IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

In re: INTER-OP HIP PROSTHESIS LIABILITY LITIGATION	:	MDL DOCKET NO. 01-CV-9000 (ALL CASES)
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	:	
	:	
	:	JUDGE KATHLEEN O'MALLEY
	:	
This Document Relates To All Cases	:	

OPPOSITION OF ESTELLE KNOWLAND TO CLASS CERTIFICATION, PRELIMINARY APPROVALOF PROPOSED SETTLEMENT AND INJUNCTION OF RELATED LITIGATION

Estelle Knowland respectfully submits her opposition to Plaintiffs' Motion for Order Conditionally Certifying a Rule 23(b)(2) and (B)(3) Class Action, Preliminarily Approving Settlement and Enjoining All Inter-Op™ Hip Prosthesis Litigation, and to Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation.

Statement of Interest

This brief is filed on behalf of Estelle Knowland. Ms. Knowland is a named plaintiff in a federal court class action seeking only medical monitoring for all recipients of Sulzer implants. She received a Sulzer hip implant on March 6, 2000 and remains asymptomatic.

In addition, counsel for Ms. Knowland have been authorized to submit this brief on behalf of attorneys representing more than 500 individuals with cases currently pending in the Texas and Florida state courts. Three of these cases are currently in trial in Corpus Christi, Texas and dozens more are slated for trial throughout the fall of this year. These individuals would certainly opt out of a settlement that provides so inadequately for the victims of the defective Sulzer implants. However, as will be made clear below, the proposed settlement is not

really a class settlement at all. Rather it is an attempt to seize and cordon off the assets of Sulzer and its various affiliates and insurers so as to place them beyond the reach of the injured implant recipients. Accordingly, despite the pyrrhic opt out rights putatively protected through the settlement, these hundreds of state court litigants are at risk of having all potential judgments rendered unenforceable even if they were to attempt to opt out of the proposed settlement

Introduction

At the heart of this litigation are individuals who have received defective hip implants and who face the prospect, in many cases already realized, of grievous personal injury and significant medical and surgical complications as a result. Hundreds of individuals, almost certainly over a thousand already have filed individual personal injury cases, primarily in state courts, seeking compensation for the harms caused them. These personal injury suits assert high-value claims for failure to warn, breach of express warranty, product liability, consumer fraud, and other matters which traditionally have been litigated in separate trials in the civil justice system. Under the terms of the proposed settlement, these personal injury claimants will be compelled to either accept a financially paltry settlement or be allowed to "opt out" and sue entities that have been denuded of all assets.

The settlement proponents heartily invoke the language of limited assets to justify this significant infringement of the individual right to sue for personal harms. But they do so outside the settled, legally-recognized alternative mechanisms for the orderly disposition of truly limited assets: the limited fund provisions of Rule 23(b)(1) or the protections of the bankruptcy code. Instead, the settlement's proponents seek to have this Court ratify an unprecedented freezing of defendant's assets through an unheard of (although clever) lien arrangement. The effect of the lien would be to cordon off a limited section of the available insurance and other assets, make that available only to those implant recipients who agreed to the settlement terms, and leave all other claimants without recourse.

For the reasons set forth below, the proposed settlement should not be given preliminary approval. First, this Court should reject the settlement because it is an attempt to circumvent

bankruptcy law and the limited fund provision of Rule 23(b)(1)(B). Instead, Sulzer is attempting to use Rule 23(b)(3) in a novel and unprecedented attempt to create what would amount to a constructive trust over its assets. Sulzer seeks to have this Court impose an overbroad and impermissible lien that would restrict the ability of opt-out tort claimants to satisfy any judgments against Sulzer. The settlement also seeks a comprehensive release from liability for Sulzer AG without including any financial contribution from the company. Second, the proposed class does not meet the standards for certification. Under controlling Supreme Court and Sixth Circuit precedent, the settlement's proponents have failed to adhere to the controlling precedents concerning mass harm class actions. *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997); *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999); *In re Bendectin Prods. Liab. Litig.*, 749 F.2d 300 (6th Cir. 1984); *In re American Medical Systems, Inc.*, 75 F.3d 1069 (6th Cir. 1996); *In re Telectronics Pacing Systems, Inc.*, 221 F.3d 870 (6th Cir. 2000). The class action also attempts to resolve claims that have not yet arisen and injuries that are not yet manifest, in violation of the Supreme Court's admonition that such "future" claims raise severe problems of due process because meaningful notice and opt-out opportunities cannot be provided. Accordingly, the settlement proponents have failed to discharge their burden of showing that the requirements of Rule 23 have been met. *In re General Motors Corp. Pick-Up Truck Fuel Tank Products Liability Litigation*, 55 F.3d 768, 792 (3d Cir.), *cert. denied*, 516 U.S. 624 (1995). Those requirements are fully applicable at the preliminary approval stage: a court may certify a class only "if it performs 'rigorous analysis' of the requirements of" Rule 23. *Stout v. J.D. Byrider*, 228 F.3d 709, 716 (6th Cir. 2000). "Conditional certification is not a means whereby the District Court can avoid deciding whether, at that time, the requirements of the Rule have been substantially met." *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1088 n.21 (6th Cir. 1996) (internal quotation omitted) (granting mandamus and reversing conditional certification order).

The proposed class also fails to meet the Rule 23(a)(4) requirement of adequate representation. In particular, there is an obvious and disabling conflict of interest between those

class members who have already filed suit against Sulzer (or will soon do so) and those class members whose claims will arise in the future. The former have an interest in maximizing current payouts from Sulzer; the latter have the opposite interest, in order to ensure that sufficient funds will remain when their own claims arise in the future. This conflict between "current" and "future" plaintiffs is precisely the same conflict identified by the Supreme Court as dooming the settlement conflict in *Amchem*.

