

**PRECEDENTIAL**

UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT

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Nos. 03-3401, 03-3402, 03-4465 & 04-3661

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IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

Clara Clark, Linda Smart and all other  
class members represented by Fleming  
& Associates, L.L.P.,

Appellants in No. 03-3401

Hariton & D'Angelo, LLP and  
Napoli, Kaiser, Bern & Associates, LLP,  
on behalf of themselves, claimant  
James Axford and similarly situated  
class members represented by the  
Hariton and Napoli Firms whose claims  
are affected by Pretrial Order No. 2929,

Appellants in No. 03-3402

Shanne Webb-Cochran, Renai Kuykendall,  
Willa Sartin, Dawn Stewart and  
Joanne Valenti, on behalf of themselves

and all other class members who have  
ingested fen-phen and who suffer, or  
will suffer, from elevated pulmonary  
hypertension not secondary to valvular  
heart disease,

Appellants in No. 03-4465

Doris Weller and Ellen Carey,  
whose claims are affected by  
Pretrial Order No. 3849,

Appellants in No. 04-3661

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Appeals from the United States District Court  
for the Eastern District of Pennsylvania  
(MDL No. 1203)  
District Judge: Honorable Harvey Bartle, III

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Argued on April 22, 2005

Before: ROTH, FUENTES and STAPLETON, Circuit  
Judges.

(Filed: November 30, 2005)

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OPINION

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**ROTH, Circuit Judge:**

These appeals arise from the District Court's efforts to oversee the Nationwide Class Action Settlement Agreement in the multi-district (MDL) 1203 litigation between Wyeth<sup>1</sup> and a class comprising former users of Wyeth's diet medications, fenfluramine and dexfenfluramine. This appeal is the consolidation of challenges by three different groups of Appellants, all claiming that they should not be bound by the Settlement Agreement. For the reasons discussed, we find that all three groups of Appellants are bound by the Settlement Agreement and we will affirm the District Court's decision.

**I. The Settlement Agreement**

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<sup>1</sup> In March 2002, the manufacturer of the drugs in question changed its name from American Home Products to Wyeth. We will refer to it as Wyeth.

The history of this case is detailed in In re Diet Drugs Prods. Liab. Litig., 282 F.3d 220, 225-29 (3d Cir. 2002) and will only be briefly summarized here. In 1999, Wyeth reached a settlement that provided a variety of remedies for users and former users of its diet medications. The District Court approved the plan in Pretrial Order 1415 and the accompanying memorandum. The remedies provided depended on whether the class members were ultimately diagnosed with one of several heart conditions.

Each class member was placed into one of five groups. Class 1 consisted of class members who did not know whether they had a condition termed FDA positive ventricular heart disease (VHD)<sup>2</sup>, and was further subdivided into class members who had used the diet drugs for more than 60 days

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<sup>2</sup> “FDA Positive VHD” refers to a severity of heart valve regurgitation, as defined in the Settlement Agreement.

and class members who had used the drugs for less than 60 days. Class 2 consisted of class members who knew they had FDA positive VHD and was also subdivided based on diet drug usage of more or less than 60 days. Class 3 was comprised of class members who did not know whether they had FDA positive VHD at the time of settlement, but were diagnosed with a less serious condition called mild mitral regurgitation by the end of the settlement screening period.

The settlement provided funding for screening tests to determine whether class members had qualifying heart disease and for compensation for the cost of the drugs and medical treatment, depending on the ultimate diagnosis. The Settlement Agreement expressly barred participating class members from pursuing any settled claims against Wyeth.

The settlement provided the option for class members to opt out at the time of settlement (“initial opt outs”) or to be

bound by the Settlement Agreement. Those class members diagnosed as having FDA positive VHD by a specified date could either register for further benefits or exercise an “intermediate opt out” and sue Wyeth in the state tort system. In addition, those class members diagnosed as having a lesser condition, mild mitral regurgitation, could either claim compensation under the settlement or exercise a “back end opt out” and sue Wyeth in the tort system. The class members who exercised intermediate or back end opt outs are collectively referred to as “downstream opt outs.” In exchange for Wyeth’s waiver of a statute of limitations defense, class members exercising downstream opt out rights cannot sue for punitive damages.

The Settlement Agreement explicitly excluded those individuals with a more serious condition, primary pulmonary hypertension (“PPH”), allowing them to sue Wyeth in the



state tort system. The settlement did not include any recovery for plaintiffs alleging a variety of conditions, including neurotoxicity and elevated pulmonary hypertension (“PH”), because the District Court found that the evidence did not support a connection between the use of diet drugs and these conditions.

