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"THE PHILADELPHIA STORY": MASS TORTS IN THE CITY OF BROTHERLY LOVE*

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I. INTRODUCTION

Philadelphia has played a significant role in the development of the jurisprudence of mass torts, which, as used in this paper, refers to multi-plaintiff products liability and toxic tort litigation. As early as 1975, one of the first products liability litigations to be subject to coordinated pretrial proceedings pursuant to an order of the Judicial Panel on Multidistrict Litigation – the Celotex Corp. "Technifoam" Litigation[1] – was transferred to Judge Charles Weiner of the United States District Court for the Eastern District of Pennsylvania. Early in the 1980s, the school asbestos property damages litigation was centered in Philadelphia, and the United States Court of Appeals for the Third Circuit was among the first federal appellate courts to uphold certification of a nationwide Rule 23 (b)(3) class action for products liability claims. *In re Asbestos School Litigation,* 104 F.R.D. 422 (E.D. Pa. 1984), *modified sub nom.*, *In re School Asbestos Litigation,* 789 F.2d 996, 1108 (3d Cir.), *cert. denied*, 479 U.S. 852 (1986).[2] Later the Third Circuit, anticipating what have since come to be known as *Daubert*[3] hearings, addressed the role of expert evidence in proving causation in mass torts in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), *cert. denied*, 510 U.S. 1044 (1994), a bendectin case, and *In re Paoli Railroad Yard PCB Litigation (Paoli I)*, 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 499 U.S. 961 (1991), a PCB case.[4] The unsuccessful class action "futures" settlement in asbestos bodily injury litigation, in which the United States Supreme Court first addressed the requirements for mass tort class action settlements, also originated in the Eastern District of Pennsylvania. *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), *aff'g Georgine v. Amchem Prods., Inc.*, 83 F.3d 610 (3d Cir. 1996), *rev'g* 157 F.R.D. 246, 309-310 (E.D.Pa. 1994). Recently, the Third Circuit considered and rejected a medical monitoring class for smokers to detect latent disease where the court found that the presence of numerous individual issues, such as addiction and causation, failed to meet the requirement that a Rule 23(b)(2) class be cohesive. *Barnes v. American Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998), *cert. denied*, 526 U.S. 1114 (1999)[5].

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1 68 F.R.D. 502 (J.P.M.L. 1975).

2 Prior to the Third Circuit's decision in *Schools Asbestos,* class certification in a products liability action had survived appellate scrutiny only in the Second Circuit, which denied mandamus in *In re Agent Orange Product Liability Litigation,* 725 F.2d 858 (2d Cir.), *cert. denied,* 104 S. Ct. 1417 (1984).

3 *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

4 *See* Margaret S. Woodruff, *The Judge as Gatekeeper - Daubert and its Progeny* S-35-36 (1996).

5 The Fifth Circuit did not have the opportunity to decide the same issue two years earlier in *Castano v. American Tobacco Co.*, 84 F.3d 734, 738-39 (5th Cir. 1996), because plaintiffs did not appeal the district court's denial of Rule 23(b)(2) certification of a nationwide class of smokers for medical monitoring.

In the last decade, the Judicial Panel on Multi-District Litigation has transferred four product liability litigations to Philadelphia for coordinated pretrial treatment:

MDL 875	In re Asbestos Personal Injury Litigation	1991	Senior Judge Charles R. Weiner
MDL 1014	In re Orthopedic Bone Screw Product Liability Litigation	1994	Senior Judge Louis C. Bechtle
MDL 1148	In re Latex Gloves Product Liability	1997	Senior Judge Edmund V. Ludwig
MDL 1203	In re Diet Drugs Product Liability Litigation	1997	Senior Judge Louis C. Bechtle

This paper will review these four MDL proceedings and use them as a tool to examine various approaches to recurring issues in mass tort litigation and to consider whether the goals of aggregate resolution were accomplished. Viewing the cases comparatively reveals both differences and similarities that (1) highlight problems inherent in consolidations, some of them highly intractable, (2) highlight as well the opportunities that consolidation offers to provide justice efficiently and effectively, and (3) remind us again, what many commentators have observed, that perhaps the most salient characteristic of mass tort litigation is the uniqueness of each mass tort.

II. HISTORICAL PERSPECTIVE

The Honorable Anthony J. Scirica of the United States Court of Appeals for the Third Circuit, and Chairman of the Judicial Conference's Working Group on Mass Torts,[6] has characterized the problem of personal injury mass torts as "[a]rguably the most vexing issue in modern civil litigation."[7] He described the mass tort as one involving "thousands (even millions) of . . . personal injury suits that are truly national in scope, implicating primarily state law, involving unresolved issues of causation and the possibility of latent injury."[8]

When we speak of mass torts, we are referring to personal injury or property damage claims by numerous individuals arising from exposure to defective products or toxic substances. For purposes of this paper, a mass tort has the following characteristics which, as we will discuss later, have a dramatic impact on the resolution of mass tort litigation:

(1) a large number of claims in federal and state court;

(2) injury manifested over extended periods of time;

(3) an unpredictable number of claims;

(4) geographic dispersion of claims;

(5) a variety of claimed injuries, often covering a broad range of conditions and diseases attributable to the product or toxin, and a variety of damages ranging from damages for risk of injury to present harm to punitive damages; and

(6) uncertain liability and causation.[9]

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6 In 1999, following a year of study, an informal "Working Group" organized by the Judicial Conference's Civil Rules Advisory Committee and chaired by Judge Scirica, issued a *Report on Mass Tort Litigation* which summarized its analysis of the problems in mass tort litigation. Working Group & Civil Rules Advisory Committee, *Report on Mass Tort Litigation* (February 15, 1999).

7 Anthony J. Scirica, *Symposium on Mass Torts,* 148 U. Pa. L. Rev. 1859 (2000).

8 *Id.* at 1859.

9 For purposes of this paper, we are not talking about commercial or consumer torts; in other words, we are not including in our definition antitrust violations, securities fraud, or consumer fraud. Also, we are not referring to mass accidents or other claims that arise from a single event. The prototype of a single event mass tort, if we can use "mass tort" in this way, is an airplane crash. In such a situation, there is usually a finite number of people who were injured and their identities are easily ascertainable. Generally, in a single event mass tort, the law of a single state provides the governing law, although that may not be true for some damage claims. We have excluded the "single event" claims from our discussion of mass torts because the judicial system has been successful with traditional methods of aggregation which avoid duplicative discovery and trials and, generally, has been able to manage the single event mass tort in an efficient and competent fashion.

Multi-year exposure, unknown numbers of possible claimants, and the potential for future claimants due to latency in the manifestation of injury are the grist for the mass tort mill. Although not a separate characteristic as such, future claims, *i.e.* claims where no injury is yet cognizable and exposure is either known or unknown to the potential claimant, are probably the most difficult aspect of mass tort litigation. As described in the *Report on Mass Tort Litigation*:

> Some future claimants are aware of their exposure to the injury-causing agent, but not of their injury. Thus, we may know a person took a particular medicine that is suspected of causing injury, but often we do not yet know whether that person will suffer any actual injury. (In some states such future claimants are entitled to pursue claims for medical monitoring or fear of future injury. The availability of these remedies is a matter of continuing controversy.) Other futures claimants may not even be aware that they have been exposed to the injury-causing agent. For them, there is no effective present remedy. Claimants in this category present especially difficult questions of notice and representation.[10]

Unlike the mass accident or other single event tort, where each of the injured persons can be definitely identified, in the mass tort, problems of latency and variable responses to exposures to the harmful product combine to create a situation in which it is not clear which exposed individuals will eventually suffer injury, when, or of what kind. The effect of this uncertainty can be, on the one hand, decades of litigation as individuals become ill from long-past exposures; or, on the other hand, numerous suits by individuals who are not yet ill but who are concerned that a statute of limitations or a defendant's limited assets may deprive them of recovery should they become ill and who may believe that the possibility of a future illness entitles them to medical monitoring or damages for their fear of future injury.[11] It is the unknown future of each mass tort that makes it so difficult to achieve the aim of "resolv[ing] an entire mass tort with finality."[12]

The mass tort "phenomenon" is a remarkably recent development, particularly given the widespread consensus that mass torts are "probably here to stay." *See Report on Mass Tort Litigation* at 9. The thalidomide[13] and MER/29[14] cases in the late 1950s and early 1960s foreshadowed the development of mass tort litigation. Nonetheless, as recently as 25 years ago, the threshold event for the launch of a mass tort was much higher than it is today. For example, in 1977, the FDA announced that saccharin might cause bladder cancer. "In the year following that announcement, no lawsuits – zero – were filed seeking to recover for bladder cancer caused by saccharin. Zero lawsuits were filed seeking medical monitoring expenses. Zero lawsuits were filed to recover for plaintiffs' fears that they might get sick in the future because they had ingested saccharin in the past. Sales of saccharin were affected, but no companies declared bankruptcy because of saccharin-related litigation costs."[15]

Today, however, an assertion that exposure to a given product or substance may have harmful effects – whether through the filing and successful prosecution of a group of individual suits, a regulatory ruling by an agency such as the EPA or the FDA, or an exposé on a television

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10 *Report on Mass Tort Litigation* at 13.
11 *See* Geoffrey C. Hazard, Jr., *The Futures Problem*, 148 U. Pa. L. Rev. 1901 (2000).
12 *See* Francis E. McGovern, *Toward a Cooperative Strategy for Judges in Mass Tort Litigation*, 148 U. Pa. L. Rev. 1867, 1873 (2000).
13 Thalidomide was a pharmaceutical sedative that was sold in the late 1950s and that allegedly increased the risk of birth defects when taken during pregnancy. *Report on Mass Tort Litigation*, Appendix D at 61-63.
14 MER/29 is a cholesterol reduction drug that was distributed in the early 1960s and allegedly caused cataracts, baldness, and severe dermatitis. This litigation resulted in the first award of punitive damages in a product liability case. *Report on Mass Tort Litigation*, Appendix D at 41-42. It was in the context of the MER/29 litigation that Judge Friendly first raised issues concerning repeated awards of punitive damages for the same conduct in *Roginsky v. Richardson- Merrell, Inc.,* 378 F.2d 832 (2d Cir. 1967).
15 Mark Hermann, *From Saccharin to Breast Implants: Mass Torts, Then and Now*, 26 Litigation 50, Fall 1999.

program such as *60 Minutes* or *20/20* – frequently gives rise to a ground swell of litigation. Sometimes such litigation is well-founded; in other cases,[16] thousands of claims costing millions, if not billions of dollars, have been brought in the absence of verifiable scientific evidence or, as one of the authors of this paper is fond of saying, "a mass without a tort."

Whatever the merits of an individual mass tort litigation, a litigation industry has developed in the mass tort area. The parties on both sides of the courtroom are represented by highly-financed and competent lawyers who specialize in mass torts. Both plaintiffs' and defendants' counsel network among themselves, coordinating cases throughout the nation. Some would say they are both motivated by the potential for lucrative fees.[17]

The mass tort plaintiffs' bar has developed such that distinct styles of representation are readily apparent. The traditional approach for plaintiffs' tort lawyers is to prosecute actions on a case by case basis. Some plaintiffs' lawyers continue in this tradition, limiting their representation to those relatively few individual claimants with very significant liability and/or damages claims. In the last two decades, however, a highly-organized and competent segment of the plaintiffs' bar has focused on aggregation of cases with the goal of an ultimate class action settlement or a class trial. For these plaintiffs' counsel, individual trials of claims are a last resort. Counsel for the aggregation plaintiffs acquire power that counsel for individual plaintiffs lack, enhancing – and perhaps exaggerating – their clients' underlying rights. Yet, individual plaintiffs' counsel serve the necessary purpose of pressing cases to trial so that the value of the claims can be tested.[18]

The defendants, perhaps because of a lack of complete unanimity of interests, are perceived to be not as well organized nor do they have as coherent a strategy for the defense of these cases as do the plaintiffs' lawyers who specialize in mass tort aggregation.[19] The divergence among the defendants about the best strategy for fending off plaintiffs' claims is based on a variety of factors, but primarily on each defendant's liability exposure and insurance coverage position. For example, some defendants feel that individual litigation gives them the ability to avoid extensive and burdensome discovery that an individual plaintiff may choose not to pursue, while other defendants believe that aggregation for purposes of discovery eliminates duplication and reduces their costs. Similarly, with respect to the resolution of claims, some defendants seek to resolve claims as promptly as possible, while other defendants seek to wind the litigation through the process, developing defenses and resolving individual cases as time passes. While aggregation gives the defendant the opportunity to buy, as one plaintiffs' counsel puts it, "world peace," aggregation is viewed by other defendants as exerting unreasonable pressure to settle relatively weak, and arguably spurious, claims because the alternatives to settlement – including a single jury verdict determining the defendant's total liability – are risky. That risk puts the defendants under enormous pressure to agree, in Judge Friendly's words, to "blackmail settlements." *See In the Matter of: Rhône-Poulenc Rorer, Inc.,* 51 F.3d 1293, 1298 (7th Cir. 1995), quoting Henry J. Friendly, *Federal Jurisdiction: A General View* 120 (1973). The complexities of mass tort litigation for defendants are further exacerbated by extensive litigation between defendants and their insurers over insurance coverage for the defective product.

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16 For example, during the long course of the bendectin litigation, medical science has reached a clearer and clearer consensus that bendectin is not a teratogen. Similarly, in breast implant litigation, there is substantial evidence that breast implants do not substantially increase the risk of breast cancer. *See* Scirica, *supra* note 7, at 1861 n. 13.

17 In mass tort litigation, more so than in individual personal injury litigation, plaintiffs' counsel are in fact the entrepreneurial principals and it is through the lead counsel in aggregated litigation that decisions are made about the extent of investment in the litigation. Frequently, lead counsel have few, if any, individual clients and are appointed because of their experience and proven ability to conduct mass tort litigation. Their fees are derived subject to court approval from the successful conclusion of the litigation.
Defense counsel perform the traditional lawyers' role as agents for their clients with the clients as the decision-makers. Defense counsel are generally compensated on an hourly rate basis subject to restrictions imposed by particular clients or their insurers. The major risk of defense counsel is the inability of clients or insurers to pay, which has occurred in asbestos litigation.

18 *See* McGovern, *supra* note 12, at 1883.

19 *See id.* at 1884-86.

