits) by Winterthur International Insurance Company and Winterthur Swiss Insurance Company pursuant to and under the following policies: (i) Master Policy No. 3.307.351 (4/1/2000 to 4/1/2001); (ii) Excess Policy No. 3.307.352 (4/1/2000 to 4/1/2001); (iii) Excess Policy No. 3.307.353 (4/1/2000 to 4/1/2001); (iv) Excess Policy No. 3.167.933 (4/1/2000 to 4/1/2001); (v) Excess Policy No. 3.167.934 (4/1/2000 to 4/1/2001); and (vi) Excess Policy No. 3.312.133 (4/1/2000 to 4/1/2001).

(gg) "Liens" shall mean, with respect to any asset, any mortgage, lien, pledge, charge, security interest or encumbrance of any kind in respect of such asset.

(hh) "Matrix" shall have the meaning set forth in Section 3.5(a).

(ii) "Matrix Compensation Benefits" shall have the meaning set forth in Section 3.5(a).

(jj) "Maximum Amount" shall have the meaning set forth in Section 2.9(d).

(kk) "Medical Monitoring Fund" shall have the meaning set forth in Section 2.5(e).

(ll) "Medical Monitoring Fund Amounts" shall have the meaning set forth in Section 2.3(a).

(mm) "Medical Monitoring Period" shall have the meaning set forth in Section 2.3(a)(ii).

(nn) "Opt-Out Period" shall mean the period to be established by the Court during which Class Members may exercise the Opt-Out Right described in Section 3.6.

(oo) "Opt-Out Right" shall have the meaning set forth in Section 3.6(a).

(pp) "Parties" shall have the meaning set forth in the preamble.

(qq) "Patient Benefit Fund" shall have the meaning set forth in Section 2.5(e).

(rr) "Patient Benefit Fund Amounts" shall have the meaning set forth in Section 2.5(a).

(ss) "Plaintiffs' Counsel" shall mean any contingent-fee attorney who represents one or more individual Class Members pursuant to a written agreement executed and delivered by such Class Member on or prior to August 2, 2001.

(tt) "Preliminary Approval" shall mean the Federal District Court's conditional certification of the Settlement Class and preliminary approval of this Settlement Agreement pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3).

(uu) "Preliminary Approval Date" shall mean the date on which Preliminary Approval occurs.

(vv) "Released Parties" shall mean SOUS and each of its affiliates, including SML and each of SML's other past, present and future parent companies and direct or indirect subsidiaries, including without limitation those U.S. entities listed on Annex III, together with each of their respective past, present and future directors, officers, affiliates, insurers and agents, including without limitation, sales agents; Sulzer AG, a limited company organized under the laws of Switzerland, and all of its past, present and future parent companies and direct or indirect subsidiaries, its and their respective past, present and future directors, officers, affiliates, insurers and agents; Wintethur and all of its past, present and future parent companies and direct or indirect subsidiaries, its and their respective past, present and future directors, officers, affiliates, insurers and agents; all surgeons who performed primary and/or Revision Surgery with respect to Affected Products and affiliated physicians or physician groups, organized medical specialty organizations, raw material or other suppliers of Sulzer of materials used in the manufacture of the Affected Products, distributors of the Affected Products; and any other person or entity involved in the design, manufacture, distribution, implant or explant of an Affected Product.

(ww) "Representative Claimant" shall mean an estate, administrator or other legal representative, heir or beneficiary of an Affected Product Recipient.

(xx) "Reprocessed Shells" shall mean InterOp Shells identified in SOUS's Safety Alert dated December 5, 2000 that were not previously implanted and were then re-cleaned and implanted.

(yy) "Research Fund" shall have the meaning set forth in Section 2.1(e).

(zz) "Research Fund Amounts" shall have the meaning set forth in Section 2.2(a).

(aaa) "Revision Surgery" means surgical replacement of an Affected Product for reason other than trauma.

(bbb) "Secured Assets" shall have the meaning set forth in Section 2.8(a).

(ccc) "Securities Act" shall have the meaning set forth in Section 6.2.

(ddd) "Security Agreement" shall have the meaning set forth in Section 2.8(a).

(eee) "Settled Claims" shall mean any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the Affected Products. These "Settled Claims" include, without limitation and by way of example, all claims for damages or remedies of whatever kind or character, known or unknown, that are now recognized by law or that may be created or recognized in the future by statute, regulation, judicial decision, or in any other manner, for:

(i) personal injury and/or bodily injury, damage, death, fear of disease or injury, mental or physical pain or suffering, emotional or mental harm, or loss of enjoyment of life;

(ii) loss of wages, income, earnings, and earning capacity, medical expenses, doctor, hospital, nursing, and drug bills;

(iii) loss of support, services, consortium, companionship, society or affection, or damage to familial relations, by spouses, parents, children, other relatives or "significant others" of Settlement Class Members;

(iv) wrongful death and survival actions;

(v) medical screening and monitoring, injunctive and declaratory relief;

(vi) consumer fraud, refunds, unfair business practices, deceptive trade practices, Unfair and Deceptive Acts and Practices ("UDAP"), and other similar claims whether arising under statute, regulation, or judicial decision;

(vii) medical screening and monitoring, injunctive and declaratory relief;

(viii) compensatory damages, punitive, exemplary, statutory and other multiple damages or penalties of any kind including, without limitation, economic or business losses or disgorgement of profits arising out of personal injury; and

(ix) pre-judgment or post-judgment interest.

(fff) "Settlement Class" shall mean all persons or entities wherever located, who have or may in the future have any unsatisfied claim (whether filed or unfiled, pending or reduced to judgment, existing or contingent, and specifically including claims for alleged injuries and damages not yet known or manifest), including assigned claims (e.g., subrogation claims by workers compensation insurers, employers and/or health care insurers or providers), against any or all of Sulzer and the other Released Parties and arising out of, based upon, related to, or involving Affected Products, including (1) all Affected Product Recipients (whether or not such Affected Product has been or may be removed), (2) all Derivative Claimants and (3) all Representative Claimants. The Settlement Class specifically includes persons who have or may have claims with respect to injuries not yet manifested. The Settlement Class shall expressly exclude any person or entity that entered into a settlement with Sulzer (which included a release) related to claims arising out of the implantation of an Affected Product.

(ggg) "Settlement Trust Brokerage Account" shall mean the brokerage account established by the Trustee for the purpose of holding and distributing ADRs pursuant to this Settlement Agreement, as to which the Settlement Trust shall be the sole owner of any and all securities deposited therein until distributed to Class Members and Plaintiffs' Counsel in accordance herewith, provided that the Trustee shall not exercise voting rights with respect to the ADRs (to the extent such restrictions are permitted under the laws of the State of New York).

(hhh) "Shares" means the shares, CHF 30 nominal value, of Sulzer Medica Ltd.

(iii) "SML" shall have the meaning set forth in the Preamble.

(jjj) "SOUS" shall have the meaning set forth in the Preamble.

(kkk) "Special Master" shall have the meaning set forth in Section 3.5(b).

(lll) "Spouse" shall mean a spouse or other statutory spousal beneficiary of an Affected Product Recipient who was so at the time of the implant of the Affected Product.

(mmm) "Subclass I" shall mean all Class Members who have an unsatisfied claim arising out of (i) Revision Surgery performed prior to the Final Judicial Approval Date and/or (ii) facts that exist prior to the Final Judicial Approval Date that may be a basis for such Class Member to receive benefits under the Extraordinary Injury Fund.

(nnn) "Subclass II" shall mean all Class Members who have an unsatisfied claim arising out of (i) Revision Surgery performed on or after the Final Judicial Approval Date and/or (ii) facts that exist on or after the Final Judicial Approval Date that may be a basis for such Class Member to receive under the Extraordinary Injury Fund.

(ooo) "Sulzer" shall have the meaning set forth in the Preamble.

(ppp) "Term Sheet" shall have the meaning set forth in Section 14.11.

(qqq) "Trial Court Approval" shall mean the granting, by order entered on the docket thereof, of the approval of the Settlement Agreement by the Federal District Court.

(rrr) "Trial Court Approval Date" shall mean the date upon which Trial Court Approval occurs.

(sss) "Trust" or "Settlement Trust" shall mean a trust established to receive funds to be paid by Sulzer as provided in this Settlement Agreement pursuant to the Trust Agreement.

(ttt) "Trustee" shall mean those individuals approved by the Court as Trustee of the Settlement Trust in accordance with the Trust Agreement.

(uuu) "Trust Agreement" shall mean the Settlement Trust Agreement substantially in the form to be agreed to by the Parties.

(vvv) "Winterthur" shall have the meaning set forth in Section 2.9(b).

ARTICLE 2. SETTLEMENT TRUST AND FUNDS

Section 2.1 ESTABLISHMENT OF SETTLEMENT TRUST

(a) A Settlement Trust shall be established to receive the Research Fund Amounts, Medical Monitoring Fund Amounts, Patient Benefit Fund Amounts and Extraordinary Injury Fund Amounts to be paid by Sulzer and to receive the ADRs to be transferred by Sulzer under the terms of this Settlement Agreement pursuant to the terms of the Trust Agreement.

(b) Promptly following the execution and delivery of this Settlement Agreement, the Parties shall agree on an interim Trustee to serve as Trustee of the Settlement Trust. At any time following Preliminary Approval (but in any event, no later than Final Judicial Approval), there shall be a single corporate Trustee of the Settlement Trust. The Trustee shall be a bank organized and doing business under the laws of the United States of America, any State thereof or the District of Columbia, authorized under such laws to exercise corporate trust powers, having a combined capital and surplus of at least $500,000,000, subject to supervision and examination by federal or state authority and shall be jointly appointed by Sulzer and Class Counsel, subject to the approval of the Court. The Trustee may serve as the paying agent responsible for distribution of payments, as specified in Article 3 herein.

(c) The Settlement Trust will begin as a reversionary trust and will become non-reversionary upon Final Judicial Approval. If Final Judicial Approval is not obtained, or if this Settlement Agreement is terminated in accordance with Article 10 hereunder, all amounts of cash or property remaining in the Settlement Trust after payment of any charges and expenses that the Settlement Agreement expressly authorized or required to be incurred and expended prior to the reversion date, including any amounts expended to assist in seeking Final Judicial Approval, shall be returned to Sulzer.

(d) Sulzer shall have no right to any of the funds previously deposited into or property previously transferred to, nor to any of the funds subsequently deposited into or property subsequently transferred to, the Settlement Trust, as of the date the Trust becomes non-reversionary. Sulzer shall have no further claim to such funds or property for any purpose.

Upon satisfaction in full of all obligations hereunder, any remaining funds and property shall be distributed in accordance with Section 14.7 hereunder.

(e) Subject to the conditions set forth in this Settlement Agreement, Sulzer shall be obligated to make or cause to be made payments as set forth in Section 2.2 (the "Research Fund"), Section 2.3 (the "Medical Monitoring Fund"), Section 2.4 (the "Patient Benefit Fund") and Section 2.5 (the "Extraordinary Injury Fund") below to the Settlement Trust, in each case in accordance with the terms of this Settlement Agreement. Such payments shall be made by wire transfer. If any date of payment provided herein is not a Business Day, such payment shall be due and payable on the first Business Day following such date.

