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## COMMENT

### VIABILITY OF A NATIONWIDE FEN-PHEN/REDUX CLASS ACTION LAWSUIT IN LIGHT OF *AMCHEM V. WINDSOR*

#### I. INTRODUCTION

In 1995, Linda Rhoades was first introduced to the “miracle” drug combination known as fen-phen. Her doctor prescribed the popular diet drug combination of fenfluramine and phentermine, better known as “fen-phen,” so she could lose weight. After successfully losing some weight, Linda went to see her doctor for a routine examination. Unfortunately for Linda, the examination revealed that Linda’s heart valve was severely damaged.<sup>1</sup> Sadly, Linda’s heart valve was so severely damaged that she inevitably needed open-heart surgery to replace her damaged valve.

Last year, Linda had her heart valve replaced; however, this did not solve Linda’s heart problems. Linda’s recovery from heart valve surgery was complicated due to a second damaged heart valve.<sup>2</sup> Although her symptoms from the second damaged valve are controlled with medication, the second valve will likely have to be replaced some time in the future.<sup>3</sup> For Linda, that means frequent visits to her cardiologist and the constant fear of not knowing what lies in her future. Linda stated, “it’s pretty disconcerting . . . I don’t know if I have the normal life expectancy that I would have had . . . I’m kind of playing a waiting game to see what’s gonna happen.”<sup>4</sup>

While heart valve damage is not a wholly new phenomenon, what is new is the cause of her damaged heart valves, fen-phen. After Linda Rhoades’s doctor first discovered valve damage, Linda was referred to the Mayo Clinic in Rochester, Minnesota, where Dr. Heidi Connolly treated her. Dr. Connolly was the first doctor in the United States to make the connection between the use of fen-phen and heart valve damage.<sup>5</sup> Then in July 1997, the Mayo clinic released a study showing that twenty-four people, including Linda, with no prior heart conditions had developed heart valve damage after taking fen-phen.<sup>6</sup> These initial findings by the Mayo Clinic eventually led

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1. See *CBS This Morning: Analysis: Long-term Health Problems Caused by Obesity Drugs* (CBS television broadcast, Feb. 24, 1998).

2. See *id.*

3. See *id.*

4. *Id.*

5. See *id.*

6. See Paul D. Rheingold, *Fen-Phen/Redux Diet Drugs*, MEALEY’S LITIG. RPT.: DRUG &

the FDA to request that the “fen” part of fen-phen and dexfenfluramine, also known as Redux or Pondimin (which is chemically similar to fen) be removed from the market.<sup>7</sup>

Unfortunately, it seems that fen-phen was not removed from market shelves soon enough. It has been reported that approximately six million Americans took the diet drugs and of that number, approximately twenty-five to thirty-three percent of those persons will develop serious physical conditions.<sup>8</sup>

With so many millions of people exposed to these diet pills, the inevitable questions remain as to who is to blame and who is going to pay for all the damage. While the allegations of who is to blame are still long from be-

MEDICAL DEVICES, Aug. 1, 1997, at 22. In July 1996, a report from the Mayo Clinic was released stating that they had seen some 24 patients (all women) who had developed heart valve damage while on fen-phen. *See id.* This was perhaps the most startling bad news about the diet drugs, and indeed provided the catalyst for the current attention to litigation.

In the report, Dr. Heidi Connolly and others at Mayo and at a clinic in Fargo, North Dakota, reported 24 women with no previous heart or lung disease who were on fen-phen for a mean duration of 12 months, had developed very unusual and specific heart valve damage. *See id.* This led to surgical replacement of at least five valves. *See id.*

7. *See id.* In late 1996, the FDA requested that Wyeth-Ayerst issue a “dear doctor” letter regarding fenfluramine. *See id.* The letter cautioned physicians about Primary Pulmonary Hypertension as a possible side effect. *See id.* The letter stated that fenfluramine should only be used by persons whose Body Mass Index is 30 or more and not for “cosmetic” weight loss. *See id.* (for a discussion of Body Mass Index, see *infra* Part II.B). It also stated that neither the FDA nor Wyeth approved the combined use of fenfluramine and phentermine. *See id.* However, it did not advise doctors not to prescribe the combination, and obviously the seller of fenfluramine obtains benefits from the combination sale. *See id.*

On July 8, 1997, after the Mayo study was released, the FDA issued a Public Health Advisory about heart valve disease. *See id.* The FDA reported it was aware of 33 such cases and was obviously describing the Mayo study. *See id.* It sought reports from physicians on fen-phen and Redux to its MEDWATCH program. *See id.* MEDWATCH is the FDA medical reporting program that requires manufacturers, packers and distributors to report to the FDA adverse affects of new drugs. *See New Drugs*, 21 C.F.R. § 310.305 (1998). The FDA advisory reminded all doctors that the safety and effectiveness of fen-phen has not been established and that “serious concerns about the safety of such combined use have been raised.” Rheingold, *supra* note 6, at 22. If doctors were to prescribe it, the FDA recommended that doctors “follow patients closely with thorough cardiac evaluations, and if signs and symptoms of cardiopulmonary disease developed further cardiac evaluation should be pursued.” *Id.*

The future of Pondimin and Redux was destroyed in early September, when the FDA received the results of echocardiograph studies (an echocardiograph is the record produced from an ultrasound of the heart that displays an image of the heart valves indicating the extent of damage) conducted on patients who had used the drugs. *See id.* Even though the number of subjects was just 284 among five studies, the results were alarming: Nearly one in three had evidence of heart valve disease. *See id.* Under pressure from the FDA, American Home Products and Interneuron, manufacturers of the diet drugs, recalled Pondimin and Redux. *See id.* Although an AHP spokesperson refused to confirm the figure, “it’s been reported that the recall cost the company between \$200 million and \$300 million.” Bob Van Voris, *Fen-Phen Suits Grow: Panel Mulls MDL Forum For Diet-Drug Litigation as Feds Urge Heart Exams*, NAT’L L.J., Dec. 1, 1997, at A1.

8. *See* Jacqueline Soteropoulos, *Attorneys Court Diet-Drug Clients*, TAMPA TRIBUNE, Dec. 8, 1997, at 1. The potential plaintiff class is about three or four times the number of women who received breast implants, which sparked a tremendous wave of lawsuits. *See id.*

ing resolved, one thing that is certain is how they are going to find out - litigation. Within the framework of litigation, plaintiffs' lawyers are hotly contesting the merits of pursuing class action lawsuits versus individual lawsuits.<sup>9</sup>

Aside from strategic considerations, lawyers are also faced with the Supreme Court's July 1997 decision in *Amchem v. Windsor Products*<sup>10</sup> making the requirements for class action certification more stringent. This Comment will explore the legal implications of the *Amchem* decision using the fen-phen/Redux scenario as a model. Part I of this Comment will discuss the evolution and medical implications of the fen-phen/Redux predicament. Part II will focus on the *Amchem* decision and its effects on recent lawsuits seeking class action certification. Part III will discuss the various approaches to resolving the fen-phen/Redux litigation as well as the likelihood of successful class certification.

## II. THE EVOLUTION AND MEDICAL IMPLICATIONS OF THE FEN-PHEN/REDUX PREDICAMENT

### A. *The Introduction of the Drug Combination Fen-Phen and FDA Approval of Redux*

The drugs comprising the fen-phen combination have been around for years. Phentermine ("phen") was approved by the U.S. Food and Drug Administration (FDA) in 1959 and fenfluramine ("fen") in 1973, both for short-term weight loss treatment.<sup>11</sup> But it was not until 1992 that a study sponsored by the National Institute of Health suggested that patients could achieve dramatic weight loss by taking the drugs in combination.<sup>12</sup>

The FDA never approved the combined use of these two drugs.<sup>13</sup> "Hence the physician who prescribed a fen-phen regimen made an off-label use of a prescription drug."<sup>14</sup> Although physicians may prescribe drugs in a manner that does not comport with FDA indications, there are inherent risks

9. See Mark Hansen, *Fen-Phenomenal Tort Battle Brewing*, 84 A.B.A. J. 24 (1998).

10. 117 S. Ct. 2231, 2243 (1997).

