204 F.R.D. 330
United States District Court,
N.D. Ohio,
Eastern Division.

In re INTER–OP HIP PROSTHESIS LIABILITY LITIGATION.

No. MDL NO. 1401.
|
Aug. 31, 2001.

Synopsis
After products liability claims against manufacturer of hip replacement components were transferred by Judicial Panel on Multidistrict Litigation, parties moved for conditional certification of class and preliminary approval of class settlement. The District Court, O'Malley, J., held that: (1) numerosity, commonality, typicality, and adequacy of representation requirements for certification were satisfied; (2) persons who received reprocessed hip implant components and persons who received knee implants would be excluded from class; (3) common issues of law and fact predominated over issues affecting individual class members; (4) class action was superior procedure for handling dispute; (5) requested injunctive relief in form of medical monitoring program warranted class certification; and (6) proposed settlement agreement was preliminarily fair, reasonable, adequate, and consistent with public interest, warranting conditional approval of agreement.

Class provisionally certified and settlement agreement preliminarily approved.

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Opinion

*335 *MEMORANDUM AND ORDER*

O'MALLEY, District Judge.

On August 29, 2001, this Court provisionally certified a class and granted preliminary approval to the parties' settlement agreement. This memorandum sets forth the Court's reasoning.

I. Background.
Sulzer Orthopedics, Inc. ("Sulzer Orthopedics") is a designer, manufacturer and distributor of orthopedic

implants for hips, knees, shoulders, and elbows. One of its products is known as the "Inter–Op acetabular shell," which is one component of a system used for complete hip replacements. Specifically, the Inter–Op shell is a socket-like device inserted into the acetabulum, which is a part of the pelvis; the shell is designed to receive a separate, ball-like device, which is inserted into the femur, or thigh bone. The two components thereby replace the articulating ball-and-socket structure of the hip joint. The Inter–Op shell is regulated by the federal Food and Drug Administration ("FDA").

Proper surgical attachment of these replacement components in the body is critical. Orthopedic implants are often cemented or screwed into position. Some implants are also designed to allow the bone to grow into and around them, holding them securely in place. The Inter–Op acetabular shell was designed to bond with the natural bone.

Unfortunately, a manufacturing defect apparently prevented some of Sulzer Orthopedics' Inter–Op shells from bonding with the acetabulum. In early December of 2000, Sulzer Orthopedics announced a voluntary recall of certain manufacturing lots of its Inter–Op shells. Most of the recalled products were manufactured during or after October of 1999, but a limited number were produced as early as June of 1997. The recall stated that Sulzer Orthopedics had "received reports of post-operative loosening" of some of the Inter–Op shells, apparently "related to a reaction of the body to a slight residue of lubricant used in the manufacturing process." Sulzer Orthopedics recalled approximately 40,000 units of its Inter–Op shell, of which about 26,000 had already been implanted in patients.[1] About 90% of these implants occurred in the United States.

[1] Sulzer Orthopedics then "reprocessed" some of the returned units—that is, it "re-cleaned" some of the never-implanted, recalled shells—and then resold them. About 5,000 of these reprocessed units were then implanted. Persons who received these "reprocessed" shells are not included in the conditionally certified class.

One of the documents issued by Sulzer Orthopedics in connection with the voluntary recall included the following explanation:

> Sulzer Orthopedics is the manufacturer of a hip implant that you received during hip replacement surgery. We sincerely regret to inform you that we have recently learned that a small number of the many implant parts that we manufactured may have a trace of lubricant residue on the surface that was not completely removed during the manufacturing process.
>
> * * * * * *
>
> The hip implant part is the acetabular "shell" which was implanted into the upper part of your hip called the acetabulum. Normally, the bone would form an integrated bond with the shell; however, it appears that bone does not always bond with shells when the lubricant residue is present. Reported symptoms include severe groin pain and inability to bear weight on your leg. These symptoms are caused by the shell being loose from the bone. Only a small number of patients who received the shell during their total hip replacement have experienced loosening of the shell.

In fact, to date, about 2,400 of the patients who received implants of the Inter–Op shells have undergone "revision surgery"—removal of the defective[2] implant and replacement with a new one. For a variety of reasons, ***336** not all of the patients who were implanted with recalled Inter–Op shells will undergo revision surgery. For example, some patients will not experience any bone-bonding failure; other patients may suffer severe failure but be medically ineligible for revision surgery. Ultimately, Sulzer Orthopedics estimates that approximately 4,500 patients will undergo revision surgery to replace the defective Inter–Op acetabular shells, and that the need for revision surgery will, in virtually all instances, become manifest within the next two years.

[2] The Court recognizes that the defect is, at this juncture, merely alleged and not proved. For ease of reference, however, and in light of Sulzer Orthopedics' voluntary recall and certain apparent concessions made in the proceedings to date, the Court occasionally refers in this memorandum to the Inter–Op acetabular shell as "defective," rather than "allegedly defective."

Shortly after Sulzer Orthopedics issued its voluntary recall in December of 2000, a number of plaintiffs around the country filed lawsuits, in both state and federal courts. To date, there are pending about 1,300 civil suits nationwide, about 200 of which are in federal court.

These cases involve about 2,000 named plaintiffs, primarily including implant recipients and their spouses. Over 90% of the state court actions have been filed in California, Texas, Florida, or New York. About 19 of the state court cases are styled as class actions, as are about 34 of the federal court cases. The defendants named in these lawsuits include not only Sulzer Orthopedics, but also: (1) Sulzer Medica USA Holding Company ("Sulzer Medica USA"), a holding company that owns Sulzer Orthopedics; (2) Sulzer Medica Ltd., a Swiss holding company that owns Sulzer Medica USA;[3] (3) Sulzer AG, a Swiss company that previously owned a majority of the stock of Sulzer Medica Ltd.; (4) various other Sulzer-related entities; and (5) various surgeons, hospitals, and medical supply companies connected to the distribution or implantation of the defective product. The causes of action in these lawsuits include claims for defective design, marketing and manufacture; breach of express and implied warranties; negligence; strict liability; and other legal theories of recovery. Trial proceedings have already begun in at least one state court case.[4]

3 Sulzer Medica Ltd. is a publicly traded company, its stock listed on the New York Stock Exchange (symbol: SM).

4 Trial began on August 20, 2001 in the Nueces County, Texas state court case of *Rupp v. Sulzer Orthopedics, Inc.,* no. 01–60581–4, ending in a verdict exceeding $15 million on August 30, 2001. Notably, these state court proceedings involved only Sulzer Orthopedics, Inc. as a defendant, and did not involve claims against Sulzer Medica, Sulzer AG, or any other related entity.

Pursuant to 28 U.S.C. § 1407, three different federal plaintiffs filed motions with the Federal Judicial Panel on Multi–District Litigation ("MDL Panel"), seeking to consolidate and centralize 30 of the federal lawsuits.[5] MDL docket no. 1401. On June 19, 2001, the MDL Panel granted these motions, consolidating and transferring all related pending federal litigation to the Northern District of Ohio and assigning oversight of the MDL proceedings to the undersigned. Thus, virtually all of the federal cases involving the Inter–Op acetabular shell have either been transferred to this Court or are in the process of being transferred to this Court.[6]

5 Interestingly, Richard Heimann is one of the attorneys who filed a motion with the MDL Panel for consolidation. Mr. Heimann asked that the MDL Panel transfer all federal "Sulzer hip implant" cases to the Northern or Central Districts of California; Mr. Heimann had filed a putative class action, in the Northern District of California, seeking to represent a nation-wide class of persons who received Inter–Op hip implants. Mr. Heimann is now one of the most vocal objectors to class certification and the proposed class settlement agreement.

6 As of August 28, 2001, about 160 federal cases have been transferred or conditionally transferred to this Court. Some cases have not been transferred pending resolution of the plaintiffs' objections to transfer. Apparently, one or more of the conditionally transferred cases relates to a *different* implant manufactured by Sulzer Orthopedics, Inc.—the "Natural Knee Tibial Baseplate"—and does not involve the Inter–Op acetabular shell. As will be discussed below, persons who received these knee implants are not included in the conditionally certified class.

On July 7, 2001, this Court issued an Order setting out the "practices and procedures" it would follow during its administration of the MDL proceedings. Among other things, this Order: (1) temporarily appointed liaison and co-lead counsel for plaintiffs; (2) set an initial case management conference for August 17, 2001; and (3) directed counsel to submit an agenda for this conference, to include a discovery plan and also proposed deadlines for amendment of pleadings, expert ***337** and non-expert discovery, dispositive motions, expert reports, and so on. Shortly before this conference, however, counsel for the parties informed the Court that they planned to submit an agenda including another significant item: discussion of a proposed class certification and class settlement. The parties then filed motions for an order conditionally certifying a class, motions for preliminary approval of a class settlement, and motions to enjoin related litigation pending final approval of a class settlement.[7] As the Court had previously required, plaintiffs' liaison counsel forwarded copies of these motions, including a copy of the proposed settlement agreement, to counsel for all plaintiffs whose cases had been consolidated in the MDL proceedings. In addition, plaintiffs' liaison counsel made available the same materials to virtually every plaintiffs' counsel pursuing litigation against Sulzer Orthopedics, both in federal and state court.

[7] At the case management conference, the Court granted the parties' joint oral motion to voluntarily withdraw their motions to enjoin related litigation, without prejudice. To date, the motion to enjoin related litigation has not been renewed.

Given the quickly changing nature of the litigation, the Court used the initial case management conference to question the parties in open court regarding their motions for class certification and class settlement. The Court directed its questions to plaintiffs' liaison and co-lead counsel, and also defendants' counsel. Given the wide publication of the pending motions, about 125 attorneys from around the country, representing plaintiffs and groups of plaintiffs, also attended the hearing. The Court permitted any attorney present to address the Court. The Court heard from those proposing preliminary certification and approval, and also heard from a number of counsel, including counsel representing the interests of various state court plaintiffs who are not parties to the MDL proceedings but whose interests could be affected by class treatment of the Sulzer-related claims. Some spoke strongly in favor of the proposed certification and settlement, while others strongly opposed it.

During the course of the hearing, it became apparent that the proposed settlement agreement, as drafted, contained provisions that did not accurately reflect the understanding of the parties. Accordingly, the Court directed the parties to submit an amended proposed class settlement agreement by August 24, 2001. The Court then indicated it would allow any person (including persons not parties to any federal proceeding) wishing to offer additional objections to the proposed class and amended proposed class settlement agreement to submit their positions in writing by August 24, 2001. The Court received about 41 such comments, all of which it has reviewed in detail.[8]

[8] The comments arrived in the form of letters to the Court, letters to liaison counsel, e-mails to the Court, and formal docket entries within the MDL proceeding. Some were filed by counsel representing putative class members, and others were submitted directly by individuals who received an Inter–Op hip implant.