Whatever the objectives of the litigants and their lawyers, increasingly it is the judge who is critical in the process leading to the resolution of mass torts – for it is the judge who decides whether to try the cases one at a time, with an inevitable chilling effect on the filing of new cases, or to create inexpensive and expeditious case management procedures that invite new filings.[20] As mass torts place a "strain [on] existing procedural mechanisms and judicial capabilities,"[21] judges increasingly look to aggregation as a mechanism for resolving mass tort litigation.[22] Aggregation – whether through class actions, MDL treatment, or state-federal coordination – is viewed by many judges as the tool for accommodating the competing interests of the participants in a mass tort litigation. Those interests were described by Judge Spencer Williams, one of the first judges to seek to certify a mandatory class action in products liability litigation:[23] "each plaintiff clamoring for his slice of a large, but finite, damage pie; the defendant seeking a binding final determination of its liability for a product run amok; and the judicial system searching for the most equitable and efficient solution for all the interests involved in such controversies."[24]

The Working Group recognized that the decision to aggregate mass tort cases, while intended for more efficient disposition, frequently results in the generation of additional cases, including marginal or sham claims that are filed with the hope of participating in recovery because the "mass" discourages attention to the merits of individual cases.[25] This aspect has been described as "[i]f you build a highway, you will have a traffic jam."[26]

Sometimes a rush to obtain aggregation of cases at a very early stage may lead to more difficult problems than if the litigation were allowed to mature somewhat in individual cases.[27] This is so because after repeated trials and settlements in different venues, involving different parties and/or attorneys with different strategies, a consensus evolves which allows knowledgeable parties to assess the value of a claim. Even with a consensus on valuation, however, disputes persist concerning exposure, causation, and injury in individual cases. Nevertheless, a more mature mass litigation provides a sufficient number of resolved cases to ascertain appropriate evaluations of damages. The knowledge developed as the tort matures also provides the basis for developing pretrial procedures that may lead to class action settlements or remand for individual trials. Although there is no readily accepted consensus that maturation of a tort is necessary before resolution, many observers believe that a thorough understanding of the unique problems of a particular tort, whether acquired during the maturation process or otherwise, greatly enhances the likelihood of successful resolution of mass tort litigation.

As a result, the question posed by Judge Scirica, "how much aggregation, at what point in the litigation, and for what purpose?"[28] is, as he recognized, not easily answered in mass tort litigation:

> In many cases, these claims compete for a limited fund or insufficient assets and may threaten the financial stability of the defendants. Multiple individual filings threaten prompt adjudication of legitimate claims.

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20 *Id.* at 1869-90.
21 *Report on Mass Tort Litigation* at 12.
22 For example, in certifying a statewide class action in Texas in the asbestos bodily injury litigation, Judge Robert Parker noted that 448 class members had died waiting for their cases to be heard and that, even if the court could have closed 30 cases per month, it still would have taken 6-1/2 years to try the 2300 cases consolidated in that action, during which time 5000 more cases would have been filed. *See Cimino v. Raymark Indus., Inc.,* 751 F. Supp. 649, 651-52, (E.D. Tex. 1990), *rev'd*, 151 F.3d 297 (5th Cir. 1998).
23 *In re Northern Dist. of Cal., Dalkon Shield IUD Prods. Liab. Litig.*, 526 F. Supp. 887 (N.D. Cal. 1981), *vacated by* 693 F.2d 847 (9th Cir. 1982), *cert. denied*, 459 U.S. 1171 (1983).
24 Spencer Williams, *Mass Tort Class Actions: Going, Going, Gone?,* 98 F.R.D. 323, 325 (1983).
25 *Report on Mass Tort Litigation* at 16-17.
26 Francis E. McGovern, *An Analysis of Mass Torts for Judges,* 73 Tex. L. Rev. 1821, 1840 (1995).
27 *See* Francis E. McGovern, *Resolving Mature Mass Tort Litigation,* 69 B.U.L. Rev. 659 (1989) (defining mature mass torts).
28 Scirica, *supra* note 7, at 1859.

> Unreasonable delay, limited funds, and disparate verdicts on liability and damages raise serious questions of fairness. But aggregation has its price. It threatens individual consideration of cases and undermines the traditional lawyer/client relationship.[29]

Many of the dynamics and discrete problems of the mass tort phenomenon, as found in litigations that have been aggregated by the Judicial Panel, are evident in the four Philadelphia MDL litigations. This paper will review briefly the four MDL litigations listed above to examine common issues such as structures utilized by the MDL judge to organize discovery, efforts to settle, federal-state coordination, future claims, and how the courts have handled scientific/causation issues, and to draw some general conclusions about processing mass tort litigation. Along the way, we hope the reader will consider whether the techniques utilized by the MDL judges in these cases accomplish the four objectives of any resolution of mass tort litigation identified by Judge William W. Schwarzer, former Executive Director of the Federal Judicial Center:

1) A fair determination – whether by agreement or adjudication – of liability and damages;

2) Reasonable assurance that parties entitled to it will be able to collect compensation;

3) Minimum adverse impact on enterprises and the related economy consistent with achieving deterrence of objectionable conduct; and

4) Minimum transaction costs.[30]

III. CASE STUDIES

A. *In re Asbestos Personal Injury Litigation*: MDL No. 875

The asbestos litigation is a mass tort the likes of which the judicial system never before saw and prays never to see again. Indeed, one might describe it as a mega-tort. Although asbestos has been used for millennia and has been known to cause disease since the time of the Roman Empire,[31] the litigation began in the l970s in Texas with the Fifth Circuit decision in *Borel v. Fibreboard Paper Products Corp*., 493 F.2d 1076 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974). Thereafter, hundreds of thousands of cases have been filed throughout the United States claiming diverse injuries, some specific to asbestos, some not. Among the asbestos-related diseases, the injury can range among the non-malignant diseases from asymptomatic pleural plaques to debilitating asbestosis and among the malignant diseases from lung cancer to always fatal mesothelioma. Even with a diagnosis of asbestos-related disease, however, specific causation of an individual injury may be difficult to determine. The latency period, *i.e.* the time from exposure to injury, can extend decades after exposure.

Asbestos personal injury claims are among the most widely dispersed of the mass torts. Although there are no good nationwide data about the total number of asbestos claims filed in the country, few would dispute that there are more than 150,000 claims currently dispersed in federal and state courts in every state across the country. Exacerbating

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29 *Id.*
30 William Schwarzer, *Settlement of Mass Tort Class Actions; Order Out of Chaos*, 80 Cornell L. Rev. 837 (1995).
31 *See* Irving J. Selikoff and Douglas H.K. Lee, *Asbestos and Disease* 3-5, 20 (1978).

the impact of these huge numbers is the impossibility of identifying future claimants. Estimates of the number of persons exposed,[32] the number of claims, and the length of time claims will be made have been made frequently but all the predictions have underestimated the impact of asbestos and the scope of the resulting litigation. In 1999, the Working Group reported estimates that upwards of 21 million people have been exposed to asbestos[33] and that between 300,000 and 700,000 asbestos personal injury claims would be filed through 2050.[34] It already appears that these figures are too low. For example, the Manville Trust had already received more than 400,000 claims by the end of 1999, with 478,000 additional claims projected for the years 2000-2049.[35] It has been estimated elsewhere that more than 550,000 claims have been filed since the beginning of the litigation, with 390,000 to 750,000 claims still to be filed.[36]

The combination of the number of claims, their dispersion across the country, and the impossibility of predicting future claims has made asbestos personal injury litigation a mind boggling drain on the judicial system. Further complicating the situation is the large number of defendants. The Working Group, for example, has estimated that up to 2,400 individual defendants have been sued in the asbestos personal injury litigation,[37] with the plaintiffs shifting their focus as major defendants – at least 30 at last count[38] – have sought the protection of the federal bankruptcy court. Even in an individual suit, there are numerous defendants because an individual plaintiff may have been exposed to scores of different asbestos products at dozens of different locations throughout his working life.

The history of the Panel's consideration of transferring the asbestos litigation under Section 1407 illustrates how difficult and persistent have been the problems in managing this litigation. The Panel considered transfer of asbestos personal injury cases under Section 1407 five times from 1977 until 1991.[39] In 1977, the Panel was asked to transfer 103 personal injury cases.[40] The Panel examined the reasons that the responding parties unanimously opposed transfer and denied transfer, recognizing the "only questions of fact common to all actions relate to the state of scientific and medical knowledge at different points in time concerning the risks of exposure to asbestos."[41] In support of its denial of transfer, the Panel said there were many factual questions unique to each action or group of actions and many of the actions were "already . . . well advanced."[42] Thereafter, in 1980, 1986, and 1987,[43] the Panel refused to transfer asbestos personal injury cases primarily because the failure of the movant to demonstrate why a disposition different from the 1977 Panel decision was warranted.

In 1991, after a letter in late 1990 from eight federal district judges asking the Panel to reconsider consolidation under Section 1407, the Panel on its own initiative reconsidered for the fifth time transfer of the asbestos personal injury litigation and ordered

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32 Of those, an unknown and incalculable number are either aware of the exposure but unaware of any injury produced by it or unaware of the exposure. Although few, if any, asbestos-containing products are still being manufactured in this country, another group of futures is comprised of people who have not yet been but may be exposed to asbestos through manipulating asbestos-containing products already in place in buildings, ships, trains, and automobiles, or other places where asbestos or asbestos-containing products were installed over the years.

33 *Report on Mass Tort Litigation*, Appendix D, Table I.

34 *Report on Mass Tort Litigation*, Appendix D, Table I.

35 B. Thomas Florence, Revised Estimate of the Number of Future Claims to be Filed with the Manville Personal Injury Settlement Trust for Compensation for Injuries Arising from Asbestos Exposure, February 28, 2000.

36 Credit Suisse First Boston Equity Research, *Asbestos*, November 28, 2000, at 5.

37 *Report on Mass Tort Litigation*, Appendix D, Table 2.

38 According to statistics maintained by the Council for Asbestos Resolution.

39 In addition, in 1985, the Panel refused to transfer asbestos property damage claims of school districts. *In re Asbestos School Products Liability Litigation*, 606 F. Supp. 713 (J.P.M.L. 1985). However, in 2000, the Panel ordered the transfer of the asbestos property damage claims of homeowners with asbestos-containing Zonolite Attic Insulation in their homes. *In re Zonolite Attic Insulation Products Liability Litigation,* MDL 1376 (J.P.M.L. Dec. 7, 2000).

40 *In Re Asbestos and Asbestos Insulation Material Product Liability Litigation*, 431 F. Supp. 906 (J.P.M.L. 1977).

41 *Id.* at 910.

42 *Id.*

43 *In re Asbestos Products Liability Litigation (No. II)*, MDL 416 (J.P.M.L. March 1980)(unpublished order); *In Re Ship Asbestos Products Liability Litigation,* MDL 676 (J.P.M.L. February 4, 1986) (unpublished order); and *In Re Leon Blair Asbestos Product Liability Litigation,* MDL 702 (J.P.M.L. February 6, 1987) (unpublished order).

centralization of the asbestos personal injury litigation in the Eastern District of Pennsylvania before Judge Charles Weiner. The Panel explained that the dramatic increase in the number of actions and parties led them to conclude that Section 1407(a) transfer was appropriate: "In short, we are persuaded that this litigation has reached a magnitude, not contemplated in the record before us in 1977, that threatens the administration of justice and that requires a new, streamlined approach."[44]

Citing the parties' "differing (and often inconsistent) visions of section 1407 proceedings" – including class action trials or settlements, single issue trials or reverse bifurcation, pleural registries that defer resolution of the claims of unimpaired claimants, severance of punitive damages, limited fund class actions, and global settlement mechanisms – the Panel emphasized that Judge Weiner was not limited in any way in his use of pretrial techniques or other tools to manage the pretrial proceedings before him.[45] Although the Panel noted some of the techniques previously used in the Eastern District of Pennsylvania to expedite resolution of claims, it emphasized that it did so in order to allay "fears of parties" – subsequently realized according to some plaintiffs' counsel – that the Section 1407 transfer would result in asbestos claims "entering some black hole, never to be seen again."[46] The Panel ended with its observations that the transfer offered "no panacea" but "a great opportunity" to resolve asbestos matters fairly and "with as little unnecessary expense as possible."[47]

From July 1991 to March 2001, the Panel has transferred 91,280 cases to United States District Court Judge Charles R. Weiner under 28 U.S.C. section 1407. These have been coordinated with an additional 7,400 cases that originated in the Eastern District of Pennsylvania. Judge Weiner has been highly successful in resolving cases before him. While some observers have pointed out that an effect of his success may be to drive asbestos plaintiffs' counsel into the state courts in order to avoid what they perceive as the disincentives of MDL 875, the fact remains that of the approximately 99,000 asbestos personal injury cases before Judge Weiner up through March 2001, he has resolved, predominately through settlement, 65,409 of them.[48]

After the Panel transferred the asbestos personal injury litigation to Judge Weiner on July 29, 1991, he lost no time in moving towards a global resolution. He appointed Plaintiffs' and Defendants' Steering Committees. Those Committees made efforts to resolve the litigation, including discussing a system to settle future claims. In November 1991, the Defendants' Steering Committee offered to settle all pending and future asbestos cases by paying a lump sum which would be distributed by the Plaintiffs' Steering Committee to claimants with asbestos exposure. After the Plaintiffs' Steering Committee rejected this offer, the negotiations terminated except for efforts by counsel for the Center for Claims Resolution ("CCR")[49] which continued to work towards a global system. Those settlement talks resulted in separate "inventory" settlements of pending cases between the CCR and certain members of the Plaintiffs' Steering Committee, as well as a proposed class action settlement of the asbestos personal injury claims of those individuals who had not theretofore filed suit (generally referred to as a "futures class"). After the agreements had been negotiated, in a single day a class action complaint, answer, settlement agreement, and a joint motion for conditional class certification were filed by the parties.

44 *In Re Asbestos Products Liability Litigation (No. VI),* 771 F. Supp. 415, 418 (J.P.M.L. 1991).
45 *Id.* at 420-21.
46 *Id.* at 423 n.10.
47 *Id.* at 424.
48 According to statistics maintained by the Multidistrict Litigation Judicial Panel.
49 The CCR was an organization of twenty asbestos defendants that defended asbestos claims against its member companies.

As we all know, this effort came to naught with the Supreme Court decision in *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). Although the Court's opinion, especially in conjunction with the subsequent decision in *Ortiz*,[50] appears to sound a death knell for using Rule 23 to achieve global resolution of the asbestos bodily injury litigation,[51] the opinion provides important guidance concerning utilizing the vehicle of a class action for resolving mass tort litigation.