Section 2.2 RESEARCH FUND

(a) Sulzer shall make payments into the Research Fund (the "Research Fund Amounts") and such payments shall become due and payable as follows:

(i) $2.0 million on the 180th day following the Preliminary Approval Date; and

(ii) $2.0 million on the 30th day following the Final Judicial Approval Date.

(b) Cash payments made into the Research Fund pursuant to this Section 2.2 shall be paid in accordance with and subject to Section 2.9 below.

Section 2.3 MEDICAL MONITORING FUND

(a) Sulzer shall make payments into the Medical Monitoring Fund (the "Medical Monitoring Fund Amounts") and such payments shall become due and payable as follows:

(i) $2.0 million on the 30th day following the Final Judicial Approval Date; and

(ii) subject to Section 2.3(b) below, at any time during the 5-year period following the Final Judicial Approval Date (the "Medical Monitoring Period"), amounts necessary in order to maintain a minimum balance of $1.0 million at all times.

(b) The aggregate amount of all of payments to the Medical Monitoring Fund shall not exceed $20.0 million.

(c) Cash payments made into the Medical Monitoring Fund pursuant to this Section 2.3 shall be paid in accordance with and subject to Section 2.9 below.

(d) Upon the expiration of the Medical Monitoring Period, any remaining Medical Monitoring Fund Amounts shall be transferred to the Patient Benefit Fund in accordance with Section 14.7 hereunder.

Section 2.4 PATIENT BENEFIT FUND

(a) Sulzer shall make or cause to be made payments into the Patient Benefit Fund (the "Patient Benefit Fund Amounts") and such payment shall become due and payable as follows:

(i) on or prior to the Final Judicial Approval Date, an amount equal to the payments owed to Class Members pursuant to Sections 3.4(a)(i), 3.4(b)(i), 3.4(c)(i) and 3.4(d)(i) hereunder; and

(ii) at any time on or after the Final Judicial Approval Date, upon approval by the Claims Administrator of a Claim, in accordance with the Claims Approval Procedures to be agreed upon by the Parties, payments in the full amount of such Claim.

(b) Cash payments made into the Patient Benefit Fund pursuant to this Section 2.4 shall be paid in accordance with and subject to Section 2.9 below.

Section 2.5 EXTRAORDINARY INJURY FUND

(a) Sulzer shall make payments into the Extraordinary Injury Fund (the "Extraordinary Injury Fund Amounts") and such payments shall become due and payable as follows:

(i) $10.0 million on the 30th day following the Final Judicial Approval Date; and

(ii) subject to Section 2.5(b) below, at any time prior to the termination of the Settlement Trust in accordance with its terms, amounts necessary in order to maintain a minimum balance of $10.0 million at all times.

(b) Sulzer shall not be obligated to make payments that aggregate in excess of $10.0 million during the first year following the Final Judicial Approval Date and $20.0 million during the first 25 months following the Final Judicial Approval Date; provided, that the aggregate amount of all payments to the Extraordinary Injury Fund shall not exceed $30.0 million.

(c) Cash payments made into the Extraordinary Injury Fund pursuant to this Section 2.5 shall be paid in accordance with and subject to Section 2.9 below.

Section 2.6 SETTLEMENT TRUST BROKERAGE ACCOUNT

(a) SOUS and/or SML shall deliver ADRs to the Settlement Trust Brokerage Account as follows:

(i) on or prior to the 10th Business Day after the Final Judicial Approval Date, a number of ADRs then sufficient to cover the non-cash portion of the distributions then owed to (x) Class Members pursuant to Sections 3.4(a)(i), 3.4(b)(i), 3.4(c)(i) and 3.4(d)(i) hereunder and (y) Plaintiffs' Counsel pursuant to Sections 5.2 and 5.3 hereof with

respect to payments made to Class Members pursuant to Sections 3.4(a)(i), 3.4(b)(i), 3.4(c)(i) and 3.4(d)(i) hereunder; and

(ii) from time to time at the written request of the Trustee as additional distributions become due hereunder, a number of ADRs sufficient to fund the non-cash portion of such distributions owed to Class Members pursuant to Sections 3.4(b)(ii) and 3.4(c)(ii) and owed to Plaintiffs' Counsel pursuant to Sections 5.2 and 5.3 hereunder.

(b) Notwithstanding the foregoing, Section 2.6(a) above shall not limit SOUS's or SML's right or ability to deliver a greater number of ADRs to the Settlement Trust Brokerage Account at any time.

Section 2.7 OTHER PROVISIONS

(a) The Parties agree that the Settlement Trust is being established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and has given rise to claims asserting liability arising out of a tort. The Settlement Trust shall be structured and managed to qualify as a Qualified Settlement Fund under Section 468B of the Code and related Treasury Regulations and will contain customary provisions for such trusts including obligations of the Settlement Trust to provide such information to Sulzer as Sulzer shall reasonably request for financial, legal, regulatory and tax purposes.

(b) The Parties agree that all of the amounts being paid to or on behalf of Class Members or Spouses of Class Members pursuant to the terms of this Settlement Agreement are being paid as damages (other than punitive damages) on account of alleged physical personal injuries or alleged physical sickness of the members of the Settlement Class including alleged emotional harm, as described in Section 104(a)(2) of the Code. The Parties further agree that the claims set forth in the definition of Settled Claims in Article I have their origin in such alleged physical personal injuries or physical sickness.

(c) Sulzer shall have no financial obligations under this Settlement Agreement other than the payment obligations explicitly set forth in this Settlement Agreement. Neither Sulzer nor any of the other Released Parties shall have any responsibility for the management of the Settlement Trust or any liability to any Class Member arising from the handling of claims by the Trustee.

(d) All cash and property transferred into the Settlement Trust from and after the Final Judicial Approval Date shall be the sole property of the Settlement Trust, and the Trustee shall be responsible for any and all tax withholding and reporting obligations with respect to distributions to Class Members and Plaintiffs' Counsel pursuant to the terms of this Settlement Agreement.

Section 2.8 SECURITY ARRANGEMENTS

(a) Promptly following the execution date of this Settlement Agreement (but in any event within 10 Business Days following such date), Sulzer shall execute and deliver a security agreement (the "Security Agreement"), the form of which to be agreed to by the Parties,

granting a security interest to the Settlement Trust in all Sulzer's assets (including intangibles such as intellectual property, patents and trademarks other than goodwill) that may be the subject of a Lien under applicable law (the "Secured Assets") for the purposes of securing Sulzer's payment obligations under this Settlement Agreement. The Security Agreement shall provide that all Liens created thereby shall be senior to any other Liens or liquidated or unliquidated interests or claims against Secured Assets, including without limitation, claims brought by or on behalf of Affected Product Recipients who exercise Opt-Out Rights (subject to prior perfected Liens); *provided, however*, that such security interests shall be junior and subordinated to any Liens granted by Sulzer on any assets to a financial or other lending institution or institutions for the purposes of securing Sulzer's obligations under a working capital credit facility (collectively, the "Credit Facility"); *provided*, that the terms of the Credit Facility shall be subject to the prior approval by Class Counsel (such approval not to be unreasonably withheld). During definitive documentation of such Credit Facility, the Parties agree that the Trustee shall enter into such agreements and documents as reasonably necessary, including without limitation an intercreditor agreement agreeing that the obligations under this Settlement Agreement and Liens created by the Security Agreement shall be subordinated to the obligations and Liens securing such obligations under the Credit Facility. Concurrently with or promptly following the execution and delivery of the Security Agreement, Sulzer shall execute and deliver to the collateral agent under the Security Escrow (the "Collateral Agent") (i) financing statements (on UCC-1 or such successor or other applicable form) necessary to perfect a security interest in the Secured Assets that constitute personal property under applicable law and (ii) mortgages and deeds of trust necessary to perfect a security interest in the Secured Assets that constitute real property or fixtures under applicable law, in each case to the extent necessary or permitted under the applicable jurisdiction governing such Secured Assets. Pursuant to the terms of the Security Agreement, the Collateral Agent shall promptly file and/or record such financing statements, mortgages and deeds of trust as are necessary to perfect the Settlement Trust's security interest in the Secured Assets.

(b) Upon the satisfaction of all of Sulzer's payment obligations under this agreement, the Security Agreement shall terminate and Liens on the Secured Assets shall be released. Upon termination of the Security Agreement, the Collateral Agent shall execute, file and/or record such termination instruments (including without limitation, UCC-3s or other evidence of release of Lien or mortgage as applicable) as may be necessary to release all Liens on Secured Assets thereunder.

(c) In the event that Final Judicial Approval is not obtained or if this Settlement Agreement is terminated in accordance with Article 10 hereunder, the Collateral Agent shall execute, file and/or record such termination instruments (including without limitation, UCC-3s or other evidence of release of Lien or mortgage as applicable) as may be necessary to release all Liens on Secured Assets, and the Security Agreement shall terminate and be of no force and effect.

(d) The Security Agreement shall provide that the Trustee shall have a right to exercise remedies with respect to the Secured Assets only after Sulzer fails to deliver to the Funds and/or an interest-bearing escrow account (as appropriate pursuant to Section 2.9(e)) in cash totaling $25 million (not including Insurance Proceeds) on the due date of any Annual

Payment Amount; *provided, however*, that no right to exercise such remedies shall arise unless Sulzer fails to make up any shortfall within six months of such due date.

(e) If Sulzer fails to make any required Annual Payment Amount hereunder when due, Sulzer shall use its commercially reasonable effects to raise capital for the purposes of making such payment (by borrowings, sale of assets, etc.).

(f) In the event that Sulzer sells assets for business purposes or for the purposes of satisfying its payment obligations hereunder, the Collateral Agent shall execute and deliver such termination instruments and/or other documents as may be necessary to release Liens on the Secured Assets subject to sale under such agreements, so long as the net proceeds therefrom are not used to pay judgments or claims of Class Members that have exercised their Opt-Out Right.

Section 2.9 FUNDING

(a) Sulzer shall fund its obligations hereunder with the following assets: (i) Insurance Proceeds; (ii) cash from operations as described in Sections 2.9(c) and 2.9(d), and (iii) ADRs, as described in Section 2.6.