Finally, this Court should not enjoin absent class members from pursuing related litigation. This Court lacks personal jurisdiction over class members who have no minimum contacts with Ohio, and it has no authority to enter an injunction against them.

ARGUMENT

I. THE PROPOSED SETTLEMENT SHOULD NOT BE PRELIMINARILY APPROVED

The proposed settlement should not be given preliminary approval under Rule 23(e) because it it is not "within the range of possible approval." *Horton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 855 F. Supp. 825, 827 (E.D.N.C.1994). "When a district court . . . certifies for class action settlement only, the moment of certification requires 'heightene[d] attention.'" *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 849 (1999). The settlement in this case must be rejected because it violates the Rules Enabling Act, 28 U.S.C. § 2072, which restricts the judicial rulemaking power to "general rules of practice and procedure" and explicitly forbids the making of judicial rules which "abridge, enlarge or modify any substantive right." § 2072(b). *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 620 (1997). The need for judicial self-restraint is reinforced in the instant proceeding by *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40 (1998) (invalidating Multidistrict Litigation Rule 14(b), which had authorized a transferee court to assign an action to itself for trial), which imposes important limits on an MDL court's substantive powers.

Sulzer seeks to use Rule 23 in an impermissible manner to create what amounts to a constructive trust over its assets that would insulate itself and its affiliates from liability and effect a severe reduction in the claims asserted against it. The blunt reality is that this is not

really a class action settlement at all. The parties to the settlement are genuinely indifferent as to the effect of any feature of this settlement other than the asset seizure effectuated through the lien arrangement. For example, it is a commonplace in class action settlements that there is a "blow-up" provision that would terminate a class settlement if more than a defined percentage of class members choose to opt out. Here by striking contrast there is no such provision. Why? The simple answer is that once the lien agreement is realized, Sulzer is indifferent as to whether class members stay in or out. Unlike legitimate class actions settlements, the proposed settlement is not about the resolution of claims brought by class members. Instead, the settlement is about an attempt to use the imprimatur of this Court to seize the assets of the Sulzer entities, place a limited amount into a pool for class members who do not opt out, but put the rest safely out of reach of injured parties.

Nor surpisingly, Sulzer's efforts find no support in class action law and must be deemed impermissible for numerous reasons:

(1) If the agreement is preliminarily approved, Sulzer will be, as a practical matter, judgment proof long before final approval is given to this agreement. Seven days after conditional class certification and preliminary approval of the settlement, Sulzer will deliver its insurance proceeds to an interest-bearing account. Settlement, Section 2.9(a). From that point forward until final approval, these funds may be used to pay compensation under the settlement and to settle non-U.S. claims, but not to pay U.S. claims of those potential class members who opt-out. *Id.* On the date the Settlement Agreement is executed, a lien will be placed on all of Sulzer's assets, Section 2.8(a), and the lien will remain in effect until sometime after December 31, 2008. Section 2.8(b).

These provisions of the settlement give unprecendented legal force to the preliminary approval process. In effect, the preliminary approval sets in motion a process which insulates the Sulzer entity assets from all claims by those persons outside the class action, including individuals with knee implantations over whom this Court has no jurisdiction under the MDL referral order. Even for the hip implant recipients, the clear effect is to effectuate a final

disposition of these assets so as to foreclose any claims by individuals outside the settlement structure. As such, the final disposition of assets exceeds this Court's limited jurisdiction under the MDL statute. As a 28 U.S.C. § 1407 Transferee Court, as recently reinforced by the Supreme Court in *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998), this Court's jurisdiction does not extend to contested final judgments, but only to pretrial determinations. The proposed Security Agreement, to the extent it is turns on implementation by this Court in the context of preliminary settlement, is the functional equivalent of a transfer of all cases – from hip implant class members and knee implant non-class members – to itself for final disposition of assets. This appears directly counter to the Supreme Court's holding in *Lexecon*.

There can be little doubt that this is the clear intent of the proposed settlement. The lien provision places all the assets of Sulzer Orthopedics, Sulzer Medica, and all of their direct and indirect subsidiaries under the protection of the federal court. The lien abridges substantive rights by rendering these assets off-limits to any claimant who attempts to opt out of the settlement. The lien gives priority instead to the trust scheme created by the settlement. Tellingly, under Section 2.8(a), the lien is junior to any security interest granted by Sulzer to lending or financial institutions for the purpose of administering a credit facility. It is only opt-out tort claimants who are burdened by the lien provision.

Although Sulzer's motion for approval of the settlement stresses the limited resources available to pay tort claims, it does not propose to comply either with federal bankruptcy law or with the requirements of Rule 23(b)(1)(B), which authorizes "limited fund" class actions. Instead, Sulzer's effort is "a self-evident evasion of the exclusive legal system established by Congress for debtors to seek relief." *Keene Corp. v. Fiorelli*, 14 F.3d 726, 732 (2d Cir. 1993). In *Ortiz*, the Supreme Court opined that the drafters of Rule 23 never contemplated that the Rule "would emerge as the functional equivalent to bankruptcy." 527 U.S. at 843 (internal quotation omitted). The Court held that the authorization for "limited fund" class actions in Rule 23(b)(1) should be narrowly construed in order to avoid "the likelihood of abuse . . . [T]his limiting construction finds support in the Advisory Committee's expressions of understanding, minimizes

potential conflict with the Rules Enabling Act, and avoids serious constitutional concerns raised by the mandatory class resolution of individual legal claims, especially where a case seeks to resolve future liability in a settlement-only action." *Id.* at 842.