Because the Third Circuit had reversed the District Court's order of class certification on the grounds that it was error to certify a settlement class that could not satisfy the prerequisites for certification of a litigation class, the Court first addressed the relevance of settlement to class certification. The Court held that, in connection with the request for settlement-only class certification, the district court "need not inquire whether the case, if tried, would present intractable management problems" but nonetheless such a class "demand[s] undiluted, even heightened, attention." 521 U.S. at 620. Thus, the Court has not foreclosed the settlement class action, but it has warned that in the context of a settlement careful attention to the requirements of Rule 23 are necessary to protect the interests of absent class members.

In this regard, the Court's attention to the predominance requirement of Rule 23(b)(3) and the adequacy requirement of Rule 23(a)(4) are instructive. In rejecting the District Court's conclusion that predominance was satisfied by the "shared experience of asbestos exposure" and the "interest in receiving prompt and fair compensation," the Court said that the predominance factor required the existence, prior to the settlement, of genuine legal or factual controversies which are "sufficiently cohesive" to support adjudication of absent class members' rights. Further, the Court said that any dispute common to all class members about the health consequences of asbestos exposure does not satisfy the predominance requirement of Rule 23(b)(3). *Id.* at 622. Does that mean that the scientific causation issue could never satisfy the predominance requirement in a Rule 23(b)(3) mass torts class?

As to the adequacy requirement of Rule 23(a)(4), the Court was particularly disturbed by the fact that the class representatives represented the entire class even though the class included currently injured members seeking "generous immediate payments" as well as exposure-only class members whose interest was to create an "inflation-protected fund" with sufficient assets to protect future claimants. *Id.* at 637. Further, the stipulated settlement in *Amchem* provided for four categories of compensable disease with a range of damages (not adjusted for inflation) for each disease category; also, a certain number of people (capped by the agreement) with "exceptional" medical claims could obtain additional compensation. The class representatives were designated as representatives for the class as a whole, and there were no subclasses for those with different levels of injury. In the face of the perceived differences among class members, the Court found insufficient assurance of adequate representation of the diverse interests in this gigantic class. Does this mean that in a mass tort class action there must be separate representation of individuals with different injuries, or who were exposed to different products, or with different legal claims, or from different states?

Further, as to notice, Justice Breyer in his dissent interprets the majority opinion as holding that the notice was inadequate even though the majority said "we need not rule, definitively, on the notice given here." *Compare id.* at 640 *with id.* at 628. The majority's comments may go further than mere inadequacy; it may be saying that there can be no

50 *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 839 (1999).
51 Hazard, Jr., *supra* note 11, at 1913 ("The Supreme Court's decision in *Ortiz* therefore seems to foredoom any use of Rule 23 to resolve futures claims in mass torts injury cases.").

adequate Constitutional or Rule 23 notice to individuals who have been exposed but are not yet impaired physically: "we recognize 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.* The Court did observe that this particular notice was not sufficient to inform people without current afflictions about the significance of their decision to stay in or opt out of the settlement.

Similarly, the majority's focus on the fact that this was a settlement of "future" claims underscores that any global resolution of a mass tort involving claims of latent injury will require substantial attention to affording due process to those individuals who were exposed to the allegedly harmful product. Justice Ginsburg's opinion for the Court, and in particular her description of the settlement negotiations, suggests that the Court was especially concerned with whether the CCR had secured cheap prices for the future claims while paying dearly for class counsel's current inventory cases.[52] However, her expressed concerns about the "futures" aspect of the settlement are not so limited.[53] Yet, because of the latency of asbestos claims, a mechanism for resolving future claims is indispensable to global resolution of the problem. In the absence of a vehicle for resolving the future claims, any latent disease tort remains indefinitely open-ended – a scenario that we submit is unacceptable to both the litigants and the judicial system.

Finally, and perhaps most importantly, after reviewing the Advisory Committee notes to the 1966 class-action amendments to Rule 23, the Court emphasized that an important limitation on the use of class actions was the "interest of individual members of the class in controlling their own litigations and carrying them on as they see fit," especially in cases such as asbestos where individual recoveries were substantial. Class actions were better suited for claims which were too small to provide the incentives necessary to support individual litigation. *See* 521 U.S. at 614-617. Does this mean that the Court believes that class actions should not be used to resolve mass torts where the claimants have experienced serious personal injuries?

After the Supreme Court's rejection of this settlement that would have created an extra-judicial claims-resolution facility for subsequently-arising cases, Judge Weiner began to process asbestos claims on a case-by-case or small group basis. Because asbestos bodily injury litigation was a mature mass tort by the time of the transfer, coordinated pretrial proceedings have not focused on the discovery of evidence relevant to defendants' potential liability – the common issues discovery that is generally the heart of MDL litigation. Rather, his emphasis has been on utilizing the forum of the MDL litigation to settle claims if possible and, if not, remanding the serious cases for trial.[54] Accordingly, although he has utilized many

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52 Interestingly, the Court ignored the District Court's finding (entered after testimony from Professor Stephen Burbank of the University of Pennsylvania Law School, who was appointed as Special Master to evaluate the inventory settlements, and of Professor Jack Coffee of Columbia University Law School who had been employed by the Objectors) "that the settlement amounts in the inventory settlements were generally consistent with historical settlement averages for comparable settlements with CCR, were not inflated, did not include a premium paid to [c]lass[c]ounsel in exchange for the *Georgine* settlement, and were not the product of collusion." *Georgine v. Amchem Products, Inc.*, 157 F.R.D. 246, 309-310 (E.D. Pa. 1994).

53 Justice Ginsburg starts with the observations that the MDL Panel has no authority to consolidate claims not yet filed and that even though the Panel order transferred only cases "already commenced in federal courts," settlement negotiations dealt with a "means of resolving . . . future cases." Further, the Court's problems with counsel who represented present claims settling future claims may find voice in Justice Ginsburg's repeated references to those claims, including by way of example the following:

- CCR resisted inventory settlement without "protection for the future."
- CCR communicated to plaintiffs' attorneys that once it found "a rational way to deal with claims expected . . . in the future, defendants would . . . address . . . pending claims."
- Settlement talks concentrated on "claims not yet in litigation."
- Plaintiffs' counsel with large inventory cases endeavored to represent the "interests of the anticipated future claimants, although those lawyers then had no attorney-client relationship with such claimants."
- "Once negotiations . . . produce[d] an agreement . . . to bind potential plaintiffs, CCR agreed to settle . . . claims . . . already filed . . . ."
- "After settling the inventory claims, CCR . . . with plaintiffs . . . launched this case, exclusively involving persons outside the MDL Panel's province – plaintiffs without already pending lawsuits."

Amchem Products, Inc. 521 U.S. at 600-601. Further, the Court continues this theme in a footnote by stating "[i]t is basic to comprehension of this proceeding to notice that no transferred case is included in the settlement at issue. . . ." *Id.* at 601-602 n.3. Can one miss the message that the Court was concerned about future claimants being "represented" by counsel with inventory claims?

54 *See In re Patenaude*, 210 F.3d 135, 139 (3d Cir. 2000), and *In re Mary Nell Collins*, 233 F.3d 809, 812 (3d Cir. 2000), where the Third Circuit observed "the transferee court's objectives in resolving the thousands of cases assigned to it – 'that the sick and dying, their widows and survivors should have their claims addressed first.'"

traditional management techniques common to much multidistrict litigation, he has sought primarily to take advantage of information developed during the long history of asbestos personal injury litigation and capitalize on the patterns that had developed over two decades.

By 1991, when the cases were transferred to Philadelphia, both Judge Weiner and counsel highly experienced in asbestos personal injury litigation, many of whom served on one of the two MDL 875 Steering Committees, understood, first, that the only repeatedly successful legal ground upon which a defendant could obtain summary judgment was lack of exposure to its asbestos-containing product and, second, that once a plaintiff produces colorable evidence of diagnosis of an asbestos-related disease and exposure to a defendant's asbestos-containing product, settlement, in most cases, is simply a matter of time, with the amount dependent on the nature of the plaintiff's disease, the identity of the plaintiff's counsel, and the jurisdiction where the case was filed. Drawing initially on these realities of asbestos personal injury litigation, Judge Weiner established a streamlined process for summary judgment motions based on lack of exposure and a detailed structure for settlement negotiations that focused on providing prompt compensation to the most seriously injured plaintiffs – *i.e.*, those involving claims of "malignancy, death and total disability." Lawyers participating on an ongoing basis in MDL 875 report that the summary judgment procedure[55] has been little used and that evidence of exposure or lack of exposure is used primarily as a bargaining chip in settlement negotiations. The settlement program, on the other hand, has been heavily utilized by Judge Weiner to resolve the serious claims, while affording an opportunity to settle the less serious claims when they are packaged with the more serious claims as part of a group settlement.

Judge Weiner's methods of effecting settlements include: (1) providing procedures for an orderly approach to settlement negotiations, (2) scheduling mandatory settlement conferences whenever requested, (3) directing that certain information be provided in advance of settlement negotiations, and (4) encouraging settlement with a carrot and stick approach. As the docket reflects, the judge has held innumerable settlement conferences over the last ten years, over which either he or his Special Asbestos Clerk presides, often to consider groups of cases brought by a single counsel or law firm. Either side may request a conference, although most are requested by plaintiffs' counsel. Most of the conferences have focused on mesothelioma cases. In order that the parties will be able to evaluate cases for settlement, plaintiffs' counsel are required to provide defendants in advance of any settlement conference with a written medical opinion by a board certified specialist concluding that exposure to asbestos or asbestos-containing products was a substantial contributing cause to the condition or death of plaintiff or plaintiff's decedent, as well as copies of all medical expert reports and a verified affidavit of the claimant or the representative of the claimant's estate, providing the other information identified by the parties as important for evaluating settlement.[56]

Judge Weiner next mandated "good faith negotiations" which, according to Judge Weiner, involve settlement demands and offers that have a reasonable relationship to historical settlement averages in the jurisdiction from which the cases originated. Administrative Order No. 3 (1992). Once negotiations began on the high priority cases, Judge Weiner required counsel to report to him on progress as often as once a week by telephone.

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55 The procedure established by Pretrial Order No. 3 allowed a defendant to serve a "letter motion" on certain designated grounds relating to lack of exposure followed by a sixty-day discovery period at the end of which the parties filed brief pleadings following forms provided by the court.

56 By way of example, the affidavit was to include (1) the claimant's Social Security number, (2) the identity of the specific defendants against whom the claim is made, (3) a complete employment history, (4) specific description of all the asbestos-containing products to which he claims exposures, (5) the dates, place, and manner of exposure, and (6) a listing of all product identification witnesses. PTO No. 3, ¶ 4(A)(2)(1992).

Judge Weiner acknowledged that "because different viewpoints of the same case are equally understandable, a finding of bad faith is not necessary in all instances where the parties are unable to reconcile their differences and settle." *Id.* Nonetheless, the judge does not appear to have been reluctant to use his judicial leverage to encourage plaintiffs and defendants to settle. His ultimate leverage with defendants is his ability to remand for trial death cases and cases involving serious disease. Administrative Order No. 3 puts the proposition about as clearly as one could:

> There shall be a presumption that where the plaintiff has acted in good faith and one or more defendants have been found to be acting in bad faith . . . the case will be immediately remanded for trial *as to such defendants*. (emphasis supplied)

If the parties are found to have been negotiating in good faith but unable to reach settlement, Judge Weiner then offers his personal services to the settlement negotiation. Pretrial Order No. 3 (1992).

With respect to plaintiffs, Judge Weiner's leverage is his ability to refuse to remand until a plaintiff cooperates fully in settlement negotiations, cooperation that requires a plaintiff to provide written exposure and medical information. In an order entered March 24, 1995, for instance, Judge Weiner denied motions to remand well over 100 cases to the United States District Court for the Northern District of California. In so doing, Judge Weiner stated:

> [T]he Court is advised by the parties that plaintiffs' counsel for these Subic Bay cases would like to utilize a remand to state court in order to proceed with depositions in the Philippine Islands of the plaintiffs. Furthermore, the Court has not been advised that any of these cases qualify as serious. The Court is very reluctant to allow the plaintiffs to use a remand to either force the defendants to participate in depositions half-way around the globe, or be forced to make economic settlement decisions without sufficient medical and exposure criteria.
>
> The Court urges the plaintiffs to make available all medical and exposure data to the defendants' counsel and to send a summary of this material to the Court.[57]

The other disincentive for a plaintiff to refuse settlement and seek remand is Judge Weiner's ruling, upheld by the Third Circuit,[58] severing punitive damage claims and remanding cases for trial without them.

The results speak for themselves: 65,409 out of 99,000 cases as of March 2001 have been resolved. Approximately 1,000 cases of serious illness have been remanded to the transferor courts for trial.[59]

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57 Order, March 24, 1995.

58 *In re Mary Collins*, 233 F.3d 809 (3d Cir. 2000). In upholding the severance, the Third Circuit made clear that its major goal was to assure that the steadily depleting resources available to asbestos claimants go to compensate the seriously injured. *Id*. at 811.

59 According to statistics maintained by the Multidistrict Litigation Judicial Panel.

B. *In Re Orthopedic Bone Screws*: MDL No. 1014

In December 1993, the television show *20/20* aired a report that was based on a "handful of lawsuits in which back pain patients claimed bone screws had broken, bent or come loose after being surgically implanted in their spines."[60] "Hugh Downs and Barbara Walters announced they had uncovered 'shocking facts' about bone screws: They were potentially dangerous devices being used by spine surgeons all over the country. The screws had not been approved by the Food and Drug Administration ("FDA") for such uses. They were being used experimentally during spine surgery and causing terrible harm. Lives were being ruined."[61] The report highlighted that orthopedic bone screws ("bone screws") were not approved by the FDA for use in the spine – "a fact apparently previously unknown to many of the recipients of the device" – although such a use was not unlawful. In the several months after the *20/20* report aired, hundreds of lawsuits flooded state and federal courts. Not only were individual claims asserted, but class action claims were also filed. These lawsuits primarily targeted the largest manufacturers of bone screws, AcroMed, Inc. and Sofamor Danek, although cases were eventually filed against at least eight other manufacturers.