(b) As promptly as practicable following Preliminary Judicial Approval, SOUS and SML shall use commercially reasonable efforts to cause Winterthur Swiss Insurance Company and/or its insurance subsidiaries (collectively, "Winterthur") to fund the aggregate cash proceeds of the Insurance Proceeds, within 7 days after the Preliminary Approval Date, up to the amount of such remaining policy limits into an interest-bearing trust or escrow account maintained for the purpose of delivering such Insurance Proceeds to the Patient Benefit Fund and Extraordinary Injury Fund pursuant to the terms of this Settlement Agreement. The Insurance Proceeds shall be used solely for the purposes of (i) paying medical reimbursement expenses for Class Members pursuant to Section 3.3 hereof, (ii) paying Class Member benefits pursuant to Sections 3.4(b), 3.4(c), and 3.4(d) hereof, (iii) paying Matrix Compensation Benefits to Class Members pursuant to Section 3.5 hereof and (iv) paying attorneys' fees pursuant to Article 5 hereof with respect to Class Member payments payable under Sections 3.3, 3.4(b), 3.4(c), 3.4(d) and 3.5 hereof. All payments made by Winterthur under this Settlement Agreement are subject to applicable limits and terms of the relevant policy or policies of insurance identified in the definition of "Insurance Proceeds" herein, including without limitation, that such policies relate only to payments on behalf of Class Members who have had Revision Surgery with respect hip replacements with Inter-Op Shells (including Reprocessed Shells), and nothing in this Settlement Agreement shall expand the limits of such insurance coverage. By entering into this Settlement Agreement, Class Members agree that they have no standing under the Winterthur policies or rights with respect to the Insurance Proceeds, and any agreement between SMS or SOUS regarding such policies, coverage, limits and payment of Insurance Proceeds shall be binding on all Class Members. The Parties also agree that, pending Final Judicial Approval, Sulzer may settle non-U.S. claims with such Insurance Proceeds. The Insurance Proceeds shall be paid to the Patient Benefit Fund and Extraordinary Injury Funds as follows:

(i) on the Final Judicial Approval Date, an aggregate of $10.0 million of Insurance Proceeds shall be deposited in the Extraordinary Injury Fund for the purpose of paying claims pursuant to Section 3.4 of this Settlement Agreement; and

(ii) following such Final Judicial Approval Date, the Insurance Proceeds shall be paid to the Patient Benefit Fund and Extraordinary Injury Fund for the purpose of paying claims to Class Members pursuant to and in accordance with this Settlement Agreement; *provided, however,* that, in the event that any such Insurance Proceeds have been paid into the Patient Benefit Fund or Extraordinary Injury Fund and no claims for payment with respect to insurable benefits in either Fund remain, then the Insurance Proceeds in either such Fund may be transferred to the other Fund for purposes of making payment for insurable claims thereunder; *provided, further,* to the extent that any such Insurance Proceeds shall be insufficient to pay all claims due and payable under this Settlement Agreement in both the Extraordinary Injury Fund and Patient Benefit Fund, the Trustee shall allocate such Insurance Proceeds first to the Patient Benefit Fund to pay benefits to Class Members pursuant to Sections 3.4(b), 3.4(c) and 3.4(d), with the remainder (if any) to be paid to the Extraordinary Injury Fund to pay Matrix Compensation Benefits thereunder.

(c) In addition to payments made with Insurance Proceeds (if applicable), within 30 days following the Final Judicial Approval Date, Sulzer shall deliver to the Settlement Trust (to be allocated among the Funds pursuant to the terms of Article 3 hereof), an amount in cash equal to (x) cash and liquid cash equivalents of Sulzer as of the Final Judicial Approval Date, plus (y) the maximum amount of borrowings available under the Credit Facility on the Final Judicial Approval Date, if any, less (z) 30 days of budgeted working capital cash requirements of Sulzer, which amount is currently estimated to be $100.0 million (the "Final Approval Funding Amount"); *provided*, that Sulzer shall not be obligated to pay any portion of the Final Approval Funding Amount that, together with any Insurance Proceeds and prior Annual Payment Amount(s) delivered to the Settlement Trust, exceeds the Initial Funding Requirement (as defined below), if any.

(d) In addition to the payments made with Insurance Proceeds to the Patient Benefit Fund, Sulzer agrees that, within 120 days following the end of each fiscal year beginning with fiscal year ended December 31, 2002, Sulzer shall deliver (or cause to be delivered) to the Funds an amount equal to the greater of (x) $25 million or (y) one-half (1/2) of Sulzer's Consolidated Net Income for the prior fiscal year (the "Annual Payment Amount"). Notwithstanding the foregoing sentence, Sulzer shall not be obligated to pay an amount pursuant to this Section 2.9(d) with respect to any fiscal year that would cause all amounts paid pursuant to this Section 2.9(d) from the date of this Settlement Agreement to exceed (1) the product of (A) $50 million times (B) the number of fiscal years from and including fiscal year ended December 31, 2002 (inclusive of this fiscal year in which payment owed) plus (2) the amount, if any, by which the total amounts payable under this Settlement Agreement within 30 days after the Final Judicial Approval Date (the "Initial Funding Requirement") exceeded the Final Approval Funding Amount and Insurance Proceeds actually paid to the Settlement Trust by such date (the "Maximum Amount"). In the event that an Annual Payment Amount for any given fiscal year shall cause all amounts paid pursuant to this Section 2.9(d) to exceed the Maximum Amount, Sulzer shall pay an amount equal to the difference between the total amount of payments made up to the applicable fiscal year and the Maximum Amount.

(e) If the amount of all cash obligations of the Settlement Trust on the due date for an Annual Payment Amount is less than the required Annual Payment Amount for such fiscal year, Sulzer may deposit the excess in an interest-bearing escrow account pending the Settlement Trust's need for such funds to pay Class Members or Plaintiffs' Counsel or other obligations. The interest on such amounts shall be the property of Sulzer and, upon termination of the Settlement Trust, any amounts remaining in such escrow account shall revert to Sulzer.

(f) In the event that Sulzer fails to make any required Annual Payment Amount, interest shall accrue on any amount owed following the payment due date until paid at the prime lending rate of the Bank of New York as in effect from time to time. Any payment made by Sulzer under the terms of this Settlement Agreement to any of the Funds shall be applied first to the oldest interest-bearing obligation.

(g) Notwithstanding anything in this Settlement Agreement to the contrary, no Class Member, or Plaintiffs' Counsel shall be entitled to any cash payment under Sections 3.4, 3.5 or Article 5, and Sulzer shall not be in breach of its payment obligations under any such sections or any other provisions of this Settlement Agreement, to the extent that it has complied with its obligations under this Section 2.9, and no interest shall accrue on any such amounts owed to Class Members and/or Plaintiffs' Counsel as result of a deficiency of amount in the Funds for the purpose of making such payments. To the extent that the Settlement Trust has payment obligations to Class Members or Plaintiffs' Counsel pursuant to the terms of Sections 3.4, 3.5 or Article 5, the Trustee shall have the discretion to make partial payments to such beneficiaries on a pro rata basis, pending additional funding from Sulzer or the Insurance Proceeds, subject to the restrictions on use of Insurance Proceeds set forth in the applicable policies.

ARTICLE 3. CLASS MEMBER RIGHTS AND BENEFITS

Section 3.1 MEDICAL RESEARCH AND EDUCATION

(a) The Research Fund Amounts shall be used to finance medical research relating to reconstructive orthopedic implants, specifically hip and knee implants to be agreed upon by the Parties and approved by the Court.

Section 3.2 MEDICAL MONITORING SERVICES

(a) Class Members who have not already undergone a Revision Surgery with respect to any Affected Product prior to the Final Judicial Approval Date Agreement shall be entitled to payment for the reasonable unreimbursed costs of one physicians visit and one set of x-rays associated therewith during each of the annual periods ending on the second year, third year and fifth year following the date of such implant surgery.

(b) Amounts paid to or on behalf of Class Members pursuant to 3.2(a) above shall be paid out of the Medical Monitoring Fund.

Section 3.3 MEDICAL EXPENSES FOR REVISION SURGERIES

(a) The Settlement Trust shall pay the reasonable and necessary unreimbursed medical expenses of Class Members who undergo a Revision Surgery with respect to any Affected Product on or before December 31, 2008. No Class Member shall be entitled to payment for reimbursement of medical expenses hereunder that have been paid or provided for by Sulzer other than pursuant to this Settlement Agreement.

(b) Amounts paid to or on behalf of Class Members pursuant to 3.3(a) above shall be paid out of the Patient Benefit Fund.

Section 3.4 PAYMENTS TO CLASS MEMBERS

(a) Class Members Who Have Not Undergone Revision Surgery.

(i) Class Members who have not undergone Revision Surgery with respect to an Affected Product on or before the Final Judicial Approval Date shall be entitled to receive, by the date that is the later of the 30th day following the Final Judicial Approval Date and the date of identification of such Class Member by the Trustee and/or Claims Administrator as an Affected Product Recipient (x) a cash payment in the amount of $750.00 and (y) 392 ADRs (less any amounts sold pursuant to Section 6.7).

(ii) Cash amounts paid to Class Members pursuant to Section 3.4(a)(i) above shall be paid out of the Patient Benefit Fund. ADRs distributable to Class Members pursuant to Section 3.4(a)(i) above shall be satisfied out of the Settlement Trust Brokerage Account.

(b) Class Members Who Undergo One Revision Surgery.

(i) Class Members who have undergone Revision Surgery with respect to one and only one Affected Product prior to the Final Judicial Approval Date shall be entitled to receive, by the date that is the later of the 30th day following the Final Judicial Approval Date and the date of identification of such Class Member by the Trustee and/or Claims Administrator as an Affected Products Recipient (x) a cash payment in the amount of $37,500 and (y) 3,922 ADRs (less any amounts sold pursuant to Section 6.7).

(ii) Class Members who have not previously undergone Revision Surgery with respect to an Affected Product and who undergo Revision Surgery with respect to one Affected Product on or after the Final Judicial Approval Date and prior to December 31, 2008 shall be entitled to receive, by the date that is the later of the 30th day following the date of such Revision Surgery and the date of identification of such Class Member by the Claims Administrator as an Affected Product Recipient (x) a cash payment in the amount of $37,500 (less any cash payment received pursuant to Section 3.4(a)(i) above) and (y) 3,922 ADRs (less any ADRs received pursuant to Section 3.4(a)(i) above and less any amounts sold pursuant to 6.7).

(iii) Cash amounts paid to Class Members pursuant to Section 3.4(b)(i) or Section 3.4(b)(ii) above shall be paid out of the Patient Benefit Fund. ADRs distributable to

Class Members pursuant to Section 3.4(b)(i) or Section 3.4(b)(ii) above shall be satisfied out of the Settlement Trust Brokerage Account.

(c) Class Members Who Undergo Multiple Revision Surgeries.

(i) Class Members who have undergone Revision Surgery with respect to two or more Affected Products prior to the Final Judicial Approval Date shall be entitled to receive, by the date that is the later of the 30th day following the Final Judicial Approval Date and the date of identification of such Class Member by the Claims Administrator as an Affected Product Recipient (i) a cash payment in the amount of $63,500 and (ii) 6,667 ADRs (less any amounts sold pursuant to Section 6.7).

(ii) Class Members who undergo Revision Surgery with respect to one or more Affected Products on or after the Final Judicial Approval Date and prior to December 31, 2008, and who have already undergone Revision Surgery with respect to an Affected Product either before or after the Final Judicial Approval Date, shall be entitled to receive, by the date that is the later of the 30th day following the date of such Revision Surgery and the date of identification of such Class Member by the Trustee (x) a cash payment in the amount of $63,500 (less any cash payments received pursuant to Section 3.4(a)(i), Section 3.4(b)(i), Section 3.4(b)(ii) above) and (y) 6,667 ADRs (less any ADRs received pursuant to Section 3.4(a)(i), Section 3.4(a)(ii) and/or Section 3.4(b)(ii) above and less any amounts sold pursuant to Section 6.7).

(iii) Cash amounts paid to Class Members pursuant to Section 3.4(c)(i) or Section 3.4(c)(ii) above shall be paid out the Patient Benefit Fund. ADRs distributable to Class Members pursuant to Section 3.4(c)(i) or Section 3.4(c)(ii) above shall be satisfied out of the Settlement Trust Brokerage Account.

(d) Spousal Payments.

(i) The Spouse of a Class Member that is entitled to payments pursuant to Section 3.4(a) shall be entitled to receive a cash payment in the amount of $500 to be paid no later than the 30th day following the Final Judicial Approval Date.