Finally, on August 28, 2001, the Court held an additional hearing on the pending motions for class certification and preliminary approval of class action settlement. Having now received extensive argument regarding the facts of this case and the applicable legal standards, the Court sets out its analysis below.

II. The Nature and Context of the Issues Presented.

Neither the Court's analysis nor the effect of its rulings can be understood without consideration of the context in which both occurred. The parties have jointly approached the Court, seeking only *conditional* certification of this matter as a class action and *preliminary* approval of their proposed settlement. As the parties understand, their motion, if granted, is only the first step in an extensive and searching judicial process, which may or may not result in final approval of a settlement in this matter.

As the Manual on Complex Litigation indicates, this threshold inquiry often involves no more than an informal presentation of the parties' proposals to the Court. ***338** *Manual for Complex Litigation,* § 30.41, at 236 (3rd ed.1995) ("in some cases this initial [fairness] evaluation can be made on the basis of ... informal presentations by the settling parties"). This is true because the Court's *conditional* certification and *preliminary* approval: (1) triggers a mechanism for more formal notice to all potential class members; (2) determines whether opt-out rights are to afforded putative class members; (3) defines the scope of discovery to be conducted from that point forward—that is, focuses discovery on the fairness and adequacy of the proposed settlement to the class, as well as on any issues which might call into question the propriety of final certification of the matter as a class action; (4) sets in motion those judicial processes that will culminate in a detailed, full, and final fairness hearing (at which time the question of fairness is reviewed de novo); and (5) establishes procedures for class members to register with the Court objections to or support for the proposed settlement.

Thus, while it is certainly not the role of this Court to simply "rubber-stamp" a motion for conditional certification or preliminary approval (or, for that matter, *any* motion), the Court also must be mindful of the substantial judicial processes that remain to test the assumptions and representations upon which the parties' motions are premised.

It is true that, to date, this case has been somewhat

unusual. Partly because of wide publicity within the plaintiffs' bar and the general public, the Court has allowed the breadth and extent of the inquiry already conducted with respect to the pending motions to far exceed what it might normally employ. Indeed, the objections raised by some of the class members and their counsel, together with the Court's own probing, have already resulted in substantial revisions to the proposed settlement agreement. The process employed to date, however, as searching as it has been, is clearly preliminary and is no substitute for that which can be, and now in this case will be, accomplished through a full fairness inquiry.

For these reasons, the Court must, to a large extent, premise its determinations at this stage of the proceedings upon certain of the representations and assumptions made by the movants, at least to the extent those representations and assumptions have been supported by sworn declarations or statements of counsel and are not, on their face, suspect. The Court reserves for another time the right and obligation to test all of the premises behind the parties' motions and the Court's ruling, through the most probing of inquiries.

III. Class Certification.

The Court first examines the propriety of conditional certification of the proposed class. On August 15, 2001, plaintiffs' co-lead counsel filed an amended complaint in this case, stating claims under the following legal theories: (1) strict liability, (2) negligence, (3) breach of implied warranty, (4) breach of express warranty, (5) "fear of future product failure" (infliction of emotional distress), (6) misrepresentation, (7) equitable relief via medical monitoring, and (8) punitive damages.[9] The amended complaint also states that plaintiffs are seeking relief "on their own behalf and as representatives of a class." Complaint at ¶ 1. In their complaint, the plaintiffs define the class as consisting of: "all citizens or residents of the United States who have had Affected Inter–Op acetabular shell hip implants placed in their bodies, ... or their estates, administrators or other legal representatives, heirs or beneficiaries, and any other person asserting the right to sue independently or derivatively." *Id.*[10] The plaintiffs also define two subclasses: "Subclass 1 consists of those Class members who have had Affected Inter–Op shells placed into their bodies and have *already undergone revision surgery* prior to the Final Judicial ***339** Approval Date and Subclass 2 consists of Class members who *may need to undergo revision surgery* after the Final Judicial Approval Date to correct problems with the Affected Inter–Op shells." *Id.* (emphasis added).

9 The amended complaint can also fairly be said to state a claim under the legal theory of loss of consortium, although it does not set out this claim separately.

10 "Affected Products" is defined in the complaint to include all of the recalled Inter–Op acetabular shells, *including* those that were returned, "reprocessed," and re-sold. As noted, however, the plaintiffs subsequently indicated they do not seek to include in the class persons who received the "reprocessed" shells.

In plain English, the plaintiffs propose that the class be made up of all Americans in whom were implanted a recalled Inter–Op acetabular shell, together with their loved ones. This class would then be divided into two sub-classes: those who have already had revision surgery, and those who have not had (but yet may have) revision surgery. The plaintiffs ask the Court to certify this class under Fed.R.Civ.P. 23(b)(3). The plaintiffs also ask the Court to certify the class under Fed.R.Civ.P. 23(b)(2), for the limited purpose of obtaining injunctive relief in the form of medical monitoring.

A. Rule 23(a).

The plaintiffs have submitted their motion to certify a class in the context, and for the primary purpose, of consummating a settlement of this case. Although there is certainly "nothing inherently wrong with this practice," this Court "must pay 'undiluted, even heightened, attention' to class certification requirements in a settlement context." *Hanlon v. Chrysler Corp.,* 150 F.3d 1011, 1019 (9th Cir.1998) (quoting *Amchem Prods., Inc. v. Windsor,* 521 U.S. 591, 620, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997)). "Strict adherence to Rule 23 in products liability cases involving drug or medical products which require FDA approval is *especially* important." *In re American Medical Systems, Inc.,* 75 F.3d 1069, 1089 (6th Cir.1996) (emphasis in original) (hereinafter, "*AMS*").

Rule 23(a) "states four threshold requirements applicable to all class actions," including actions involving proposed

certifications of a "settlement-only" class. *Amchem,* 521 U.S. at 613, 117 S.Ct. 2231. These threshold requirements are:

> (1) numerosity (a "class [so large] that joinder of all members is impracticable"); (2) commonality ("questions of law or fact common to the class"); (3) typicality (named parties' claims or defenses "are typical ... of the class"); and (4) adequacy of representation (representatives "will fairly and adequately protect the interests of the class").

Id. (quoting Fed.R.Civ.P. 23(a)(1–4)). "Subsection (a) of Rule 23 contains four prerequisites which must all be met before a class can be certified. Once those conditions are satisfied, the party seeking certification must also demonstrate that it falls within at least one of the subcategories of Rule 23(b)." *AMS,* 75 F.3d at 1079.

1. Numerosity.

[1] [2] [3] In this case, it is clear that the proposed class is so numerous that joinder of all the proposed class members is impracticable. "There is no strict numerical test for determining impracticability of joinder." *AMS,* 75 F.3d at 1079. Rather, "[t]he numerosity requirement requires examination of the specific facts of each case and imposes no absolute limitations." *General Tel. Co. v. EEOC,* 446 U.S. 318, 330, 100 S.Ct. 1698, 64 L.Ed.2d 319(1980). "When class size reaches substantial proportions, however, the impracticability requirement is usually satisfied by the numbers alone." *AMS,* 75 F.3d at 1079. The Sixth Circuit Court of Appeals has affirmed the certification of a class made up of less than 100 individuals. *See Haytcher v. ABS Industries, Inc.,* 1991 WL 278981 at *1–2 (6th Cir. Dec.27, 1991) ("approximately 61 individuals"). The numerosity requirement is also satisfied more easily upon a showing that there is wide "geographical diversity of class members," which makes joinder of all the class members more impracticable. *Council of and for the Blind of Delaware County Valley, Inc. v. Regan,* 709 F.2d 1521, 1529 (D.C.Cir.1983).[11]

[11] One objector argued that members of the proposed class are dispersed across so wide a geographic region, and have so idiosyncratic an array of circumstances, that the class is "too numerous." The Court rejects this argument. First, other cases have recognized national classes. Second, the question of highly individual circumstances goes to typicality and commonality, not numerosity. The Court does not believe that this class is so numerous that it creates substantial problems with giving adequate notice or distribution of settlement recoveries.

***340** [4] In this case, the proposed class of persons who received implantation of a recalled Inter–Op shell includes over 26,000 people—not including persons, like spouses, who have derivative claims. Over 2,400 of these people have already had revision surgery. Furthermore, these class members reside throughout the entire United States. The undisputed evidence shows that the plaintiffs have carried their burden of showing that the proposed class is so large that joinder of all members is impracticable.

2. Commonality.

[5] [6] The commonality requirement states that there must be "questions of law or fact common to the class." The commonality test "is qualitative rather than quantitative, that is, there need be only a single issue common to all members of the class." *AMS,* 75 F.3d at 1080 (quoting 1 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions,* § 3.10, at 3–47 (3rd ed.1992)). On the other hand, the reason behind the commonality requirement is that "the class-action device saves the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion under Rule 23." *Califano v. Yamasaki,* 442 U.S. 682, 701, 99 S.Ct. 2545, 61 L.Ed.2d 176 (1979). Thus, if questions of law or fact common to all of the class members are far outweighed by differences, then class certification is inappropriate.

With regard to mass torts, like the defective hip implants at issue in this litigation, there are special considerations. The Sixth Circuit Court of Appeals has explained:

> In mass tort accidents, the factual and legal issues of a defendant's liability do not differ dramatically from one plaintiff to the next. No matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action. Consequently, the mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not

dictate the conclusion that a class action is impermissible.

* * * * * *

In complex, mass, toxic tort accidents, where no one set of operative facts establishes liability, no single proximate cause equally applies to each potential class member and each defendant, and individual issues outnumber common issues, the district court should properly question the appropriateness of a class action for resolving the controversy. However, where the defendant's liability can be determined on a class-wide basis because the cause of the disaster is a single course of conduct which is identical for each of the plaintiffs, a class action may be the best suited vehicle to resolve such a controversy.

Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1197 (6th Cir.1988).