The post *20/20* flood of cases was in marked contrast to past litigation experience for the companies. From the early 1980s until late 1993, one of the leading manufacturers of bone screws had been sued in about 80 product liability cases; this included 30 claims in Louisiana brought by one lawyer. Prior to December 1993, only 3 cases had been tried to verdict. S. Elizabeth Gibson, *Case Studies of Mass Tort Limited Fund Class Action Settlements & Bankruptcy Reorganizations* 128-29 (Federal Judicial Center 2000). This was consistent with the experience of the second largest manufacturer as well: only five cases had been filed prior to 1993. Also, while bone screws had been widely used by spine surgeons around the country, the ultimate geographic distribution of the post-1993 lawsuits was not balanced, with three-quarters of the state and federal actions filed in four states – Texas, Tennessee, Pennsylvania and Oklahoma. Tennessee, the headquarters of one of the two target defendants, accounted for more than half of the filings against that company.[62]

Plaintiffs asserted traditional state common-law products liability claims, *e.g.*, design defect, manufacturing defect, failure to warn, breach of warranties, and misrepresentation, as well as novel claims relating to fraudulent promotion of bone screws. These screws were approved by FDA for use in large bones, but lacked FDA approval for use in the spine. Rather, FDA's action only controlled the labeling of the devices and doctors could decide whether to make "off label"[63] use of the bone screws.

In this litigation, the typical plaintiff had a history of serious back problems, necessitating spinal surgery, in which a brace or other device was implanted in the spine and held in place by the bone screws. Plaintiffs alleged that post-surgical back pain and other injuries that they claimed to suffer after implantation of the bone screws were caused by the screws. The defendants claimed that preexisting conditions caused the injuries. From medical records, both the product used and the plaintiff were identifiable. If there were any latency period, it was no longer than 4 months. *Report on Mass Tort Litigation* at 46-47.

60 L. Stuart Ditzen, *The Bone Screw Files,* The Philadelphia Inquirer, August 27, 2000, at 17.
61 *Id.*
62 Attached on page 152 is a graph showing a breakdown of claims by state of filing (both federal and state courts) against a major defendant in the orthopedic bone screw litigation.
63 "Off-label" use of drugs or devices - *i.e.*, for a condition other that that for which is was approved by FDA-may be a proper exercise of medical judgment by physicians.

In August 1994, nine months after the *20/20* broadcast, the Judicial Panel on Multidistrict Litigation transferred, at the request of AcroMed, all federal cases involving bone screws to the Eastern District of Pennsylvania, where they were assigned to United States District Court Judge Louis C. Bechtle.[64] The Panel found that the actions involved common questions of fact concerning the use of orthopedic bone screws, bone plates and/or spinal fixation devices for the purpose of spinal fusion and the tendency of these items to fail causing serious injury. The Panel was persuaded that the Eastern District of Pennsylvania was the most appropriate transferee court for this litigation, noting: "i) the first-filed class action [was] pending there; and ii) consolidated discovery in several actions [was] already underway; and iii) centralization in the Pennsylvania federal court may permit the federal court actions to be coordinated with numerous related actions now pending in Pennsylvania state courts in which an extensive amount of discovery [had] already taken place."[65] They noted that Judge Sandra Mazer Moss, a judge of the Court of Common Pleas, Philadelphia County, had already taken steps to coordinate pretrial proceedings in state court actions.

Judge Bechtle's mandate was to allow discovery on non-common as well as common issues concurrently, and to ensure that pretrial proceedings would be conducted in a manner leading to just and expeditious resolution of all actions to the overall benefit of the parties.[66] To this end, he established a Plaintiffs' Legal Committee ("PLC"), primarily consisting of nationally-known aggregation and class action lawyers, several of whom he had worked with before in other MDL litigation. On September 14, 1995, he appointed Robert E. Welsh, Jr., Esquire, as Special Master to administer a discovery schedule, mediate discovery disputes, and, if necessary, render decisions about disputed discovery matters.

One of the first motions considered by the Court was plaintiff's motion for class certification pursuant to Federal Rule of Civil Procedure 23. In February 1995, Judge Bechtle denied the Rule 23(b)(3) motion for class certification finding overriding individual issues. He concluded that "there are simply too many individual issues with respect to causation, liability and damages to justify certification under Rule 23(b)(3)." *In re Orthopedic Bone Screw Products Liability Litigation*, 1995 WL 273597 at *10 (E.D.Pa. Feb. 22, 1995). The Judge also denied a motion for a non-opt out class under 23(b)(1)(B), a limited fund theory, against AcroMed Corporation, a Cleveland-based medical device company that was the main target defendant[67]; plaintiffs had not demonstrated that AcroMed would be unable to satisfy the claims against it. *Id.* at *8. Judge Bechtle also denied plaintiff's motion for a supervisory medical monitoring program under 23(b)(2) because "[p]laintiffs have failed to demonstrate to the court that medical testing procedures exist which can detect warning signs of future problems which may result from spinal implantation surgery." *Id.* at *9.

In the absence of a class action, Judge Bechtle set about managing the pleadings and discovery in the individual cases. Between April 3, 1995, and May 31, 1995, plaintiffs were permitted to file what became known as "short-form" complaints, which, by stipulation of the parties, were deemed to state all elements of each of the claims for relief. Also by stipulation it was deemed that defendants denied all allegations and raised all affirmative defenses without the need for defendants to answer the complaints. Tolling of the statute of limitations was provided for, as all "short-form" complaints were deemed filed on separate dates for each manufacturer.

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64 As of December 1, 1998, 3,052 cases had been transferred to Judge Bechtle. *Report on Mass Tort Litigation*, Appendix D at 45. It has been estimated that approximately 100,000 individuals have been "exposed" to bone screws and 6,000 to 10,000 made claims in either state or federal court. *Id.* at 47.

65 Transfer Order for Docket No. 1014 (1994).

66 *Id.*

67 AcroMed's role in this litigation has been the subject of study by the Federal Judicial Center: S. Elizabeth Gibson, *Case Studies of Mass Tort Limited Fund Class Action Settlements and Bankruptcy Reorganizations* (Federal Judicial Center 2000) Chapter 7.

Complaints that came to be referred to as "omni" complaints were brought by dozens of plaintiffs against dozens of defendants, including all of the pedicle screw manufacturers, device designers, device distributors, professional medical societies, hospitals, and spine surgeons.[68] These cases were based on civil-conspiracy and concert-of-action theories, with allegations that defendants conspired to promote, market, and sell bone screw devices in violation of federal law. The court expressed concern with the general nature of the allegations, as well as with joinder of parties:

> I have some difficulty facially seeing those plaintiffs properly joined as a result of the same occurrence or transaction or a series of occurrences or transactions. I mean, I read the complaint. The pleadings setting forth these claims are very, very general. They incorporate a lot by reference. I'm very much concerned about the joinder question. And I'm anxious to see the basis upon which the joinder, for example, in that case, those like it can stand, frankly. It will be very difficult, as I understand joinder, for that to pass muster.

Transcript of 4/19/96 Status Conference before Judge Bechtle, 13-14.

Judge Bechtle addressed the issue of joinder on July 11, 1996, declaring that as a general rule all plaintiffs who had surgery with the same or similar device made by the same manufacturer, implanted by the same doctor or group of doctors, and at the same hospital could remain on the same complaint, but all other plaintiffs were dismissed pursuant to Pretrial Order No. 441. He gave plaintiffs forty-five days to file new complaints.

Then, in August 1996, Judge Bechtle addressed defendants' motions to dismiss the "omni" complaints. He dismissed conspiracy claims due to plaintiffs' failure to state a claim upon which relief could be granted, and dismissed fraud claims because "circumstances of fraud were not averred with sufficient particularity." *See* PTO No. 1235 discussing PTO No. 477. Plaintiffs had several months to prepare new complaints, and hundreds were filed by the end of October 1996. Additionally, many plaintiffs' claims were dismissed for failure to comply with Pretrial Orders Nos. 441 and 477. Originally, there was considerable question if any claims were preempted, but this issue was resolved in another context by the Supreme Court in *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996).

Vigorous discovery ensued. Defendants produced millions of pages of documents in response to a master set of interrogatories and master request for production of documents to the PLC who maintained a document depository in Philadelphia. All documents produced were made available to all plaintiffs' counsel of record in MDL No. 1014, as well as state court plaintiffs' counsel pursuant to specific criteria. *See* PTO No. 1235.

Another discovery tool Judge Bechtle used to great effect was a jointly developed questionnaire that plaintiffs were required to submit to the defendant manufacturer of their implanted device. The questionnaire incorporated authorizations for medical, employment, and workers' compensation records. The questionnaires and authorizations were invaluable for fact discovery, provided the answers were accurate. In July 1997, the court found that

68 While the primary focus of the MDL litigation has been the manufacturers of the devices, in MDL 1014 as in other mass tort litigations, non-manufacturing defendants are also named. One such defendant, an orthopedic surgeon who himself had been sued by patients in whom he had implanted the devices, recently sued the manufacturers for deception in promoting the devices. He complained that involvement in the litigation (particularly at depositions and court proceedings) had caused him to be unable to see patients and, therefore, he had lost income, seen a decline in his patient base, and been damaged in his reputation. His sole theory of recovery was the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. section 201-1 et seq., and the suit was dismissed because the court concluded that the plaintiff lacked standing, even as a purchasing agent for the patients, to assert a claim under the statute. *See Balderston v. Medtronic Sofamor Danek, Inc.,* Civil Action No. 1760 (E.D. Pa. June 11, 2001); *see also Lennon v. Wyeth-Ayerst Laboratories,* No. 1783 EDA 2000 (Pa. Super. Ct. June 14, 2001) (dismissing a patient's claim under that same statute for failure to assert ascertainable damages and, therefore, not reaching the issue of whether vaccines and other prescription drugs are covered by the statute).

certain plaintiffs' counsel who were not part of the PLC had submitted questionnaires on behalf of 225 of their plaintiff clients that were either false or misleading. Further, the answers to those questionnaires caused delay, confusion, expense, uncertainty, and disruption to defendants. Judge Bechtle sanctioned counsel $500 per questionnaire, or a total of $112,500, as well as costs associated with defendant Sofamor Danek's counsel having to take depositions in connection with the dispute. *See* PTO No. 1018.

By January 1997, a $100 million limited fund settlement had been negotiated with AcroMed and a motion for certification of a mandatory class under Rule 23(b)(1)(B) was filed to complete this settlement. AcroMed deemed its limited insurance and assets were insufficient to withstand the costs of defense of the thousands of claims against it. The motion was not served on the other defendants, and Judge Bechtle preliminarily approved the settlement without notice. *See* Gibson, *supra,* at 129-130. Objections to and appeals from this covert procedure went for naught. *See id.* at 132-133. When notice was issued for purposes of final approval, nearly twice the number of claimants responded to the settlement notice than had filed actions.

At the fairness hearing an economist blessed the settlement, opining that based on AcroMed's financial condition, limited insurance coverage, defense costs, and adverse verdict potential, the settlement "is at the outer boundary of what AcroMed can afford to pay." The Court approved the settlement overruling all of the objections asserted on behalf of 52 class members, health benefit providers with subrogation claims, and a non-settling defendant concerned with the protection of its right to contribution and indemnity. *See id.* at 148-149. In approving the settlement, the court found that the requirements for certification under Rule 23(b)(1)(B) had been met. *Fanning v. Acromed Corp.,* 176 F.R.D. 158, 176 (E.D. Pa. 1997). It relied on the expert's testimony regarding the insufficiency of the company's assets, including the insurance coverage available to satisfy the claims and the going-concern value of the company without the financial constraints of the litigation. *Id.* at 168, 177. The court also found that the settlement was fair and reasonable, and the result of good faith, arms' length negotiation. *Id.* at 184.

Within a few weeks after the settlement was declared final, according to press reports, AcroMed was sold for $325 million, more than three times the relied upon expert's estimated value of $104 million. *See* Gibson, *supra,* at 156. This, of course, calls into question whether the limited fund determination actually met the traditional requirement of Rule 23(b)(1)(B) that the limited fund distribute the "whole of the inadequate fund" to the claimants, as thereafter stated by the Supreme Court in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 839 (1999).[69] While *Ortiz* declined to decide whether Rule 23(b)(1)(B) may ever be used to aggregate individual tort claims, as it was used in the AcroMed settlement, and declined to decide whether Rule 23(b)(1)(B) requires that the entire fund always be distributed, it did make clear that the distribution to claimants must be equitable, both with respect to their treatment in relation to each other and with respect to the benefit the settlement conferred upon the defendant, that is that the defendant did not get a better deal than seriatim litigation would have produced. *Id.* at 839. Several notices of appeal of the approval of the settlement with AcroMed were filed, but all were voluntarily withdrawn,[70] some reportedly as a result of substantial payments to the objectors by AcroMed. *See* Gibson, *supra,* at 153-54. These reported "side deals" call into question both whether the

69 While *Ortiz* declined to decide precisely how close to insolvency a limited fund defendant must be brought as a condition of Rule 23(b)(1)(B) certification, it did note that if the defendant "provides only a *de minimus* contribution to the ultimate settlement fund," the protections provided creditors under the Bankruptcy Code might be undermined. 527 U.S. at 860 n. 34.

70 Nonetheless, distribution of the settlement fund was delayed while the federal government sought to assert subrogation rights related to Medicare payments. On June 29, 2001, Judge Bechtle ruled that the Medicare Secondary Payer Statute does not provide a basis for the federal government to delay settlement payments to the claimants. PTO 2000.

entirety of the limited fund was indeed distributed to the claimants and the determination that the distributions to claimants were fair vis-à-vis each other, as required by *Ortiz*.