The Supreme Court clearly identified the safeguards that must be present in 23(b)1) class actions, and which are clearly not in evidence here:

> The first and most distinctive characteristic is that the totals of the aggregated liquidated claims and the fund available for satisfying them, set definitely at their maximums, demonstrate the inadequacy of the fund to pay all the claims. The concept driving this type of suit was insufficiency, which alone justified the limit on an early feast to avoid a later famine. . . . Second, the whole of the inadequate fund was to be devoted to the overwhelming claims. . . . Third, the claimants identified by a common theory of recovery were treated equitably among themselves. The cases assume that the class will comprise everyone who might state a claim on a single or repeated set of facts, invoking a common theory of recovery, to be satisfied from the limited fund as the source of payment.

Ortiz, 527 U.S. at 838. It is noteworthy that under the terms of the proposed settlement, there is no evidence of the "totals of the aggregated liquidated clams and the funds available for satisfying them," under the Court's first precondition, and more critically, a direct repudiation of the principle that "the whole of the inadequate fund was to be devoted to the overwhelming claims . . ."

In *Telectronics*, the Sixth Circuit similarly held certification improper even though the district court "found, based on economic information provided by [the defendant] that there was a 'limited fund' from which injured plaintiffs could be paid," 221 F.3d at 876, and even though "the district court worried that some class members might be unable to recover for their injuries because [the defendant] might run out of funds . . . ." *Id.* at 878. Here by contrast, there has not even been any evidentiary inquiry or independent determination of the limited quality of the assets available to satisfy personal injury claimants. Rather, the Court is being asked to approve what amounts to a limited fund restriction on potential recoveries based on the say-so of the proponents of the settlement. Moreover, as if to parody the very settlement struck down in *Ortiz*, the terms of the settlement exempt the deepest pockets among the defendant entities in exchange

for *no contribution* whatsoever to the settlement – other than a pledge to assist in securing insurance proceeds.

Not surprisingly given the strict requirements of *Ortiz* and *Telectronics*, the settling parties do not seek certification under Rule 23(b)(1)(B). Neither should they be allowed to use Rule 23(b)(3) to seize control of the assets of the enterprise and restrict them to funding the administrative trust created by the settlement. *See Telectronics*, 221 F.3d at 880 ("The district court cannot discharge the debt in advance of the occurrence, thereby usurping the bankruptcy scheme through settlement, even it believes such an avenue to be in the best interests of most of the plaintiffs."). Although Sulzer insists that its solution is preferable to bankruptcy, that assertion is both unacceptable as a pretext for this unprecedented distortion of Rule 23 and a matter entrusted to Congress rather than the courts. Although the relative merits of bankruptcy and limited fund class actions may be contested, it is clear that Congress has authorized only these two forms of proceeding. It is further clear that the creation of specialized bankruptcy courts points to a congressional policy determination, voiced by the National Bankruptcy Review Commission, that bankruptcy "provides safeguards for the interests of mass future claimants that are unmatched in the class action system." *See* 1 REPORT OF THE NAT'L BANKR.REV. COMM'N 340-41 (1997); *Keene*, 14 F.3d at 732 ("class members in cases such as this would have no say in the conduct of the court-appointed class representatives and unlike creditors in bankruptcy, are not able to vote on a settlement. As cogently expressed by Judge Smith of the Fifth Circuit under the facts leading up to *Ortiz*:

> It is possible that the mounting costs of defending asbestos claims and paying asbestos judgments would have driven Fibreboard to take refuge in bankruptcy court. This would be unfortunate for Fibreboard's shareholders and contract creditors, but it would not be catastrophic: The Johns-Manville Corporation went through an apparently successful bankruptcy reorganization and spun off the Manville Personal Injury Settlement Trust in order to satisfy its tort liabilities. *See In re Joint E. & S. Dist. Asbestos Litig.*, 982 F.2d at 725. And in any case, the specter of eventual bankruptcy does not now render this ongoing concern a "limited fund." Up until the time of a bankruptcy discharge, tort creditors have a legally unlimited font of money from which they may demand their due. This

> proposed settlement class is in fact "a self-evident evasion of the exclusive legal system established by Congress for debtors to seek relief." *See* 11 U.S.C. § 1126.

In re Asbestos Litigation, 134 F.3d 668, 673 (5th Cir. 1998)(Smith, J., dissenting), *rev'd sub nom Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), quoting *In re Keene Corp.*, 14 F.3d 726, 732 (2d Cir. 1993). Rather than serve as an orderly bankruptcy workout with a defined list of priorities and the protections of an independent trustee, for class members the proposed settlement would be a cram-down from start to finish. More importantly, even if Sulzer were right, the federal courts are not empowered to "conduct trials over whether a statutory scheme should be ignored because a more efficient mechanism can be fashioned by judges." 14 F.3d at 733. The federal courts are not free to undertake such policy-making experiments of their own.

(2) In addition to according illegitimate financial protection to Sulzer, the lien has the pernicious effect of undermining, if not outright nullifying, the right to opt out guaranteed by Rule 23(b)(3). In class actions seeking to bind plaintiffs with respect to "claims wholly or predominantly for money damages," "due process requires at a minimum that an absent plaintiff be provided with an opportunity to remove himself from the class by executing and returning an 'opt out' or 'request for exclusion' form to the court." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 812 & n.3 (1985); *see also* 3 NEWBERG ON CLASS ACTIONS §17.16, at 17-44-45 ("when unliquidated damages are involved, the exclusion right must be afforded as a constitutional matter.").

The Supreme Court has instructed that a court should examine the substance of an opt out provision, and not its form, to determine whether class members do in fact have an opportunity to opt out. *Ortiz*, 527 U.S. at 847 n. 23. The lien provision impermissibly burdens this right. An opt- out right is meaningless if there are no assets available to satisfy the resulting judgment. As the Seventh Circuit held in another attempted cram down setllement, the "'settlement' is not a settlement; it is merely an offer to settle with a penalty, the dismissal of their federal claims, if they do not accept. We decline to put every subclass member to such an unfair choice . . . ." In *In re General Motors Corporation Engine Interchange Litigation*, 594 F. 2d 1106, 1136 (7th Cir. 1979), *cert. denied*, 444 U.S. 870 (1979).