(ii) The Spouse of a Class Member that is entitled to payments pursuant to Section 3.4(b) or Section 3.4(c) shall be entitled to receive a cash payment in the amount of $5,000 (less any cash payment received pursuant to Section 3.4(d)(i) above) to be paid no later than the 30th day following the Financial Judicial Approval Date.

(iii) Cash amounts paid to Spouses of Class Members pursuant to Section 3.4(d)(i) and Section 3.4(d)(ii) above shall be paid out of the Patient Benefit Fund.

(e) Maximum Benefits.

(i) No individual Class Member shall receive benefits pursuant to this Section 3.4 in excess of those provided for in Section 3.4(c)(i) above.

(ii) No Spouse shall receive benefits pursuant to this Section 3.4 in excess of those provided for in Section 3.4(d)(ii) above.

(iii) To the extent that Sulzer has made any advance or other payments to any Class Member prior to the Final Judicial Approval Date, any amounts owed to such Class Member pursuant to Sections 3.2, 3.3 and 3.4 shall be reduced by the amount of such advance or other payment.

Section 3.5 COMPENSATION BENEFITS PAYABLE FROM EXTRAORDINARY INJURY FUND

(a) In addition to the benefits set forth in Sections 3.2, 3.3, and 3.4 above, Class Members may be eligible to receive additional compensation under this Settlement Agreement ("Matrix Compensation Benefits") pursuant to the payment matrix (the "Matrix"), to be agreed to by the Parties, approved by the Court and subsequently attached hereto as Annex I.

(b) The Court shall appoint an individual to act as special master for the purposes of determining Matrix Compensation Benefits with respect to any Class Member (the "Special Master"). The Special Master shall have the authority to authorize payments in excess of the Matrix Compensation Benefits specified in the Matrix with respect to any Class Member; provided, however, in no event shall the aggregate of all Matrix Compensation Benefits authorized by the Special Master pursuant to this Section 3.5 exceed the maximum amount allocated to the Extraordinary Injury Fund pursuant to Section 2.5(b).

(c) In the event that any Class Member disagrees with any determination of the Special Master with respect to Matrix Compensation Benefits, such Class Member shall have the right to appeal the decision of the Special Master to the Court.

(d) The Matrix Compensation Benefits paid to Class Members pursuant to Section 3.5(a) above shall be paid out of the Extraordinary Injury Fund.

(e) Upon application to and approval of the Special Master, attorneys' fees may be paid to Plaintiffs' Counsel for Class Members entitled to receive Matrix Compensation Benefits; provided, that such Plaintiffs' Counsel had a written agreement of representation with such Class Member executed on or prior to August 2, 2001. Such attorneys' fees, if approved by the Special Master, shall be payable out of the Extraordinary Injury Fund and shall be in addition to attorneys' fees awarded pursuant to Article 5 of this Settlement Agreement but shall be in lieu of any amounts owed by the Class Member under private fee contracts.

Section 3.6 OPT-OUT RIGHTS

(a) All Class Members (except as provided in Section 3.6(b) below) are eligible to opt out of settlement represented by this Settlement Agreement (the "Opt-Out Right"). Each Class Member wishing to exercise an Opt-Out Right must sign and submit timely written notice to the Claims Administrator. The Claims Administrator shall then submit all such notices to the Court, with copies to Class Counsel, Sulzer and Plaintiffs' Counsel representing such Class Member (if any). To be effective, this written notice must be signed and submitted to by the

expiration of the Opt-Out Period. The Parties will recommend that the Court approve an appropriate Opt-Out Period.

(b) In the event that there is both a Affected Product Recipient or a Representative Claimant and on or more Derivative Claimants, the Affected Product Recipient's or the Representative Claimant's exercise or failure to exercise an Opt-Out Right shall be binding on the associated Derivative Claimant(s).

(c) Any Class Member may revoke an election to exercise an Opt-Out Right and thereby receive the benefits pursuant to this Settlement Agreement, *provided*, that the revocation takes place with the written consent of the Parties, which consent shall not be unreasonably withheld.

Section 3.7 ADDITIONAL BENEFITS TO CLASS MEMBERS

In the event that any Class Member exercises and does not revoke an Opt-Out Right, the Claims Administrator will determine the amount of benefits that would have been payable to such Class Member pursuant to the terms of this Settlement Agreement, and such amount shall added to the obligation of the Settlement Trust for payments to Class Members who did not exercise their Opt-Out Right. Such payments may be made *pro rata* among all Class Members who have not exercised Opt-Out Rights, or to the Extraordinary Injury Fund for purposes of making additional Matrix Compensation Benefits, or in such other manner as the Parties shall agree, subject to approval of the Court.

ARTICLE 4. CLAIMS ADMINISTRATION

Section 4.1 In connection with the request for Preliminary Court Approval of this Agreement, the Parties shall request that the Court approve the appointment of an interim escrow agent and interim Claims Administrator to act on behalf of the Settlement Trust pending Trial Court Approval.

Section 4.2 The administration of claims and payments to Class Members, Spouses of Class Members, and Plaintiff's Counsel under this Agreement shall be done under the supervision of the Court in accordance with the claims administration procedures agreed to Parties and submitted to the Court for approval.

ARTICLE 5. ATTORNEYS' FEES

Section 5.1 Contingency-fee Plaintiffs' Counsel representing individual Class Member(s) pursuant to a written agreement that was executed and delivered by such Class Member(s) on or prior to August 2, 2001 shall be entitled to payment of attorneys' fees with respect to such Class Member(s) solely pursuant to the terms of this Settlement Agreement.

Section 5.2 The amount of the fee paid to such contingency-fee Plaintiffs' Counsel shall equal one-third (1/3) of the total payments made to or on behalf of each such represented Class Member under Sections 3.3 and 3.4 of this Settlement Agreement; provided, that solely for purposes of determining the amount of the fee payable under this Section 5.2 with respect to any Class Member, the amount paid to or on behalf of any such Class Member pursuant to

Section 3.3 shall be deemed to be $25,000 and each ADR transferred to such Class Member shall be valued at $5.10

Section 5.3 The total attorneys' fee payable to the contingency-fee Plaintiffs' Counsel with respect to each Class Member shall be paid two-thirds (2/3) in cash and one-third (1/3) in ADRs. The number of ADRs to be issued shall be determined by dividing (i) an amount equal to one-third (1/3) of the total amount due to such Plaintiffs' Counsel pursuant to Section 5.2 above by (ii) $5.10, rounded down to the nearest whole number.

Section 5.4 Class Counsel shall also be entitled to reasonable attorneys' fees and reimbursement of their expenses, to be paid by Sulzer and approved by the Court.

Section 5.5 Cash amounts payable to contingency-fee Plaintiffs' Counsel pursuant to this Article 5 shall be paid out of the Patient Benefit Fund. Amounts payable hereunder to contingency-fee Plaintiffs' Counsel and Class Counsel are in addition to payments owed to Class Members hereunder.

ARTICLE 6. ISSUANCE OF ADRS

Section 6.1 On or prior to the Final Judicial Approval Date, Sulzer shall take all action reasonably necessary to (a) reserve out of its authorized but unissued share capital, a sufficient number of shares, CHF 30 nominal value per share, necessary to issue to Citibank, N.A., as depositary for the ADRs (the "ADR Depositary"), in order to satisfy its obligations under Sections 3.4 and Article 5 of this Settlement Agreement, and authorize the ADR Depositary to issue such ADRs upon the terms of this Settlement Agreement and (b) cause such ADRs to be authorized for listing on the New York Stock Exchange, subject to official notice of issuance.

Section 6.2 The ADRs to be delivered to the Settlement Trust Brokerage Account for distribution to Class Members and Plaintiffs' Counsel pursuant to Section 3.4 and Article 5 of this Settlement Agreement shall be issued by Sulzer in the United States pursuant to an exemption from registration under the Securities Act of 1933, as amended (the "Securities Act") by virtue of Section 3(a)(10) of the Securities Act. Sulzer shall take all action reasonably necessary to comply with the rules and regulations of the Securities and Exchange Commission and interpretations of the staff thereof to exempt the issuance of ADRs pursuant to Section 3(a)(10) of the Securities Act. It is the intent of the Parties that the ADRs received by Class Members and Plaintiffs' Counsel in the United States shall be freely tradable by such persons upon issuance, subject to the restrictions contained in Section 6.4 below.

Section 6.3 In the event that the Trustee is unable to issue ADRs to Class Members who reside in Canada due to Canadian securities law restrictions, the Trustee may sell such ADRs after the first anniversary of the Class Member's right to receive such ADRs hereunder and deliver the net proceeds to such Canadian Class Member, in lieu of the delivery of such ADRs.

Section 6.4 The ADRs issued pursuant to Sections 3.4 and Article 5 of this Settlement Agreement will be restricted and not transferable by the Class Member or Plaintiffs' Counsel for a period of one year following the date of issuance thereof. The Parties agree that certificates representing such ADRs may bear a restrictive legend to the effect of the foregoing restriction,

and may issue "stop transfer" or similar instructions to the transfer agent and registrar for such ADRs for the purpose of enforcing the foregoing restriction.

Section 6.5 In the event of any share dividend, subdivision, split, reclassification or other change in the Shares and/or the ADRs following the date of this Settlement Agreement but prior to the issuance of ADRs hereunder, appropriate adjustment shall be made to the number of ADRs issuable pursuant to Sections 3.4 and Article 5 hereof to reflect such action. The purpose of the foregoing provision is to ensure that Class Members receive the same benefits (other than cash dividends or distribution) as if they held such ADRs on the date of this Settlement Agreement.

Section 6.6 The Settlement Trust shall be the holder of record of all shares held in the Settlement Trust Brokerage Account until released therefrom and delivered to a Class Member or Plaintiffs' Counsel in accordance with Section 3.4. and Article 5 hereof, and shall be entitled to all dividends or other distributions in respect of such ADRs until so delivered, provided that the Trustee shall not exercise any voting rights with respect to the ADRs (to the extent such restrictions are permitted under the laws of the State of New York).

Section 6.7 In the event that the fair market value of the ADRs to be delivered to a Class Member or Plaintiffs' Counsel pursuant this Settlement Agreement exceeds the fair market value of such ADRs at the time of delivery of such ADRs to the Settlement Trust Brokerage Account, the Trustee shall have the right to sell that number of ADRs necessary to satisfy the Trust's tax on the appreciation of such ADRs and deliver the balance to the Class Member or Plaintiffs' Counsel.

ARTICLE 7. GENERAL TERMINATION AND RELEASE

Section 7.1 The Parties Agree that this Settlement Agreement is made in good faith and in accordance with the laws of the jurisdictions in which Affected Products Related lawsuits have been filed. If required by any court or tribunal, Class Counsel agree to cooperate with Sulzer and the other Released Parties by providing affidavits and/or testimony concerning the circumstances of the settlement contemplated by this Settlement Agreement and attesting to the fact that it is a good faith settlement.