Although the Third Circuit never directly considered the propriety of the settlement, the court had occasion to address the propriety of the notice issued in connection with the mandatory class certification. *In re Orthopedic Bone Screws Products Liability Litigation,* 246 F.3d 315 (3d Cir. 2001). In an appeal filed by class member Alexander Sambolin, whose claim was dismissed because he had failed timely to register for the settlement (although he did timely file a claim form), the Third Circuit ruled that the district court had abused its discretion in excluding Mr. Sambolin from the settlement when he had acted quickly and reasonably after learning of the settlement. In so ruling, the court applied the excusable neglect analysis laid out by the Supreme Court for bankruptcy proofs of claim in *Pioneer Inv. Servs. v. Brunswick Assoc. Ltd. P'ship,* 507 U.S. 380 (1993), and concluded that the trial court had not considered the equities of Mr. Sambolin's claim for exclusion. Although the court did not reach the constitutional issues raised by the appealing class member, it did "express . . . concerns about the notice program used in the class action and suggest[ed] some better practices." 246 F.3d at 327 n.11. The Third Circuit stated that the Supreme Court's *Ortiz* decision implied that the notice required in a limited fund class action "is the same as is required in a Rule 23(b)(3) action: the best notice practicable, 'including individual notice to all members who can be identified through reasonable effort.'" *Id.* (citations omitted). Among the improvements in the notice program that the Third Circuit concluded "would have constituted a reasonable effort to identify individual class members" were inquiries to doctors about the identity of patients, submission of information about the settlement to the medical community, and advertisements in orthopedic trade publications asking for names and addresses of bone screw recipients. *Id.* Further, after explaining that the notice by publication program had been limited to twice in USA Today, once in TV Guide, once in Parade magazine, and once in a Spanish-language newspaper in Puerto Rico, the court stated that the appellant had listed ways in which the publication notice could have been substantially improved, including a broader mix of national and local publications, better use of the internet, radio, and television advertisements, and public service announcements. The court concluded that "[w]hile all of these efforts may not be required by due process, we are inclined to believe that some combination of them would help to bring the notice program closer to 'the best notice practicable.'" *Id.*

The District Court, in 2000, considered PLC's petitions for the award of legal fees and expenses involving AcroMed related work. *Fanning v. AcroMed Corp.*, 2000 WL 1622741 (E.D.Pa. Oct. 23, 2000). The limited fund settlement had provided that 12% be set aside to apply for approved awards to the PLC members and common benefit attorneys. These fees were not in addition to any fees a claimant may be obligated to pay his or her attorney for representation in this litigation but were to be deducted from the normal fee. *Id*. at *1.

In approving that allocation, Judge Bechtle noted that a $100 million settlement "seems to be the informal marker of a 'very large settlement'". *Id*. at *7. Providing a glimpse into the economic dynamics of a mass tort litigation, Judge Bechtle found that counsel had expended almost 220,000 hours and paid out over $8.8 million in expenses. *Id*. Total assets contributed by the PLC members exceeded $6.6 million for operational expenses and over $2.7 million for payroll expenses. *Id*. at 9 n.23. Reference was made to a line of credit taken out by a PLC member to help finance the litigation. *Id*. at 9 n.21. Relying on the fact that the amount recovered by the PLC "far exceeded AcroMed's net asset value at the time of

settlement" and the litigation "has been nothing less than an uninterrupted, hard fought 'antagonistic legal battle' since it began," the Court awarded counsel fees in the amount of 12% for time and expenses through June 30, 1999, and apportioned that award among thirty-two law firms, with the top two awards of approximately $1.6 and $1.3 million going to the two leading members of the PLC. *Id.* at *5-6, 14. In June 2001, Judge Bechtle made a second fee award, with approximately $1.6 and $1.3 million going to the two leading members of the PLC.

While these awards were substantial, they were less than the $21 million in combined bills for fees and expenses submitted by the various plaintiffs' firms. As a result, disputes have arisen among the plaintiffs' lawyers concerning the division of the award and those disputes have given rise to their own bevy of litigation. For example, dissatisfied lawyers from Louisiana initially appealed Judge Bechtle's fee award; however, they eventually dismissed that appeal and, instead, started a state court action in Louisiana contending that the two co-chairs of the PLC had engaged in fraud with respect to the representations made to cooperating counsel. The PLC lawyers responded by removing the case to federal court and seeking transfer to Philadelphia as part of MDL 1014, but the federal judge in Louisiana remanded the case before the MDL panel considered the transfer petition. The PLC lawyers then filed a motion to have the Louisiana lawyers held in contempt inasmuch as the fee dispute had previously been resolved by Judge Bechtle. They also filed a separate suit in federal district court in Philadelphia — related to the MDL case — seeking to enjoin the Louisiana state court action. As of July 2001, the litigation with respect to the fee awards is continuing in both Louisiana state court and Pennsylvania federal court. *See* Shannon P. Duffy, *Disgruntled Lawyers Sue in Louisiana To Get Bigger Share of Bone Screw Fees,* The Legal Intelligencer, July 18, 2001, at 1.

The removal of AcroMed from the litigation in 1997 left Sofamor Danek, a Memphis-based manufacturer of orthopedic screws and medical devices for use in spinal surgery, as the main defendant. Although there was considerable pressure to settle, Sofamor Danek decided to defend.

A somewhat unusual *Daubert* issue arose regarding the admissibility of a so-called "Cohort Study," an epidemiological study which had been conducted by spinal implant manufacturers and which concluded that the bone screws were "safe and effective for use in the spine." When the defendants asserted that they would rely on the study as part of their defense, plaintiffs moved to exclude it under *Daubert*. Depositions of epidemiologists preceded a two-stage evidentiary hearing by the Court. The first stage was devoted to basic principles involved in various types of epidemiological studies and the second stage examined the particular study. Both sides agreed that there were flaws in the study with disagreement focusing on whether – flaws and all – there was still helpful information for a jury to consider. Judge Bechtle decided in favor of admissibility.

It soon appeared that no other settlements were going to occur, and the Court began the process of remanding cases to the transferor courts for trial. As of March 2001, Judge Bechtle had remanded 1,243 cases to the transferor courts for trial.[71] After remand, seventy-two federal judges around the country granted summary judgment in favor of Sofamor Danek. None of the remanded cases went to trial.

Similarly, state court cases began to be dismissed with thirty state court judges in eighteen states granting summary judgment. In Tennessee, the home state of Sofamor Danek,

71 According to statistics maintained by the Multidistrict Litigation Judicial Panel.

where more than sixteen hundred bone screw cases had been filed, summary judgment was granted in each of seven test cases. The remaining cases were subsequently voluntarily dismissed. All in all, more than one hundred and seventy separate summary judgments were granted in Sofamor Danek's favor in state and federal transferor courts. The bases of the summary judgments were either that there was no "defect" in the bone screws or that plaintiff had failed to establish any connection between the bone screw and plaintiff's injury.

In July 1998, FDA approved bone screws as "safe and effective" for spinal surgery. This was the death knell of the litigation, but not before the PLC, naming itself as plaintiff, sued the FDA and commenced an action based on a theory of "fraud in the FDA." The Supreme Court recently held that such an action against a regulatory consultant for spinal implant manufacturers was preempted. *Buckman Co. v. Plaintiffs Legal Committee*, 121 S.Ct. 1012 (2001).

With the retirement of Judge Bechtle as of July 1, 2001, the litigation has been assigned to the Honorable Ronald L. Buckwalter, also of the Eastern District of Pennsylvania, who is supervising what remains of the litigation.

C. *In Re Latex Gloves Product Liability Litigation*: MDL No. 1148

Natural Rubber Latex (NRL) is a natural substance made from the sap of the *hevea brasilensias* tree; it is found in some 40,000 common consumer products. Plaintiffs, primarily healthcare workers, allege a latex allergy as a result of exposure to defendants' NRL gloves. Plaintiffs further allege that they are sensitized to and develop latex allergies from exposure to certain proteins in latex gloves. There is a difference between latex sensitivity and latex allergy. A person sensitized to latex may begin to produce latex allergen antibodies but never develop any symptoms of an allergy. An unknown percentage of those sensitized to latex ever develop clinical symptoms, such as a rash. Some plaintiffs allege severe allergic reactions. At least 16 fatalities due to latex exposure have been reported to the FDA, but all 16 were related to exposure to barium enema catheters that had some latex component. Injuries range from rashes and skin lesions to more serious respiratory problems, even potentially fatal anaphylactic shock. There are more than 40,000 household products that contain latex so there is uncertainty about what is causing the sensitivity to latex. Moreover, product identification is difficult or impossible in some cases. *See Report on Mass Tort Litigation* at 37-39. An estimated 950,000 health care workers are reported to have developed sensitivity to NRL, some of whom may develop symptoms of allergy.

Litigation, mostly commenced on behalf of health care workers, started in the mid-1990s in both federal and various state courts. On February 26, 1997, the Panel transferred the latex glove litigation to United States District Court Judge Edmund V. Ludwig in the Eastern District of Pennsylvania. Thirteen actions were identified by the Panel at the time of transfer, two of which in Wisconsin were not transferred because they were sufficiently advanced toward trial to warrant their exclusion from transfer. The Panel found that this litigation involved complex common questions of fact on the issue of liability for severe toxic reaction developed by medical personnel resulting from exposure to latex gloves used in their work. Transfer under Section 1407 would eliminate "duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the Parties, their counsel and the judiciary." *In re Latex Gloves Product Liability Litigation*, MDL 1148 (J.P.M.L., February 26, 1997) (unpublished opinion). Since then, several hundred cases have been transferred involving approximately 20 defendants, mainly manufacturers and distributors of latex gloves. As of March 2001, the Panel had transferred 457 cases to join 62 cases already filed

in the Eastern District of Pennsylvania. Twenty-two cases had then been closed; none remanded.[72]

Judge Ludwig appointed as plaintiffs' lead counsel a highly competent leader of the plaintiffs' personal injury bar. There was no competition for this position, and the lawyer designated as lead counsel had in fact filed the motion to transfer with the panel at the suggestion of Judge Ludwig. As disagreements arose among defendants on various issues, they agreed on a "spokesperson" rather than on formal lead counsel.[73] In addition, Judge Ludwig appointed Perry S. Bechtle, Esquire, as a Special Master.

Relatively early in the administration of this MDL litigation, serious concerns were voiced about whether a cognizable basis of liability existed against each or any of the defendants. For example, issues arose about design and manufacturing defects as well as about the adequacy of warning, especially because FDA-suggested warnings were generally utilized. Frequently, product identification issues were involved. In addition, there were both generic and case specific causation issues implicating various medical disciplines. After four years of discovery, attempts to get test cases to trial failed. Court-encouraged mediation disclosed little interest in settlement on the part of defendants.

Judge Ludwig has stated, "the goal in this MDL is to complete as much discovery on common issues as practicable . . . so that actions may be remanded to transferor Courts and trials may go forward expeditiously in State Court actions." Case Management Order ("CMO") 46R (1999). Consistent with the overall purpose of MDL coordination to increase efficiency and consistency of pretrial discovery for all parties, Judge Ludwig has proceeded along two lines to accomplish his goal.

The first line focuses directly on streamlining discovery and weeding out defendants against whom there is inadequate product identification evidence at as early a stage as possible. The first focus of discovery is product identification. CMO 5 (1997). Each plaintiff is required to fill out an extensive form (over 40 pages in length) that provides information about product exposure, product identification, medical treatment for allergies, and relevant documents. CMO 12 (1998). Plaintiffs must also provide completed medical, school, tax, military, social security, and employment record authorization forms. Usually, one of the larger defendants is designated by the codefendants to obtain and pursue these records through a records service. The records are then accessible by all parties. Defendants must respond to plaintiffs' first set of product identification interrogatories and document requests, and both sides may then depose defendants' representatives, employees, and third parties on product identification grounds. In view of completion of the questionnaire, product identification depositions of plaintiffs may be taken only if authorized by the Special Master. Relevant depositions and exhibits from state and federal court rubber latex glove litigation, as well as copies of documents produced in prior latex glove litigation, must be made available by both sides.

At the conclusion of product identification discovery, a defendant may seek dismissal from an action as a whole or from individual counts of the action under the "Bright Line" test, under which, if there is no evidence of use of a defendant's latex gloves or exposure to the defendant's latex glove product that could reasonably cause harm, either the plaintiff must voluntarily dismiss that defendant, or the Special Master will entertain a telephonic hearing on the proposed dismissal and issue a "Bright Line" dismissal

72 According to statistics maintained by the Multidistrict Litigation Judicial Panel.
73 Before the Panel, all responding defendants had supported transfer. *In re Latex Gloves Product Liability Litigation*, MDL 1148 (J.P.M.L., February 26, 1997) (unpublished opinion).

recommendation. Bright Line dismissals can be either total or partial. Partial dismissals are utilized for Counts in the Complaint that do not depend on plaintiff's contact with the defendant's product (e.g., Market Share or other alternative liability theories). All Bright Line dismissals can be reinstated, upon newly discovered product identification evidence against the defendant, by the Special Master, Judge Ludwig, or the Section 1407 transferor court after remand.

Another method to streamline the process of ensuring that the litigation is focused on the correct defendants is CMO 38 (1998), which defines a test for dismissal of actions pursuant to the applicable statute of limitations and which is designed to operate similarly to the "Bright Line" dismissals. However, in practice this is rarely utilized since the transferee court has been disinclined to rule on issues of law of the transferor court forum.

When product identification discovery is complete and defendants who do not belong in the case are screened out to the extent possible based on that discovery, Judge Ludwig sets a schedule for completion of common issue discovery. Judge Ludwig has also set a date for expert discovery on common, non-case specific issues, including the need for and adequacy of warnings, the design and manufacture of the defendant's products, and general medical issues. CMO 46R. It presently appears that Judge Ludwig will then entertain *Daubert* motions for the "common issue" experts, and thereafter may remand for completion of case specific pretrial matters in the Section 1407 transferor court.

Another notable aspect of Judge Ludwig's handling of the cases has been his consistent efforts to cooperate and communicate with the state courts handling latex cases. For instance, he has ordered that copies of all MDL Case Management Orders be made available to the state court judges (CMO 46R); he has ordered that his MDL establish and maintain a National Latex Glove Litigation Trial Calendar of all state and federal glove trials for distribution to all state court judges assigned to latex glove cases as well as all parties of record in MDL 1148 (CMO 46R); and he has corresponded with all state judges handling latex cases and asked eight state judges who responded to form a committee to enlarge participation of the state courts in coordination of discovery and other pretrial matters. In addition, all depositions can be cross-noticed in all state and federal natural rubber latex glove cases, and access is permitted to document depositories for all plaintiff and defense attorneys upon execution of appropriate confidentiality agreements by those attorneys seeking access. There have been on-going cooperative communications among Judge Ludwig and state court judges presiding over consolidated latex glove litigation in California, New York, New Jersey and Pennsylvania. Judge Ludwig will call a state court judge if he believes it will be helpful to resolving a potential problem such as which court will resolve a privilege issue or whether a coordinated *Daubert* hearing about a particular expert is feasible.