11. See Van Voris, *supra* note 7, at A1.

12. See *id.* Fenfluramine is sold under the trade name Pondimin (also "Ponderol"), by A.H. Robins, which is a subsidiary of American Home Products, Inc. Phentermine is sold under a number of trade names including Ionamin (Medeva); Fastin (Smithkline Beecham); Adipex (Gate); Banobese (Seatrace); Obenix (Abana Pharmaceuticals); Obycap (Richwood); Zantryl (Ion). See Rheingold, *supra* note 6, at 22.

13. See Rheingold, *supra* note 6, at 22. "Fenfluramine increases the amount of available serotonin (a neurotransmitter), by inhibiting its reuptake. Increased level of serotonin gives the brain the sign of satiety. Phentermine works on dopamine, another neurotransmitter (in the catecholamine system). The increase of serotonin is directly related to the serious side effects." *Id.*

14. *Id.*

of such practices.<sup>15</sup>

The FDA approved Redux in April 1996, in the middle of the 1996 fen-phen prescription boom.<sup>16</sup> Chemically, Redux is similar to fenfluramine, but it was intended for long-term use.<sup>17</sup> The understanding was that a person must continue to take it in order to maintain the weight loss.<sup>18</sup>

Even though Redux had received FDA approval, unlike the combined use of fen-phen, the process by which Redux received FDA approval is suspect. Marianne Ewalenko, a cardiologist in Belgium, discovered leaky heart valves in seven of her patients, and found that each of them had taken diet pills.<sup>19</sup> Dr. Ewalenko informed the French manufacturer and gave several talks at obesity conferences on or detailing the unusual link between leaky heart valves and diet pills.<sup>20</sup> While this may not seem significant considering the number of people that have reported heart valve problems, Dr. Ewalenko's discovery was in 1994.<sup>21</sup> It was, in other words, more than three and a half years before the same diet pills, fen-phen, were pulled from the United States market.<sup>22</sup>

As part of the FDA approval process, U.S. pharmaceutical companies are required to notify the FDA quickly of any "serious and unexpected" adverse effects in users of drugs they market.<sup>23</sup> They must notify the FDA regardless of whether the effects occur in the United States or abroad, and whether or not they appear to be related to the drug.<sup>24</sup> American Home Products (AHP) stated after the Mayo study was released that they had known of the twenty-five Belgian cases and six others elsewhere in Europe.<sup>25</sup> AHP said it told the FDA of ten of the cases and the FDA confirms receiving eight.<sup>26</sup>

AHP decided not to report all of the patients that had developed heart valve damage because they felt the unreported cases did not fit within the reporting requirements of the FDA.<sup>27</sup> Hence, it will be left to the litigation

15. See Rheingold, *supra* note 6, at 22.

16. See Kathleen Kerr, *FDA Sued Over Diet Drug Study/Watchdog Group Investigates 'fen-phen' Safety*, *NEWSDAY*, Jan. 15, 1998, at A22. "Questions about the safety of Redux emerged in 1995 when an FDA advisory group voted not to recommend the pill for market because of concerns that it might cause brain damage in humans. But FDA officials decided to discard the advisory group's recommendation and called for another vote. In a second 6-5 vote, the group recommended that the FDA approve Redux for market." *Id.*

17. See Van Voris, *supra* note 7, at A1.

18. See Rheingold, *supra* note 6, at 22.

19. See Laura Johannes & Steve Stecklow, *Early Warning: Heart-Valve Problem That Felled Diet Pills Had Arisen Previously*, *WALL ST. J.*, Dec. 11, 1997, at A1.

20. See *id.*

21. See *id.*

22. See *id.*

23. New Drugs, 21 C.F.R. §310.305 (1998).

24. See *id.*

25. See Johannes & Stecklow, *supra* note 19, at A1.

26. See *id.*

27. See *id.* "We reported everything that we thought was 'serious and unexpected,'" says Joseph Pittelli, executive vice president of research at the company's Wyeth-Ayerst Laborato-

process to find out what exactly AHP and Interneuron knew, when they knew it, and whether they should have reported it.

*B. The Intended Use of Fen-Phen and the Reality of Use Differed Drastically*

Redux was approved by the FDA only on the further condition that it be prescribed exclusively for obesity, defined as a BMI (body mass index) of thirty kilograms per square meter or greater.<sup>28</sup> Moreover, it was to be prescribed only in conjunction with an overall regimen relating to weight loss, including active dieting and exercise.<sup>29</sup> Thus, at least as conceived by the FDA, it was a drug with some risk to be used for a serious health condition and given under controlled conditions to people who are diagnosed as obese by medical specialists.<sup>30</sup>

Although the purpose may have been to prescribe fen-phen and Redux for clinically-obese persons, the reality was something quite different. Prior to being pulled from the United States market, the prescribing of both fen-phen and Redux seem to have gotten "wholly out of hand."<sup>31</sup> Miracle weight loss ads for fen-phen appeared everywhere.<sup>32</sup> Redux was prescribed for the loss of a few pounds to persons who were not obese to begin with.<sup>33</sup> Salespersons for Redux visited every type of doctor.<sup>34</sup> The *Wall Street Journal* reported that there were eighteen million prescriptions written in one month for fen-phen in 1996.<sup>35</sup> It was reported that fen-phen was given away for free if persons signed up at diet centers such as Nutri-System.<sup>36</sup> Other reports stated a prescription could be obtained over the internet by simply using

ries. *Id.* "American Home's reason for not telling the FDA about the six European cases outside Belgium is that those pill takers' main problem was a lung disorder already known to be a possible side effect." *Id.* As for the 15 Belgian cases it did not report, the company explained that it did not consider them to be serious and unexpected because some of the Belgian patients were also taking Chinese herbs to lose weight, herbs suspected of leading to another dangerous condition, kidney disease. *See id.* *See also* New Drugs, C.F.R. § 310.305 (1998) (defining adverse drug experiences that need to be reported).

28. *See* Rheingold, *supra* note 6, at 22. Fen-phen was never assigned a BMI number by the FDA since the FDA never approved the combined use of the drugs. However, it will likely be argued by plaintiffs' lawyers that fen-phen, like Redux, should have only been prescribed for obese persons whose BMI number was greater than 30. *See id.*

29. *See id.*

30. *See id.* Redux, sold by Wyeth-Ayerst Laboratories, is also a subsidiary of American Home Products. *See id.* "The generic name for this product is dexfenfluramine, a purified form of fenfluramine. Fenfluramine is racemic, meaning that it has both levo and dextro isomers, although only the 'dextro' half is pharmaceutically active. Dexfenfluramine is just the active half of fenfluramine and the idea is that the toxicity of fenfluramine might be reduced if some side effects are being caused by the levo part." *Id.*

31. Rheingold, *supra* note 6, at 22.

32. *See id.*

33. *See id.*

34. *See id.*

35. *See id.*

36. *See id.*

their credit card.<sup>37</sup> “This conjures up pictures of a person in one state taking a faxed prescription into a drug store, signed by a doctor in another state (not licensed to practice in the state where the ‘patient’ is located).”<sup>38</sup>

Because the diet pills were so readily available, it is doubtful that the original physical examination necessary to determine suitability of the drugs was ever done, and if it was, who was then doing the follow-up physicals required to watch for side effects.<sup>39</sup> With so little medical supervision, serious heart and lung conditions were likely to go undetected until it was too late.