Section 7.2 Unless this Settlement Agreement shall have been terminated in accordance with Article 10 hereof prior to Final Judicial Approval, and after the Court approves this Settlement Agreement as a good faith, fair, adequate and reasonable settlement, the Parties hereby agree that every Settled Claim of each Class Member shall be conclusively compromised, settled and released as to Sulzer and each other Released Party. Such releases shall remain effective regardless of changes in the circumstances or condition of Sulzer, the other Released Parties or Class Members, discovery of new or additional facts, or changes in applicable law. In making such releases the Settlement Class expressly acknowledges and waives the provisions of Section 1542 of the Civil Code of the State of California, which provides that "[a] general release does not extend to claims which the creditor does not know or suspect exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor," as well as any similar provisions of other states. Consistent with the

provisions of Article 10 of this Settlement Agreement, the releases herein shall extinguish any claims for contribution and/or indemnification against Sulzer or the other Released Parties.

Section 7.3 The Parties hereby agree to request that the Court enter an order finding this Settlement Agreement to be a good faith settlement and barring and enjoining, to the extent permitted by applicable law, the commencement and prosecution of any contribution and/or indemnification claim or action by any third-party against Sulzer or any other Released Party for reimbursement for payments made or to be made to or on behalf of any Class Member for Affected Products Related claims, actions or injuries, or for expenses incurred in defending against any such claims, actions or proceedings. The Parties agree that Sulzer and the other Released Parties shall be entitled to dismissal with prejudice of any claims against them by any third party that violate or are inconsistent with this bar.

Section 7.4 The Parties agree that no Class Member (other than Class Members who properly and timely exercise their Opt-Out Rights) shall recover, directly or indirectly, any sums from Sulzer or any other Released Party other than those received under this Settlement Agreement.

Section 7.5 The Class Members shall move jointly with Sulzer and/or the other Released Parties, or any of them, for severance and continuance of the trial of claims for contribution and/or indemnification.

Section 7.6 Each Class Member otherwise entitled to receive benefits under this Settlement Agreement shall be required, as a further condition to receive benefits hereunder, to execute and deliver a separate Proof of Claim and Release with respect to Affected Products Related claims.

ARTICLE 8. SUBROGATION CLAIMS

Section 8.1 To the extent that any person has rights of subrogation by virtue of a payment or payments made to or for the benefit of any specific Class Member who has not properly and timely exercised an Opt-Out Right, such rights of subrogation may be asserted (other than by Medicare, third-party insurers and other subrogees with respect to claims for payments to health care providers) with respect to the Trustee's obligation to make payments to that Class Member from the applicable Fund but shall not be asserted directly against Sulzer and/or the Released Parties except to the extent required by applicable Federal or State law. Sulzer will promptly notify the Trustee and/or Claims Administrator(s), and the affected Class Member of the assertion of such a subrogation claim against Sulzer. The Parties shall move the Court, upon granting Trial Court Approval, to enter a bar order to preclude the assertion of such subrogation claims against Sulzer and/or the Released Parties, except to the extent that it would be impermissible to bar such claims under provisions of applicable law.

Section 8.2 The Trustee and/or Claims Administrator(s) shall provide notice of subrogation claims received by the Trustee to affected Class Members and afford them an opportunity to contest, otherwise object to or compromise any such claims. In making distribution of any amounts to which Class Members are entitled from any applicable Fund, the Trustee shall recognize and pay subrogation claims (other than Medicare, third-party insurers

and other subrogees with respect to payments to health care providers), but only to the extent that the subrogation claim is recognized by applicable law. Unless the law clearly sets forth different principles, the Trustee shall not recognize a subrogation claim unless: (a) it is affirmatively brought to their attention prior to distribution of funds to a Class Member; (b) it is based on a positive provision of law or a valid enforceable contract; (c) the putative subrogee clearly establishes that the subrogee actually made a payment or payments to or for the benefit of the Class Member which is of a type that the putative subrogee would be entitled to recover against Sulzer and/or the Released Parties, and then (d) only to the extent of the lessor of the actual payment made and the amount otherwise payable to such Class Member less an equitable debit for attorneys' fees, and any other allowable or appropriate charges against the putative subrogee. No benefits for medical expense reimbursement of any Class Member pursuant to this Settlement Agreement shall be reduced by any payment to a subrogee.

ARTICLE 9. CONTINUING JURISDICTION

Section 9.1 The Court shall retain exclusive and continuing jurisdiction of the Complaint, the Parties, all Class Members, Sulzer and the Released Parties, and over this Settlement Agreement with respect to the performance of the terms and conditions of the Settlement Agreement, to assure that all disbursements are properly made in accordance with the terms of the Settlement Agreement, and to interpret and enforce the terms, conditions and obligations of this Settlement Agreement. Other than provided herein, the Court shall have the power to approve the designation, appointment and removal of auditors, consultants and disbursing agents, and the execution of contracts as necessary and appropriate to assure the administration of this Settlement Agreement. Any dispute that arises under this Settlement Agreement shall be submitted to the Court. If any dispute is so submitted, each party concerned shall be entitled to 15 days' written notice (or otherwise as the Court may for good cause direct) and the opportunity to submit evidence and to be heard on oral argument as the Court may direct. To the extent that additional or different procedures for dispute resolution are provided, or standards to be applied in connection therewith are devised, under any other provision of this Settlement Agreement, such other provisions shall control.

ARTICLE 10. TERMINATION

Section 10.1 Sulzer shall have the option to terminate and withdraw from this Settlement Agreement, in its sole discretion, at any time prior to Final Judicial Approval by giving written notice to the Court and to Class Counsel.

Section 10.2 The Class Representatives, on behalf of the Class Members, shall have the option to terminate and withdraw from this Settlement Agreement in the event that the closing price per ADR as reported by the New York Stock Exchange as of the date that is one week prior to the Final Judicial Approval Date is below $5.10 and Sulzer has not agreed to either (a) pay an amount in cash that represents the difference between $5.10 and the price per ADR times the number of ADRs it is obligated to transfer to the Settlement Trust pursuant to Section 2.6(a)(i) hereunder, or (b) issue additional ADRs with an aggregate value based on such price equal to the difference between $5.10 and the price per ADR times the number of ADRs it is obligated to transfer to the Settlement Trust hereunder, by the Final Judicial Approval Date. If the Class

Representatives elect to exercise such right, they shall do so by giving written notice to the Court and to Sulzer immediately prior to the Final Judicial Approval Date.

Section 10.3 The Class Representatives, on behalf of the Class Members, shall have the option to terminate and withdraw from this Settlement Agreement in the event that, in the course of any due diligence performed pursuant to Section 14.3 below, such Class Representatives have discovered facts that are materially different from the facts and circumstances as represented by Sulzer as of the date of this Settlement Agreement. In addition, Class Representatives shall have the option to terminate and withdraw from this Settlement Agreement in the event that they are advised by counsel that the ADRs will not be issued in the United States in a transaction exempt from registration under the Securities Act and freely tradable in the hands of non-affiliated Class Members or the Liens created under the Security Agreement are insufficient to create a security interest in all the assets of Sulzer, subject to prior Liens and applicable law; *provided*, that no such termination right shall exist to the extent that Sulzer agrees to take reasonable action to cure such deficiencies. If the Class Representatives elect to exercise such right, it shall do so by giving written notice to the Court and to Sulzer within five Business Days prior to the Fairness Hearing Date.

Section 10.4 In the event that either Party terminates and withdraws from this Settlement Agreement in accordance with Sections 10.1, 10.2 or 10.3 above, neither party shall have any further obligations hereunder.

ARTICLE 11. SULZER AG SETTLEMENT OF CLAIMS

Section 11.1 Promptly after the date of this Settlement Agreement, Sulzer shall use commercially reasonable efforts to enter into an agreement with Sulzer AG, a limited company organized under the laws of Switzerland, to provide for "most favored nations" treatment of settlements with Class Members prior to Final Judicial Approval. Specifically, such agreement shall provide that Sulzer AG shall not enter into any settlement agreement or arrangement with any putative Class Member (a) unless such settlement provides a general release by such putative Class Member with respect to all Released Parties on substantially the terms contained in this Settlement Agreement and (b) in the event that such settlement terms are any more favorable, from a financial point of view, than those that such Class Member would have received under the terms of this Settlement Agreement, Sulzer AG shall also pay all Class Members under this Settlement Agreement as such excess financial consideration.

ARTICLE 12. CHANGE OF CONTROL; ACCELERATION OF PAYMENTS

Section 12.1 In the event a Change of Control occurs prior to the satisfaction of Sulzer's obligations to fund any payments owed to the Settlement Trust pursuant to the terms of this Settlement Agreement, then Sulzer shall be obligated to immediately pay to the Settlement Trust the full amount payable and then unpaid pursuant to this Settlement Agreement, including accrual and unpaid interest thereon under the Research Fund, the Patient Benefit Fund and the Extraordinary Injury Fund.

Section 12.2 From and after the date a Change of Control occurs, the provisions of the Security Agreement with respect to cure periods on failures to make payments pursuant to this

Settlement Agreement shall automatically be amended to be "one month" instead of "six months" as described in Section 2.8(d) of this Settlement Agreement.

Section 12.3 In the event of any Change of Control involving a transaction with a third-party to which SML is a party, SML shall require (to the extent reasonably possible) that, as a condition to such transaction, the successor company or entity shall agree to honor (or cause Sulzer to honor) the payment obligations of Sulzer under this Settlement Agreement.

ARTICLE 13. SETTLEMENT IMPLEMENTATION

Section 13.1 GENERAL

(a) In order to become effective, the Settlement must receive Final Judicial Approval, as well as necessary SML board of director and shareholder approval.

Section 13.2 APPROVAL PROCESS PROVISIONS

(a) Within 10 days after executing this Settlement Agreement, the Parties shall jointly move the Court, by filing a motion for the entry of an order granting Preliminary Approval.

(b) No later than 120 days following the Preliminary Approval Date, the Parties shall file a joint motion to distribute and publish notice of settlement and request that the Court schedule a Fairness Hearing.

(c) Sulzer shall pay up to a maximum $4.5 million of the total actual costs of (i) printing, publishing and otherwise disseminating the notice and (ii) administering the terms of this Settlement Agreement pursuant to the Claims Administration Procedures agreed to by the Parties; provided, that Sulzer's maximum obligation to pay such costs shall not exceed $2.5 million in the first annual period following the date of this Settlement Agreement, $1.0 million in the second annual period following the date of this Settlement Agreement and $1.0 million in the third annual period following the date of this Settlement Agreement. To the extent of any such costs exceed $4.5 million, they will be paid by the Settlement Trust.

(d) Sulzer shall retain its right to contest class certification for any purposes other than the approval of this Settlement Agreement.

(e) The Parties shall cooperate and assist in all of the filings and proceedings relating to the obtaining of Preliminary Approval as well as Trial Court Approval and in any further filings and proceedings necessary to obtain Final Judicial Approval of the settlement, and in any related appeals.

(f) Upon Final Judicial Approval, the Class Counsel and all Class Members shall cooperate with Sulzer and any other Released Party to cause the dismissal, with prejudice and without costs, of any action against Sulzer or any Released Party asserting a Settled Claim brought by or on behalf of any Class Member entitled to benefits hereunder, including but not limited to class actions, whether or not certified as such, which are pending in any State or federal court. Upon Trial Court Approval, the Class Counsel and all such Class Members shall

cooperate with Sulzer and any other Released Party to cause further proceedings in all such settled actions to be stayed pending Final Judicial Approval.