In addition to attempts to utilize streamlined discovery procedures to ready the cases for trial after remand, Judge Ludwig created a group of six "Fast Track" cases, three selected by plaintiffs and three by defendants, all of which were originally filed in the Eastern District of Pennsylvania.[74] Presumably, the intention was to create a litigation track record that would help the settlement process for all cases. CMO 63 (2000) specified a fact and expert discovery schedule for these "Fast Track" cases that would culminate in *Daubert* hearings, with trial to be held immediately thereafter. Court-directed mediation of the first two cases selected by plaintiffs for the "Fast Track" failed to develop a basis for settlement,

74 The cases to be tried had to have been initially filed in the Eastern District of Pennsylvania in light of the Supreme Court's holding in *Lexecon, Inc. et al. v. Milberg Weiss*, 523 U.S. 26 (1998). In that case, the Court held that MDL litigations arise from a transfer by the panel pursuant to 28 U.S.C. Section 1407(a) to a federal judicial district "for coordinated or consolidated pre-trial proceedings" and that the transferee judge cannot invoke 28 U.S.C. Section 1404(a) to assign transferred cases to him/herself for trial. This "restriction" on the transferee judge's ability to try cases has impacted each of the four litigations. As this paper is written, Congress is considering legislation that would allow the transferee judge to keep the transferred cases for trial. *See* H.R. 860, 107th Cong. (2001).

mainly because of factual and legal problems in those cases. The first case was subsequently dismissed without payment and a partial summary judgment severely limited the second case. The "Fast Track" program was subsequently abandoned. Judge Ludwig now appears to intend to try the cases originally filed in the Eastern District of Pennsylvania commencing this Fall.

To date, a handful of NRL glove product liability cases have been tried to verdict in the state courts, with mixed results. Although several of the cases resulted in defense verdicts, others have resulted in plaintiff's verdicts, including one verdict in Texas for five million dollars[75] and one verdict in Wisconsin for one million dollars that was upheld on appeal by the Wisconsin Supreme Court.[76] At the same time, cases continue to be settled in the state courts.[77]

At this stage in the MDL litigation, the plaintiffs are not of one mind and many want their cases to be remanded to the appropriate transferor court. The Court is in the process of scheduling *Daubert* hearings regarding witnesses identified by plaintiffs on several "generic" issues, but plaintiffs suggest that will be a wasted and expensive effort, with the transferee judge's decision not binding on the transferor court. No trials are scheduled and there is no settlement on the horizon. In the state courts, however, there is increased activity and cases in several jurisdictions should be called for trial in the coming months. If there is in fact a tort here, it is certainly taking a long time to mature.

D. *In re Diet Drugs Products Liability Litigation*: MDL 1203

In the "fen/phen" litigation, also known as the Diet Drugs Litigation, plaintiffs seek compensation for existing personal injuries that they have attributed to one or more of the several prescription drug products that they had taken to assist in combating obesity; or currently uninjured plaintiffs seek to fund medical monitoring for these alleged adverse physical consequences of the fen/phen regimen. This litigation presented new and unique challenges to the mass tort procedures in that the MDL aggregated cases involving claims against three separate pharmaceutical products: fenfluramine ("Pondimin" or "fen"), phentermine ("phen") and dexfenfluramine ("Redux").

Despite the widespread misconception that "fen/phen" was a single product, each of these anorectic medications was tested, manufactured, and distributed by different companies. The medications – particularly fenfluramine and phentermine – had distinct chemical structures, pharmacological profiles, and physiological actions. FDA had approved phentermine as a short-term ("up to 12 weeks") treatment of obesity in 1959. Because it was a generic drug, there were about a dozen manufacturers and distributors of phentermine, all of whom were joined as defendants in the MDL. Pondimin had been approved for short-term use as a prescription appetite suppressant since 1973. Redux received FDA approval in 1996, as a prescription appetite suppressant for longer term use in markedly obese persons, noting that safety beyond one year of use had not been established in clinical trials. In contrast to the plethora of phentermine defendants, American Home Products ("AHP") manufactured and distributed Pondimin and later distributed Redux, having licensed rights to it from Interneuron Pharmaceuticals, which also was named as a defendant in some actions.

75 *Goolsby v. Baxter Healthcare, Inc.,* No. D-148,574 (Jefferson County, Texas, Dist. Ct. April 11, 2001).
76 *Green v. Smith & Nephew AHP, Inc.,* 2001 WI 109, 2001 Wisc. LEXIS 439 (Wis. Sup. July 12, 2001). It is worthy of note that, in affirming the verdict for the plaintiff, the court reaffirmed its consumer-contemplation test and rejected the requirement of Section 2(b) of the ALI's Restatement (Third) of Torts (1998) that the risk of harm be foreseeable by the manufacturer.
77 For example, in the Court of Common Pleas of Philadelphia, Pennsylvania, more than 40 cases have been resolved through a mediation program.

In the mid-1990s, after both fenfluramine and phentermine had been marketed for decades, but before dexfenfluramine received FDA approval, the concomitant prescription of fenfluramine and phentermine became a relatively common practice. This practice was primarily based on the results of a 1992 study sponsored by the National Heart, Lung and Blood Institute of the National Institutes of Health ("NIH") and conducted by independent researchers. The 1992 study showed that a daily regimen of both fenfluramine and phentermine produced better weight loss results than did use of either medication alone. Neither the phentermine manufacturers nor AHP sought FDA approval to promote a combined product, and the manufacturers of each product never sold the other's product. Between 1995 and 1997, it is estimated that approximately 14 million prescriptions involving 4-5 million patients had been written for the drugs in combination.

In 1997, information began to accumulate that associated fenfluramine with certain adverse events. In January 1997, AHP sent a "Dear Healthcare Professional" letter warning that Pondimin may increase the risk of primary pulmonary hypertension ("PPH"), "a relentlessly progressive disease that leads to death in virtually all circumstances":

> It is a disease that affects pulmonary circulation. PPH is characterized by scarring and fibrosis of the pulmonary arteries which carry deoxygenated blood from the right side of the heart to the lungs. This scarring prevents the blood cells from effectively absorbing oxygen as they pass the alveoli in the lungs. Moreover, the scarring within the pulmonary arteries obstructs the flow of blood within the vessels, causing the blood pressure in the pulmonary arteries to rise. The right ventricle of the heart attempts to overcome the increasing resistance to the flow of blood through the pulmonary arteries by growing larger and more muscular. Ultimately, this dilatation and hypertrophy of the right ventricle will cause the heart to fail and result in the patient's death.[78]

In mid-1997, researchers at the Mayo Clinic observed, in a study of less than two dozen subjects, valvular heart disease ("VHD") associated with fenfluramine use. In contrast to the severe disease of PPH, valvular heart disease can range from mild, asymptomatic valvular regurgitation to severe valvular regurgitation, necessitating valve replacement surgery. Also in contrast to PPH, which is rare, VHD occurs in a relatively significant percentage of the population absent any diet drug use. On September 15, 1997, the FDA asked that fenfluramine and dexfenfluramine be voluntarily withdrawn from the market. Both drugs were withdrawn immediately. No request was made for the withdrawal of phentermine.

While some litigation, particularly in state court,[79] preceded the FDA's withdrawal of fenfluramine and dexfenfluramine, the litigation escalated in the wake of the FDA action, as reported by a *Philadelphia Inquirer* business columnist:

> Immediately, with this news, lawsuits began to flutter down on courthouses throughout the United States. By the hundreds, the suits landed – and then by the thousands. Overnight, a "mass litigation" was born. Anybody who made those diet pills, distributed them, sold them, or prescribed them was going to get sued.

78 *In Re Diet Drugs*, 2000 WL 1222042, *16 (E.D. Pa. Aug. 28, 2000).
79 It is reported that the first "fen/phen" case filed was in Massachusetts state court on May 5, 1997. *Linnen v. AH Robins*, Civil Action No. 97-2307, Massachusetts Superior Court, Middlesex County.

> The main target of the litigation became American Home Products Corp., a Madison, New Jersey, pharmaceutical firm with billions of dollars in assets that had marketed the prescription pills through its Wyeth-Ayerst Laboratories division in St. David's, Pennsylvania.
>
> The theme of the lawsuits was that American Home, while making enormous profits on the diet drugs, failed to notify the FDA or the public of potential health risks associated with the drugs.
>
> Lawyers rushing to recruit clients proclaimed a national health emergency. To judges and to the news media, they declared that thousands of diet-drug users – maybe millions – might have heart damage. . .[80]

The deluge of litigation – both state and federal – had begun.[81] Within two months of removal from the market, the Judicial Panel on Multidistrict Litigation transferred the federal cases to Judge Louis Bechtle in the Eastern District of Pennsylvania.[82] Discovery was already underway in state courts, most notably in Texas, and coordination of state court actions had occurred in California, New York, New Jersey and Pennsylvania. In transferring the diet drug litigation to Judge Bechtle, the Panel identified the core issues in the litigation as involving "the causal connection between use of the three diet drugs (singly or in combination) and the alleged incidence of serious side effects such as valvular heart disease and primary pulmonary hypertension." 990 F. Supp. at 836. The Panel explained also that it had selected Judge Bechtle because of the "obvious need for a transferee judge with the ability and temperament to manage this large and growing litigation in an efficient and expeditious manner." *Id.*

Judge Bechtle held an organizational hearing on January 15, 1998. The overflow crowd required the use of the ceremonial courtroom, rather than Judge Bechtle's normal courtroom. Judge Bechtle designated Arnold Levin, a well-known Philadelphia plaintiffs' class action and mass tort lawyer, as interim counsel for plaintiffs. Plaintiffs came to the hearing organized. A week or so prior to the January 1998 hearing, several hundred lawyers for plaintiffs had met at a Philadelphia airport hotel to see whether they could coordinate their efforts.

Mr. Levin served as master of ceremonies for the plaintiffs' presentations at the hearing. More than twenty plaintiffs' lawyers made presentations about their own experience, suggestions about the types of lawyers that Judge Bechtle should consider appointing to a Plaintiff's Management Committee ("PMC"), and procedures that should be considered for administering the litigation. The Court invited those who wished to serve on the PMC to submit written applications and he received over 100 applications. He appointed eleven lawyers to the PMC and he designated Arnold Levin, John Cummings, and Stanley Chesley as the co-chairs. Several other members of the newly constituted PMC had served on the PLC in the Orthopedic Bone Screws MDL litigation. The appointments of counsel experienced in "high stakes" class action and mass tort litigation reflected the view of the Court that the goals of MDL litigation are best served by appointing individuals with "the staying power to go the distance." In order to fund the operation of the PMC and to compensate those attorneys who assisted the PMC with discovery across the country, Judge Bechtle established a cost and fee account to be funded by the sequestration of 9% of all

80 L. Stuart Ditzen, *Mass Litigation Lawyers: A Wolf Pack or Robin Hood?*, The Philadelphia Inquirer, November 1, 1999, at A01.

81 Attached at page 152 are graphs showing a breakdown of claims by state of filing (both federal and state courts) against a phentermine defendant in diet drugs. Approximately 60% of the diet drug claims were filed in Texas, Louisiana, Mississippi and Alabama. By way of contrast, Ohio, Michigan and Illinois accounts for .7% of the claims. Why is there this prevalence of claims filed in the Gulf states, when diet drugs were distributed nationally?

82 *In re Diet Drugs Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L.1998).

payments made by defendants in settlements or satisfaction of judgments of cases transferred to MDL 1203, whether those cases were resolved in the transferee court or in the transferor court following remand from the MDL. PTO Nos. 467 & 517.

Judge Bechtle also appointed lead and liaison counsel for AHP and the phentermine defendants, as well as liaison counsel for health care providers and pharmacy defendants even though their involvement in the MDL litigation was peripheral. Additionally, early in the MDL litigation, Judge Bechtle appointed Gregory P. Miller, Esquire, as Special Master to help resolve discovery and related disputes and generally to try to keep the litigation running smoothly. *See* PTO No. 35. Also, to facilitate access to court documents and MDL docket information, the court established a website which permits anyone interested in the litigation to have access to all of the orders and decisions of both Judge Bechtle and Special Master Miller. The website can be visited at www.fenphen.verilaw.com. *See* Pretrial Orders Nos. 172, 173, and 309.

By the end of 1998, no cases had been tried to verdict. (Several cases believed to involve primary pulmonary hypertension were settled individually by AHP as called for trial; settlement amounts were kept confidential.) Review of the pretrial orders and of the memoranda and recommendations of decisions of the special discovery master in MDL 1203 demonstrates that Judge Bechtle set out a "fast track" discovery plan so that the cases would be ready for trial upon remand in the event that they were not settled.

A Plaintiffs' Document Depository of documents responsive to plaintiffs' Document Production Requests was maintained by plaintiffs' counsel and gave free access, except for copying costs, to all plaintiffs' counsel, including counsel with state court cases, provided that they agreed to abide by the master confidentiality stipulation. PTO No. 22. Defendants were protected against waiver for inadvertent production of privileged or protected work product documents. *See* PTO No. 41. PTO No. 21 established detailed rules for the conduct of depositions. Special Discovery Master Memorandum ("SMM") No. 9 required the parties to report to the Special Master on a regular basis about progress in plaintiffs' taking approximately 85 depositions of defendants' witnesses on liability issues and punitive damages as well as defendants' depositions of 22,000 core witnesses (case specific fact depositions) and further directed that 20 simultaneous deposition tracks be established to take those depositions expeditiously. PTO No. 417 established an expert discovery schedule, which divided the experts into "generic" experts (*i.e.*, general causation experts), case specific experts, and economic experts, and required F.R. Civ. P. 26 disclosures with respect to all three categories. Recognizing that the case-specific treating physician and the economic experts are frequently located in the transferor forum, the court permitted the deposition of the economic experts and one treating physician to be deferred until remand; these depositions are the only discovery that remains to be completed when the cases are remanded. *See* PTO No. 1962.

To ensure a regular flow of relevant information from plaintiffs to defendants, Judge Bechtle used a number of tools. First, in PTO No. 22, he required each plaintiff to submit to defendants a completed "Plaintiff's Fact Sheet," a twenty-four page questionnaire negotiated by the parties requiring detailed information on a plaintiff's personal history, exposure history, medical history, including family medical history, and medical diagnosis. Plaintiffs were required to provide defendants with a list of all health care providers and signed authorizations to allow defendants to obtain medical and other records. Identification of the particular phentermine defendants whose product was involved in a particular case presented a problem because plaintiffs would frequently name several, if not all, the phentermine defendants. Efforts were made in the plaintiff's questionnaire to obtain precise descriptions

of the pills taken by each plaintiff, but that information was not always provided. The phentermine defendants agreed to provide the PMC with a consolidated chart identifying all phentermine products manufactured and/or distributed after January 1, 1994, together with information on the geographical distribution of each product and color photographs of each product if there was no photograph of it in the Physician's Desk Reference.