[7] [8] The Court concludes that, in this case, there do exist questions of law or fact common to all members of the class.[12] The most obvious of these common questions is "[w]hether the Inter–Op acetabular shells designed, developed, manufactured, distributed, fabricated, supplied, advertised, promoted and/or sold by [Sulzer Orthopedics] had a defect(s)." Complaint at ¶ 26a. Other questions common to each class member are whether the defendants adequately tested the safety of their product, when the defendants learned of the defect, and whether they timely took action upon learning the defect might exist. All of these questions go to Sulzer Orthopedics' course of conduct, and when "the cause of [a] disaster is a single course of conduct which is identical for each of the plaintiffs, a class action may be the best suited vehicle to resolve such a controversy." *Velsicol,* 855 F.2d at 1197. There are also common questions pertaining to the relationships between the various "Sulzer-related" corporate entities and, hence, the potential liability of those entities for the activities of Sulzer Orthopedics, Inc. These questions, necessitating detailed factual ***341** inquiry and complex legal analysis, are common to all class members and can be resolved most efficiently in a class action context.[13]

12 Indeed, the MDL Panel has already so found. *See* Transfer Order from MDL Panel at 2 (June 19, 2001) ("the Panel finds that the actions in this litigation involve common questions of fact").

13 Indeed, as experience has shown, attempts by some of the state court plaintiffs' counsel to resolve these questions on an individual basis have been both cost-prohibitive (particularly given the complexities of the Hague Convention and Swiss law) and pointedly unsuccessful.

It is true, of course, that there are also substantial differences of fact and law between class members. For example, some class members may suffer no adverse medical affects, while others may suffer (and have suffered) terribly. Some class members may live in states where the law allows them to recover only if they suffer actual physical injury, while the state law applicable to other class members may allow them to recover even absent actual physical injury. And, even under legal theories normally allowed to class members by all states (e.g., negligence or strict liability), the legal formulation of those theories may vary from state to state. *See generally In re Northern Dist. of Calif., Dalkon Shield IUD Prods. Liab. Litig.,* 693 F.2d 847, 854 (9th Cir.1982), *cert. denied,* 459 U.S. 1171, 103 S.Ct. 817, 74 L.Ed.2d 1015 (1983) (on issues of negligence, strict products liability, adequacy of warnings, fraud, and conspiracy, "commonality begins to be obscured by individual case histories"). The Court concludes, however, that the questions of fact and law that are common to the members of the class are substantial, and are not outweighed by questions of fact and law idiosyncratic to each plaintiff. Accordingly, the Court concludes that the plaintiffs have carried their burden of showing that the proposed class meets the requirement of Rule 23(a)(2).

3. Typicality.

[9] The typicality requirement is meant to ensure that the named parties' claims are typical of the claims advanced by the entire class. A plaintiff's claim is typical "if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." *AMS,* 75 F.3d at 1081 (quoting 1 Newberg, *supra,* § 3–13, at 3–76 (footnote omitted)). The typicality requirement ensures that the representative plaintiffs' interests are aligned with those of the proposed class, and in pursuing their own claims, the named plaintiffs will also advance the interests of the class members. *Id.*

"Sometimes the issues are plain enough from the pleadings to determine whether the interests of the absent parties are fairly encompassed within the named plaintiff's claim, and sometimes it may be necessary for the court to probe behind the pleadings before coming to rest on the certification question." *General Telephone Co. of Southwest v. Falcon,* 457 U.S. 147, 160, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982).

In the plaintiffs' amended complaint, there are five named representative plaintiffs: Harlan and Brenda Herman, Linda Wells, and George and Mary Jean Yasenchack. Harlan Herman was implanted with a recalled Inter–Op shell, but has not undergone a revision surgery. The same is true of Linda Wells. George Yasenchack was implanted with a recalled Inter–Op shell and, on April 9, 2001, underwent revision surgery to correct problems he was experiencing with the implant.

Based on these allegations, Harlan Herman and Linda Wells appear to have claims common to the proposed "Subclass 2" of plaintiffs—persons who may need, but have not yet undergone, revision surgery to correct problems with the Affected Inter–Op shells. Harlan's wife, Brenda, appears to have claims common to those plaintiffs in Subclass 2 who have derivative claims, such as loss of consortium.

Similarly, George Yasenchack appears to have claims common to the proposed "Subclass 1" of plaintiffs—persons who have already undergone revision surgery to correct problems with the Affected Inter–Op shells. And George's wife, Mary Jean, appears to have claims common to those plaintiffs in Subclass 1 who have derivative claims, such as loss of consortium.[14]

14 While one objector contends that Mr. Yasenchak has "disavowed" the settlement and, hence, cannot be considered an adequate representative for post-revision-surgery claimants, the record does not support that contention. The Court finds that Mr. Yasenchak has neither rescinded his support for the settlement nor withdrawn his willingness to represent certain members of the proposed class.

***342** **[10]** The Court's review of those cases that have been transferred to the undersigned pursuant to the MDL Panel's orders—including other putative class actions—reveals that, in fact, the claims asserted by the five named representative plaintiffs in this case are altogether typical of the claims asserted by other prospective class members. Repeatedly, the plaintiffs in these other lawsuits invoke the same theories of liability against the same defendants as do Wells and the Yasenchaks and the Hermans, and assert that the defendants' liability stems from the same course of conduct.

It is worth noting that some of the plaintiffs in these other, transferred cases refer to particular *models* of the Inter–Op shell implants they received. The Court's own research allowed it to view a copy of Sulzer Orthopedics' original recall notification to the FDA.[15] The notification makes clear that Sulzer Orthopedics is recalling four different models of Inter–Op acetabular shells. *See* letter from Larry Beeman to Sherry Krolczyk (Dec. 14, 2000) at 1, ¶ 3 (stating Sulzer Orthopedics was recalling the "Rim Flare, Hemispherical, Revision and Protrusio" models of the Inter–Op acetabular shell). That there exist different models of the recalled implants raises concerns that typicality may not exist. *See AMS,* 75 F.3d at 1082 ("[E]ach plaintiff used a different model, and each experienced a distinct difficulty. * * * These allegations fail to establish a claim typical to each other, let alone a class."). The evidence presented to the Court shows, however, that, in fact, the different models of Inter–Op shells are really just different sizes, made to attach to different pelvic configurations, and that the underlying function of the models are entirely equivalent. *See* Beeman letter at 6 ¶ 7 ("The Inter–Op Acetabular Shell is provided in four basic configurations and is offered in various sizes within these configurations"); *see also* Beeman's Supplemental Declaration (docket no. 52) (same).

15 This document may well be a part of the record in this case by virtue of having been included as an exhibit to one of the pleadings contained in one of the cases transferred by the MDL Panel. The Court's view of this document, however, was actually obtained via its own research on the internet. *See http://www.hipimplantlaw.com/sitemap.htm* (website maintained by Lieff Cabraser Heimann & Bernstein, LLP, which represents a number of plaintiffs in this case, and allows viewing of an Adobe Acrobat reproduction of "Sulzer's Recall Notification letter to the Food and Drug Administration, December 14, 2000").

Furthermore, the evidence shows that the alleged reason for the failure of each of these implant models is the

same—the differences in model configuration are essentially irrelevant to their reason for failure. Thus, the Court is satisfied that the claims asserted by the five named representative plaintiffs are typical, notwithstanding the fact that the implants they received may bear different model numbers than the implants received by other class members.

In sum, the Court concludes that the representative plaintiffs' interests are aligned with those of the proposed class, and in pursuing their own claims, the named plaintiffs will also advance the interests of the class members. As such, the plaintiffs have carried their burden of showing that the proposed class meets the requirement of Rule 23(a)(3).

4. Adequacy.

[11] [12] The adequacy requirement ensures that the named representative plaintiffs "will fairly and adequately represent the interests of the class." Fed.R.Civ.P. 23(a)(4). The Sixth Circuit Court of Appeals has "articulated two criteria for determining adequacy of representation: '1) the representative must have common interests with unnamed members of the class, and 2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel.' " *AMS,* 75 F.3d at 1083 (quoting *Senter v. General Motors Corp.,* 532 F.2d 511, 525 (6th Cir.1976), *cert. denied,* 429 U.S. 870, 97 S.Ct. 182, 50 L.Ed.2d 150 (1976)). Essentially, the adequacy ***343** requirement is meant to test "the experience and ability of counsel for the plaintiffs and whether there is any antagonism between the interests of the plaintiffs and other members of the class they seek to represent." *Cross v. National Trust Life Ins. Co.,* 553 F.2d 1026, 1031 (6th Cir.1977). "The adequate representation requirement overlaps with the typicality requirement because in the absence of typical claims, the class representative has no incentives to pursue the claims of the other class members." *AMS,* 75 F.3d at 1083.

There does not appear to be any serious question of inadequacy in this case. At the hearing, even those attorneys who expressed some concern regarding the propriety of class certification agreed that proposed class counsel had the ability and experience to prosecute the case as a class action, and had reputations for doing so quite vigorously in other, similar cases. The Court has appointed the following individuals as class co-counsel: (1) John R. Climaco, of Climaco Lefkowitz Peca Wilcox & Garofoli (Cleveland, Ohio); (2) R. Eric Kennedy, of Weisman, Goldberg & Weisman (Cleveland, Ohio); (3) Donald Barrett, of Barrett Law Office, P.A. (Lexington, Mississippi); (4) Keith M. Fleischman, of Milberg Weiss Bershad Hynes & Lerach, LLP (New York, New York); (5) Richard S. Wayne, of Strauss & Troy (Cincinnati, Ohio); (6) Stanley M. Chesley, of Waite, Schneider, Bayless & Chesley Co. LP (Cincinnati, Ohio); (7) Wendell H. Gauthier, of Gauthier, Downing, LaBarre, Beiser & Dean (Metairie, Louisiana); and (8) Daniel E. Becnel, Jr., of The Law Offices of Daniel E. Becnel, Jr. (Reserve, Louisiana). These individuals and their experience in representing plaintiffs in other national class action lawsuits is known to the Court and appears to be known, to an even greater extent, to those many attorneys who have attended the hearings conducted to date in this matter.

Furthermore, there does not appear to be any antagonism between the interests of the named plaintiffs and other members of the class they seek to represent. As noted, the proposed class is separated into two subclasses—implantees who have not yet had revision surgery, and implantees who have. The five named plaintiffs, themselves, are split between these subclasses. As the Supreme Court has noted, these subclasses might have interests that do not completely align: "for the currently injured, the critical goal is generous immediate payments," but "[t]hat goal tugs against the interest of exposure-only plaintiffs in ensuring an ample, inflation-protected fund for the future." *Amchem,* 521 U.S. at 626, 117 S.Ct. 2231. Thus, "a class divided between holders of present and future claims ... requires division into homogeneous subclasses under Rule 23(c)(4)(B), with separate representation to eliminate conflicting interests of counsel." *Ortiz v. Fibreboard Corp.,* 527 U.S. 815, 856, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999) (citing *Amchem,* 521 U.S. at 627, 117 S.Ct. 2231).