Section 13.3 CONDITIONS

(a) Sulzer's obligations under this Settlement Agreement, will be subject to the following conditions:

(i) Trial Court Approval of the settlement, which approval order or orders shall:

(1) Confirm the certification of the Settlement Class, under Fed. R. Civ. P. 23(a) and 23(b)(3) for Settlement purposes only;

(2) Confirm the appointment of the Class Representatives as the representatives of the Settlement Class;

(3) Approve this Settlement Agreement in its entirety pursuant to Fed. R. Civ. P. 23(e) as fair, reasonable, adequate, and non-collusive;

(4) Dismiss with prejudice and without costs all claims and actions asserting Settled Claims against Sulzer pending before the Court, with the condition that such complaints may be reinstated in the event that Final Judicial Approval is not obtained;

(5) Bar and enjoin all Class Members entitled to benefits hereunder from asserting and/or continuing to prosecute against Sulzer or any other Released Party any and all Settled Claims which the Class Member had, has, or may have in the future in any federal or State court;

(6) Bar and enjoin the commencement and/or prosecution of any claim or action against Sulzer in any federal, state or territorial court based on rights of subrogation by virtue of a payment or payments made to or for the benefit of a Class Member arising out of or in relation to any Settled Claims, except to the extent that it would be impermissible to bar such claims under provisions of applicable law;

(7) Reserve the Court's continuing and exclusive jurisdiction over the Parties, including Sulzer and the Class Members, to administer, supervise, interpret, and enforce this Settlement Agreement in accordance with its terms and to supervise the operation of the Settlement Trust; and

(8) Enter such other orders as are needed to effectuate the terms of the Settlement Agreement;

(ii) Final Judicial Approval of this Settlement Agreement; and

(iii) the Insurance Proceeds shall be delivered in accordance with Section 2.9(b) hereunder.

ARTICLE 14. MISCELLANEOUS

Section 14.1 Any information provided by or regarding a Class Member or otherwise obtained pursuant to this Settlement Agreement shall be kept confidential and shall not be disclosed except to appropriate persons to the extent necessary to process Claims or provide benefits under this Settlement Agreement or as otherwise expressly provided in this Settlement Agreement. All Class Members shall be deemed to have consented to the disclosure of this information for these purposes.

Section 14.2 This Settlement Agreement shall be binding on the successors and assigns of the Parties.

Section 14.3 Class Members shall have the right to conduct due diligence on all issues related to this Settlement Agreement prior to the Fairness Hearing Date. Sulzer agrees to cooperate in such due diligence by providing reasonable access to any such information reasonably requested by the Class Representatives on behalf of the Class Members. Sulzer also agrees to use commercially reasonable efforts to obtain Sulzer AG's cooperation in such due diligence investigation if reasonably necessary.

Section 14.4 The Parties to the settlement, including Sulzer, the Released Parties, or any Class Member, shall not seek to introduce and/or offer the terms of the Settlement Agreement, any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement, any statements in the notice documents appended to this Settlement Agreement, stipulations, agreements, or admissions made or entered into in connection with the fairness hearing or any finding of fact or conclusion of law made by the Trial Court, or otherwise rely on the terms of this Settlement Agreement, in any judicial proceeding, except insofar as it is necessary to enforce the terms of the Settlement Agreement (or in connection with the determination of any income tax liability of a Party). If a Class Member who is not entitled to benefits hereunder seeks to introduce and/or offer any of the matters described herein in any proceeding, the restrictions of this Section 14.4 shall not be applicable to Sulzer and the Released Parties with respect to that Class Member. If a Class Member who has timely and properly exercised an Opt-Out Right seeks to introduce and/or offer any of the matters described herein in any proceeding, the restrictions of this Section 14.4 shall not be applicable to Sulzer and the Released Parties with respect to that Class Member.

Section 14.5 Neither this Settlement Agreement nor any Annex, Exhibit, document or instrument delivered hereunder nor any of the statements in the notice documents attached to this Settlement Agreement or in connection herewith, nor any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement, is intended to be or shall be construed as or deemed to be evidence of an admission or concession by Sulzer or the Released Parties of any liability or wrongdoing or of the truth of any allegations asserted by any plaintiff against it or them, or as an admission by the Class Representatives or members of the Settlement Class of any lack of merit in their claims, and no such statement, transaction or proceeding shall be admissible in evidence for any such purpose except for purposes of obtaining approval of this Settlement Agreement in this or any other proceeding.

Section 14.6 The headings of the sections and paragraphs of this Settlement Agreement are included for convenience only and shall not be deemed to constitute part of this Settlement Agreement or to affect its construction.

Section 14.7 All amounts allocable to any particular Fund (other than the Patient Benefit Fund and the Research Fund) that are not used to satisfy the obligations of such Fund at the time such obligation has been satisfied in full, shall automatically revert to the Patient Benefit Fund. Any amounts remaining in the Patient Benefit Fund upon the satisfaction in full of all obligations to pay Class Members pursuant to the Patient Benefit Fund shall be donated to a neutral medical research institute or university or to charities selected by Parties and approved by the Court; *provided, however* that the Trustee shall first use any amounts remaining in the Patient Benefit Fund after satisfaction of all obligations to Class Members to either pay for or create a reserve for payment of all administrative expenses that have been or will be incurred in connection with the winding-up of the administration of the Settlement Trust.

Section 14.8 Any notice, request, instruction or other document to be given by Sulzer to Class Counsel or Class Counsel to Sulzer shall be in writing and delivered personally or sent by Federal Express or facsimile as follows, or as otherwise instructed by a notice delivered to the other Party pursuant to this subsection:

(i) If to Sulzer:

Sulzer Medica USA Inc.
3 East Greenway Plaza, Suite 1600
Houston TX 77046-0391
Attention: David S. Wise, Esq.
Facsimile: (713) 561-6300

with copies to:

Crosby, Heafey, Roach & May
Two Embarcadero Center
Suite 2000
San Francisco, CA 94111
Attention: Kenneth M. Seeger, Esq.
Facsimile: (415) 391-8269

and

Weil, Gotshal & Manges LLP
100 Crescent Court, Suite 1300
Dallas, TX 75201
Attention: Martin A. Sosland, Esq.
Facsimile: (214) 746-7777

(ii) If to the Class Representatives or Class Counsel:

Weisman, Goldberg & Weisman Co., L.P.A.
1600 Midland Building
Landmark Office Towers
Cleveland, Ohio 44115
Attention: R. Eric Kennedy, Esq.
Facsimile: (216) 781-6747

Section 14.9 Any form or other documentation required to be submitted under this Settlement Agreement shall be deemed timely if postmarked on or before the date by which it is required to be submitted under this Settlement Agreement.

Section 14.10 No provision of this Settlement Agreement or any Exhibit or Annex hereto is intended to create any third-party beneficiary to this Settlement Agreement.

Section 14.11 This Settlement Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes and cancels all previous agreements, negotiations, and commitments in writings between the Parties hereto with respect to the subject matter hereof, including without limitation that certain term sheet dated as of August 2, 2001 (the "Term Sheet"). This Settlement Agreement may not be changed or modified in any manner unless in writing and signed by a duly authorized officer of Sulzer and by a duly authorized representative of the Class Representatives.

Section 14.12 This Settlement Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without regard to conflict of laws principles thereunder.

Section 14.13 The Parties acknowledge and agree that in the event that SML, SOUS and any other subsidiary of SML shall file for bankruptcy protection under any applicable bankruptcy or insolvency laws, or a petition for an involuntary bankruptcy or insolvency proceeding is initiated against any such party prior to the termination of this Settlement Agreement, any plan of reorganization or liquidating plan shall incorporate the terms of, and continue to implement, this Settlement Agreement.

Section 14.14 In the event that the Court approves a certification of the Settlement Class other than that contemplated by this Settlement Agreement, the parties hereby agree that they shall amend this Settlement Agreement to reflect such certification.

Section 14.15 Sulzer shall bear all costs associated with the issuance of ADRs to the Settlement Trust and filing of financing statements and other instruments pursuant to the Security Agreement.

Section 14.16 Sulzer agrees that it shall not enter into any settlement agreement or compromise any claim of any Class Member resident in the United States with respect to a claim arising out of or relating to an Affected Product from and after the Preliminary Approval Date

through the Final Judicial Approval Date, other than with the consent of Class Counsel (which consent shall not be unreasonably withheld); *provided*, that nothing in this Section 14.16 shall prevent Sulzer from entering into settlements with Medicare or third-party insurers with respect to the reimbursement of health care expenses.

Section 14.17 The Parties hereby agree that Sulzer may, in lieu of issuing ADRs to Class Members and Plaintiffs' Counsel hereunder, issue other securities of equivalent economic value as such ADRs to be otherwise issued to any such Class Member or Plaintiffs' Counsel, and the issuance of such equivalent securities shall be deemed to satisfy Sulzer's obligations to issue ADRs hereunder; *provided*, that such security has been agreed to by Class Counsel and approved by the Court.

Section 14.18 This Settlement Agreement may be signed in multiple counterparts, each of which shall be deemed to be an original and all of which shall be deemed to be one and the same instrument.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Parties have duly executed this Class Action Settlement Agreement among SOUS and SML and the Class Representatives, by their respective counsel as set forth below, on this 15th day of August, 2001.

SULZER ORTHOPEDICS INC.

By:_____

SULZER MEDICA LTD.

By:_____

By:_____

CLASS COUNSEL

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Waite, Schneider, Bayless & Chesley Co., L.P.A.
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John R. Climaco, Esq.
Climaco, Lefkowitz, Peca, Wilcox & Garofolico Co., L.P.A.
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FOR SUBCLASS II

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Strauss & Troy
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150 East 4th
Cincinnati, OH 45202-4018

Annex I

MATRIX COMPENSATION BENEFITS

[TO BE ATTACHED AFTER COURT APPROVAL]

Annex II

AFFECTED PRODUCTS
PART AND LOT NUMBERS

[TO BE ATTACHED AFTER COURT APPROVAL]

Annex III

U.S. SUBSIDIARIES

Sulzer Medica USA Holding Company
Sulzer Biologics Inc.
Sulzer Carbomedics Canada Inc.
Sulzer Carbomedics Inc.
Sulzer Carbomedics International Holding Co.
Sulzer Carbomedics UK Ltd.
Sulzer Cardiovascular AG
Sulzer Cardiovascular Inc.
Sulzer Cardiovascular SA
Sulzer Dental Corp.
Sulzer Dental GmbH
Sulzer Dental Inc.
Sulzer Dental Ltd.
Sulzer Dental Sarl
Sulzer IntraTherapeutics Inc.
Sulzer Medica Canada Inc.
Sulzer Medica International FSC Inc.
Sulzer Medica USA Inc.
Sulzer Mitroflow Corp.
Sulzer Orthopedics Canada Inc.
Sulzer Orthopedics Inc.
Sulzer Spine-Tech Inc.
Sulzer Spine-Tech Surgical Inc.
Sulzer Vascutek USA Inc.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	MDL Docket No. 01-CV-9000 ALL CASES (JUDGE KATHLEEN O'MALLEY)

DECLARATION OF LARRY BEEMAN IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION

I, Larry Beeman, declare:

1. I am Vice-President, Quality Assurance and Regulatory Affairs for Sulzer Orthopedics Inc. ("SOI"). As Vice-President, my job responsibilities include handling and reviewing any complaints with SOI's products. I make this Declaration in support of Defendant Sulzer Orthopedics Inc.'s Motions for Preliminary Approval of Class Settlement, Approval of Class Notice and Enjoining All Related Litigation. I have personal knowledge of the matters set forth in this Declaration. If called as a witness, I could and would competently testify to these matters.