Through PTO No. 418, the Court imposed obligations upon plaintiffs to attempt to establish product identity and directed the special discovery master to declare when a plaintiff is unable to identify a diet drug product. At that point, the matter would be referred to Judge Bechtle. SMM No. 7 provides forms of "Plaintiff's Notice" and "Defendant's Notice," directs plaintiffs to inform the master when they determine that they cannot identify a product, and allows defendants to bring to his attention that they have not obtained product identification information from plaintiffs. SMM No. 11 requested defendants to identify plaintiffs who have not responded to product identification notices and gave the identified plaintiffs a final opportunity to correct the situation. This procedure, while cumbersome, gradually began to work mainly because of the efforts of the Special Master and his staff.

Where individual plaintiffs failed to comply with PTOs regarding case specific expert disclosures, the Special Master wrote to each individual plaintiff's counsel advising that defendants contended that a plaintiff's case specific expert disclosures failed to comply with Rule 26 and that he had reviewed the matter and found certain deficiencies. The letter offered an opportunity to cure the deficiencies but provided that failure to respond could result in preclusion of the expert's testimony.

To ensure the flow of discovery information from defendants to plaintiffs, Judge Bechtle (a) ordered the defendants to produce copies of <u>all</u> discovery materials that they had produced in any individual diet drug case that predated MDL 1203, as well as copies of all affidavits or transcripts of depositions or other proceedings in any of those cases, and (b) required that all defendants respond to a master set of interrogatories from the PMC and to a master request for production of documents. PTO No. 22

To ensure that the parties had access to the latest medical evidence on causation, the Court established criteria for determining whether or not a scientific or medical study is "currently ongoing," which exempted it from discovery, or not "currently ongoing," which made it susceptible to discovery. PTO No. 420 (1999).

Further, to coordinate the ongoing discovery in state and federal courts, the court established two committees: (i) a Discovery Committee consisting of attorneys involved in state and federal cases who were charged with seeking to reduce discovery costs and (ii) a State/Federal Coordination Committee to address concerns other than discovery. *See* PTO Nos. 38 and 39. Additionally, more formal coordination efforts were undertaken with respect to cases pending in the State of California; Judge Bechtle and California's designated state judge for all California diet drug cases entered into a Joint Agreement that consolidated the state and federal committees for the administration of discovery, including depositions. *See* PTO No. 467.

A year or so into the litigation, Judge Bechtle directed the parties to identify those plaintiffs who had been diagnosed with serious injuries in order to give these cases expedited attention. These cases involved plaintiffs with diagnosed PPH and those requiring surgical repair or replacement of heart valves. Only eleven cases were identified – less than one per cent of the federal cases. As discussed below, the PPH cases were excluded from the MDL

settlement with American Home Products and those cases, state and federal, estimated to be between 100 and 150, were settled separately.

One frequent criticism of MDL aggregation is that, in the rush to file cases, baseless claims may be filed. Early in 1999, a lawyer from one of the busiest mass tort firms in the country appeared in court and requested dismissal of eighty-eight of her cases on the basis that these plaintiffs had no personal injuries, contrary to the allegations in their complaints of serious injuries. It appeared that this firm had over five thousand diet drug clients and that one hundred and fifty cases had been filed in federal courts. As the complaints recited, the allegations had been made "upon information and belief." When this "information" did not "check out," the cases were dismissed.[83]

As the MDL progressed, there were several settlement initiatives. In September 1998, about nine months after the MDL had begun, the PMC filed a class action complaint on behalf of "a nationwide class of all persons who were prescribed and who have taken [Redux]" against Interneuron Pharmaceuticals, Inc., the small publicly traded company that had tested, developed and received approval to market dexfenfluramine in the United States market and then licensed its rights to AHP. *Wish v. Interneuron Pharmaceuticals, Inc.*, 1999 WL 782560, *3 (E.D.Pa. Sept. 27, 1999). The Court initially granted plaintiff and Interneuron's joint motion for conditional class certification of a non-opt-out, limited fund class, and stayed all Federal and State litigation against Interneuron. *Id.* "At the close of registration for the class, there were over 20,000 claimants registered in the Interneuron settlement class." *Id.*

Interneuron agreed, in return for a release of all claims against it, to contribute $15 million in cash to the settlement fund and all of the proceeds of its three insurance policies which amounted to $28 million. Further, Interneuron agreed to make payments on a bi-annual basis of 7% of gross sales of Interneuron products; 15% of cash dividends received by Interneuron from its subsidiaries; and 15% of license revenues received by Interneuron. This was to continue for 7 years after the establishment of the fund or until the payments reached $55 million. If the payments fell short of $55 million, Interneuron would make up the shortfall by distributing stock. *Id.* at *3-4.

The Court, in September 1999, vacated the conditional class certification and stay. It concluded that "while this court does not read *Ortiz* as a bar to limited fund class certification in all mass tort cases, *Ortiz* does counsel against those class certifications which would deprive the class of the protections available under the traditional model."[84] *Wish v. Interneuron Pharmaceuticals, Inc.*, 1999 WL 782560, *14 (E.D.Pa. Sept. 27, 1999).

Turning to the phentermine defendants, the PMC decided after discovery of the phentermine defendants' insurance coverage and financial condition that several of the smaller defendants did not have adequate assets to respond to the claims. Although there was no indication of interest in a voluntary settlement, the PMC filed a motion for certification of a mandatory class and a limited fund settlement. Although one of the smaller phentermine defendants did file for reorganization, none of the others flinched by reason of the motion, which the PMC did not press and ultimately withdrew.

As MDL 1203 progressed through discovery, there was increasing activity in several state courts. In Texas, AHP lost one or two verdicts and settled several cases for undisclosed amounts. Counsel for plaintiffs had succeeded in nine states in having statewide medical

83 L. Stuart Ditzen, *Mass Litigation Lawyers: A Wolf Pack or Robin Hood?*, The Philadelphia Inquirer, November 1, 1999, at A01.
84 *See also Ortiz v. Fibreboard Corp.*, 527 U.S. 813 (1999).

monitoring classes certified for those who had taken Pondimin or Redux.[85] It is noteworthy that plaintiffs' counsel in these actions were not cooperating with the PMC and in fact were in competition with them. Trial of the New Jersey medical monitoring class began but two weeks into trial it was put on hold as serious settlement negotiations covering both the MDL litigation and the state court classes had developed.

Settlement negotiations between the PMC and AHP began in late April 1999, at AHP's invitation to state and federal plaintiffs to reach a "global resolution." The court described the negotiations thereafter as "intense, adversarial and arms-length." *In Re Diet Drugs*, 2000 WL 1222042, *4 (E.D.Pa. Aug. 28, 2000). In part, this was because the plaintiffs' negotiators were willing and able to litigate their clients' claims in the event the negotiations broke down. The negotiations did not start with a focus on the value of individual cases. Instead, the discussions focused on the types of screening and compensation necessary for class members and the requirements for eligibility to receive those benefits. Only after the benefits and eligibility criteria had essentially been resolved was there discussion of how much AHP would have to pay. *Id.* According to Judge Bechtle, "[d]uring the negotiations, AHP never offered, and the plaintiffs never requested, payment of a lump sum to resolve the claims of class members." *Id.* The focus was the development of a structure for resolution of the claims of all individuals who had taken Pondimin and Redux. Claims of PPH were excluded from the settlement. *Id.* In an effort to distinguish the settlement from *Amchem*, where intra-class conflicts proved fatal to the settlement, Judge Bechtle emphasized that in Diet Drugs "under the settlement process that was employed, there was no intra-class trading off of benefits." *Id.* Further, the subject of attorneys' fees was not considered until the end of the negotiations and then only to limit the award of fees that might otherwise be payable. *Id.* at *5. The settlement negotiations resulted in the execution of a Nationwide Class Action Settlement Agreement with AHP on November 18, 1999. *Id.* State court actions were covered by the settlement agreement; and Judge Bechtle convened most of the judges presiding over the state court diet drug medical monitoring classes for a presentation by AHP and PMC of the rationale for and the substance of the settlement agreement so that they would agree to their cases being encompassed by the national class.

The settlement class consisted of "all persons in the United States who ingested Pondimin and Redux and their associated consortium claimants." *Id.* at *19. However, the settlement agreement was structured in relation to exposure and severity of illness. *Id.* The class was divided into five discrete subclasses based on the class members' length of ingestion of the diet drugs and severity of illness. *Id.* Again, in contrast with *Amchem*, each subclass was represented by competent counsel with no conflict of interest. *Id.* at *44-45. As to the concern of the class member individually controlling his or her own litigation, the Court found that the combination of medical monitoring and multiple opt-out rights allowed a class member to make an informed choice about how to control his or her claim whether it be through settlement or through litigation. *Id.* at *49.

The settlement benefits to fenfluramine users included a "screening program," compensation for demonstrated cardiac injuries, and reimbursement for the cost of the drug. None of these benefits were to be distributed, however, until the settlement receives final

85 *See Lamping v. American Home Prods., Inc.,* No. DV-97-85786/93 (Mont. 4th Jud. Dist. Missoula County Feb. 2, 2000); *St. John v. American Home Prods. Corp.,* No. 97-2-06368-4 (Wash. Super. Ct. Spokane County Dec. 4, 1998); *In re Pennsylvania Diet Drugs Litig.,* 41 Pa. D. & C.4th 78 (1999); *Vadino v. American Home Prods. Corp.,* No. MID-L-425-98 (NJ Middlesex County Jan. 25, 1999); *Burch v. American Home Prods. Corp.,* No. 97-V-204(1-11) (W. Va. Cir. Ct. Feb 11, 1999); *Earthman v. American Home Prods., Inc.,* No. 97-10-03790-CV (Tex. Montgomery County Oct. 1998); *Rhyne v. American Home Prods. Corp.,* No. 98 CH 04099 (Ill. Cir. Ct. Cook County Ch. Jan. 26, 1999); *In Re: New York Diet Drug Litigation*, No. 70000/98, *Mary Lee Cunningham, et al. v. American Home Products Corp., et al.*, Nos. 401962/98, 401963/98, 401372/99, 401606/98, 403537/98 (N.Y. Sup., N.Y. Co.); G*uard v. A.H. Robins Co., Inc.,* No. 98-CI-795 (Ky. Boone County May 5, 1999).
There are at least four decisions that rejected class certification in diet drug cases: *Baker v. Wyeth-Ayerst Labs.*, 992 S.W.2d 797 (Ark. 1999); *In re Diet Drugs Cases*, JCCP 4032 (Cal. Super. Ct. Los Angeles County, Aug. 19, 1999); *Wood v. Wyeth-Ayerst Labs.*, No. 1999-CA-001717-MR (Ky. Ct. App. Oct. 27, 2000); *Luce v. Gate Pharm.*, No. 00-174 (Iowa Dist., Polk County Jan. 10, 2000).

judicial approval, which could take years.[86] The medical monitoring benefit is available to everyone who ingested fenfluramine for more than 60 days regardless of the existence of a current injury. These claimants will receive an echocardiogram and associated interpretive visit with a physician and, if he or she suffers from valve disease, $10,000 of heart valve medical services or $6,000 cash. Those who ingested fenfluramine for 60 days or less do not participate in the screening program but if they are found to have heart valve damage independently, they receive $5,000 in heart valve related medical services or $3,000. *Id.* at *19-24.

Anyone who currently suffers from serious heart valve disease or who subsequently develops such a condition will receive payment under "The Matrix" – a grid setting the level of compensation, ranging from $7,389 to $1,485,000, depending on the age of the plaintiff, the length of use of fenfluramine, the severity of the condition, and the likelihood that alternative causes contributed to the condition. The estimated net present value of all payments under The Matrix is $2.55 billion. *See* Official Court Notice of Nationwide Diet Drug Class Action Settlement at 16, *available at* http://www.settlementdietdrugs.com. The various settlement matrices are indexed for inflation, unlike the settlement in *Amchem*. The settlement also funds a registry to "track" the condition of fenfluramine users and medical research and education regarding cardiovascular disease. 2000 WL 1222042 at *24.

Unlike the "humongous" class in *Amchem*, 83 F.3d at 626-27, the Diet Drug class in the AHP Settlement consists basically of people exposed to one substance, manufactured by one defendant, over a relatively short period of time, and subject to one particular type of injury. *Id.* at *42-43. More importantly, in MDL 1203, there were no "futures" as that term was used in *Amchem*. *Id.* at *46. In approving the settlement, Judge Bechtle found that the diseases allegedly caused by fenfluramine and dexfenfluramine are not latent. *Id.* at *47. Moreover, the Court found that no class member was unwittingly exposed to a diet drug, as they were available only through a doctor's prescription and had to be consciously ingested. *Id.* at 39. Class members were made aware of the risks the drugs posed in 1997, when the FDA requested AHP to withdraw them from the market. *Id.* There was an expansive notice to class members and, because all class members were aware of their exposure to diet drugs, the initial opt-out right was meaningful. *Id.* Moreover, the agreement's intermediate and back-end opt-out rights (as discussed below) allowed class members to make informed choices about whether to remain in or exclude themselves from the settlement. *Id.* The settlement's provision for medical monitoring provides a mechanism to inform class members of their injury status. *Id.*

Notwithstanding the Court's conclusion that the Diet Drug Litigation does not include "future" claims, the settlement agreement protected the interests of class members whose awareness of their injury evolved over time by providing for four separate opt-out opportunities:

- There was the initial opt-out right provided by Rule 23(b)(3).
- Second, there is "an intermediate opt-out" right whereby a class member, not a member of the subclasses for the more seriously injured and who is diagnosed with a more serious injury by the end of the Screening Period, may pursue AHP for all claims based on

86 The $1 billion allocated to a program of monitoring which will not start for a few years after fenfluramine and dexfenfluramine were taken off the market raises questions about the utility of such a program given the lack of a latent condition, the prevalence of valvular heart disease in the population at large, and the fact that, given the widespread publicity, many, if not most of those exposed to diet drugs have had monitoring from their physicians in the interim.

injury to his or her heart valve except claims for punitive, multiple or exemplary damages, common fraud damages, and medical monitoring.

- Third is the "back-end opt-out" right whereby a class member who is diagnosed with the most serious level of disease by the end of the Screening Period, who reaches a matrix level condition after the cut-off date for the least injured subclass but before December 31, 2015, and who has registered within 120 days after the end of the Screening Period, may pursue all his or her settled claims against AHP and the AHP Released Parties except claims for punitive, multiple or exemplary damages, common law fraud, and medical monitoring.

- The fourth opt-out right is the financial insecurity opt-out which is triggered by a condition of financial insecurity with respect to the payment of AHP's obligation under the Settlement Agreement.