Moreover, there is no rational relationship between the length of the lien and the purported need for the lien to be kept in place. The affected hip implants were recalled on December 5, 2000, and Sulzer has stated that in well over 50% of the cases, patients will know within six (6) months of implantation whether they require revision surgery. Yet the lien is retained until December 31, 2008. The seven-year delay is not necessary to protect class members and has the illegitimate effect of burdening the right to opt out.

(3) The protection afforded by the lien appears to be broader than the funding obligations imposed by the settlement. The lien extends not only to Sulzer Orthopedics and Sulzer Medica, but also to all of their direct and indirect subsidiaries. By comparison, there has been no showing that these direct and indirect subsidiaries would contribute all of their available assets to the settlement. Moreover, the settlement purports to release claims for defective knee implants even though there are no identified plaintiffs with knee implantations among any of the named plaintiffs and – perhaps most significantly – even though the MDL transfer order specifically gives this Court authority over *hip implantation litigation*, and that alone.

(4) The settlement contains a broad release of liability (Section 1.1(vv)) that extends to persons and entities having no payment obligations under the settlement. Most prominently, Sulzer AG is given a full and complete release from all claims even though it has no obligation to contribute a penny to the settlement and even though Sulzer AG has been named as a defendant in existing hip implant litigation. *See* Declaration of Adam R. Salvas in Support of Defendant Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, at ¶ 4. The settlement therefore suffers from the same defect condemned by the Sixth Circuit in *Telectronics*. *See* 221 F.3d at 874 ("[Defendant's] corporate parents were released from liability without close scrutiny by the parties as to whether they might be liable. The facts that came out during the personal jurisdiction phase of the litigation below make it doubtful that they would have escaped all liability had they been forced to go to trial. . . . There seems to be no dispute that the parent corporations have sufficient funds to undertake individual litigation and to pay any claims that

might result. Their release, therefore, undermines the appropriateness of the settlement even more than the settlement in *Ortiz*.").

The settlement also provides a complete release to parties whose claims are not even included in the MDL transfer order, including to Sulzer's suppliers and to physicians. *See* Declaration of Adam R. Salvas in Support of Defendant Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, at ¶ 4. Neither class counsel nor Sulzer has provided one word of explanation why it is necessary to grant releases to parties who have not contributed at all to any settlement.

(5) The settlement creates a system of alternative dispute resolution replacing state law with administrative compensation schedules that in effect establish a nationwide applicable law. The settlement in this case abridges substantive rights by purporting to resolve the rights of "future" claimants, even though, under the laws of at least some states, "[a] general release is inapplicable to an unknown claim."[1] In addition, the settlement extinguishes claims by families of class members, even spouses yet to be married. Further, the minors in the class receive no separate representation — even though under the law of many states, a waiver of liability entered into by a parent before the minor child's cause of action accrued is invalid. *See, e.g., Meyer v. Naperville Manner, Inc.*, 634 N.E.2d 411, 414 (Ill. App. 1994) (citing cases); *cf. Clark v. Jeter*, 486 U.S. 456, 463-64 (1988); *Mills v. Habluetzel*, 456 U.S. 91, 99-100 (1982). The settlement thus violates principles of federalism and the Rules Enabling Act, 28 U.S.C. § 1652, because the diversity actions involved in this proceeding are governed by the laws of the several states. *See Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938); *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 412 (1990) (Stevens, J., dissenting); *Hanna v. Plumer*, 380 U.S. 460, 469-70, 472 (1965); *Byrd v. Blue Ridge Electrical Cooperative, Inc.*, 356 U.S. 525, 536-37 (1958); *Bernhardt v. Polygraphic*

[1] *Farm Credit Bank of St. Louis v. Whitlock*, 581 N.E.2d 664, 667 (Ill. 1991). *See also* Cal. Civ. Code § 1542; *Fair v. International Flavors & Fragrances, Inc.*, 905 F.2d 1114, 1115 (7th Cir. 1990).

Co., 350 U.S. 198, 202-05 (1956); *Guaranty Trust Co. v. York*, 326 U.S. 99, 108-10 (1945); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943).

Notably, the compensation afforded under the settlement falls far short of the verdicts and settlements that may be obtained in the tort system – further illustrating the inadequacy of the proposed settlement. Under the settlement, subclass I members will receive $37,500 cash plus certain shares of securities, in addition to medical expenses, and subclass II will receive $63,500 cash plus securities and medical expenses. Yet jury verdicts in hip and knee implant cases have ranged as high as $1,793,842. Declaration of Adam R. Salvas in Support of Defendant Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, at ¶¶ 7, 8. Sulzer is currently negotiating with a Texas attorney who is seeking $200,000 to $500,000 for plaintiffs who have undergone revision surgery. *See* Declaration of Brian J. Devine in Support of Defendant Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, at ¶ 8. *See also* Paul D. Carrington & Derek Apanovitch, *The Constitutional Limits of Judicial Rulemaking: The Illegitimacy of Mass Tort Settlements Negotiated Under Rule 23*, 39 ARIZ. L REV. 461 (1997) (explaining how administrative compensation schemes created by class action settlements may violate the Rules Enabling Act). Not a single case has established the value of claims against Sulzer under the facts of the state of knowledge and indifference claimed in the hundreds of state court actions currently proceeding toward trial. This proposed settlement is the classic "immature tort" in which the Court is being asked to do nothing more than apply an impressionistic "chancellor's foot" estimation of what would be a good value for a settlement. This is precisely the approach condemned by the Supreme Court in *Amchem*, 521 U.S. at 621.