## **II. Jurisdiction and Standard of Review**

We have jurisdiction over Pretrial Orders 2929, 3849 and 3085 because they are all final orders of the District Court within the meaning of 28 U.S.C. § 1291.

The District Court’s legal conclusions are subject to plenary review. In re Prudential Ins. Co. of Am. Sales Practices Litig., 261 F.3d 355, 363 (3d Cir. 2001). We review the District Court’s determination of adequacy of representation as an exercise of its discretionary authority in class action proceedings for abuse of discretion. In re

Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 284, 299 (3d Cir. 1998). All underlying factual issues are reviewed for clear error. Id.

### **III. Due Process Protections for Class Members**

In all three appeals before us, Appellants argue that they are not bound by the Settlement Agreement because their due process rights were not upheld, either because of inadequate notice or inadequate representation. A threshold question in all three of these appeals is whether these Appellants are entitled to bring a collateral attack on the Settlement Agreement.

A class member must have certain due process protections in order to be bound by a class settlement agreement. The general principle is that “there has been a failure of due process only in those cases where it cannot be

said that the procedure adopted, fairly insures the protection of the interests of absent parties who are to be bound by it.” Hansberry v. Lee, 311 U.S. 32, 42 (1940). In a class where opt out rights are afforded, these protections are adequate representation by the class representatives, notice of the class proceedings, and the opportunity to be heard and participate in the class proceedings. Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 811-12 (1985). The adequate representation requirement “serves to uncover conflicts of interest between named parties and the class they seek to represent.” Amchem Products, Inc. v. Windsor, 521 U.S. 591, 625 (1997). This requirement is codified in Fed. R. Civ. P. 23(a)(4), which requires that “the representative parties will fairly and adequately protect the interests of the class.”

There must be a process by which an individual class member or group of class members can challenge whether

these due process protections were afforded to them. Grimes v. Vitalink Comm'ns Corp., 17 F.3d 1553, 1558 (3d Cir. 1994). This challenge can take the form of an appeal of the class certification itself, a collateral attack on an already-certified class, or a Rule 60(b) motion. In re Real Estate Title & Settlement Servs. Antitrust Litig., 869 F.2d 760, 767 (3d Cir. 1989).

Class members are not, however, entitled to unlimited attacks on the class settlement. Once a court has decided that the due process protections did occur for a particular class member or group of class members, the issue may not be relitigated. Appellants understandably rely heavily on Stephenson v. Dow Chemical Co., 273 F.3d 249 (2d Cir. 2001), *aff'd* by equally divided Court, 539 U.S. 111 (2003), in support of their insistence that they have a right to collaterally attack the adequacy of representation determination of the

class action court. While Stephenson supports appellant's position on this issue, it is inconsistent with circuit case law by which this panel is bound. In Carlough v. Amchem Products, Inc., 10 F.3d 189 (3d Cir. 1993), we held that notice and failure to exercise an opportunity to "opt out" constitutes consent to the jurisdiction of the class action court by an absent member of a plaintiff class even when that member lacks minimum contact with the class action forum. Then, in Grimes v. Vitalink Communications Corp., 17 F.3d 1553 (3d Cir. 1994), we further held that, where the class action court has jurisdiction over an absent member of a plaintiff class and it litigates and determines the adequacy of the representation of that member, the member is foreclosed from later relitigating that issue. Thus, it follows that challenges to the terms of a settlement agreement, itself, are not appropriate for collateral review. See In re Orthopedic Bone Screw Products

Liab. Litig., 350 F.3d 360, 364-65 (3d Cir. 2003) (holding that a “challenge to the propriety of the settlement agreement and its terms” is foreclosed by the approval of the settlement agreement in a final, unappealable order.)

#### **IV. Current Challenges to the Settlement Agreement**

The appeals before this Court are from three Pretrial Orders of the District Court, all addressing variations on the same situation. Pretrial Order 2929 (appeals docketed at 03-3401 and 03-3402) was the denial of a motion made after settlement by Appellants, all of whom were downstream opt outs, arguing that their due process rights were violated by inadequate representation at settlement. Pretrial Order 3085 (appeal docketed at 03-4465) was the denial of a motion made after settlement by Appellants, all of whom had PH, a condition not covered by the settlement, arguing that their due process rights were violated by inadequate representation at

settlement.<sup>3</sup> Pretrial Order 3849 (appeal docketed at 04-3661) was the grant of a motion by Wyeth to enjoin Appellants, who were not diagnosed by the settlement deadline, from bringing suit in New York to challenge the adequacy of their notice and representation at settlement.