### *C. Medical Implications From Use of Fen-Phen and Redux*

Currently, there are two very serious side effects that are being linked to use of fen-phen and Redux. They are Primary Pulmonary Hypertension (PPH) and heart valve damage. PPH is characterized by an increased blood pressure in the blood vessels of the lungs.<sup>40</sup> PPH is a disease of relative recent recognition.<sup>41</sup> “The literature on PPH states that it is fatal in 50% or more cases, even with attempted treatment.”<sup>42</sup> “The linkage of the diet drugs to PPH has been suggested to tie to the increase of serotonin caused by taking the diet drugs.”<sup>43</sup> The Mayo study of the diet drugs found a high incidence of PPH among those with heart valve problems, “the two side effects are undoubtedly interrelated in some fashion.”<sup>44</sup>

The damage to the heart valves is the appearance of glistening white valves that are abnormally thickened and as a result, cause regurgitation, allowing blood to flow back into the heart.<sup>45</sup> Although a recent study showed

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37. *See id.*

38. John Haman, “*Fen-phen*” *Lawsuits Build Momentum*, ARK. BUS., Jan. 26, 1998, at 1. In Arkansas, the number of potential plaintiffs could be extremely large. The reason is that people from other states would travel to Arkansas to get their diet pills because it was illegal in their resident state. *See id.* “We have so many people from Mississippi and in particular, Tennessee, that came over to Arkansas by the bus load to get their prescriptions,” Nibloack, an Arkansas law firm stated. *Id.* “In Tennessee, the board of health wouldn’t allow doctors to prescribe the medication, nor would they allow pharmacies to carry them.” *Id.* “The reason we have so many potential plaintiffs in eastern Arkansas is that they were running pill mills.” *Id.*

39. *See* Rheingold, *supra* note 6, at 22.

40. *See id.* The term “primary” implies no known cause, so that if the drugs under consideration are found to be causes, the term primary can be replaced with the term secondary. *See id.*

41. *See id.*

42. *Id.* Since the earliest signs are non-specific and the doctor may not have alerted the patient to them, the condition unfortunately may not be detected in its earliest stages, and, in any case, is said to be hard to diagnose. *See id.*

43. *Id.* The serotonin constricts the veins, raising the pressure and also making the lungs more stiff, again creating resistance to air flow. *See id.*

44. *Id.*

45. *See* Rheingold, *supra* note 6, at 22. “The peculiarities of the valve damage are a glistening white or wax appearance, plaque-like encasements of the leaflets and chords, with a ‘stuck on’ appearance.” *Id.* Clinically, there was regurgitation. *See id.* All four valves were

that use of Redux for less than three months is "safe," the study fails to answer the more obvious question of the danger of longer use since it was intended to be a long-term drug.<sup>46</sup>

However, the Mayo report concludes that the drugs caused the valve condition.<sup>47</sup> The Mayo Clinic report states that the circulating serotonin is linked to the damage caused by the drugs, and further states that the drug is delivered to the right side of the heart first, which is where the PPH and valve damage has been detected.<sup>48</sup> The early signs of disease, as reported both by the Mayo Clinic and in those who have PPH, are similar: shortness of breath, especially while exercising, fatigue, and swelling (water retention) in the lower extremities.<sup>49</sup>

On November 13, 1997, the federal Department of Health and Human Services (HHS) recommended medical examinations for anyone who has taken fenfluramine, the "fen" half of fen-phen combination, or Redux.<sup>50</sup> HHS recommended that all persons who took fen-phen, Pondimin, or Redux see a physician for a thorough medical checkup with special attention to the heart and lungs.<sup>51</sup> In addition, people with a new heart murmur or heart disease symptoms such as shortness of breath or swelling in the legs should get an echocardiogram.<sup>52</sup>

Those who will have no choice but to have valve transplants will have an altered lifestyle forever.<sup>53</sup> They generally must stay on blood thinners for the rest of their lives, plus take other drugs and keep special diets.<sup>54</sup>

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involved in the cases, but the mitral valve was involved more than others. *See id.*

46. *See* Daniel Q. Haney, *Large Study Exonerates Diet Pill Redux as Cause of Heart Valve Damage*, ASS. PRESS, Mar. 31, 1998, available in 1998 WL 6648692. The study included over 1000 person some of whom were taking Redux, and others that were taking a placebo. *See id.* After taking the pill for three months, Redux was recalled and the study ended. *See id.* Afterwards, each person was given an echocardiogram to make sure there was no valve damage. *See id.* The percentage of persons who showed signs of valve damage were similar for both the Redux group and the placebo group suggesting that Redux is safe. *See id.* However, because the study ended when Redux was recalled, the effects of long term use are still unknown.

47. *See* Rheingold, *supra* note 6, at 22.

48. *See id.* The Mayo Clinic reported having only twice seen similar valve conditions; those with carcinoid syndrome, which also involves an increase of serotonin, and in those who take large dosages of ergotamine, a drug that acts similar to serotonin. *See id.*

49. *See id.*

50. *See id.*

51. *See* *Headline: On Call . . . Knight-Ridder*, DES MOINES REG., Feb. 16, 1998, at 3.

52. *See id.*

53. *See* Rheingold, *supra* note 6, at 22.

54. *See id.*



### III. *AMCHEM* AND ITS EFFECTS ON RECENT LAWSUITS SEEKING CLASS ACTION CERTIFICATION

#### A. *Federal Rule of Civil Procedure 23 and the Development of Mass Torts*

Rule 23 of the Federal Rules of Civil Procedure, governs the requirements of certification of class action law suits.<sup>55</sup> The Advisory Committee for the 1966 revision of Rule 23 noted that mass accident cases are likely to present significant questions, not only of damages, but of liability and defenses of liability affecting individuals in different ways.<sup>56</sup> The Committee advised that such cases are ordinarily not appropriate for class treatment.<sup>57</sup> The Committee's warning called for caution when individual stakes are high and disparities among class members great.<sup>58</sup>

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55. Fed. R. Civ. P. 23 (a) and (b) require:

(a) Prerequisites to a Class Action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

(b) Class Actions Maintainable. An action may be maintained as a class action if prerequisites of subdivision (a) are satisfied, and in addition:

(1) the prosecution of separate action by or against individual members of the class would create a risk of:

(A) inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class, or

(B) adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or

(2) the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or

(3) the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of the class action.

*Id.*

56. See Fed. R. Civ. P. 23 advisory committee's note.

57. See *id.*

58. See *id.*

However, when the Advisory Committee suggested changes to the class action rule in 1966, the phenomenon of mass torts did not exist. Since the 1960s, medical and environmental sciences have become more adept at detecting toxins and links between certain products and injuries.<sup>59</sup> As a result, the mass media have become more willing to cover consumer and safety issues, thereby raising public consciousness regarding potential or alleged hazards in the environment and in the marketplace.<sup>60</sup> Moreover, increased legal advertising has brought more potential plaintiffs into the legal system.<sup>61</sup> Consequently, tort litigation addressing environmental and product-related hazards has grown dramatically. With the advent of thousands of seemingly identical pieces of litigation, the term “mass tort” has emerged and become a mainstay in legal rhetoric.<sup>62</sup>

Before a class action is certified, the proposed class has to satisfy Rule 23’s requirements. First, a proposed class has to meet the prerequisite requirements of Rule 23(a), then the class has to satisfy Rule 23(b) requirements. Of importance for discussion of mass tort class actions is specifically Rule 23(b)(3), requiring commonality or predominance of factual and legal issues and Rule 23(a)(4), adequacy of representation among class members.

A class will be able to meet the commonality requirement if the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members.<sup>63</sup> The commonality requirement is readily met in certain cases alleging consumer or securities fraud or violations of the antitrust law.<sup>64</sup> Even mass tort cases arising from a common cause or disaster may, depending upon the circumstances, satisfy the predominance requirement. But it is unclear whether a mass tort such as the fen-phen/Redux tort will be able to survive the commonality test.