II. THE STANDARDS FOR CLASS CERTIFICATION HAVE NOT BEEN MET

A. The Exacting Standard for Certification of Non-Economic Class Actions

On previous occasion, the Sixth Circuit has cautioned that there is "a national trend to deny class certification in drug or medical product liability/personal injury cases," and it has

warned that "strict adherence to Rule 23 in products liability cases involving . . . medical products . . . is *especially* important." *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1089 (6th Cir. 1996) (emphasis in original). It is certainly noteworthy that the Supreme Court has never approved the certification of a products liability class action and has further cautioned that the fact of settlement does not obviate the requirements of orderly class certification. In *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), the Supreme Court affirmed the decertification of a nationwide settlement-only class of product liability (asbestos) plaintiffs. The Court warned that the provisions of Rule 23 "demand undiluted, even heightened, attention in the settlement context." *Id.* at 620. "Each plaintiff [in an action involving claims for personal injury and death] has a significant interest in individually controlling the prosecution of [his case]; each ha[s] a substantial stake in making individual decisions on whether and when to settle." *Id.* at 616 (internal quotation omitted; brackets in original). "While the text of Rule 23(b)(3) does not exclude from certification cases in which individual damages run high, the Advisory Committee had dominantly in mind vindication of 'the rights of groups of people who individually would be without effective strength to bring their opponents into court at all.'" *Id.* at 617 (citation omitted). The breadth of the *Amchem* decision was made clear in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999). After the Fifth Circuit certified a settlement-only nationwide asbestos class action in *In re Asbestos Litigation*, 134 F.3d 668 (5th Cir. 1998), the Supreme Court granted review and ordered the decertification of the class before it, warning that the lower courts had failed to properly apply the commonality and typicality requirements, among other provisions of Rule 23. *Ortiz*, 527 U.S. at 831-32.

The Sixth Circuit's decisions are to the same effect. For example, in *In re Bendectin Prods. Liab. Litig.*, 749 F.2d 300 (6th Cir. 1984), the Sixth Circuit granted mandamus to reverse class certification in a Bendectin products liability class action. The court held that the district court's certification "was clearly erroneous as a matter of law." *Id.* at 306. In *In re American Medical Systems, Inc.*, 75 F.3d 1069 (6th Cir. 1996), the Sixth Circuit granted a petition for writ of mandamus to decertify a class action against the manufacturer of a medical device. The court

held that the commonality, predominance, typicality, and adequacy requirements were not satisfied and provided an extensive analysis of why class action issues must be handled with care in medical devices products liability cases. "[T]he economies of scale achieved by class treatment are more than offset by the individualization of numerous issues relevant only to a particular plaintiff." *Id.* at 1084. "In fact, a number of other courts have denied class certifications in drug or medical product liability actions for these reasons." *Id.* at 1085. *See also Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988) ("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.").

Similarly, in *In re Telectronics Pacing Systems, Inc.*, 221 F.3d 870 (6th Cir. 2000), the Sixth Circuit held that the certification of a mandatory, limited-fund class action and the approval of an accompanying settlement were abuses of discretion. The court of appeals explained that "[t]he traditional norm of our legal system is the adversary trial by an individual plaintiff claiming redress for a particular wrong." *Id.* at 872. "Both Seventh Amendment jury trial rights and the Fifth Amendment due process principle regarding the right to a 'day in court' are implicated in aggregating individual claims in tort." *Id.* at 881. The Sixth Circuit noted that the release of the defendant's corporate parents from liability raised grave questions as to the class action settlement: "the defendants may be able to settle cases by providing, relatively speaking, a small amount of money for seriously injured class members while providing large attorneys fees for lawyers for the class as an inducement to settlement." *Id.* at 874. The Sixth Circuit warned that "the legal system runs the risk of eliminating adversary trials conducted to redress wrongs individually by actual plaintiffs through a process by which defendants pay off a small group of plaintiffs' class action lawyers who actually represent other parties." *Id.*

It is highly instructive to contrast this proposed settlement to the two most successful mass harm settlements that have survived judicial review: the national fen-phen settlement and

the Shiley heart valve settlement. *See In re Diet Drugs,* 2000 WL 1222042 (E.D. Pa., Aug. 28, 2000); *Bowling v. Pfizer,* 143 F.R.D. 141 (S.D. Ohio 1992), *aff'd and appeal dismissed* 14 F.3d 600 (6th Cir. 1993). Each had one critical feature missing here. Each permitted full and unencumbered opt out rights at the front end, together with the right to subsequently re-enter the tort system for any individual who developed an aggravated condition after the settlement was enacted. In both instances, the reviewing courts gave great emphasis to the availability of such meaningful opt out rights. *See, e.g., Bowling,* 143 F.R.D. at 166. The opt out served to preserve the right of individual control and to protect against the statistically certain eventuality that some class members would progress into significantly worsened conditions as a result of the exposure to the defective products.

The lessons of *Amchem*, *Ortiz*, the governing Sixth Circuit precedent, and the structurally fair class action settlements have been lost on class counsel and Sulzer. The settling parties have sought to create the shell of a single federal nationwide class action out of the thousands of individual actions pending in state courts, along with untold numbers of additional claimants, including those who are currently asymptomatic and possibly even unaware of their potential status as class members. The injury is only compounded by the cynical attempt to give hollow opt-out rights to these same class members. The true effect of certification would be to bind class members every bit as effectively as in the settlement struck down in *Ortiz*. For those who would claim the right to opt out under 23(b)(3), they would quickly discover that the lien provisions and the releases had allowed a right to opt out into oblivion. Given the empty opt out provision in this (b)(3) class, the terms of the settlement are intended to be imposed simply as "an offer you can't refuse."