[13] In this case, plaintiffs have provided "structural assurance of fair and adequate representation for the diverse groups and individuals affected," by dividing the class into homogeneous subclasses and providing each subclass with its own counsel. *Amchem,* 521 U.S. at 627, 117 S.Ct. 2231. Subclass 1 is separately represented by Mr. Kennedy, and subclass 2 is separately represented by Mr. Wayne. Thus, to the extent there exists any "antagonism" between the interests of the named plaintiffs amongst each other, and as against other class members, the plaintiffs have cured this conflict by the use of separately represented subclasses.

[14] In light of this structure, the only real "adequacy" concern asserted by some objectors is that class counsel cannot be deemed adequate, within the meaning of Rule 23(a)(4), because they have not "adequately" protected the interests of those individuals who might choose to opt *out* of the proposed settlement. This argument makes no sense. While it is true that "opt-out claimants" are entitled to certain procedural and even constitutional protections, which this Court must safeguard (a point discussed further below), it is *not* true that class counsel is charged with negotiating a settlement as beneficial to "opt-out claimants" as to claimants who choose to participate in the settlement. If class counsel does their job "adequately," moreover, the structure of the settlement will contain protections designed ***344** to assure that class participants actually do receive the payments they have agreed to accept. And, if class counsel does their job "adequately," the sums promised, along with any assurances of payment, will be such that few claimants, if any would hesitate to participate in that settlement.

[15] What these objectors fail to recognize is that "opt-out" claimants not only opt out of the settlement, but opt out of the class as well. As long as a claimant's right to opt out remains intact—a point which, again, is discussed further, below—class counsel has no further obligation to protect the interests of that claimant. Indeed, the objectors would place an impossible and inherently irreconcilable obligation upon class counsel—to negotiate a class-wide settlement which is fair, adequate, and beneficial to its participants, while leaving *completely unaffected* the interests of those who would choose not to participate in it. The Court does not believe that Rule 23 imposes any such burden on class counsel and does not believe "adequacy," within the meaning of that Rule, is to be measured in such a fashion. Tellingly, the objectors provide no case law supporting their interpretation of Rule 23 and class counsel's obligation to opt-out claimants.

Accordingly, the Court concludes that the plaintiffs have carried their burden of showing that the named representative plaintiffs will fairly and adequately represent the interests of the class in this case.

B. Class Definition.

[16] Notably, over the course of the last few weeks, the parties have presented the Court with different class definitions. For example, the first version of the proposed settlement agreement defines the settlement class to include persons having an unsatisfied claim involving: (1) Inter–Op shells "identified in the Safety Alert dated December 5, 2000;" (2) "Natural Knee Tibial Baseplates identified in a Special Notification dated May 17, 2001;" and (3) "Reprocessed Shells." Proposed agreement at § 1.1(d & eee). The most recent version of the proposed settlement agreement does not include in the settlement class persons having unsatisfied claims related to "reprocessed shells," and the class proposed in the amended complaint does not refer to persons having unsatisfied claims related to knee implants. Thus, the Court addresses here the precise definition of the conditionally certified class.

The Court conditionally certified the following class:

> "All citizens or residents of the United States who have had Affected Inter–Op acetabular shell hip implants placed in their bodies, together with their associated consortium claimants."[16] Further, this class shall be divided into two subclasses, as follows: Subclass 1 shall consist of those class members who undergo revision surgery prior to the Final Judicial Approval Date to correct problems with the Affected Inter–Op shells, and their associated consortium claimants. Subclass 2 shall consist of class members who may need to undergo revision surgery after the Final Judicial Approval Date to correct problems with the Affected Inter–Op shells, and their associated consortium claimants.[17]

16 In this context, the term "Affected Inter–Op acetabular shell hip implants" means the Inter–Op Acetabular shells identified in the Safety Alert issued by Sulzer Orthopedics, Inc., dated December 5, 2000, and also certain other Inter–Op Shells machined after porous coating, all of which will be identified with particularity by the parties to the proposed settlement agreement.

17 In this context, the term "Final Judicial Approval Date" means the date (if any) on which this Court's approval of the proposed settlement agreement becomes final by the exhaustion of all appeals.

For two primary reasons, this conditional class does *not* include persons in whom were implanted reprocessed shells. First, the parties explicitly excluded such persons

from the settlement class definition used in the most recent version of the proposed settlement agreement. Second, even had the parties not excluded persons asserting claims related to reprocessed shells, the Court had serious concerns whether commonality, typicality, and adequacy existed in connection to these claims. Because it appears that there may exist significant factual and legal differences between (a) persons who received Inter–Op ***345** hip implants bearing lubricant residue on their surface and (b) persons who received implants that, at one time, had lubricant residue on their surface but were first reprocessed and cleaned, it is appropriate that the parties agreed not to include the latter claimants in the class.

[17] Turning to knee implant claimants, in the most recent version of the proposed class settlement agreement, the parties *did* include in the settlement class persons having unsatisfied claims involving certain knee implants. For at least three separate reasons, the Court concludes that the conditionally certified class cannot include these persons (and, therefore, that the parties must submit an amended proposed class settlement agreement that does not purport to settle claims related to the implantation of "Natural Knee Tibial Baseplates").

First, the Court does not currently have jurisdiction over any case involving a knee implant. Although there are apparently one or more "knee implant cases" that have been *conditionally* transferred to this Court by the MDL Panel, the Court does not believe any of those transfers have become final. Until transfer of a knee implant case is final, subject matter jurisdiction over any related claim is lacking. Second, there again exist serious questions regarding whether the persons bringing "knee implant cases:" (1) sufficiently share questions of law or fact in common with the hip implant cases, (2) state claims that are "typical" of those made by the "hip implant class," or (3) would be adequately represented by the "hip implant" class counsel. At the very least, it appears that "knee implant" plaintiffs would need their own subclass counsel.[18]

18 Indeed, the Court was presented with virtually no factual development regarding the reason the knee implants are allegedly defective, the effect of the alleged defect, the type and level of damages suffered by persons who received knee implants, and so on. Without this factual development, the Court cannot assess adequacy, typicality, commonality, or even numerosity, as those requirements apply to knee implant claimants in particular, either as a subclass or as included within a larger "hip and knee implant" class.

And third, the defendants' identification of knee implants as problematic on *May 15, 2001*—and not within the April 2000 / April 2001 time period—suggests that claims related to knee implants may be covered by a different insurance policy. If there exist insurance funds available to pay for knee implant claims additional to and different from insurance funds to pay for hip implant claims, then inclusion of the knee implant claimants in the settlement class, pursuant to the existing provisions contained in the settlement agreement is inappropriate. Accordingly, the Court has been careful to conditionally certify a class consisting only of persons who received Inter–Op acetabular shell hip implants, together with persons who have closely associated claims.

C. Rule 23(b)(3).

Not only must the "four prerequisites [of Rule 23(a)] ... *all* be met before a class can be certified," "the party seeking certification must also demonstrate that it falls within at least *one* of the subcategories of Rule 23(b)." *AMS,* 75 F.3d at 1079 (emphasis in original). The plaintiffs in this case assert they fall within both the subcategories outlined in Rules 23(b)(3) and also 23(b)(2).

[18] Rule 23(b)(3) requires the court to find "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Subdivision (b)(3) parallels subdivision (a)(2) in that "both require that common questions exist, but subdivision (b)(3) contains the more stringent requirement that common issues 'predominate' over individual issues." *AMS,* 75 F.3d at 1084 (citing 1 Newberg, *supra,* § 3.10, at 3–56). The rule states that common issues need only predominate, not outnumber individual issues. *See In re School Asbestos Litigation,* 789 F.2d 996, 1010 (3rd Cir.1986) ("There may be cases in which resolution of one issue or a small group of them will so advance the litigation that they may fairly be said to predominate. Resolution of common issues need not guarantee a conclusive finding on

liability, ... nor is it a disqualification that ***346** damages must be assessed on an individual basis.").

The Sixth Circuit Court of Appeals, discussing class action treatment of cases (like this one) involving mass torts, has drawn a distinction between two sorts of cases. There are those, on the one hand, "where no one set of operative facts establishes liability, no single proximate cause applies to each potential class member and each defendant, and individual issues outnumber common issues." *Velsicol,* 855 F.2d at 1196–97. On the other hand, other "mass tort accidents [share] factual and legal issues of a defendant's liability [that] do not differ dramatically from one plaintiff to the next." *Id.* In these latter cases, "no matter how individualized the issues of damages may be," the fact that "questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is impermissible." *Id.; see Amchem,* 521 U.S. at 625, 117 S.Ct. 2231 ("[e]ven mass tort cases arising from a common cause or disaster may, depending upon the circumstances, satisfy the predominance requirement").

The evidence so far provided to the Court suggests this case falls solidly into the latter category. It appears that a single set of operative facts establishes liability in this case—the Court has read many of the complaints transferred here by the MDL Panel, and the plaintiffs repeatedly recite identical allegations, with no substantial factual additions or differences, to support their claims. Furthermore, it appears a single proximate cause applies to each potential class member and defendant—that is, Sulzer Orthopedics' manufacture and sale of Inter–Op shell implants with, as it has admitted, "a trace of lubricant residue [left] on the surface."

In concluding that class certification under Rule 23(b)(3) was appropriate in another medical product mass tort case, one well-respected court wrote:

> the diet drugs at issue here are essentially a single product ... marketed by a single major manufacturer .... In addition, use of the diet drugs spanned a finite and relatively short period of time. Moreover, there is, in general, a common injury type ... [and] there is a common body of science establishing the causal connection between the diet drugs and [the] ... injuries. In addition, plaintiffs' claims in this litigation all stem from allegations involving a common course of conduct followed by [the defendant]. Plaintiffs' negligence and failure to warn claims will revolve around [the defendant's] conduct and knowledge in developing and marketing [the drugs]. Although there are some individual differences among class members, the common class-wide focus on [the defendant's] knowledge and conduct predominate such that judicial efficiency will be improved through the class mechanism as opposed to relitigating these same issues in a series of individual cases. Furthermore, the class wide need for medical monitoring ... establish another concern common to the class. In sum, these common concerns which preexisted the settlement confirm the cohesiveness of the class.

In re Diet Drugs, 2000 WL 1222042 at *41–42 (E.D.Pa. Aug.28, 2000) (Bechtle, J.) (certifying a nationwide settlement class and approving the settlement). Every statement in this excerpt applies equally to this case. A single manufacturer (Sulzer Orthopedics) marketed a single product (the Inter–Op acetabular shell) over a finite and relatively short period of time (1997–2000). There exists a common body of science establishing how implantation of this product caused plaintiffs a common type of injury. The focus of each plaintiff's case includes Sulzer Orthopedics' conduct and knowledge in developing and marketing the Inter–Op shell. It is clear in these circumstances that "judicial efficiency will be improved through the class mechanism as opposed to relitigating these same issues in a series of individual cases." *Id.* at *42.