The adequacy of representation requirement is met when the needs of the various members of a class are not in conflict. As will be discussed in further detail later, class members that have suffered a present injury and those who may suffer in the future are in conflict. The conflict arises because persons who are presently injured need large immediate pay-outs from any settlement or verdict. In contrast are persons who may suffer future harm who need a large inflation-protected settlement fund so that when their injury arises, they will be able to get compensation. Therefore, only if the class members’ needs are not in conflict will the adequacy of representation requirement will be satisfied.

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59. See Peter H. Schuck, *Mass Torts: An Institutional Evolutionist Perspective*, 80 CORNELL L. REV. 941, 946 (1995).

60. See *id.* at 947.

61. See *id.*

62. See *id.*

63. FED. R. CIV. P. 23(b)(3).

64. See *Amchem Products, Inc. v. Windsor*, 117 S. Ct. 2231, 2250 (1997).

*B. Amchem Products, Inc. v. Windsor*

The reason for the confusion as to the fate of the fen-phen/Redux attempts for class certification is the recent Supreme Court case making the requirements for class certification harder to satisfy. On June 25, 1997, the Supreme Court held that the requirements for class certification for settlement purposes only had not been satisfied in *Amchem Products, Inc. v. Windsor*.<sup>65</sup>

In *Amchem*, the settlement class included nine lead plaintiffs designating themselves and members of their families as representatives of a class that comprised persons who had been exposed to asbestos either occupationally or through exposure of a spouse or household member.<sup>66</sup> The class included persons who had manifested physical injuries and persons who had had not manifested injuries but had been exposed to the asbestos.<sup>67</sup>

Unlike other proposed class actions that will go to trial, the *Amchem* class was seeking certification for settlement only. The Supreme Court had yet to answer the question of what consideration the fact that the class was for settlement only would play in the decision of certification. The district court held that since the class was for settlement, it did not have to meet Rule 23 requirements.<sup>68</sup> The Third Circuit held that while a class could be certified for settlement only, it had to meet the requirements of Rule 23, and did not consider the settlement at all.<sup>69</sup> However, the Supreme Court held that not only must a proposed class meet the Rule 23 requirements, but a court will also consider the adequacy of the settlement.<sup>70</sup> The Supreme Court reasoned that the requirements for certification are designed to protect absentee class members by blocking unwarranted and/or overbroad class definitions. Therefore, proposed-settlement class actions demand undiluted, even heightened attention to the other requirements because the court will lack the opportunity to adjust the settlement class as it could have done once informed by the proceedings as they unfold.<sup>71</sup>

In finding that the proposed class did not meet Rule 23's requirements, the Court first focused on the requirement of commonality, holding that questions of law or fact did not predominate over questions affecting only individual members.<sup>72</sup> The Court defined the commonality inquiry as focusing "on the legal or factual questions that qualify each class member's case

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65. 117 S. Ct. 2231, 2237 (1997).

66. *See id.* at 2239.

67. *See id.* The defendant, Center for Claims Resolution, represented twenty former asbestos manufacturers. *See id.*

68. *See Georgine v. Amchem Products, Inc.*, 157 F.R.D. 246, 315 (E.D. Pa. 1994).

69. *See Georgine v. Amchem Products, Inc.*, 83 F.3d 610, 624 (3d Cir. 1996).

70. *See Amchem*, 117 S. Ct. at 2248. The requirement of Rule 23(b)(3)(D) that trial would present intractable management problems is not a consideration for settlement-only certification because there is to be no trial. *See id.*

71. *See id.*

72. *See id.* at 2249.

as a genuine controversy.<sup>73</sup> The Court noted that the commonality requirement is not met when there exists a greater number of significant questions peculiar to the several categories of class members and to individuals within each category.<sup>74</sup>

The significant questions in *Amchem* were the means of exposure to different asbestos-containing products, for various lengths of time.<sup>75</sup> Other questions included the resulting disparities in injury and complications of causation arising from cigarette smoking.<sup>76</sup>

The commonality question also focuses upon the cohesiveness of the class as to commonality of remedies, which involves considerations of the applicable law available to different members of the proposed class, namely medical monitoring. The proposed class action sought to achieve global settlement of current and future asbestos-related claims.<sup>77</sup> The fact that all members had been exposed to asbestos products was insufficient to meet the predominance standard because different members were exposed to different products for different amounts of time in different ways and the differences in state law compounded those issues.<sup>78</sup>

Besides finding that the proposed class did not satisfy the commonality requirement, the court also held that the proposed class did not satisfy the adequacy of representation requirement.<sup>79</sup> In finding that the requirement was not met, the Court held that the named parties did not fairly and adequately protect the interests of the class because the named parties sought to act on behalf of a single giant class rather than on behalf of discrete subclasses.<sup>80</sup> The goal of class members who were currently injured and needed immediate payment conflicted with the interests of exposure-only plaintiffs in ensuring an ample, inflation-protected fund for the future. Further, the proposed settlement had no structural assurance of fair and adequate representation for diverse groups and individuals affected.<sup>81</sup>

### *C. Proposed Class Action Lawsuits after Amchem*

Since the Supreme Court's decision in *Amchem*, there have been three noteworthy cases seeking class certification in the area of mass torts. Each of those cases focused on either the commonality requirement or the adequacy of representation requirement. Only one of the three was able to satisfy both requirements and be certified as a class action.

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73. *Id.*

74. *See id.* at 2250.

75. *See id.*

76. *See id.*

77. *See id.* at 2245.

78. *See id.* at 2250.

79. *See id.* at 2251.

80. *See id.*

81. *See id.*

The first case since *Amchem* to deal with the questions of commonality and representation was *Walker v. Liggett Group, Inc.*<sup>82</sup> decided on August 5, 1997. The proposed class had received preliminary approval of a mandatory settlement class brought against cigarette manufacturers.<sup>83</sup>

The proposed class consisted of all past and present smokers of cigarettes or users of tobacco products manufactured by Liggett who reside in the United States and who claim to have suffered injury as a consequence thereof.<sup>84</sup>

The proposed class in *Liggett* is even more expansive than the proposed class in *Amchem*. The *Liggett* court was concerned with the proposed class because the complaint only named one plaintiff as representative to the class that could number in the millions.<sup>85</sup> The named plaintiff suffers from serious cancers allegedly caused by the Liggett products.<sup>86</sup>

In comparison, the proposed class sought to encompass not only smokers whose prolonged habits led to their current injury, but presumably any one of the following as well: 1) those picking up a Liggett-manufactured cigarette for the first time today, who may have manifestations 10 years, 20 years, or never; 2) those who have smoked Liggett brand with varying levels of nicotine and carcinogens; 3) those who smoked cigarettes but who also might have independent competing causal factors such as exposure to work-related chemicals; 4) those who do not have cancer now but may have it or a number of other smoking related injuries; 5) those who have been exposed to second hand smoke; 6) and a number of others whose exposure varies widely from the named representative.<sup>87</sup>

The court denied certification because the various combinations of subclasses within this "gargantuan" assembly of plaintiffs would appear to defy definition, much less division.<sup>88</sup> While the plaintiffs also sought certification for medical monitoring, West Virginia does not recognize a cause of action for medical monitoring.<sup>89</sup>

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82. 175 F.R.D. 226 (S.D.W. Va. 1997).

83. See *Walker*, 175 F.R.D. at 227.

84. See *id.* at 226. The group also included the estates of smokers, spouses, children, relatives, and significant others as their heirs or survivors, and all persons in the United States who have been, or claim to have been, exposed to environmental or second-hand smoke and have suffered an injury. See *id.* The group goes on to include all persons in the United States who have incurred losses as a result of paying for or providing treatment for diseases, illnesses, or medical conditions of the persons defined above allegedly caused by tobacco products. See *id.* Finally, all persons in the United States who have either smoked or used tobacco products, or have been exposed by way of environmental or second hand smoke, and claiming to have suffered injury as a consequence thereof and in connection with such a claim, allege that the defendants engaged in a fraud, conspiracy, or concerted activity with one or more other tobacco product manufacturers in the manufacturing, sale, or marketing of tobacco products. See *id.*

85. See *id.* at 332.

86. See *id.*

87. *Id.*

88. *Id.* at 232.