B. The Class Cannot Meet the Requirements of Predominance and Typicality

Class counsel argue that the predominance requirement is met because all members of the class were implanted with Affected Inter-Op™ shells. According to class counsel, "[t]he Complaint alleges a problem with a single product and a single problem." Memorandum In Support Of Plaintiffs' Motion For Order Conditionally Certifying A Rule 23(b)(2) and (b)(3)

Class Action, Preliminarily Approving Settlement, And Enjoining All Inter-Op™ Hip Prosthesis Litigation, at 12. Yet the proposed class action includes reprocessed hip implants within the class and therefore seeks certification of a lawsuit involving at least *two* separate products and *two* separate problems. See [Proposed] Order To Conditionally Certify Class, Preliminarily Approve Settlement, Set Briefing Schedule Re Notice To Class, And Enjoin Parallel Litigation at 1 ("For purposes of this Order, 'Affected Products' shall mean, collectively, (1) Inter-Op™ acetabular shells identified in the Sulzer Orthopedics Inc. ('SOI') Safety Alert dated December 5, 2000, and (2) reprocessed Inter-Op™ acetabular shells sold prior to August 15, 2001.").

In any event, under the Supreme Court's holding in *Amchem* and the Sixth Circuit's holding in *American Medical Systems*, class counsel's assertion that Inter-Op™ shells were all designed and manufactured by the same company does not satisfy the predominance requirement. In *Amchem*, the Supreme Court noted that the district court had relied upon the commonality that "[t]he members of the class have all been exposed to asbestos products supplied by the defendants," but the Supreme Court held that these common questions could not justify certification under Rule 23(b)(3): "[T]he predominance criterion is far more demanding. Given the greater number of questions peculiar to the several categories of class members, and to individuals within each category, and the significance of those uncommon questions, any overarching dispute about the health consequences of asbestos exposure cannot satisfy the Rule 23(b)(3) predominance standard." 521 U.S. at 624. The Supreme Court agreed with the Third Circuit, which had held that the common issues arising from the harmfulness of asbestos or the misconduct of the defendants standing alone did not satisfy the predominance requirement of Rule 23(b)(3). "[T]he huge number of important individualized issues overwhelm any common questions. Given the multiplicity of individualized factual and legal issues, magnified by choice of law considerations, we can by no means conclude 'that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members.'" 83 F.3d at 630. The Third Circuit added that the typicality requirement of Rule 23(a)(3) was also not met under the proposed class settlement because "this class is a hodgepodge of factually as

well as legally different plaintiffs." *Id.* at 632. The Supreme Court also agreed with the Third Circuit that "[d]ifferences in state law . . . compound these disparities." 521 U.S. at 624. The court of appeals pointed to "disparate applications of legal rules, including matters of causation, comparative fault, and the types of damages available to each plaintiff." 83 F.3d at 627. The nationwide nature of the class action introduced a further complication, because it multiplied the number of legal standards applicable to the various class members:

> Furthermore, because we must apply an individualized choice of law analysis to each plaintiff's claims, the proliferation of disparate factual and legal issues is compounded exponentially. The states have different rules governing the whole range of issues raised by the plaintiffs' claims: viability of futures claims; availability of causes of action for medical monitoring, increased risk of cancer, and fear of future injury; causation; the type of proof necessary to prove asbestos exposure; statutes of limitations; joint and several liability; and comparative/contributory negligence.

Id. at 627.

The Supreme Court concluded that "the sprawling class the District Court certified does not satisfy Rule 23's requirements." 521 U.S. at 622. *See also Ortiz*, 527 U.S. at 831 n.12 ("[C]lass members' shared exposure to asbestos was insufficient to meet the demanding predominance requirements of Rule 23(b)(3).").

In *American Medical Systems*, the Sixth Circuit similarly held that the fact that the medical devices in question had all been manufactured by the same company did not mean that common issues predominated. The Sixth Circuit explained that "in medical device products liability litigation of the sort involved here the factual and legal issues often do differ dramatically from individual to individual because there is no common cause of injury." 75 F.3d at 1084 (emphasis omitted). The Sixth Circuit cited *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 (1983), for the proposition that "on issues of negligence [and] strict products liability . . . 'commonality begins to be obscured by individual case histories.'" 75 F.3d at 1081. "[S]ignificant questions, not only of damages, but of liability and defenses of liability, would be present, affecting the individuals in different ways. In these circumstances an action conducted nominally as a class

action would degenerate in practice into multiple lawsuits separately tried." *Id.* at 1084 (internal quotation omitted). "Thus, even assuming common questions of law or fact, it cannot be said that these issues predominate, and that class treatment would be superior to other methods of litigation." *Id.* at 1085.

The same analysis applies in this case. The point here is not that there can never be class actions in the mass harm context, only that such cases are difficult and must be approached with extreme caution. The undersigned counsel are counsel of record in the *In re Diet Drugs* settlement, which we submit provides a roadmap for the appropriate aggregate resolution of mass harm cases. Key to *In re Diet Drugs* is the fact that the requirements of Rule 23 were studiously obeyed and that the individual rights of class members, most notably the protection of effective opt out rights, were rigorously respected.

III. THE CLASS ACTION CANNOT MEET THE SUPERIORITY REQUIREMENT

The proponents of the settlement have failed to show that they satisfy the "superiority" requirement of Rule 23(b)(3) for several reasons.

A. Individual Actions Are Superior

As the Third Circuit held in *Georgine*, "[e]ach plaintiff has a significant interest in individually controlling the prosecution of separate actions." 83 F.3d at 633. "This is not a case where 'the amounts at stake for individuals [are] so small that separate suits would be impracticable.' Fed. R. Civ. P. 23(b)(3) Advisory Notes to 1966 Amendment. Rather, this action involves claims for personal injury and death – claims that have a significant impact on the lives of the plaintiffs and that frequently receive huge awards in the tort system. . . . Plaintiffs have a substantial stake in making individual decisions on whether and when to settle." *Id.* at 633.