2. SOI is an Austin, Texas-based manufacturer of orthopedics devices, such as knee, hip and shoulder replacement systems. Specifically, SOI manufactured the Inter-Op™ Acetabular Shell and Natural Knee II™ tibial baseplate. SOI is, and has been, the only manufacturer of these finished devices in the United States. SOI first introduced the Inter-Op™ shell in 1996 and the Natural Knee II tibial baseplate in 1995.

3. On December 5, 2000, SOI announced a voluntarily recall of approximately 40,000 hip replacement components known as the Inter-Op™ acetabular shells. It did so after receiving reports that some patients with implanted Inter-Op™ shells were experiencing "early loosening." After the recall, SOI notified governmental regulatory agencies, issued a public apology and explanation, and offered repeated assurances that it would address patient's needs.

4. SOI's investigation into these failures revealed that a contaminant was found on the shell's surface which prevented a patients' hip

bone, or acetabulum, from growing into the hip implant. SOI believes that the shells were contaminated when SOI changed its manufacturing process and performed some machining after the Cancellous-Structured Titanium™ porous coating was applied to the implant.

5. As part of SOI's investigation, SOI reviewed all of its manufacturing processes for all of its products to see if other products could have been contaminated. SOI's Natural Knee II™ tibial baseplate knee implant is the only other product sold in the United States that was machined at SOI after the application of SOI's porous coating. SOI withdrew the device from the market in March 2001 and again notified the FDA.

6. Hereinafter an "affected" product shall refer to: (a) any Inter-Op™ shell identified in SOI's December 5, 2000 Safety Alert; (b) any Natural Knee II™ tibial baseplate identified in SOI's Special Notification dated May 17, 2001; (c) those Inter-Op™ shells which were returned to SOI as part of the recall, recleaned and subsequently implanted; as well as (d) any additional Inter-Op™ shell which was machined after the application of porous coating at SOI and then subsequently implanted to date but was not identified in SOI's December 5, 2000 Safety Alert.

7. Approximately 31,284 Inter-Op™ shells and 1,600 Natural Knee II™ tibial baseplates were manufactured in this fashion and implanted into a patient. An additional 2,420 reprocessed Inter-Op™ shells have been distributed internationally, but SOI does not have accurate information as to how many of these were implanted.

8. As of August 2001, SOI is aware of 2,371 revision surgeries involving patients who received an affected Inter-Op™ shell and 280 revision

surgeries involving patients who received an affected Natural Knee II™ tibial baseplate. As indicated by our records of 1,178 patients, the average age of these patients is approximately 62.8 years old. At least, forty of these patients have undergone multiple revision surgeries either because both of the patient's hips or knees needed to replaced (otherwise known as a "bilateral" hip/knee replacement) or because the patient received more than one affected implant.

9. Because there are many individualized factors which influence whether a patient requires a revision surgery (including, but not limited to, each patient's medical history and lifestyle as well as the amount of contaminant, if any, found on a particular implant), it is difficult at this time to predict how many patients will require a revision surgery before December 2008. Currently, approximately 7.5% and 17% of the number of implanted affected shells and knees, respectively, have been revised. Our records indicate that the number of revision surgeries appears to have peaked approximately 10 weeks after SOI stopped selling its affected Inter-Op™ shells. Attached as Exhibit A is a graph demonstrating the number of Inter-Op™ shell revision surgeries by explant week that have been reported to SOI since September 19, 1999. Based upon the preliminary analysis of available data, SOI anticipates that the percentage of affected knee implants that will be revised will continue to increase until

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approximately September 2001. Attached as Exhibit B is a graph demonstrating the number of Natural Knee forged baseplate revision surgeries by explant date that have been reported to SOI since January 1, 2001.

I declare under penalty of perjury under the laws of the United States that the foregoing is true.

DATED: August 14, 2001.

Larry Beeman

EXHIBIT "A"

August 10, 2001

Inter-Op Revision Surgeries by Explant Week

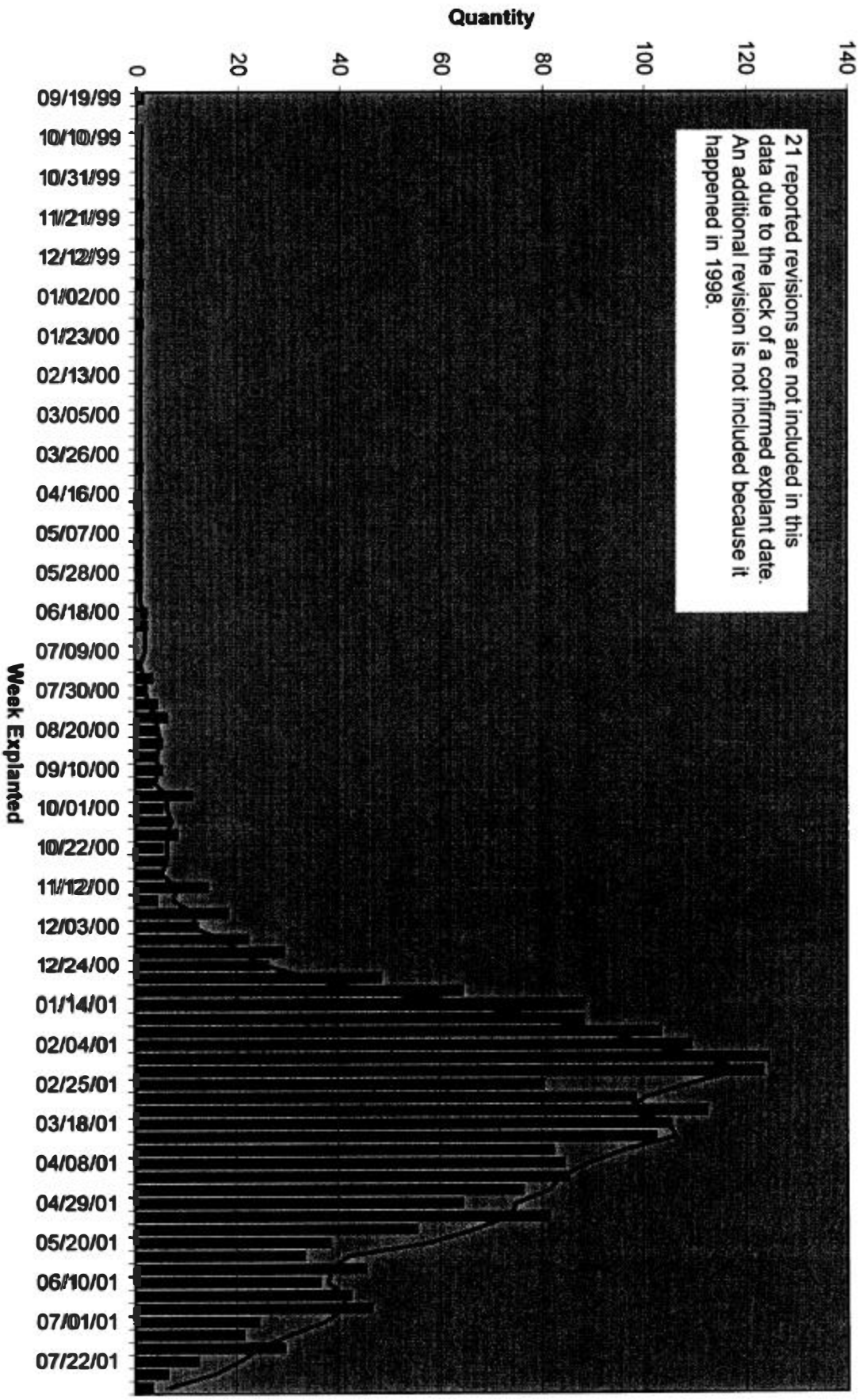
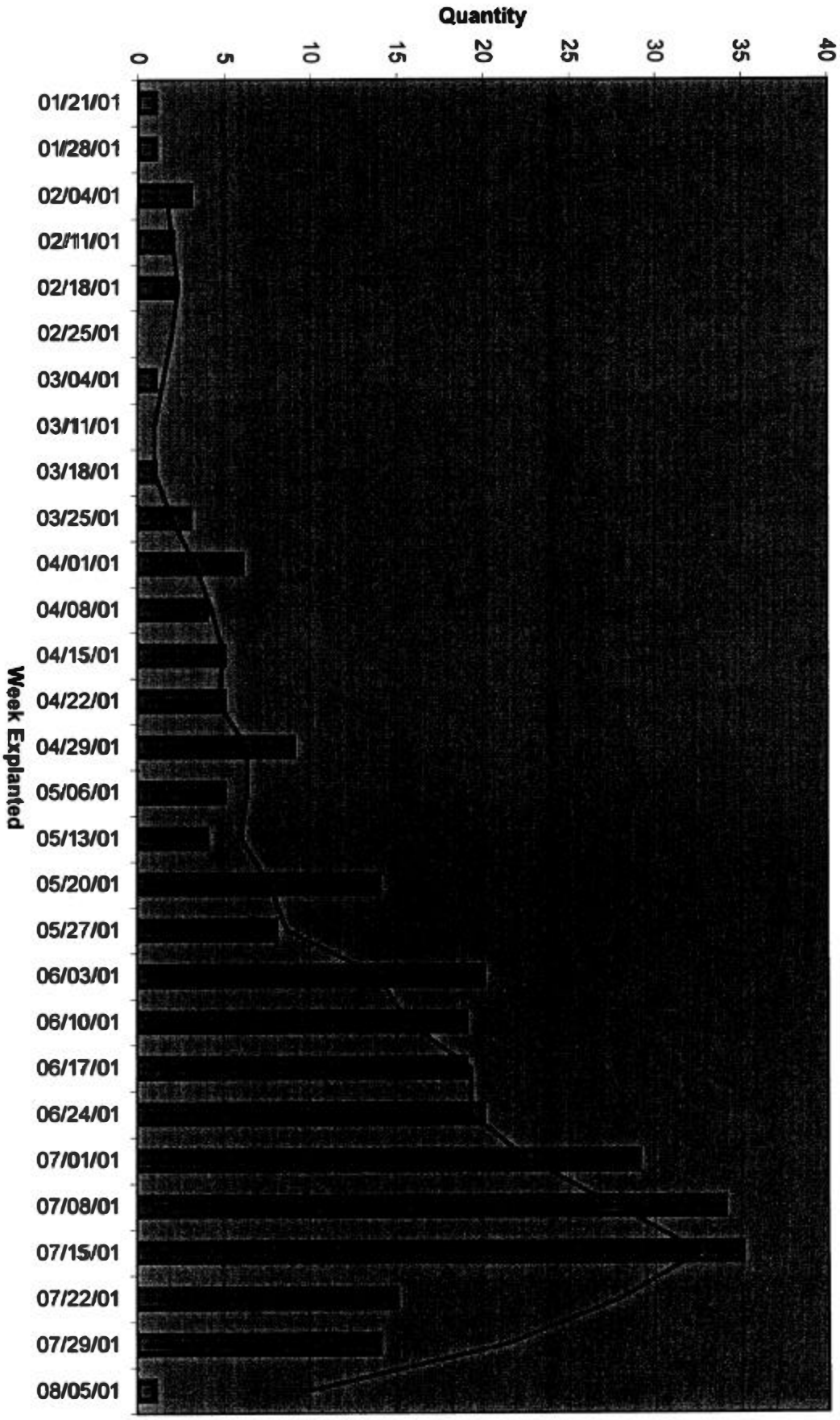


EXHIBIT "B"

August 10, 2001

Natural Knee Forged
Baseplate Revision Surgeries by Explant Date



UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	MDL Docket No. 01-CV-9000 ALL CASES (JUDGE KATHLEEN O'MALLEY)

DECLARATION OF BRIAN J. DEVINE IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION

I, Brian J. Devine, declare:

1. I am Assistant General Counsel, Product Liability for Sulzer Medica USA Inc. Prior to May 2001, I was Risk Manager. As Assistant General Counsel and Risk Manager I am familiar with the insurance coverage and litigation involving Sulzer Medica Ltd. and its subsidiaries concerning Sulzer Orthopedics Inc.'s hip and knee implants. I make this Declaration in support of Defendant Sulzer Orthopedics Inc.'s Motions for Preliminary Approval of Class Settlement, Approval of Class Notice and Enjoining All Related Litigation. I have personal knowledge of the matters set forth in this Declaration. If called as a witness, I could and would competently testify to these matters.