89. See *id.* at 227. See also *supra* note 83 and accompanying text.

The court also held that the adequacy of representation requirement for certification of a class action was not met.<sup>90</sup> The court held that the “bedrock consideration for the court in any certification is whether a proposed class has sufficient unity so that absent members can fairly be bound by decisions of class representatives.”<sup>91</sup> As stated in Rule 23(a)(4) “the representative parties will fairly and adequately protect the interests of the class.”<sup>92</sup> One necessary element in this requirement is whether there are conflicts of interest between named parties and the class members they seek to represent.<sup>93</sup>

The Supreme Court in *Amchem* was concerned about the conflicting interests between plaintiffs who were currently injured, needing generous immediate payments, and the exposure-only plaintiffs needing an ample inflation-protected fund for the future.<sup>94</sup> Likewise, the *Liggett* court held that the conflicting interests did not satisfy the requirement of fair and adequate representation of the class.<sup>95</sup>

The second case involving a mass tort injury, decided on August 28, 1997, was *In re Ford Motor Co. Ignition Switch Products Liability Litigation*.<sup>96</sup> Again, the court focused on the requirements of commonality and found that they had not been met.

The case contained two different classes. The first class comprised plaintiffs seeking certification of an action brought on behalf of purchasers and lessees whose vehicles had caught fire as a result of a defective ignition switch.<sup>97</sup> The second class was a nationwide consolidation of cases from various courts each involving plaintiffs owning a Ford automobile with the defective switch.<sup>98</sup> However, in the second class, there were no allegations that the class members’ vehicles had caught fire as a result of the ignition switch, and therefore, they had not sustained smoke or fire damage in their vehicles.<sup>99</sup>

In rejecting the proposed classes, the court held that common factual issues did not predominate because the questions of defect likely may have turned on facts particular to each plaintiff or at the very least, assessments of risk for each of the 158 models at issue.<sup>100</sup> The court also considered the differences in state law as precluding satisfaction of the commonality requirement.<sup>101</sup> For example, in order to prove an implied warranty claim in some

90. *See id.*

91. *Id.* (quoting *Amchem*, 117 S. Ct. at 2248).

92. FED. R. CIV. P. 23(a)(4), cited in *Walker*, 175 F.R.D. at 230.

93. *Id.* at 231 (quoting *Amchem*, 117 S. Ct. at 2248).

94. *See Amchem*, 117 S. Ct. at 2250.

95. *See Walker*, 175 F.R.D. at 227.

96. 174 F.R.D. 332 (D.N.J. 1997).

97. *See id.* at 336.

98. *See id.*

99. *See id.* at 337. Similar to a cause of action for future damages in that they have been exposed to a danger and may need compensation in the future.

100. *See Ford Motor Co.*, 174 F.R.D. at 341.

101. *See id.* at 346.

states, the plaintiff must demonstrate contractual privity with the defendant.<sup>102</sup> Plaintiffs from these states will have to prove that they purchased their Ford vehicle either from Ford itself or one of its agents as opposed to an independent car dealer or another individual.<sup>103</sup> This would require the court to undertake an inquiry that will turn on facts particular to each individual. Because both cases failed to satisfy the predominance requirement, the court concluded that certification would not be appropriate.<sup>104</sup>

The third mass tort case decided on October 17, 1997, is *In re Orthopedic Bone Screw Products Liability Litigation*.<sup>105</sup> Unlike the two previous cases, this case was given class certification for settlement purposes.<sup>106</sup> In certifying the proposed class for settlement, the court went through each of Rule 23's requirements, specifically the commonality and adequacy of representation requirements, and held that each had been met.

The settlement class consisted of all orthopedic bone screw recipients in whom an orthopedic bone screw was implanted on or before December 31, 1996, who have or may have claims against Acromed.<sup>107</sup> Spinal fusion surgery involving orthopedic bone screw implants is a substantial medical procedure.<sup>108</sup> Individuals who have undergone this substantial procedure know that the surgery has occurred.<sup>109</sup> Exposure to spinal fusion surgery is, therefore, unlike exposure to hazardous substances, where persons may not learn of their exposure until years after it occurred.<sup>110</sup> The court also received medical evidence that "the consequences of a failed spinal fusion surgery, no reduction in preoperative pain and no improvements in preoperative function or mobility, virtually always become apparent within four months or less after surgery."<sup>111</sup>

The court first focused on what consideration was to be given to the fact that the class was for settlement only. The court applied the rule from *Amchem* that while a proposed settlement may be considered as a factor, it may not be a substitute for any of Rule 23's requirements.<sup>112</sup>

The court must first find that questions of law or fact common to the members of the class predominate over any questions affecting only individual members.<sup>113</sup> First, the *Orthopedic Bone Screw* settlement class is not

102. *See id.*

103. *See id.*

104. *See id.* at 351.

105. 176 F.R.D. 158 (E.D. Pa. 1997).

106. *See id.* at 165. The problem with the bone screws was first made public in December 1993 on the ABC News program 20/20 that featured the screws. After the broadcast, thousands of people filed suit against Acromed, the manufacturer. *See id.*

107. *See id.* at 173.

108. *See id.*

109. *See id.*

110. *See id.*

111. *Id.*

112. *See id.* at 172.

113. *See* FED. R. CIV. P. 23(b)(3).

sprawling like the *Amchem* class. The class here is much more defined and congruous.<sup>114</sup> Second, there is no “futures” problem like the one present in *Amchem* because all persons who had the surgery done with the defective screw will know they are injured within four months.<sup>115</sup> A common question of fact or law is one that arises from a common nucleus of operative facts.<sup>116</sup> The common questions of law and fact in the bone screw case are on the issue of whether the orthopedic bone screws are defective products that are unreasonably dangerous.<sup>117</sup>

Rule 23(a)’s adequacy of representation requires that the representative parties fairly and adequately protect the interests of the class.<sup>118</sup> The question of adequacy of representation has two components designed to ensure that absentee class members’ interests are fully pursued.<sup>119</sup> First, “the interests of the named plaintiffs must be sufficiently aligned with those of the absentees.”<sup>120</sup> This component includes an inquiry into conflicts among various class members. The named class members must have the ability and incentive to vigorously represent the claims of the class as well as their own claims.<sup>121</sup> Second, class counsel must be qualified and must advance the interests of the entire class not just the named members.<sup>122</sup>

In *Orthopedic Bone Screws* all the members of the class were interested in seeking equitable relief and maximizing the size of the settlement fund.<sup>123</sup> The court declined to create subclasses because there were no great divergent conflicts.<sup>124</sup> Further, the claims of individuals implanted with orthopedic bone screws on or after January 1, 1997, were not included in the settlement class.<sup>125</sup> The settlement fund will not be disturbed or affected by those claims and the settlement does not bar any such claims.<sup>126</sup> Therefore, as discussed above, there is no “futures” conflict in this class like the one in *Amchem* because the court found that the representative plaintiffs did not have interests antagonistic to those of the absent class members.<sup>127</sup>

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114. See *Orthopedic Bone Screw*, 176 F.R.D. at 173.