It is also worth noting that the proposed class "is more cohesive than the classes sought to be certified in the asbestos and tobacco litigation arenas." *Id.* The proposed class is not as "sprawling" as the class rejected by the Supreme Court in *Amchem,* where class members: (a) experienced different means of exposure to asbestos, (b)

were exposed ***347** to a wide array of asbestos-containing products, (c) were exposed to products manufactured by 20 different asbestos defendants, and (d) suffered a variety of injuries involving several scientific theories of causation. *Amchem,* 521 U.S. at 624, 117 S.Ct. 2231. To the contrary, the proposed class in this case appears to avoid all of the class deficiencies noted in *Amchem.* Importantly, there is no question in this case regarding *who* was actually exposed to the defective product. *Cf. Amchem,* 521 U.S. at 627, 117 S.Ct. 2231 ("[m]any persons in the [class] ... may not even know of their exposure, or realize the extent of the harm they may incur").

[19] [20] Moreover, when taking the proposed settlement (discussed in more detail below) into consideration for purposes of determining class certification, "individual issues which are normally present in personal injury litigation become irrelevant, allowing the common issues to predominate." *In re Diet Drugs,* 2000 WL 1222042 at *43. For example, "differences in state law ... do not destroy class cohesion because the settlement agreement provides for distribution of benefits based on the objective criteria described therein." *Id.* Similarly, individual issues relating to causation, injury, and damage also disappear because the settlement's objective criteria provide for an objective compensation scheme. The Court does not mean to state that the benefits of the settlement itself provide a common issue which satisfies the predominance requirement; rather, this Court finds that "the common issues that preexisted the proposed settlement—involving a common product, defendant, and course of conduct—when considered in light of the proposed settlement, predominate over any individual issues between class members." *Id.*

[21] [22] In addition to finding that questions of law or fact common to the members of the proposed class predominate over any questions affecting only individual members, the Court also concludes that allowing the plaintiffs to litigate this case as a class action will provide a superior method for fairly and efficiently adjudicating the controversy. When assessing whether a class action is superior under Rule 23(b)(3), the Court must normally consider "(A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; [and] (D) the difficulties likely to be encountered in the management of a class action." Fed.R.Civ.P. 23(b)(3). In the settlement context, however, the latter consideration is not relevant. *See Amchem,* 521 U.S. at 620, 117 S.Ct. 2231 ("[c]onfronted with a request for a settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems, for the proposal is that there be no trial").

With regard to the interest of class members in individually controlling their litigation, the Court notes that the parties withdrew their motions to enjoin related litigation. Thus, there is nothing that currently prevents any plaintiff from continuing to prosecute his or her case individually, and the opt-out provision of the proposed settlement agreement preserves this right. *See In re Diet Drugs,* 2000 WL 1222042 at *55 ("the combination of medical monitoring and ... opt out rights allows ... class member[s] to make informed choices about how to control their own destinies, whether through settlement or through litigation"). On the other hand, the Court was presented with evidence showing the fantastic expense and difficulties plaintiffs have faced in simply organizing the massive amounts of discovery obtained to date, much less merely procuring discovery from the foreign defendants. Pursuant to the proposed settlement agreement, however, (as discussed further below) the defendants (including foreign defendants with consistently asserted jurisdictional defenses) will provide and assist plaintiffs in organizing further discovery regarding their financial condition. The practical reality of this powerful class action discovery mechanism, incorporated into the proposed settlement agreement, overwhelms the interests any ***348** individual plaintiff may have in pursuing her litigation individually.

[23] An additional factor weighing in favor of superiority, moreover, is that the medical monitoring relief provided in the settlement agreement would not be available, as a practical matter, in the absence of class treatment. The "most compelling rationale for finding superiority in a class action ... [is] the existence of a negative value suit." *Allison v. Citgo Petroleum Corp.,* 151 F.3d 402, 420 (5th Cir.1998). Negative value claims are claims in which the costs of enforcement in an individual action would exceed the expected individual recovery. In this case, it appears that about 70–80% of the class members may have negative value claims—they were implanted with recalled Inter–Op shells, but are not expected to need revision surgery.[19] As to these class members, the most important component of relief is medical monitoring, to determine

whether, in fact, they fall in the minority of class members needing revision surgery or experiencing subsequent pain or limitation of movement. The small monetary amount involved with a medical monitoring claim "makes an individual claim for monitoring prohibitive in the absence of class treatment." *In re Diet Drugs,* 2000 WL 1222042 at *56.

[19] In this context, the Court is not characterizing those who may need revision surgery but, for whatever reason, cannot have this surgery and suffer pain or debilitation from the very absence of surgery. Rather, the Court is referring to those who will never need revision surgery because, even though their Inter–Op implant may have been manufactured defectively, their implant does not fail.

With regard to the extent and nature of any litigation already commenced by class members, this factor "is intended to serve the purpose of assuring judicial economy and reducing the possibility of multiple lawsuits." *Zinser v. Accufix Research Institute, Inc.,* 253 F.3d 1180, 1191 (9th Cir.2001) (quoting 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 1780 at 568–70 (2nd ed.1986) (footnotes omitted)). If "several other actions already are pending and ... a clear threat of multiplicity and a risk of inconsistent adjudications actually exist, a class action may not be appropriate since, unless the other suits can be enjoined, ... a Rule 23 proceeding only might create one more action." *Id.* "Rather than allowing the class action to go forward, the court may encourage the class members who have instituted the Rule 23(b)(3) action to intervene in the other proceedings." *Id.*

Here, it is certainly the case that other actions are pending—over a thousand of them. But this fact tends to support the proposition that allowing this case to proceed as a class action *would* tend to reduce the possibility of multiple lawsuits. It is likely that many class members will accept class treatment and choose not to opt out of this case, and will forego their individual lawsuits. Because there is virtually no likelihood that class members will simply "intervene in other proceedings," and because class certification will actually tend to increase judicial economy by reducing the number of related lawsuits, the factor recited in Rule 23(b)(3)(B) weighs in favor of class certification.

Finally, with regard to the desirability of concentrating the litigation of the plaintiffs' claims in this particular forum, the MDL Panel has already answered this question to some degree. *See* Transfer Order from MDL Panel at 2 (June 19, 2001) ("the Panel finds that ... centralization in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation"). "[F]rom the perspective of judicial efficiency, there is a strong desirability in implementing a settlement in this MDL ... transferee court." *In re Diet Drugs,* 2000 WL 1222042 at *55. This is especially true given that plaintiff's liaison counsel is located in this judicial district, as are some of plaintiffs' proposed co-lead counsel and plaintiffs' proposed separate counsel for Subclass 1.

In sum, this Court concludes that certification of this litigation as a class action under Rule 23(b)(3) is appropriate because the questions of law or fact common to the members of the class do predominate over any questions affecting only individual members, and because a class action is superior ***349** to other available methods for the fair and efficient adjudication of the controversy. Accordingly, the Court grants the pending motions for settlement-purposes class certification.

D. Rule 23(b)(2).

In addition to class certification under Rule 23(b)(3), plaintiffs also seek class certification under Rule 23(b)(2). Certification of a plaintiff class under this rule is appropriate when the defendant "has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Subsection (b)(2) class actions are "limited to those class actions seeking primarily injunctive or corresponding relief." *Barnes v. American Tobacco Co.,* 161 F.3d 127, 142 (3rd Cir.1998) (quoting 1 Newberg, *supra,* § 4.11, at 4–39).

Plaintiffs in this case seek equitable relief and injunctive relief through "the creation of a medical monitoring fund," which would:

> provide for a medical monitoring program, including: notifying Plaintiffs and the Class and subclasses of the defects and the potential medical harm; funding of a program for the surgical removal

> of the Inter–Op acetabular shells; funding a study of the long term effects of the Inter–Op acetabular shells within the body of Plaintiffs and the Class; gathering and forwarding to treating physicians information relating to the diagnosis and treatment of injuries which may result from the product; aiding in the early diagnosis and treatment of resulting injuries; and providing funding for diagnosis and preventable medical treatment, particularly radiological monitoring and for the surgical removal of the defective Inter–Op acetabular shells.

Complaint at ¶ 77. The establishment of a court-supervised program through which class members would undergo periodic medical examinations in order to promote early detection of physical harm is a "paradigmatic request for injunctive relief." *Barnes,* 161 F.3d at 132.

[24] In this case, the primary benefit provided under the settlement agreement to plaintiffs in Subclass 1–that is, those persons who received an Inter–Op implant but who have not "rejected" the implant and have not had to undergo revision surgery—is medical monitoring of their condition.[20] This monitoring is critical to diagnose any future rejection of the implants, in which case the plaintiff will probably need revision surgery (under the settlement agreement, the plaintiff will then receive additional monetary compensation and defendants will pay for the surgery). The evidence shows that Subclass 1 is expected to be the substantially larger of the two subclasses—of the roughly 26,000 class members implanted with a recalled Inter–Op shell, less than 5,000 are expected to undergo revision surgery. Thus, it is fair to say that the injunctive relief requested by the class is more than merely tangential and is an appropriate element of the redress awarded to the class as a whole. Accordingly, the Court concludes that certification of this litigation as a settlement class action under Rule 23(b)(2) is also appropriate. *See In re Diet Drugs,* 2000 WL 1222042 at *59 (certifying a mass tort settlement class action, in which the settlement provided both monetary compensation and medical monitoring, under Rules 23(b)(2) and 23(b)(3)).

[20] The proposed settlement provides Subclass 1 implantees with, inter alia, monetary compensation worth about $2,750, plus reimbursement for costs of medical monitoring in the form of periodic physician visits and x-rays.

IV. Fairness of the Proposed Settlement Agreement.

A. Standards under Rule 23(e).

[25] [26] In addition to the plaintiffs' motion for class certification are motions by both the plaintiffs and defendants for preliminary approval of the class settlement agreement. Thus, the Court must undertake a separate inquiry to determine the fairness of the proposed class action settlement, pursuant to Fed.R.Civ.P. 23(e). When, as here, the parties simultaneously seek class certification and settlement approval, a court should "be even more scrupulous than usual" ***350** when examining the fairness of the proposed settlement. *In re General Motors Corp. Pick–Up Truck Fuel Tank Products Liability Litigation,* 55 F.3d 768, (3rd Cir.1995), *cert. denied,* 516 U.S. 824, 116 S.Ct. 88, 133 L.Ed.2d 45 (1995); *see In re Prudential Ins. Co. of America Sales Practices Litigation,* 148 F.3d 283, 317 (3rd Cir.1998), *cert. denied,* 525 U.S. 1114, 119 S.Ct. 890, 142 L.Ed.2d 789 (1999) ("[t]his heightened standard is designed to ensure that class counsel has demonstrated 'sustained advocacy' throughout the course of the proceedings and has protected the interests of all class members"). The Court must determine whether the settlement is "fair, adequate, and reasonable, as well as consistent with the public interest." *United States v. Jones & Laughlin Steel Corp.,* 804 F.2d 348, 351 (6th Cir.1986); *Williams v. Vukovich,* 720 F.2d 909, 921 (6th Cir.1983).