2. On December 5, 2000, Sulzer Orthopedics Inc. recalled certain lots of its Inter-Op™ Acetabular shells. At the time of the recall, Sulzer Medica Ltd. and all of its subsidiaries (hereinafter referred to collectively as "Sulzer"), including Sulzer Orthopedics Inc., were insured under a primary policy, a Master policy and four excess policies. Sulzer Orthopedics Inc.'s agents and its distributor(s) are also named or additional insureds under all of these policies. Aside from these six policies, no other insurance is available to Sulzer for any claim stemming from a product identified in Sulzer Orthopedics Inc.'s December 5th recall.

3. Soon thereafter, Sulzer Orthopedics Inc. launched a product investigation pertaining to certain lots of its Natural Knee II™ porous coated tibial baseplates. Sulzer's insurer has taken the position that the only insurance policy that responds to claims arising out of products within the scope of the tibia product investigation are the same insurance policies and the same policy limits that cover the December 5th Inter-Op™ recall.

4. The primary policy was underwritten by Winterthur International Americas Insurance Company and had $5 million in limits. As of August 2001, Sulzer was informed that it had exhausted the policy limits.

5. The Master and excess policies are underwritten by Winterthur Schweizerische Vericherungs-Gesellschaft and have an aggregate limit of CHF 400 million or approximately $235 million. According to the policies' terms, all legal fees and costs deplete the policies' limits.

6. As of August 2001, Sulzer has paid, or has incurred, approximately $8.5 million in legal fees and costs as a result of Sulzer Orthopedics Inc.'s hip and knee implant litigation and estimates that it will incur approximately $2 million monthly in legal fees and costs if this litigation continues.

7. As of August 2001, Sulzer has settled 92 claims in the United States relating to Sulzer Orthopedics Inc.'s hip and knee implants for an aggregate total of $8,880,196, or on average, $96,524 per claim.

8. Plaintiffs actively litigating their claims are seeking larger settlements. For example, Sulzer is currently negotiating with an attorney from Corpus Christi, Texas representing 23 plaintiffs, 20 of whom have been revised. He is currently demanding between $200,000 and $500,000 for each plaintiff who has undergone a revision surgery and approximately $100,000 for those who have not been revised.

I declare under penalty of perjury under the laws of the United States that the foregoing is true.

DATED: August 14, 2001.

Brian J. Devine

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	MDL Docket No. 01-CV-9000 ALL CASES (JUDGE KATHLEEN O'MALLEY)

DECLARATION OF RICHARD J. MAY IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION

I, Richard J. May, declare:

1. I am the Group Vice President, Finance, and Tax Counsel for Sulzer Medica USA Inc. I am also Treasurer of Sulzer Medica USA Holding Co. As Group Vice President, Finance, and Tax Counsel, my job responsibilities include assisting and/or supervising the preparation of any required Securities and Exchange Commission filings and United States federal and state tax returns for Sulzer Medica Ltd. and all of its affiliated companies and subsidiaries, including Sulzer Medica USA Inc. I make this Declaration in support of Defendant Sulzer Orthopedics Inc.'s Motions for Preliminary Approval of Class Settlement, Approval of Class Notice and Enjoining All Related Litigation. I have personal knowledge of the matters set forth in this Declaration. If called as a witness, I could and would competently testify to these matters.

2. Sulzer Medica Ltd., a medical technology company based in Winterthur, Switzerland, owns all the stock in Sulzer Medica USA Holding Co. as well as 18 other non-United States corporations located throughout the world. One of these subsidiaries, Switzerland-based Sulzer Orthopedics Ltd., also makes and sells orthopedic implants. In addition, Sulzer Medica Ltd. owns a partial interest in five other non-US corporations. Sulzer Medica Ltd. is publicly traded on the New York and Zurich stock exchanges.

3. Until recently, Sulzer Medica Ltd.'s majority shareholder was a Swiss industrial company called Sulzer AG, which owned approximately 74 percent of Sulzer Medica Ltd.'s outstanding stock. However, on July 10, 2001, Sulzer AG distributed substantially all of its interest in Sulzer Medica Ltd. to its shareholders.

4. Sulzer Medica USA Holding Co. is a holding company whose sole business is owning stock in other corporations. Its holdings include all the stock in Sulzer Orthopedics Inc. as well as nine other companies based in the United States.

5. Hereinafter "Sulzer" or "Sulzer entities" shall refer to Sulzer Medica Ltd. and all of its United States and non-United States subsidiaries, collectively, unless otherwise specifically noted.

6. As of March 30, 2001 (the most currently available public information), Sulzer reported net consolidated assets (excluding goodwill) of approximately $700 million. This figure does not reflect any costs or liability related to the Class Action Settlement Agreement (hereinafter "Settlement Agreement").

7. As of March 30, 2001, Sulzer reported gross consolidated assets (excluding goodwill) of approximately $1,027 million. Such assets encompass land, buildings, machinery and equipment, other operational assets, inventory, cash and cash equivalents (including all bank accounts), accounts receivables, intellectual property (e.g. patents, licenses, capitalized developments) and investments. Generally speaking, and as explained in greater detail on pages 14, 15 and 16 of its 2000 Consolidated Financial Statements, these items are generally stated at the lower value of the item's cost or market value less depreciation (or for other permanent impairment in value where required). Other items such as its accounts receivables are stated at their face value net of any necessary allowance for any doubtful accounts.

8. Although the above reported figures fairly and accurately present the financial position of Sulzer in accordance with the standards formulated by the International Accounting Standards Committee, if Sulzer re-stated each of its tangible assets to the greater of (a) the reported amounts or (b) the estimated fair market value and assumed that all accounts receivable would be paid in full, I estimate that the amount of net assets would only be increased by approximately $28 million.

9. Although the reported value of Sulzer's net assets (excluding goodwill and the costs associated with the Settlement Agreement) is approximately $700 million, if Sulzer were forced to liquidate its assets, the amount of cash it would realize would be far less than $700 million. This is because Sulzer would have to find a buyer for these assets in the absence of a liquid market. In addition, Sulzer would be forced to sell these assets under time pressure, which would also impact the price. I estimate that Sulzer's "so-called" liquidation value in such a scenario would be approximately $200 to $250 million. I arrived at this figure by estimating that Sulzer's property, plant and equipment could be sold for approximately $100 million; its financial investments for $60 million; and accounts receivable for $220 millions. These amounts combined with approximately $100 million of "unpledged" cash (e.g. after consideration for the dividend that was paid in April 2001) and $320 million in liabilities, lead me to my estimated liquid value mentioned above.

10. For the three months ended, March 30, 2001, Sulzer's consolidated net income was approximately $33 million. Adjusted for exceptional items, the net income for normal operations was approximately $20 million, whereas it was nearly $31 million for the same period in 2000. In addition to the

dramatic decline in net income from normal operations, Sulzer is experiencing a decline in profitability (return on sales) and liquidity.

11. Because of the financial uncertainty created by Sulzer Orthopedics Inc.'s recall of its Inter-Op™ acetabular shell and the later safety announcement regarding its Natural Knee II™ tibial baseplate, banks and other financial institutions have been hesitant to lend Sulzer any money. As of now, Sulzer is able to draw from a CHF 4 million ($2.4 million) line of credit with Credit Swiss Group, Switzerland. In addition, Chase and Citibank have been reviewing the possibility of making a securitized (asset backed) loan with all of Sulzer Medica USA's receivables and inventories as collateral. Negotiations are currently ongoing.

12. Under the terms of the "Settlement Agreement," Sulzer estimates that it may pay between $750 to $800 million in cash and stock to the class members and their attorneys over next 7 years.

I declare under penalty of perjury under the laws of the United States that the foregoing is true.

DATED: August 15, 2001.

Richard J. May

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re INTER-OP™ HIP PROSTHESIS PRODUCT LIABILITY LITIGATION	MDL Docket No. 01-CV-9000 ALL CASES (JUDGE KATHLEEN O'MALLEY)

DEFENDANT SULZER ORTHOPEDICS INC.'S CERTIFICATE OF SERVICE

PROOF OF SERVICE

I hereby certify that on August 15, 2001, a copy of the foregoing documents listed below was filed electronically and served by method indicated below. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

DEFENDANT SULZER ORTHOPEDICS INC.'S MOTION FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT; [PROPOSED] ORDER TO CONDITIONALLY CERTIFY CLASS, PRELIMINARILY APPROVE SETTLEMENT, SET BRIEFING SCHEDULE RE NOTICE TO CLASS, AND ENJOIN PARALLEL LITIGATION; DEFENDANT SULZER ORTHOPEDICS INC.'S MOTION FOR ORDER ENJOINING RELATED LITIGATION PENDING FINAL APPROVAL OF CLASS SETTLEMENT; DECLARATION OF ADAM R. SALVAS IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTION FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION; DECLARATION OF BRIAN J. DEVINE IN SUPPORT OF DEFENDANT SULZER ORTHOPEDIC INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION; DECLARATION OF RICHARD J. MAY IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION; AND DECLARATION OF LARRY BEEMAN IN SUPPORT OF DEFENDANT SULZER ORTHOPEDICS INC.'S MOTIONS FOR PRELIMINARY APPROVAL OF CLASS SETTLEMENT AND FOR ORDER ENJOINING ALL RELATED LITIGATION

☒ by transmitting via facsimile on this date from fax number (415) 391-8269 the document(s) listed above to the fax number(s) set forth below. The transmission was completed before 5:00 p.m. and was reported complete and without error. The transmission report, which is attached to this proof of service, was properly issued by the transmitting fax machine. Service by fax was made by agreement of the parties, confirmed in writing.

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Executed on August 15, 2001, at San Francisco, California.

s/Kenneth M. Seeger
Kenneth M. Seeger
(Cal. State Bar No. 135862)

CROSBY, HEAFY, ROACH & MAY
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Two Embarcadero Center, Suite 2000
Tel: (415) 543-8700
Fax: (415) 391-8269
e-mail: kseeger@chrm.com

Attorneys for Defendant
Sulzer Orthopedics Inc.

[INSERT INFORMATION HERE]