115. See *id.*

116. See *id.* at 174.

117. See *id.*

118. See *Amchem*, 117 S. Ct. at 2250.

119. See *Orthopedic Bone Screw*, 176 F.R.D. at 175.

120. *Id.*

121. See *id.*

122. See *id.* at 176.

123. See *id.*

124. See *id.*

125. See *id.*

126. See *id.*

127. See *id.*



#### IV. DIFFERENT APPROACHES TO RESOLVING THE FEN-PHEN/REDUX LITIGATION AND THE LIKELIHOOD OF CLASS ACTION CERTIFICATION

##### A. *The Current Status of Class Action Certification*

In September of 1997, plaintiffs' lawyers litigating over the diet drugs fen-phen and Redux filed an application with the Judicial Panel on Multi District Litigation (JPMDL) in Washington seeking to consolidate the suits for pretrial proceedings.<sup>128</sup> In December, the JPMDL ordered the consolidation.<sup>129</sup> The effect of this order will be that all lawsuits currently filed and any future lawsuits filed in federal court will be handled by U.S. District Judge Louis Bechtle.<sup>130</sup> Bechtle will coordinate all pretrial hearings and lawyers on both sides will use depositions and other evidence gathered in the proceedings.<sup>131</sup> In February of 1998, Bechtle selected nine nationally known litigators to form a committee that will coordinate all of the pretrial stages of the litigation.<sup>132</sup> In May of 1998, Bechtle appointed defense liaison counsel for retailers, diet centers, and physicians in the multi-district litigation.<sup>133</sup> As discovery continues to unfold, battles over on-going medical studies continue with hopes of beginning depositions in the fall.<sup>134</sup>

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128. See Joanne Wojcik, *1997 Risk Management: Courts, Plaintiffs Lash Out at Mass Tort Settlements*, BUS. INS., Dec. 22, 1997, at 16. At the time there were just seven cases, according to papers filed with the panel. See *id.* But the plaintiffs promised more cases would follow. See *id.* By December 1997, lawyers for AHP and Internueron reported to the panel that they had already been sued in nearly 300 cases throughout the country, 200 of which are in federal court. See *id.* Thirty of the federal cases seek certification of nationwide classes; 70 are content to limit themselves to statewide classes. See *id.*

129. See *Philadelphia Federal Court to Handle Diet Drug MDL: Judge Bechtel to Oversee*, MEALY'S LITIG. RPT.: DRUGS AND MEDICAL DEVICES, Dec. 19, 1997, at 11. The JPMDL decided that locating the diet drug MDL in the Eastern District of Pennsylvania "will serve convenience of the parties and witnesses and promote the just and efficient conduct of this litigation." *Id.* Because of more than 200 individual and nationwide or statewide class actions, "centralization under section 1407 is thus necessary in order to eliminate duplicative discovery, prevent inconsistent or repetitive pretrial rulings (especially with respect to class certification), and conserve the resources of the parties, their counsel and the judiciary," the panel said in its order. *Id.*

130. See *In Brief*, LAS VEGAS REVIEW-JOURNAL, Dec. 13, 1997, at 1D.

131. See *Philadelphia Federal Court*, *supra* note 129, at 11.

132. See Richard B. Schmitt, *Judge Names Nine Lawyers as Members of Steering Committee in Diet-Pill Case*, WALL ST. J., Feb. 6, 1998, at B2. The lawyers include Stanley Chesley, of Cincinnati, Arnold Levin of Philadelphia, John Cummings of New Orleans, Di-anne Nast of Lancaster, Will Kemp of Las Vegas, Darryl Tschirn of La Jolla, Michael Hausfeld of Washington D.C., Roger Brosnahan of Minneapolis and Elizabeth Cabraser of San Francisco. See *id.* Under an order issued by Judge Bechtle, the lawyers said they expect to move quickly, hopefully launching pretrial fact finding, such as the taking of depositions, in a month or two at most. See *id.* In addition, the judge ordered the lawyers to develop a detailed list of plaintiffs in the case, including information about their alleged injuries, in an effort to gauge the scope of the proceeding. See *id.*

133. See *MDL Defense Liason Counsel Designated for Retailers, Physicians, Diet Centers*, MEALY'S LITIG. REP.: FEN-PHEN/REDUX, May 1998, at 8.

134. See *Fen-Phen Plaintiffs Seek Ongoing Study; Scientific Privilege Cited*, MEALY'S

Most important to the discussion of class action is that Bechtle will be the judge that will ultimately determine whether any of the proposed class actions will be certified.<sup>135</sup> However, once the cases have completed pretrial proceedings, including determinations of class action certification, they will be returned to the federal courts in which they were originally filed.<sup>136</sup>

### *B. Individual Lawsuits versus Class Action Lawsuits*

Perhaps one of the more contested aspects of the fen-phen/Redux litigation is whether to pursue individual lawsuits or class action lawsuits.<sup>137</sup> Both approaches have their supporters among plaintiffs' lawyers. But the considerations of which to pursue go far beyond having to satisfy Rule 23's requirements. At the heart of the debate are the equitable considerations of plaintiffs' needs: 1) the need for swift resolution of their claim, that is better resolved by individual suits; and 2) the need to represent potentially millions of plaintiffs with common claims, that is best resolved by class actions.<sup>138</sup>

The issues presented by the *Amchem* settlement are of interest to all lawyers struggling with the question of individual rights and aggregate justice.<sup>139</sup> The fundamental question is whether the traditional models of adjudication and due process, designed to protect the individual rights of litigants, can be expanded to meet the needs posed by mass product liability involving hundreds or thousands of cases.<sup>140</sup> Plaintiffs' lawyers like Paul Rheingold, head of American Trial Lawyers Association's section on diet pill litigation, prefer the case-by-case approach, which he says is not only faster than a class action but more equitable. In his opinion, the biggest problem with class action lawsuits is attorneys who accept clients solely to enhance the power of the class action lawsuit.<sup>141</sup> In the end, this benefits lawyers with large attorney fees for cases that were too weak to survive on their own.<sup>142</sup> In addition, by rewarding class action lawsuits with large settlements, the inevitable result will be to reduce the compensation available to plaintiffs with serious medical needs such as heart valve or lung transplants.<sup>143</sup> In other

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LITIG. RPT.: DRUGS AND MEDICAL DEVICES, May 22, 1998, at 21; Zina Moukheiber, *Management, Strategies, Trends*, FORBES, July 6, 1998, at 176.

135. See Schmitt, *supra* note 132, at B2.

136. See *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The Court held that a district court conducting the pretrial proceedings cannot transfer the case to itself for trial. *See id.*

137. See Hansen, *supra* note 9, at 24.

138. *See id.*

139. See Eric D. Green, *Advancing Individual Rights Through Group Justice*, 30 U.C. DAVIS L. REV. 791 (1997).

140. *See id.*

141. See Hansen, *supra* note 9, at 24.

142. See Sheila R. McCann, *The Jury is Still Out on Class Action Lawsuits Option Serves Plaintiffs Well, Some Say; Others Claim the Only Winners Are the Lawyers; Class Actions are On Trial*, SALT LAKE TRIB., Mar. 22, 1998, at A1.

143. See Hansen, *supra* note 9, at 24.

words, adjudication and due process do not appear to be unlimited resources; supplying all resources to one class action may inevitably deprive others of their share.

The potential outcomes reflect the natural progression of a relatively new phenomenon—mass tort litigation—from a collection of individual cases to a consolidated or class-wide case subsuming thousands of parties.<sup>144</sup> In mass tort class actions, because of the numerosity requirement, one must be concerned simultaneously with the rights of thousands of individuals.<sup>145</sup> “Given the nature of our legal system, some of these individuals are going to be at the end of a very long line, figuratively shouting up the line ‘turn on the due process’ only to hear echoing back, ‘sorry, you’ll have to wait ten years,’ or worse, ‘sorry, it’s all run out.’”<sup>146</sup> Because class actions involve thousands of plaintiffs, most of whom are not known, it is hard to accurately formulate a result. The potential for a settlement fund to run out of money before meeting the needs of all persons injured by fen-phen or Redux is great. The one way to avoid the problem of an insufficient fund is to have individual lawsuits where each claim is assessed for its own merit and compensated accordingly.