It is important to note that the parties currently seek only *preliminary* approval of the class settlement agreement. The Manual for Complex Litigation explains that:

> Approval of class action settlements involves a two-step process. First, counsel 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 or other obvious deficiencies, such as unduly preferential treatment to class representatives or 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 Rule 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, § 30.41, at 236–37 (3rd ed.1995). Thus, the Court, at this juncture, is not obligated to, nor could it reasonably, undertake a full and complete fairness review. Nor is the Court obligated, at this time, to allow affected persons to object to the proposed settlement agreement—although the Court has, in fact, done so. *Id.* at 237 (noting that objections to the settlement are normally solicited only at the full, final fairness hearing). The *Manual* also warns that, "[w]here settlement is proposed early in the litigation, before significant discovery, the court and class counsel may have a limited factual basis for assessing its merits. In some cases, the court may require further discovery to justify the settlement or to secure information needed to implement it, such as determining a fair allocation." *Id.* § 30.42, at 238.

[27] [28] In making a preliminary assessment of the fairness of the proposed settlement agreement, the Court's "intrusion upon what is otherwise a private consensual agreement negotiated between the parties to a lawsuit must be limited to the extent necessary to reach a reasoned judgment 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." *Officers for Justice v. Civil Serv. Comm'n of the City and County of San Francisco,* 688 F.2d 615, 625 (9th Cir.1982), *cert. denied,* 459 U.S. 1217, 103 S.Ct. 1219, 75 L.Ed.2d 456 (1983). A preliminary fairness assessment "is not to be turned into a trial or rehearsal for trial on the merits," for "it is the very uncertainty of outcome in litigation and avoidance of wasteful and expensive litigation that induce consensual settlements." *Id.* Rather, the Court's duty is to conduct a threshold examination of the overall fairness and adequacy of the settlement in light of the likely outcome and the cost of continued litigation. *Ohio Public Interest Campaign v. Fisher Foods, Inc.,* 546 F.Supp. 1, 7 (N.D.Ohio 1982).

[29] As part of this evaluation, the Court may not second guess the settlement terms. *See Armstrong v. Board of School Directors of City of Milwaukee,* 616 F.2d 305, 315 (7th Cir.1980) ("[j]udges should not substitute their own judgment as to optimal settlement terms for the judgment of the litigants and their counsel"); *Officers for Justice,* 688 F.2d at 625 ("[t]he proposed settlement is not to be judged against a hypothetical or speculative measure of what might have been achieved by the negotiators"). Moreover, ***351** when a settlement is the result of extensive negotiations by experienced counsel, the Court should presume it is fair. *Vukovich,* 720 F.2d at 923; *see Duhaime v. John Hancock Mut. Life Ins. Co.,* 177 F.R.D. 54, 68 (D.Mass.1997) ("[i]n 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) ("[s]ignificant weight should be attributed 'to the belief of experienced counsel that settlement is in the best interest of the class' ") (internal citations omitted).

[30] The Court's assessment of the fairness of the proposed settlement will necessarily involve a balancing of several factors which may include, among others, some or all of the following: (1) the strength of plaintiffs' case, both as to liability and damages; (2) the risk, expense, complexity, and likely duration of further litigation; (3) the risk of maintaining class action status throughout the trial; (4) the amount offered in settlement; (5) the extent of discovery completed, and the stage of the proceedings; (6) the experience and views of counsel; (7) the reaction of the class members to the proposed settlement; (8) the public interest; and (9) the ability of the defendants to withstand a greater judgment. *Girsh v. Jepson,* 521 F.2d 153, 157 (3rd Cir.1975); *Officers for Justice,* 688 F.2d at 625 (citations omitted); *In re Southern Ohio Correctional Facility,* 173 F.R.D. 205, 211 (S.D.Ohio 1997).

[31] Ultimately, the Court's determination is nothing more than "an amalgam of delicate balancing, gross approximations and rough justice." *Officers for Justice,* 688 F.2d at 625 (citations omitted). And the Court "must not ... overlook[ ] that voluntary conciliation and settlement are the preferred means of dispute resolution. This is especially true in complex class action litigation ...." *Id.*

B. The Terms of the Settlement Agreement.

The parties filed a proposed settlement agreement on August 15, 2001. At the August 17, 2001 case management conference, the Court heard the parties' initial explanation of the terms of the agreement, and also allowed counsel for various interested parties to offer an

initial critique of the agreement. The parties agreed that some of the critical statements were valid, both because the proposed settlement agreement, as drafted, contained provisions that did not accurately reflect the understanding of the parties, and because they had not fully addressed certain issues. Accordingly, on August 24, 2001, the parties submitted an amended proposed settlement agreement. In addition, on August 27, 2001, the parties submitted revisions to the amended version (docket no. 50). The provisions of the agreement are lengthy and complex. Thus, the Court sets out only the basic elements of the agreement here, in simplified fashion.

• The parties will create a "Settlement Trust," which will administer a Research Fund, a Medical Monitoring Fund, a Patient Benefit Fund, and an Extraordinary Injury Fund.

• The defendants will put $4 million in cash into the Research Fund, which will be used for "medical research relating to reconstructive orthopedic implants ... for the benefit of Class Members."

• The defendants will put $20 million in cash into the Medical Monitoring Fund, which will be used to monitor the implants of claimants who have not yet had revision surgery, by paying 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" the original implantation.

• The defendants will put at least $361.5 million in cash and stock into the Patient Benefit Fund (more if required), to pay compensation to implantees and their associated consortium claimants, as follows:

— to claimants who do not have revision surgery, $750 in cash, $2,000 in stock,[21] and $500 to their spouses.

***352** — to claimants who have one revision surgery, $37,500 in cash, $20,000 in stock, and $5,000 to their spouses.

— to claimants who have more than one revision surgery, $63,500 in cash, $34,000 in stock, and $5,000 to their spouses.

• The defendants will put another $125 million in cash into the Patient Benefit Fund, to pay for any medical expenses a claimant incurred in connection with revision surgery (or to pay related subrogation claims).

• The defendants will also provide $33.3 million in cash and stock as payment of attorney fees to claimants' individual attorneys, at the rate of 1/3 of the claimants' compensation.

• The defendants will also provide $4.5 million in cash to cover the costs of administration of the Settlement Trust.

• The defendants will put a minimum of $30 million in cash and stock into the Extraordinary Injury Fund, to pay for additional compensation to implantees and their associated consortium claimants.

• Any amounts not paid out of the other Funds will be transferred into the Extraordinary Injury Fund, so that this Fund may ultimately exceed $100 million in cash and stock.

• None of the money or stock placed into the Settlement Trust will revert to the defendants; rather, it will all eventually be paid to participating class members.

• There will not be any reduction of the amounts that the defendants must pay into the Settlement Trust based on claimants who opt out of the class.[22]

• The defendants will place liens on virtually all of their assets in favor of the Settlement Trust, to secure all of their obligations; these liens will not be released until the defendants have met all of their obligations.[23]

21 Actually, the claimant receives a certain number of shares of "stock" in Sulzer Medica Ltd.—that is, a certain number of American Depositary Receipts ("ADRs"), valued at $5.10 per ADR. If the ADRs have a higher value when issued, that value goes to the benefit of the claimant. The value of a share of Sulzer Medica at the market's close on August 30, 2001 was $7.95. Participating class members and their counsel will ultimately receive about a third of all the outstanding stock in Sulzer Medica Ltd.

22 The effect of this provision is that the more claimants who opt out of the class, the higher will be the amounts ultimately paid to claimants who do not opt out.

[23] It is predicted that the Settlement Agreement will have paid out all amounts owed within about six years. Accordingly, the Court refers to these liens, below, as "six-year liens."

• To pay the amounts listed above, the defendants will: (a) put all available insurance proceeds into the Settlement Trust; (b) put all available cash into the Settlement Trust, except for one month's working capital; (c) put the required number of stock shares into the Settlement Trust; and (d) put 50% of their net annual income into the Settlement Trust.

• If the defendants settle a case with an opt-out claimant on terms more favorable than are received under the Settlement Agreement by participating claimants, then the defendants agree to pay all participating claimants the increment.

C. Analysis.

At *this stage* of the litigation, the Court is principally obligated to determine whether there are "grounds to doubt its fairness or other obvious deficiencies, such as unduly preferential treatment to class representatives or of segments of the class, or excessive compensation for attorneys, and appears to fall within the range of possible approval." *Manual for Complex Litigation,* § 30.41, at 236–37 (3rd ed.1995). As noted above, there are a multitude of factors that might enter into the Court's preliminary analysis of whether the terms of the proposed settlement agreement are fair, reasonable, adequate, and in the public interest.

[32] After considerable analysis, the Court concludes that, in fact, there are no substantial grounds to doubt the preliminary fairness, reasonableness, or adequacy of the proposed settlement agreement, and that the agreement is in the public interest. The Court focuses below on a few of those factors it considers the most important in reaching its conclusion.

***353** • *The Ability of Defendants to Withstand a Greater Judgment.*

This factor is one of the keys to the fairness of the proposed settlement agreement. The agreement is designed with the understanding that plaintiffs' counsel will have a period of time to pursue further discovery regarding the defendants' financial wherewithal. Put simply, the defendants have agreed to make available all information plaintiffs' reasonably request that would reveal: (1) all of the assets of Sulzer Orthopedics, its parent Sulzer Medica USA, and its Swiss grandparent, Sulzer Medica Ltd.; (2) all of the insurance policies held by these entities that might be available to pay claims; and (3) the likelihood the plaintiffs could "pierce the corporate veil" and pursue claims against Sulzer Orthopedics' "great grandparent," Sulzer AG. If plaintiffs conclude that the information they obtain through this discovery shows there is more money available to pay plaintiffs than is currently contemplated by the settlement agreement, then the plaintiffs can withdraw from the agreement, or insist it be modified to account for those other sources of payment; class counsel has assured the Court, in fact, that plaintiffs will withdraw from the proposed agreement if they conclude that the defendants are contributing to this settlement less than substantially all of their available and reachable assets.