The Supreme Court stressed the same considerations and approved the Third Circuit's discussion on this point. 521 U.S. at 616. The Supreme Court added that Rule 23(b)(3) was generally not intended for the aggregation of high value claims like plaintiffs' claims: "While the text of Rule 23(b)(3) does not exclude from certification cases in which individual damages run

high, the Advisory Committee had dominantly in mind vindication of 'the rights of groups of people who individually would be without effective strength to bring their opponents into court at all.'" 521 U.S. at 617.

The same is true here. As Sulzer's own documents show, hip implant suits involve high value claims that can be of substantial monetary worth. They are not penny-stock claims or any other classic negative value claim. The Declaration of Adam R. Salvas in Support of Defendant Sulzer Orthopedics Inc.'s Motion For Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, at ¶¶ 7, 8, reveals that verdicts and settlements in hip or knee implant cases routinely run in the hundreds of thousands or millions of dollars. These claims could be tried separately, or in small consolidated actions where appropriate. Further, the desire of individual plaintiffs to control their own litigation is evident from the fact that may hundreds of those individuals affected by the defective hip implants have already filed individual actions on their own behalf.

Moreover, hip implants claims are still immature torts. Many trials against Sulzer are scheduled to begin in the near future, and one is currently underway in Texas as this brief is submitted. Class action treatment is particularly unsuitable with respect to immature torts. *See Castano*, 84 F.3d at 750 ("Through individual adjudication, the plaintiffs can winnow their claims to the strongest causes of action. The result will be an easier choice of law inquiry and a less complicated predominance inquiry. State courts can address the more novel of the plaintiffs' claims, making the federal court's *Erie* guesses less complicated. It is far more desirable to allow state courts to apply and develop their own law than to have a federal court apply 'a kind of Esperanto [jury] instruction.'") (citations omitted).

B. "Futures" Claims Should Not Be Included in a Class Action

The proposed settlement class includes all persons "who have *or may in the future* have" any claim against Sulzer "whether filed or unfiled, . . . existing or contingent, and specifically including claims for alleged injuries and damages not yet known or manifest." Proposed Class Action Settlement Agreement at 7. Hence, a class member who has not experienced any

problem with his Sulzer implant (and who may not even be aware that his implant was manufactured by Sulzer) will be bound by the proposed settlement. The settlement would even cover the consortium claims of a "future spouse" who has yet to meet, let alone to marry, a recipient of a defective Sulzer device.

Numerous courts have recognized that adequate notice to asymptomatic and other "futures" plaintiffs is impossible and that such persons cannot reasonably be expected to be able to exercise a meaningful opt-out opportunity. As the Third Circuit explained, "class members who know of their exposure but manifest no physical disease may pay little attention to class action announcements. Without physical injuries, people are unlikely to be on notice that they can give up causes of action that have not yet accrued." 83 F.3d at 633. "[I]f this class action settlement were approved, some plaintiffs would be bound despite a complete lack of knowledge of the existence or terms of the class action. It is equally obvious that this situation raises serious fairness concerns." *Id.* at 634.

The Supreme Court similarly recognized the "[i]mpediments to the provision of adequate notice," especially for persons who do not yet manifest health problems. 521 U.S. at 628. "Even if they fully appreciate the significance of class notice, those without current afflictions may not have the information or foresight needed to decide, intelligently, whether to stay in or opt out." *Id.* In addition, "[f]amily members . . . may ultimately have ripe claims for loss of consortium. Yet large numbers of people in this category – future spouses and children . . . – could not be alerted to their class membership." *Id.* Indeed, the Court went so far as to note "the gravity of the question whether class action notice sufficient under the Constitution and Rule 23 could ever be given to legions so unselfconscious and amorphous." *Id.* Due process and Rule 23(c)(2) require that notice be tailored to allow an absent class member to "make a rational judgment on whether to exclude himself from the action." 7B CHARLES A. WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1787, at 220 (1986). The MANUAL FOR COMPLEX LITIGATION (THIRD) § 30.45, at 244 (1995) warns that "persons who may not

currently be aware that they have a claim or whose claim may not yet have come into existence. . . . cannot be given meaningful notice," and their opt-out rights may be "illusory."

"For class members who cannot currently identify themselves for purposes of protecting their interests with respect to a class action purportedly commenced on their behalf, an opt-out right within a court-designated period of time . . . is of no beneficial use." 1 Herbert B. Newberg & Alba Conte, NEWBERG ON CLASS ACTIONS § 1.23, at 1-55 (3d ed. 1992).

IV. THE REQUIREMENT OF ADEQUATE REPRESENTATION IS NOT MET

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." *Amchem* and *Ortiz* establish the importance of Rule 23(a)(4)'s requirement of adequate representation. *See, e.g., Amchem,* 521 U.S. at 627 (class settlements must provide "structural assurance of fair and adequate representation for the diverse groups and individuals affected"); *see also* 5 J. Moore, T. Chorvat, D. Feinberg, R. Marmer, & J. Solovy, MOORE'S FEDERAL PRACTICE § 23.25[5][e], p. 23-149 (3d ed.1998). In *Georgine*, the Third Circuit explained that a court must be wary of potential conflicts of interest among potential class members: "the interests of the named plaintiffs must be sufficiently aligned with those of the absentees. This component includes an inquiry into potential conflicts among various members of the class, because the named plaintiffs' interests cannot align with those of absent class members if the interests of different class members are not themselves in alignment." 83 F.3d at 630. The court held that "serious intra-class conflicts preclude this class from meeting the adequacy of representation requirement." *Id.* The Supreme Court agreed. *See* 521 U.S. at 626-27.