However, some of the values furthered by class actions, access, economic efficiency, flexibility and economic optimality, and elimination of risk, cannot be achieved by individual lawsuits.<sup>147</sup>

The primary virtue of class actions is that they provide a mechanism for access to thousands of people who might not otherwise be represented or have any realistic chance of getting their case heard.<sup>148</sup> Many former users of fen-phen and Redux need to have an echocardiogram to ascertain the health of their heart but unfortunately, many of those persons cannot afford the cost of test. Their only hope is to join a class action lawsuit that will try to force the diet pill manufacturers and other defendants to pay for the procedure.<sup>149</sup> Thus, without the class action, it is unlikely that their individual case would ever be heard because it would be too expensive for each person to litigate compared to the approximately \$1,000 cost of an echocardiogram.<sup>150</sup>

The second benefit is economic efficiency, both in resources and in time.<sup>151</sup> Class actions can be an incredibly powerful tool by allowing individual victims to come together to fight a larger, stronger, more well-armed defendant. For plaintiffs’ lawyer Bill Marler, who filed a class action lawsuit for victims of E. coli infected hamburgers from Jack in the Box, class ac-

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144. See Green, *supra* note 139, at 791.

145. See *id.* at 798.

146. *Id.* at 799.

147. See *id.* at 801.

148. See *id.*

149. See McCann, *supra* note 142, at A1.

150. See *infra* note 159 and accompanying text.

151. See Green, *supra* note 139, at 801.

tions level the playing field.<sup>152</sup> Plaintiffs' lawyer Wendell Gauthier, who filed the first national class action lawsuit against the tobacco industry in 1994, says that he was able to discuss settlement only because of the power of class action lawsuits; before class actions, the tobacco industry was able to use all of their economic resources to defeat every individual lawsuit.<sup>153</sup>

The third benefit is flexibility and economic optimality in shaping the remedy, allowing for the types of remedies that are needed in many of these situations. For example, different types of pay-outs for different types of proof, taking into account the fact that some people have certain kinds of proof and other people do not.<sup>154</sup>

Finally, a major benefit of settlement classes is elimination of risk.<sup>155</sup> Without a known limit on liability, there is a risk that defendants could go bankrupt paying litigation fees for individual cases and some plaintiffs would never recover.

Weighing both of these considerations, it seems that class action lawsuits are most effective for the small financial claims such as consumer fraud, for which the rule was originally intended.<sup>156</sup> Within that framework, claims for medical testing and monitoring would be best resolved in the class action arena.<sup>157</sup> In contrast, claims for serious injuries, such as valve transplants or even wrongful death claims, are better left to individual lawsuits because individualized justice will ensure full compensation as opposed to merely being part of some monstrous class action.

### *C. Satisfying the Requirements of Class Action Certification*

Of the complaints alleging a class action in federal court, there are two predominate themes; one class action seeks costs of medical monitoring and the other seeks damages for serious present and future injuries.<sup>158</sup> While the two different class actions seek different remedies, both will still have to meet the requirements of Rule 23 as interpreted in *Amchem*. Of significance are the requirements of adequacy of representation and commonality of the class.<sup>159</sup>

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152. See McCann, *supra* note 142, at A1.

153. See *id.*

154. See Green, *supra* note 139, at 801-02.

155. See *id.* at 802.

156. See FED. R. CIV. P. 23 advisory committee's note.

157. See McCann, *supra* note 142, at A1.

158. See *Fen-Phen/Redux*, MEALEY'S LITIG. RPT., Sept. 1997, at D-1. Class actions for medical monitoring seek compensation for the cost of medical examinations both past and future for all users of the diet drugs and also medical tests including the expensive echocardiogram test that can cost upwards of \$1,000. See *id.* Class actions for serious injuries seek to represent persons in the United States and U.S. territories who have suffered or may suffer injury from fenfluramine, phentermine and dexfenfluramine. See *id.* Injuries include persons who have developed or will develop PPH, valvular disorder, or other serious injury. See *id.*

159. See discussion, *supra* Part III.

To succeed in getting a class action certified, the requirement of adequacy of representation first has to be satisfied. After considering *Amchem* and the cases that have subsequently been decided, it seems that present and future injuries cannot be maintained in the same class. The conflicts between recovery for immediate harm and recovery for possible future harm are in conflict. They are in conflict because plaintiffs with present injuries will want full compensation immediately for their injury. Plaintiffs seeking future damages want there to be a limited pay-out now to ensure that if they develop valvular disease or PPH there will be enough money in the fund to award full compensation of their injury. Of the cases discussed *supra* Part III, two were denied class certification and the only one that was granted class certification was the class without damages for future plaintiffs. Therefore, it seems the one clear lesson learned from *Amchem* is that in order to satisfy the adequacy of representation requirement, class actions for future injuries cannot be combined with class actions for present injuries to form one huge class.

However, some class action lawsuits that have been filed in federal courts seeking certification have not followed this conclusion.<sup>160</sup> Instead, they are seeking to represent both present and future victims of the diet drugs in a "serious injury class."<sup>161</sup> Although the court has made no determination on certification of any class actions, it seems unlikely that the serious injury class will win certification because of the conflict in representing class members whose compensation needs are at odds with each other.

Although the solution to this problem would seem to be simply dividing the two classes, one for present injury and one for future injury, the subclasses will still likely not succeed in their attempts at certification for failure to meet the second requirement of commonality discussed below.

Distinct from present and future serious injury class actions are medical monitoring class actions.<sup>162</sup> Unlike the serious injury class, the medical monitoring classes do not have the same representation conflicts as the serious injury classes. The reason is that the medical monitoring class actions are seeking damages that will have a known pay-out now and in the future, namely medical examinations and echocardiograms.<sup>163</sup> In contrast, the serious injury class does not have a known pay-out as it is impossible to ascertain who and to what degree class members will be injured now and in the

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160. See *Fen-Phen/Redux*, *supra* note 158, at D-1.

161. *Id.*

162. See *id.* The first class action was filed in San Francisco with a claim that the manufacturers of fenfluramine and phentermine failed to adequately warn that the FDA had not approved concomitant use of the drugs, plaintiffs contend in a class action filed July 9, 1997. See *id.* The complaint lists counts for strict product liability pursuant to Restatement (Second) of Torts Section 402A (1965), failure to warn, negligence, and breach of express and implied warranty. See *id.*

163. See *Class Action Complaint Filed Against Makers of Fen-Phen Diet Drugs*, MBALY'S LITIG. RPT.: DRUGS AND MEDICAL DEVICES, July 18, 1997, at 8.

future.<sup>164</sup> As a result of the different remedy sought in the medical monitoring class, there is no conflict between plaintiffs trying to collect now and in the future for undetermined amounts and the requirement of adequate representation will likely be satisfied.

As mentioned previously, even if the adequacy of representation requirement is satisfied by dividing the present and future injury classes, the classes will have a difficult time overcoming the commonality requirement because there are many issues as to causation and possible defenses.<sup>165</sup> In both class actions (medical monitoring and serious injuries), the defendants include the diet pill manufacturers, distributors, doctors and diet centers that gave away or prescribed the diet pills.<sup>166</sup> The likely defenses that each one will assert will depend on whether the class action is seeking damages purely because they were exposed to the diet drugs (medical monitoring) or damages for injuries that have or have not yet manifested in the form of heart valve damage or PPH. The success of the class action certification will likely turn on whether the class action is seeking damages for medical monitoring or damages for present and future serious injury.