Furthermore, the parties contemplate sharing all of this discovery information with counsel for all class members, including counsel appearing only in state court. This arrangement will ensure an extremely thorough viewing of the defendants' financial circumstances by those persons most interested in ensuring that, in fact, the defendants are "suffering" the maximum judgment they can withstand.

It is also notable that, by virtue of the settlement agreement, at least one of the defendants (Sulzer Medica Ltd.) is forgoing jurisdictional defenses and contributing to the funds available to the class. It appears that a strong argument can be made that the total judgment available to the plaintiffs pursuant to the settlement agreement is far larger than the sum of any judgments they could ever collect individually. This, again, is an assumption that will be subject to challenge by way of the fairness hearing and discovery process.

The real question, though, is whether the settlement agreement could be even "sweeter." The Court has already received objections suggesting that, as currently arranged, the settlement agreement does not ensure the greatest possible amount of funds available to the plaintiffs, and that certain "retained funds" should instead go to them. Some of these objections do not withstand analysis—for example, Sulzer Orthopedics' retention of a portion of its profits simply allows it to survive and

continue doing business, and will ultimately inure to the benefit of the plaintiffs by virtue of their stock ownership. Other objections may be well-taken—for example, the defendants are allowed to settle claims with certain persons outside the class (e.g., "non-U.S. claims"), and the defendants have not adequately explained how diversion of funds to a Research Fund benefits the current class of claimants. Despite these lingering questions, the Court's current ruling is premised on the belief that the discovery period will ensure that, in fact, the defendants are forced to suffer as great a judgment as is possible. Ultimately, the Court concludes that the proposed terms are "reasonably within the range" of possible arrangements to maximize payments to the plaintiff class.

• *The Availability of Opt–Out Rights.*
Under the terms of the proposed settlement agreement, any claimant may choose to "opt out" of class membership and not participate in the agreement. By doing so, that claimant forgoes all of the benefits guaranteed to participating class members. If the claimant timely and properly exercises his opt-out right, he may initiate, continue with,[24] or otherwise prosecute any legal claim against the defendants, without any limitation, ***354** impediment or defense arising from the terms of the settlement agreement. Of course, the defendants may then assert against the opt-out claimant any defenses and rights they would otherwise have, in the absence of the settlement agreement.

[24] As noted, there is currently nothing preventing any claimant who expects to opt out from continuing with his separate, individual lawsuit; thus, he may continue to do so even before formally opting out of the class.

The calculus an opt-out claimant would make in this particular case is similar to the calculus an opt-out claimant would make in any Rule 23(b)(3)class action: the claimant can decide to take the risk of foregoing *certain* benefits guaranteed to him by the settlement agreement, and instead take the risk of suing the defendants "on his own," with the hope of obtaining *uncertain* but possibly greater benefits. In this case, the certain benefits the opt-out claimant would decide to forego include: (1) payment of all medical expenses associated with revision surgery; (2) freedom from any subrogation claims seeking reimbursement of medical expense payments already made on his behalf; (3) receipt of compensation in the form of amounts certain in stock and cash, for himself, his spouse, and his attorney; (4) the opportunity to receive additional compensation for "extraordinary injuries;" (5) medical monitoring, if needed; (6) the knowledge that certain of the "Sulzer-related" defendants have effectively dropped possibly meritorious defenses (e.g., Sulzer Medica, Ltd.); and (7) substantially reduced time and expense in connection with pursuing his claims. On the other hand, a claimant could possibly obtain even greater benefits by opting out of the settlement and, for example: (1) obtaining a judgment for a greater amount; (2) obtaining a judgment against certain "Sulzer-related" defendants that may not have contributed settlement funds in an amount satisfactory to the claimant (e.g., Sulzer AG); and (3) obtaining a judgment against certain other defendants that have not contributed to the settlement (e.g., the surgeon or medical supply company).

That a claimant may undertake this calculus and choose to opt out of the settlement speaks to the fairness of the proposed agreement—if a claimant does not believe the agreement is reasonable, adequate, or equitable, he may sue the defendants, just as he could in the complete absence of the settlement agreement. In this case, however, many of the objectors argue that the proposed settlement agreement leaves them with an unacceptable calculus, because the possible benefits of opting out are too low. The objectors note that, under the proposed settlement agreement, the defendants will place preferential six-year liens on their assets in favor of the class; this means that an opt-out plaintiff would have to "stand in line" behind participating class members for several years before he could collect on a successful judgment. The objectors also note that, under the proposed settlement agreement, any settlement funds allocated to claimants who opt out will be awarded to participating class members; this means that an opt-out plaintiff who succeeds in obtaining a judgment might have fewer assets against which to collect, since the settlement share allocated to him was not retained by the defendants. In addition, the objectors note that, if the defendants settle with an opt-out claimant on terms more favorable than are received under the Settlement Agreement by participating claimants, then the defendants agree to pay all participating claimants the excess financial consideration; objectors assert this gives the defendants a strong disincentive to afford them "better" settlements. The objectors go so far as to argue that the proposed agreement does such a thorough job of ensuring all of the defendants' assets will be paid to the settlement class, the settlement class is really the sort of Rule

23(b)(1)(B) "mandatory" class that has been disallowed by the Supreme Court in *Amchem* and *Ortiz.*

The Court rejects this argument completely. The essence of this complaint is that the settlement agreement is "too good" to opt out of. If true, this is an extremely strong indication that the settlement is fair. These objectors, however, push their position even farther, asserting that so minuscule a benefit is left to an opt-out claimant that opting out is "illusory" or "hollow" or "a sham;" that, ultimately, the Sulzer-related defendants have collected virtually all of their assets, created a "limited fund," and arranged to make conditions so onerous to an opt-out claimant that participation in the settlement agreement is effectively mandatory.

***355** This argument, however, ignores the reality that opt-out claimants are entirely free to: (1) pursue their own litigation, wherein they can name their "own" defendants and follow their own strategy; (2) secure an immediately-collectible judgment against those defendants whom they have most objected should not be released from liability, including Sulzer AG, physicians and hospitals, and medical suppliers; (3) also secure a judgment against those defendants that placed six-year liens on their assets; and (4) enjoy the accumulation of post-judgment interest on any such judgments until the liens are released, and then fully collect on those judgments. Indeed, given the likelihood that any successful judgment may be appealed, having to wait for release of the "six-year liens" does not really represent a substantial delay. This list of benefits may not be as long as an opt-out claimant would like, but it is not "illusory." Moreover, there is currently no impediment preventing any claimant from pursuing their own case; the Court has not enjoined any related litigation. Thus, at this juncture, a claimant who wants to opt out does not even have to actually do so before proceeding with his own lawsuit.

Woven through these same objections is the assertion that class settlement of mass torts, where it is likely that the total of individual judgments against a defendant would exceed the entirety of its assets, is never appropriate. This assertion, however, is based on a misreading of *Amchem* and *Ortiz.* It is true that these cases stand for the proposition that treatment of mass tort cases as mandatory class actions under Rule 23(b)(1)(B) is highly problematic. *E.g., Ortiz,* 527 U.S. at 844–45, 119 S.Ct. 2295 (stating "[i]t is simply implausible that the Advisory Committee, so concerned about the potential difficulties posed by dealing with mass tort cases under Rule 23(b)(3), with its provisions for notice and the right to opt out, see Rule 23(c)(2), would have uncritically assumed that mandatory versions of such class actions, lacking such protections, could be certified under Rule 23(b)(1)(B)," but adding the Court did not "decide the ultimate question whether Rule 23(b)(1)(B) may ever be used to aggregate individual tort claims"). The Supreme Court was also careful to state, however, that "the text of the Rule does *not* categorically exclude mass tort cases from class certification." *Amchem,* 521 U.S. at 625, 117 S.Ct. 2231 (emphasis added). Further, the Supreme Court suggested quite explicitly that Rule 23 is "understood ... to authorize the courts to provide for class treatment of mass tort litigation," and that "the Rule's growing edge for that purpose would be the opt-out class authorized by subdivision (b)(3), not the mandatory class under subdivision (b)(1)(B)." *Ortiz,* 527 U.S. at 862, 119 S.Ct. 2295.

The Sixth Circuit Court of Appeals has recently reaffirmed the viability of class action settlements in mass tort cases where opt-out rights are preserved. *In re Telectronics Pacing Systems, Inc.,* 221 F.3d 870 (6th Cir.2000). In *Telectronics,* the Court examined the question of "how far the courts should go in allowing class action, mass tort cases to deviate from th [e] tradition" of allowing for an "adversary trial by an individual plaintiff claiming redress for a particular wrong." *Id.* at 872. The Court noted that "[c]lass certification, whether mandatory or not, necessarily compromises various rights of absent class members." *Id.* at 881. Accordingly, "class members' rights to notice and an opportunity to opt out should be preserved whenever possible." *Id.* at 881 (quoting *Jefferson v. Ingersoll Int'l Inc.,* 195 F.3d 894, 899 (7th Cir.1999)). This means that certification of a class under Rule 23(b)(1)(B) should be "carefully scrutinized and sparingly utilized." *Id.* On the other hand, the Sixth Circuit emphasized that "Rule 23(b)(3), with its notice and opt-out provisions, strikes a balance between the value of aggregating similar claims and the right of an individual to have his or her day in court." *Id.* The Court of Appeals noted, moreover, that this balance is maintained as long as opt-out rights exist, even if, as practical matter, an opt-out claimant would have little chance of actually collecting on an individual judgment. *See id.* at 877 ("[c]learly any potentially large judgment creates the risk of depletion of a defendant's assets and sets up the possibility that, as a practical matter, adjudication may be 'dispositive of the interest of other members not parties to ***356** the adjudications' or may 'substantially impair or impede their ability to

protect their interests' ") (quoting Fed.R.Civ.P. 23(b)(1)(B)). Thus, despite the contention of some objectors that *Telectronics* prohibits the use of all class action settlements in mass tort cases, *Telectronics,* instead, simply steers district courts away from Rule 23(b)(1)(B) and toward Rule 23(b)(3) as the appropriate vehicle for such settlements. *Telectronics,* quite correctly, followed the Supreme Court's lead in *Amchem* on this point. *See Amchem,* 521 U.S. at 625, 117 S.Ct. 2231 (holding that Rule 23(b)(3) is the "Rule's growing edge" for class treatment of mass tort litigation). This Court does the same.[25]

25 Some objectors contend that *Telectronics* stands for two sweeping propositions: (1) class action treatment is *never* appropriate in the mass tort context; and (2) bankruptcy is always the preferred option when a defendant faces potentially debilitating personal injury judgments. Because this Court is bound by Sixth Circuit precedent, the objectors contend, this Court may not certify a class in this case, conditionally or otherwise, and may not consider endorsing the proposed settlement agreement. While this Court agrees that it is, of course, bound by all Sixth Circuit precedent, including *Telectronics,* it does not read *Telectronics* nearly as broadly as do the objectors. This Court believes, moreover, that its decision here is not inconsistent with *Telectronics* and, in fact, is true to its lead.