In this case, there are several disabling conflicts of interest that preclude certification under Rule 23(a)(4), including but not limited to potential differences in state laws governing the various claims. But the most central and obvious is the conflict between plaintiffs who have already filed suit against Sulzer and those who have not. Indeed, the Motion of Sulzer Orthopedics, Inc. for Preliminary Approval of the Class Settlement is premised on the existence of this conflict. Sulzer predicts that "there will be opposition to this settlement" from lawyers

and their clients who "will argue that they should be allowed to take their individual cases to trial and 'take their shot' at SOI while the getting is still good. It is an understandable position for zealous lawyers to take in light of their duties to their individual clients." Sulzer Motion at 2. Sulzer insists that this system "would benefit only the relative few at the great expense of the many." *Id.* In fact, however, the supposed "problem" described by Sulzer is simply the manner in which our civil justice system is designed to operate: individual plaintiffs pursuing their own self-interest by seeking the maximum amount of damages to which they are entitled. *See David v. Bauman*, 196 N.Y.S.2d 746, 748 (N.Y. Sup. Ct. 1960) ("The contest of multiple plaintiffs for the limited assets of a common defendant is one which the common law has generally solved in terms of chronological priority."); Corpus Juris Secundum § 1697 *Multiple Claims; Priorities and Settlements* (1993) ("first in time, first in right"). When counsel for the settling parties in *Adams v. Robertson*, 520 U.S. 83 (1997) (per curiam), complained that this "race to the courthouse" regime favored the "lucky few," who were injured early and were the first to sue, over "the vast majority" of later claimants, who "would be left with nothing," Justice Scalia remarked: "So what? That often happens. That most often happened under common law." Tr. Oral Arg. in No. 95-1873, at 43.

Of course, if there were truly a limited corpus that could be exhausted through case by case judgments, there are accepted procedures for handling that problem. Sulzer's insurers could file an interpleader action; individual plaintiffs could file a 23(b)(1)(B) limited fund class action; or Sulzer could seek bankruptcy protection. Each of these pathways has its established procedural protections to insure that all legal rights are respected. None of these has been invoked in this case.

Put another way, Sulzer acknowledges that the interests of class members dramatically diverge. Those who have already experienced problems with their implants, have already undergone replacement surgery, and have already filed suit are interested in *maximizing* current payouts – even if that means leaving insufficient funds for claimants in the future. Conversely, those who have not yet experienced any difficulties and will not undergo replacement surgery

until months or years have passed have an interest in *minimizing* current payouts. The conflict between currently injured plaintiffs and future plaintiffs is precisely the same conflict identified by the Supreme Court as dooming the class in *Amchem*. *See* 521 U.S. at 626 ("[T]he interests of those within the single class are not aligned. Most saliently, for the currently injured, the critical goal is generous immediate payments. That goal tugs against the interest of exposure-only plaintiffs in ensuring an ample, inflation-protected fund for the future."). Indeed, *Amchem* observed that the conflict between present and future claimants is exacerbated in "a 'limited fund' case." *Id.* at 627; *see also Ortiz*, 527 U.S. at 845 (recognizing "the tension between the limited fund class action's pro rata distribution in equity and the rights of individual tort victims at law"); *id.* at 857 ("The settlement decides that the claims of the immediately injured deserve no provisions more favorable than the more speculative claims of those projected to have future injuries. . . . The very decision to treat them all the same is itself an allocation decision with results almost certainly different from the results that those with immediate injuries . . . would have chosen."); *Walker v. Liggett Group*, 175 F.R.D. 226, 231 n.8 (S.D.W.Va. 1997) ("the alleged limited fund exacerbates the apparent conflicts creating what has been described as a zero-sum game"). Hence, the very existence of the limited resources touted by Sulzer as a reason to approve the settlement is in fact a reason that the adequacy of representation requirement of Rule 23(a)(4) is an obstacle to certification, certainly as the case is presently postured.

V. THIS COURT SHOULD NOT ENJOIN RELATED LITIGATION

This Court should not enjoin absent class members from pursuing related litigation. Under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), a federal court sitting in diversity must look to the law of the state in which it sits to determine whether personal jurisdiction exists. *See Walker v. Armco Steel Corp.*, 446 U.S. 740, 753 (1980); *Arrowsmith v. United Press Int'l*, 320 F.2d 219, 221-24 (2d Cir. 1963) (Friendly, J.). In this case, a state court could not exercise personal jurisdiction over class members lacking minimum contacts with the forum state of Ohio without affording them an opportunity to opt out. *See Shutts*, 472 U.S. at 812. An injunction

that purported to restrain plaintiffs outside Ohio from pursuing related litigation – at a time in the litigation where there has been no right to opt out – would violate *Erie* by impermissibly extending the jurisdiction of this Court outside Ohio. Although *Shutts* itself involved a state court, this principle of personal jurisdiction, which arises because of the *Erie* doctrine, is not limited to state courts – as even the cases cited by the settling parties establish. *See Carlough v. Amchem Products, Inc.*, 10 F.3d 189, 200 (3d Cir. 1993) ("traditional minimum contacts requirement applies" in a federal diversity class action); *Waldron v. Raymark Industries*, 124 F.R.D. 235, 238 (N.D. Ga. 1989) (language in *Shutts* is "equally applicable to federal courts"). After all, "[t]he disadvantages of distant forum abuse are not mitigated by the forum's federal rather than state character." Arthur R. Miller & David Crump, *Jurisdiction and Choice of Law in Multistate Class Actions After* Phillips Petroleum Co. v. Shutts, 96 Yale L.J. 1, 31 (1986).

CONCLUSION

Plaintiffs' Motion for Order Conditionally Certifying a Rule 23(b)(2) and (B)(3) Class Action, Preliminarily Approving Settlement and Enjoining All Inter-Op™ Hip Prosthesis Litigation, and Sulzer Orthopedics Inc.'s Motion for Preliminary Approval of Class Settlement and For Order Enjoining All Related Litigation, should be denied.

Respectfully submitted,

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Certificate of Service

A copy of the foregoing has been served on the below named liaison counsel pursuant to the Court's instructions via email and regular US Mail on this the 23rd day of August, 2001.

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