The advantages of class actions that are seeking medical monitoring costs over class actions that are seeking damages for serious injuries are significant. The strategy of pursuing medical monitoring costs avoids many causation and damages issues peculiar to individual plaintiffs.<sup>167</sup> In the medical monitoring class, all class members used either fenfluramine ("fen") or dexfenfluramine ("Redux"), and are seeking medical expenses related to the exposure of the diet drugs. Any defenses that would consider the individual plaintiffs' medical history would be irrelevant because they are seeking damages for testing and not compensation for manifested injuries. Further, as mentioned previously, the HHS advised fenfluramine and dexfenfluramine users to take precautionary steps by getting a medical exam, which might include an echocardiogram. The pronouncement by HHS does not distinguish the need for medical monitoring based upon individualized case histories, circumstances of usage, or whether the drugs were used in combination with other drugs, such as phentermine ("phen").<sup>168</sup> Unfortunately, there is one serious drawback to the medical monitoring class action. The

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164. *See id.* Plaintiffs seek to represent persons nationwide who have taken fenfluramine, phentermine, and dexfenfluramine, either individually or in combination. *See id.* The purported class seeks a medical monitoring program to monitor alleged dangerous side effects, including PPH and valvular heart disease. *See id.* The complaint states that defendants encouraged the combination use of the drugs in order to increase sales. *See id.* Plaintiffs contend that the drug makers undertook an "advertising blitz" to create widespread use of the drugs. *See id.* Also, plaintiffs assert that the manufacturers understated health hazards and risks associated with use of the drugs. *See id.*

165. *See Fen-Phen/Redux*, *supra* note 158, at D-1.

166. *See id.*

167. *See Van Voris*, *supra* note 7, at A1.

168. *See Medical Monitoring Class Certification Sought in New Jersey, MEALY'S LITIG. RPT.: FEN-PHEN/REDUX*, June 22, 1998, at 12.

drawback is that the cause of action for medical monitoring is not recognized in certain jurisdictions.<sup>169</sup> As a result, plaintiffs in some jurisdictions will not be able to be a part of the class and will be left to pursue alternate means of compensation.<sup>170</sup>

While the medical monitoring cause of action will likely be able to satisfy the commonality requirement, it is doubtful that the serious injury class will also. For the serious injury class, there are too many questions as to causation and defenses. For example, age is a relevant factor in determining the possible causes of valvular damage.<sup>171</sup> A person of advanced age may have had a rheumatic disease due to infection earlier in their life that could manifest itself now as valve damage.<sup>172</sup>

Another consideration is the severity of the injury. Valvular disease can range from minor to severe damage. Some doctors have suggested that once you have valvular disease, the damage will continue to become more severe even if you stop taking the diet drugs.<sup>173</sup> Therefore, once you show signs of minor valve damage you can be sure that it will become more severe. However, that statement does not reflect reality. In a study of over 1,000 persons, some using the diet drugs and others not, both groups had almost the same percentage of persons with minor valvular disorder.<sup>174</sup> The study merely shows what experts already knew—that minor valve disorder can be found with sophisticated diagnostic machines in almost everyone.<sup>175</sup> The implication is that persons with minor valvular disorder may develop a serious injury resulting in a valve transplant or the minor valve disorder could remain minor because it is not caused by the diet drugs but is rather a common occurrence in most people. Although the solution to this problem would be to include only persons who have severe heart damage, that solution is also flawed. The severe valvular disease may have been caused by something in their childhood.

Therefore, having a class action for persons with serious injuries does not meet the common questions of causation because not all valvular disorders will lead to severe damage and not all severe valve damage is caused by fen-phen or Redux. With these differences, it seems unlikely that plaintiffs'

169. See Van Voris, *supra* note 7, at A1.

170. See *id.* Alternative means of compensation include filing individual lawsuits or joining a different class action hoping to recover costs that have already been paid out. See *id.* The obvious problems with this choice are that diet drug users may not have the economic resources to front the medical costs for an indefinite period of time. See *id.* In addition, plaintiffs will have a hard time getting their case to trial because the dollar amount is so low. See *id.*

171. See Guy P. Curtis, Lecture on fen-phen at Thorsnes, Bartolotta, McGuire & Padilla (Feb. 23, 1998). Dr. Curtis is the Director of Cardiac Electrophysiology at the Scripps Clinic in La Jolla, CA.

172. See *id.*

173. See *CBS This Morning*, *supra* note 1.

174. See Haney, *supra* note 46.

175. See *id.*

lawyers will be able to tailor a class of plaintiffs that can overcome the problems of causation. The end result is, of course, that the class will not meet the requirement of commonality.

In addition to problems of causation, the serious injury class will also have problems with various defenses asserted by some of the defendants. Possible problems include which defendants had knowledge of the potential health hazards. While AHP and Interneuron may have known of the health hazards because of similar reports in Europe, it is not likely that the diet centers or doctors knew of those cases.

Other possible problems that involve individual issues include prescribing fen-phen/Redux to persons who were not obese, prolonged use, overdosing, failure to or inappropriate monitoring, prescribing off label, and lack of informed consent. Redux was approved for use by persons whose BMI number was thirty or above. However, in many cases, persons whose BMI number was significantly lower than thirty were still prescribed Redux.<sup>176</sup> Therefore, defendants will argue that since not all purported class members should have been prescribed the diet drugs, individual questions as to BMI numbers of each plaintiff will predominate the lawsuit. Similar to the problems with individual class members' BMI number, individual questions as to how long plaintiffs were prescribed the diet drugs and in what dose will predominate the lawsuit.<sup>177</sup> Another issue is how quickly the plaintiffs were first diagnosed with medical problems. The physicians had a duty to monitor and do periodic examinations on all persons who were prescribed the diet pills. Individual issues remain as to which doctors competently monitored, or even monitored at all, their patients health and whether they should have been able to detect heart murmurs in a timely manner.

Finally, the diet pill manufacturers will to assert that it was the doctors' responsibility to adequately warn the patients and it was the doctors, not the manufacturers, who prescribed the diet pills to persons who were not clinically obese. In addition, most of the plaintiffs in the purported class will have had different doctors. The defendant doctors will likely have their case severed from the class action, requiring them to be pursued on an individual basis if at all. What is left for the class action is the fact that each doctor may have informed their patients to varying degrees, some may have had no in-

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176. See Paul J. Napoli, *Physician Liability in Diet Drug Litigation*, N.Y.L.J., Apr. 20, 1998, at 1. The reason the BMI number is significant is that the rationalization for approving Redux was balancing the health risks of obesity with the health risks of Redux. See *id.* The FDA decided that the risks of obesity far outweighed any possible side effects of Redux. See *id.* However, for persons who were not obese and needed to lose only ten or fifteen pounds, the risks were not outweighed. See *id.*

177. See *id.* Fenfluramine and phentermine were approved for use on a short-term basis, i.e., over a few weeks. See *id.* The reason was that after a few weeks, the person would start to develop a tolerance for the diet drugs and their effectiveness would be gone. See *id.* Instead of discontinuing the use, physicians were continuing to prescribe the diet drugs in either the same dosage (which was futile) or would increase the dosage thereby making the injury to plaintiff that much worse. See *id.*



formation while others may have had full disclosure. By having various defenses by various defendants, the requirements of commonality, especially common questions of law and fact, are not present within this class. What is present are lingering questions that are tailored to the individual plaintiff or defendant and are not common among the entire class.

#### V. CONCLUSION

After considering both the causation issues and various defenses of knowledge and disclosure, it does not seem likely that a class for serious injuries will be certified. Even if the class was divided into present and future injuries in order to overcome the representation requirement, the classes would still fail to meet the commonality requirement. Too many questions regarding the individual plaintiffs' severity of injury and cause of injury, as well as different defenses available to the defendants, ends up resembling less of a unified common class and more of a group of individual cases. Consequently, it is probable that the only class action lawsuits that will be certified are those seeking medical monitoring, provided that the respective jurisdiction allows it. Moreover, the serious injury class, whether present or future, will not meet the rigid requirements of Rule 23 as interpreted in *Amchem* because there is neither adequate representation nor commonality among the class members.

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