The proposed settlement agreement in this case, repeatedly characterized by even its detractors as inventive, simply is not a mandatory class action. Rather, it appears to be on the "growing edge" of Rule 23(b)(3)'s provisions for an opt-out class action. The opt-out provisions provided to the class are not illusory, and present a calculus not very different from that which a claimant in any opt-out class action must undertake. The opt-out structure of the proposed settlement agreement passes the test for preliminary fairness and is within the range of reasonableness.

• *The Fairness of the Procedure for Processing Individual Claims.*

The Court admits it is somewhat unsettled with regard to this factor. The settlement agreement provides that an individual plaintiff can apply to receive payment of additional damages under the "Extraordinary Injury Fund." To process these applications, the Court will appoint a "claims administrator," who will award additional damages; the size of these awards will be controlled by factors contained in a written "matrix." Thus, for example, the claims administrator will award additional payments to persons who developed medical complications during revision surgery, who bore pain to an unusual degree, who suffered extreme loss of income, and so on.

The matrix, however, is yet to be created. Precisely what factors will be included, and precisely what each factor is "worth" in the calculus of extraordinary injuries, has not been determined. The question of the degree to which the claims administrator exercises his own discretion is not settled. *Cf. In re Diet Drugs,* 2000 WL 1222042 at *43 ("the determination of a matrix benefit is not subject to the exercise of discretion by the Administrators of the Settlement or by any court. Rather, benefits determinations are based on the sworn certification of a board certified physician—primarily a board certified cardiologist or cardiothoracic surgeon"). Furthermore, the actual amount of money available in this fund remains vague—at least $30 million, but perhaps as much as $100 million. The Court's final determination of the fairness of the settlement will depend in large part upon the parties' ability to craft a fair and equitable scheme for awarding "matrix compensation benefits," and the amount of money available to pay them. A full description of these benefits, and of those qualified to receive them, will need to be determined, moreover, prior to any opt-out notices being sent to class members; in the absence of such information, no informed opt-out decision could be made.

At this juncture, however, the Court concludes preliminarily that the fairness of this scheme is supported by: (1) the fact that the parties have provided for *some* mechanism to process individual claims; (2) the parties' tentative identification of appropriate factors to include in the matrix; (3) the apparent fairness of the tentative claims administration mechanism, which is designed to include an independent administrator and "appeal ***357** rights;" and (4) the apparent likelihood that the amount of money in the Extraordinary Injury Fund will be substantially more than $30 million. Thus, while the Court retains real concerns regarding the sufficiency of the total funds contained in, and the details of administration of, the Extraordinary Injury Fund, the Court concludes preliminarily that the fairness of the procedure for processing individual claims is within the range of reasonableness.

• *Treatment of Subrogation Interests.*
The Court finds that the key provision in the proposed settlement agreement regarding subrogation claims is this: "[t]he Settlement Trust shall defend and hold Class Members and Plaintiffs' Counsel harmless against any claims by a subrogee directly against such Class Member or Plaintiffs' Counsel for reimbursement of medical expenses ...." Agreement at § 8.1. This provision ensures that any amounts received by class members will not later be taken from them by, for example, medical insurers who paid for revision surgery.

The agreement also states, however, that the parties will "move the Court ... to enter a bar order to preclude the assertion of ... subrogation claims against Sulzer and/or the Released Parties ...." The parties admitted that this provision was unclear, and was meant only to preclude a subrogee from recovering twice; the parties stated it was their intent, under the settlement agreement, that defendants would negotiate with subrogees and work out payment on their subrogation claims. Accordingly, the Court concludes that the proposed agreement is *intended* to treat subrogation interests fairly, but that the provisions as written do not reflect this intent. For this reason, the Court preliminarily approves the proposed class settlement agreement *conditioned upon* the submission of an amended proposed class settlement agreement clarifying the treatment of subrogee's claims under "Article 8."

• *Reaction of the Class to the Settlement.*
As noted, despite the fact that the Court is here undertaking only a *preliminary* fairness evaluation, the Court undertook the unusual step of allowing *any* interested party or counsel to submit written comments regarding the proposed settlement agreement, and received argument from some of those counsel during the August 17, 2001 hearing. The Court received 41 written submissions; some of these were filed on behalf of a single plaintiff, and some on behalf of as many as 60 or more plaintiffs. The comments represent the impressions of about 300 allegedly injured individuals or their counsel, and also a number of their subrogees (e.g., medical insurers). The remaining 90–plus % of the roughly 35,000 class members (including consortium-type claimants) were silent.

Importantly, virtually none of these commentors objected to class certification in its entirety. Indeed, a large number of the comments were submitted by counsel seeking to pursue their own class action cases. To the extent these comments objected to class certification, they expressed dissatisfaction with the *subclassification* scheme, or with the *nationwide* scope of the proposed class, or with the concept of a "settlement class," not the idea of class treatment. Primarily, the commentors attacked the fairness of the proposed settlement agreement, tending to focus on the argument that the opt-out provisions of the agreement were a "sham." The Court addressed this particular argument earlier.

The Court notes here, however, that the absence of written comments supportive of the proposed settlement is not tantamount to *lack* of support. The Court, at this stage, invited objections only. It did not establish a mechanism for, or encourage the filing of, letters of support, leaving to the proponents the task of arguing in favor of the motions and partly eliminating the burden upon the Court of a multiplicity of submissions. Several attorneys did orally address the Court on August 17, 2001, however, and strongly urged approval of the settlement. At least one of these attorneys, who has filed a putative class action lawsuit, admitted to being highly suspicious of the proposed agreement initially, but contended his research led him to believe it was in his clients' best interest to accept its terms. *See also* John Caniglia, ***358** "Plan to Pay Hip Patients Approved Here," The Plain Dealer, August 30, 2000, at A1 (quoting a New Jersey attorney who represents some class members as stating, "I'm disappointed in the amounts, but I'm pleased to tell my clients, some of whom are elderly, that they won't have to wait eight years for a company to get out of bankruptcy court to get their money").

In sum, this factor tends to weigh at least slightly in favor of the conclusion that the proposed settlement agreement is fair and within the range of reasonableness.

• *Likelihood of Prompt Recovery.*
The Court cannot ignore the reality that the settlement agreement creates a very high likelihood of prompt recovery of not insignificant compensatory relief by participating class members. In contrast, the most likely outcome if this case does not settle as a class action is that at least one of the Sulzer-related entities will go bankrupt, the majority of the class members will not actually

receive compensatory relief promptly (if at all), and a business that has historically provided valuable medical products will cease continuing to do so.[26] It is in the greater interest of the class as a whole (and especially this class, which has an average age over 60 years old) to obtain some prompt payments; and it is in the greater public interest to avoid, if reasonably possible, forcing the defendants into bankruptcy and liquidation. This factor weighs in favor of finding preliminarily that the settlement agreement is fair.

26 The Sixth Circuit discussed the defendant's option of filing for bankruptcy in mass tort class action cases certified under Rule 23(b)(1)(B), stating: "[s]imply demonstrating that there is a possibility, even a likelihood, that bankruptcy might at some point occur cannot be the basis for finding that there is a 'limited fund' in an ongoing corporate concern." *Telectronics,* 221 F.3d at 880. This statement is almost completely unrelated, of course, to the question of whether, *in a Rule 23(b)(3) class action,* bankruptcy would serve the interests of the participating class or the greater public more than would an opt-out settlement agreement.

• *Other Factors.*
There are a number of other factors that, to varying degrees, did weigh into the Court's *preliminary* conclusion that the proposed settlement agreement is fair, adequate, and reasonable, as well as consistent with the public interest. Some of these other factors, which are also reflected in the discussion above, include: (1) a comparison of the recovery the class will likely receive pursuant to the settlement agreement to the total recoveries that actually might be received (and collected) by claimants acting individually; (2) the complexity, expense, and likely duration of the litigation; (3) the stage of the proceedings and the amount of discovery so far completed and yet to be done; (4) the risks of establishing liability and damages; (5) the allocations and trade-offs contained within the settlement agreement; (6) the risk of maintaining a class action throughout trial; (7) counsel's negotiations;[27] (8) the reasonableness of attorney fees that will be paid to class counsel, defense counsel, and class members' individual counsel;[28] and (9) the ***359** reasonableness of the settlement fund in light of the best possible recovery and all attendant risks of litigation.

27 The parties have assured the Court that the settlement negotiations in this case were extensive, heated, and conducted at arm's length. There has been nothing submitted to date that would cause this Court to doubt that representation. The Court expects, however, that it will examine this factor in more detail during the final fairness hearing.

28 Given the ethical constraints on class counsel—essentially prohibiting negotiation of class counsel fees during negotiation of the class settlement—this particular sub-factor remains somewhat undefined. While the Court has questioned class counsel more than once on this issue, no clear response has been, nor indeed could be, provided to date. The Court was encouraged, however, by class counsel's preliminary indications that the absolute percentage of the fee recovery sought would be relatively low and that class counsel would consider accepting some or all of their fees in the form of stock (or "ADRs"), if that could be done without undue dilution of the stock's value. The Court has informed class counsel both that an unreasonable fee request could alone cause the Court to withhold final approval of the settlement agreement, and also that the measure of any anticipated fee request must be determined prior to, and included in, any opt-out notice to the class. Similarly, the Court retains concerns regarding the amount of fees the defendants have promised their retained counsel, but the Court was encouraged that defense counsel suggested a willingness to submit his own fee arrangement for Court approval.

In light of the Court's discussion above, and in light of the fully developed record, the Court concludes it is not necessary to explicate its analysis of each one of these factors. It is sufficient to state here that, having undertaken a thorough, but preliminary, analysis of the fairness of the proposed settlement agreement, the Court concludes the agreement satisfies the fairness requirement of Rule 23(e). Accordingly, the Court conditionally approves the parties' proposed settlement agreement.

Within the next several days, the Court shall issue a case management Order, which, among other things, will define the scope and timing of discovery, establish procedures for notice to the conditional class, provide a mechanism for the assertion of comments regarding the proposed settlement agreement, and set a date for a full fairness hearing. The case management Order will also identify more particularly those issues to which the Court

expects to give strong scrutiny, at the full fairness hearing.

IT IS SO ORDERED.

All Citations

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