If a class member properly exercises an intermediate or back-end opt-out right and brings a lawsuit against AHP Released Parties within one year from the date of exercise of that right, the defendants cannot assert any defense based on any statute of limitations or repose, the doctrine of laches, any other defense predicated on the failure timely to pursue the claim, any defense based on "splitting" a cause of action, any defense based on any release signed pursuant to the Settlement Agreement, and any other defenses based on the existence of the Settlement Agreement. *Id.* at *25-26.

To preclude any challenge to the settlement based on conflicts of class counsel, the formulas for attorneys' fees are similarly complex. For those claims in which payments are made for screening and medical services, a $200 million escrow account has been established by AHP for attorneys' fees. For those claims in which payments are made under The Matrix, attorneys' "fees shall be deducted from each payment made to a Class Member . . . in an amount equal to 9% of the total" compensation paid to the Class Member. The Class Member is still responsible to pay his or her personal attorney pursuant to their contingent fee agreement; however, the personal attorney's fee will be reduced by 9%. *Id.* at *31-32.

Judge Bechtle conducted a fairness hearing at which the PMC and AHP developed an extensive record in support of the fairness of the settlement. *Id.* at *6-8. There were, however, numerous objectors to the settlement, as well as accusations by the proponents
of the settlement that many of the objections were intended as leverage to get a more favorable settlement from AHP. Judge Bechtle rejected the objections and approved the settlement. *Id.* at *60. Some twenty separate appeals were taken to the Third Circuit. Many of the appeals have been withdrawn as the objections have been addressed in some instances or as settlements have apparently been reached. As of July 2001, no appeals were pending that challenged the terms of the settlement. Rather, the remaining appeals address the proper method for protecting third party payers, such as health insurance companies.[87]

There are reported to be approximately 50,000 opt-outs from the settlement. *Id.* at *60. AHP in its Annual Report for 2000 reported that by year end, approximately 40,000 of the opt-out claims had been settled, leaving only 10,000 unresolved. AHP

87 Among the third party payers that seek to recover from the settlement is the federal government. Judge Bechtle refused the federal government's request to postpone the distribution of settlement funds until the government could determine how much it is owed in reimbursements to Medicare and other federally funded health insurance programs. PTO No. 1823 (2001). In so ruling, Judge Bechtle noted that in the Bone Screw litigation, where the parties had cooperated with the government, distribution of settlement funds had been postponed for nearly two years. *See* note 70, *supra.*

continues to attempt to settle as many of the outstanding claims as possible in order to bring the diet drug problems to conclusion. (It has been reported that AHP has taken, in the aggregate, financial charges of $12.5 billion for this litigation, which represents $4.11 per share in 2000 and $2.51 per share in 1999.) However, in April 2001, in a state court case in Texas against AHP, a jury awarded $11 million in compensatory damages and $45 million dollars in punitive damages to a plaintiff who had moderate aortic regurgitation but who is not presently disabled.[88]

As to those cases that cannot be settled, the cases filed in federal courts by opt-outs are being remanded to their transferor courts. Shortly before Judge Bechtle resigned from the Federal bench and was succeeded by Judge Harvey Bartle as the judge supervising MDL 1203, Judge Bechtle initiated a remand program. In connection therewith, he entered a final pretrial order that explained the efforts undertaken by the transferee court to administer the case, the discovery taken as part of the MDL process, and the documents to be included in the record for each case when the cases are remanded. *See* PTO No. 1962 (2000). The Special Master is overseeing remand of the cases in "waves" once pretrial matters have been concluded. *See*, *e.g.*, Tr. SM Conf. Nov. 3, 2000. As part of the process, the parties are required to complete and submit Remand Questionnaires to the Special Discovery Master. Those questionnaires solicit information about any remaining discovery in the case and any disputes between the parties. In Judge Bechtle's words, the process "is designed to do everything possible to finalize each parties' pretrial efforts prior to remand". PTO No. 1962 at 12.

The remanded cases are being returned to the transferor court with a "Joint Record on Remand," as is required by J.P.M.L. Rule 1.6(d)(v). It is comprised of "those parts of the files and records produced during the . . . consolidated pretrial proceedings which have been stipulated to or designated by counsel as being necessary for any or all proceedings to be conducted following remand." *Id.* In contrast to, for example, Orthopedic Bone Screw cases, the Diet Drug Joint Record on Remand will be relatively detailed, including many relevant PTOs and Settlement Master decisions and recommendations, as well as discovery such as common fact witness depositions and generic expert witness disclosures and depositions. Among the materials included in the record on remand are Judge Bechtle's orders in connection with the *Daubert* motions that he heard; and, as part of his final pretrial order, PTO No. 1962, he suggested that the transferor judge, on remand, review his *Daubert* decisions and determine whether the issue should be revisited or whether that ruling should control in light of the extent to which state law may bear upon the issues decided.

Although, after three and one-half years, the Diet Drug MDL litigation is winding down for fenfluramine and dexfenfluramine, there is much left to be done both in the administration of the trust created under the AHP settlement and consideration of fee petitions by the PMC and the common benefit attorneys.

The phentermine defendants, however, did not participate in settlement negotiations and are not a released party under the AHP Settlement Agreement. Nonetheless, phentermine defendants are being dismissed from the litigation. The PMC had not identified any generic causation expert witnesses against any phentermine defendant, and the PMC is not now contending that phentermine was the medical or pharmacological cause of any of the plaintiffs' injuries. A significant number of plaintiffs' counsel outside of the PMC, however, decided to press their claims against phentermine, and they advanced two expert witnesses to implicate phentermine as a causative agent.

88 *Lopez v. American Home Products, Inc.,* No. 99-07-37723, Tex. Dist., Jim Wells Co. (April 2001).

Faced with a *Daubert* challenge to each of these witnesses, Judge Bechtle developed an efficient procedure for a three-day evidentiary hearing in March 2000 preceded by depositions of experts on both sides.

The record before the Court at the start of the hearing consisted of Rule 26 disclosures and deposition testimony for each of the two witnesses for plaintiffs and each of the approximately eight witnesses for the phentermine defendants, including experts in such disciplines as epidemiology, cardiology, pulmonology and pharmacology. The defense witnesses challenged the methodology of the plaintiffs' witnesses, as well as their conclusion that phentermine caused PPH or valvular heart problems. Also in the record was a joint exhibit of all relevant medical literature on the subject. Extensive briefs were furnished to the Court in advance of the hearing. The Court, with the aid of the Special Master, established a detailed time line for the direct and cross examination of each witness and argument by counsel. During the hearing, all record materials were available to the Court in binders which he kept on the bench and he frequently referred to the medical literature as it was referenced in testimony. The hearing was concluded within the established time line. Judge Bechtle subsequently handed down a detailed opinion sustaining the *Daubert* challenge and finding that there was no sound, reliable evidence to implicate phentermine as a causal factor in plaintiffs' injuries. (*See* PTO No. 1351).

Since the successful conclusion of the *Daubert* hearing, the phentermine defendants have been involved in the slow process of extricating themselves from individual cases either through seeking voluntary dismissals or dismissal for failure to comply with Judge Bechtle's pretrial orders regarding identification of expert witnesses who would implicate phentermine. Procedures adopted by the Special Master helped this process and avoided the necessity of filing formal motions with the Court. On March 26, 2001, Judge Bechtle issued a Rule to Show Cause why plaintiffs' claims against phentermine defendants should not be dismissed where plaintiffs have failed to comport with pretrial deadlines. *See* PTO No. 1845. On April 4, 2001, the return date of the Rule, the Court dismissed over three hundred cases against phentermine defendants with prejudice, leaving only a few active cases against phentermine defendants.

IV. CONCLUSION

There are several perspectives from which to assess whether the goals of mass tort litigation were realized in these four litigations and there will be basic disagreements concerning any such assessment. The judicial or institutional perspective might be that the judicial goal, especially in multi-district litigation, is to get the cases trial ready with the hope that a global settlement can be achieved. From this perspective, the goals were satisfied in Orthopedic Bone Screw and Diet Drugs in that settlements were reached as to some defendants and compensation was or would be available to injured plaintiffs. Even in asbestos, where attempts at a global solution were judicially rejected, Judge Weiner has succeeded in resolving an extraordinary number of cases.

With respect to the cases that have not settled, the proceedings in the MDL transferee court have facilitated the resolution of the cases through summary judgment or their preparation for trial in the transferor court. For example, *Daubert* hearings concerning the common scientific issues occurred in three of the four litigations. In the Diet Drugs litigation, the Court's pretrial rulings have resulted in the dismissal of over 300 cases against the phentermine defendants. In the Bone Screws litigation, the cases against the non-settling defendants have been or are being remanded. In the Latex Gloves litigation, the

coordinated proceedings arguably have advanced the cases so that they may be remanded shortly. Even in asbestos, where most of the common discovery had been taken before the Judicial Panel ordered transfer of the cases, Judge Weiner's efforts have assured that the cases are trial-ready when they are remanded and his deferral of remand of the less serious cases, accompanied by the bifurcation of all plaintiffs' punitive damages claims, is a modest step towards assuring compensation of the plaintiffs in the serious cases. Thus, in retrospect, the institutional view might be that these litigations were handled expeditiously and effectively. On the other hand, the litigants may not all share that view.

There is still no light at the end of the asbestos litigation tunnel. More and more defendants are seeking bankruptcy protection in order to obtain the global resolution that the non-bankruptcy courts have been unable to provide. Indeed, eight companies have filed for reorganization since January 1, 2000. At the same time, the present president of ATLA, a prominent plaintiffs' lawyer in asbestos litigation, stated that since MDL No. 875 was created there had been few, if any, federal asbestos filings and that plaintiffs' counsel were doing everything possible to avoid the "black hole" in Philadelphia.

All concerned, the Court as well as the parties, appear frustrated with the progress of the Latex Gloves litigation. With the benefit of hindsight, it appears there are comparatively few serious injury cases and these have significant legal hurdles to overcome. Many of the plaintiffs face statute of limitations problems and the various defendants appear to have different defenses. The *Lexecon*-imposed restriction on trials in the transferee court has not helped. To date no basis for an MDL settlement has developed.

AcroMed might contend that, although there was no valid basis for the Bone Screw litigation, it was fortunate that a "limited fund" settlement procedure was available which enabled it to put the litigation behind it without seeking bankruptcy protection. Plaintiffs might question whether the settlement truly represented all that AcroMed could afford to pay, especially in light of the additional funds made available to settle with objectors and the subsequent sale of the company at a substantial multiple of the value of the company used for approval of the settlement. The other defendants, most notably Sofamor Danek, would question a system that cost $75 million in defense costs to end up with summary judgments in its favor and might join in AcroMed's frustration about meritless claims. Plaintiffs, on the other hand, might question the power of a single judge effectively to terminate a nationwide litigation by virtue of an evidentiary ruling on the admissibility of an admittedly flawed epidemiological study.

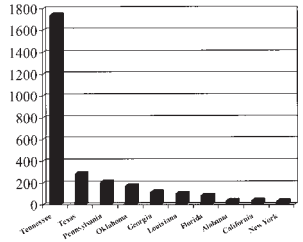
In the Diet Drugs litigation, American Home Products might see MDL 1203 as having been a useful vehicle in which ultimately to obtain a national settlement class but be frustrated with how a defendant can be whip-sawed by the lack of cooperation between the MDL Court and certain state courts. By contrast, the plaintiffs would view the state court litigation as an integral facet of the maturation of the litigation – a maturation that was necessary to bring AHP to the settlement table. Moreover, the settlement did not terminate the litigation for AHP; there have already been 50,000 opt-outs, with 10,000 of those remaining to be resolved, and there could be a significant number of additional "intermediate" opt-outs after final judicial approval of the settlement. The phentermine defendants might be pleased with the Court's willingness to entertain *Daubert* motions challenging the scientific validity of claims. Further, there would be satisfaction that they have been dismissed from almost all the MDL cases and, with the exception of one or two states, from state court litigation, although they might question why it cost over $150 million to extricate themselves from the litigation.

At a minimum, these case studies demonstrate that mass torts are "complex and multi-faceted," presenting unique problems in each tort. As the Working Group recognized, "[t]here is no single problem that is subject to a single comprehensive solution. Indeed, practices that prove beneficial for one type of mass tort may prove harmful in another." *Report on Mass Tort Litigation* at 26. On the other hand, as the case studies of four MDL consolidations in federal court in Philadelphia demonstrate, there are lessons to be learned and applied. The overarching lesson is that courts of consolidation, to achieve justice, must identify and study the unique aspects of each mass tort and put that knowledge to use. Accordingly, we believe that the experience in Philadelphia sheds light on how approaches can be shaped to address the unique problems posed by each mass tort.

Orthopedic Bone Screw Litigation

Breakdown of Claims Against One Defendant
By State of Filing (Both State and Federal Courts)

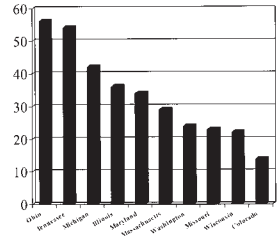
- 54% of plaintiffs filed in TN
- 88% of plaintiffs filed in ten states:
  - Tennessee (54%)
  - Texas (8.8%)
  - Pennsylvania (6.4%)
  - Oklahoma (5.4%)
  - Georgia (3.7%)
  - Louisiana (3.3%)
  - Florida (2.7%)
  - Alabama (1.3%)
  - California (1.3%)
  - New York (1.1%)



Diet Drugs (Phentermine)

Breakdown of Claims Against One Phentermine Defendant
By State of Filing (both Federal and State Courts)

- 1.7% of plaintiffs filed in ten large states:
  - Ohio (0.3%)
  - Tennessee (0.3%)
  - Michigan (0.2%)
  - Illinois (0.2%)
  - Maryland (0.2%)
  - Massachusetts (0.2%)
  - Washington (0.1%)
  - Missouri (0.1%)
  - Wisconsin (0.1%)
  - Colorado (0.1%)



Diet Drugs (Phentermine)

Breakdown of Claims Against One Phentermine Defendant
By State of Filing (both Federal and State Courts)

- 91.9% of plaintiffs filed in ten states:
  - Texas (30.5%)
  - New York (14.7%)
  - Mississippi (13.8%)
  - Alabama (10.5%)
  - Florida (7.3%)
  - Louisiana (5.7%)
  - Oklahoma (3.5%)
  - California (3.3%)
  - Pennsylvania (1.5%)
  - Kentucky (1.2%)