Applying due process protections to the facts of each set of Appellants, we find that they have already received adequate procedural protections. No collateral review is available when class members have had a full and fair hearing and have generally had their procedural rights protected during the approval of the Settlement Agreement. Collateral review is only available when class members are raising an issue that was not properly considered by the District Court at

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<sup>3</sup> PTO 3085 also included class members who have PPH, raising a challenge based on inadequate representation, but those PPH-diagnosed class members are not part of this appeal.

an earlier stage in the litigation. Here, the District Court carefully examined the adequacy of representation and procedural protections at the fairness hearing, and that examination duly covered the variations presented by the appeals before us. Thus, the District Court was correct in rejecting all three challenges. To illuminate this conclusion, we will address the three appeals before us individually.

**A. Downstream Opt Outs**

As to the first group of Appellants, the downstream opt outs, it is clear that the issue of adequacy of representation was explicitly addressed by the District Court at the fairness hearing. See PTO 1415 Memorandum at 99-122.

The District Court specifically considered Appellants' arguments regarding intraclass conflicts. The District Court gave considerable treatment to the argument that this Settlement Agreement had problems analogous to those in



Amchem Products, Inc. v. Windsor, 521 U.S. 591 (1997).

The District Court specifically found that there is no “futures” problem with this Settlement Agreement because, unlike in Amchem, where asbestos class members could not know of their exposure or disease, potential class members are aware of their exposure to diet drugs and any injuries from that exposure are detectable in medical tests – the injuries will not remain latent for 30 or 40 years. The District Court specifically found that the medical evidence overwhelmingly shows that the heart conditions caused by these diet drugs are detectable shortly after use of the drugs ceases and that there is no evidence that the conditions caused by these drugs are latent. See PTO 1415 Memorandum at 105 (discussing numerous medical studies).

Further, the District Court also rejected the argument that this Settlement Agreement lacks the structural protections

that doomed the settlement agreement in Amchem. The District Court specifically found that this Settlement Agreement includes structural protections to protect class members with varying diagnoses, pointing to the ability of a particular class member to “step up” to higher compensation levels as their disease progresses. PTO 1415 Memorandum at 113-4.

The District Court also considered the argument that class members who would exercise downstream opt out rights were subject to an improper trade-off during settlement negotiations. After considering the relevant case law, the District Court concluded:

In sum, the court finds that Class Counsel’s agreement to waive punitive damage claims on intermediate and back end opt outs in exchange for protection against statute of limitations and claim splitting defenses represents

a fair and wholly appropriate trade-off. These provisions do not represent an improper allocation, nor do they affect the procedural fairness of the settlement.

PTO 1415 Memorandum at 115.

These Appellants argue that because the specific individuals who are Appellants in this case were not the specific individuals who raised objections at the fairness hearing, they must have the opportunity to litigate the issue themselves. This argument ignores the underpinnings of the class action mechanism. If this argument were to be accepted, each class member would be able to relitigate each issue, rendering the class action mechanism pointless. While it is true that the specific Appellants in this case did not, themselves, litigate this issue at the fairness hearing, other class members who are representative of them did litigate this issue and the District Court considered all of the arguments

and evidence in that regard. Appellants were represented by other class members at the fairness hearing and because the District Court decided that the class was adequately represented, the issue of adequate representation of Appellants has already been fairly litigated.

Appellants also argue that this Court has not yet addressed the adequacy of representation because the appeal from the approval of the class settlement was voluntarily withdrawn due to settlement between Wyeth and the individual class members filing that appeal. There is no support for the proposition that because a party does not pursue an appeal of a District Court's order, that order does not bind the class members or cannot be considered for its preclusive effect. See Orthopedic Bone Screw, 350 F.3d at 361 (noting that "appeal of class settlement was voluntarily dismissed, rendering the District Court's order final and

unappealable.”)

It is also worth noting that this Court has, in other appeals from this class settlement, addressed the adequacy of representation. See In re Diet Drugs, 282 F.3d 220, 231 (3d Cir. 2002) (“That various subclasses in the Brown class could find themselves in competition does not by itself establish an actual conflict undermining adequacy of representation”), In re Diet Drugs, 93 Fed. Appx. 338, 344 (3d Cir. 2004) (observing “[t]hat certain class members were differently situated with respect to filing deadlines should not be taken to mean that their overall interests diverged from that of the general class” and concluding that representation was adequate).

This first group of Appellants, the downstream opt outs, were adequately represented at settlement and that same issue has already been raised and litigated. These Appellants

have been afforded the due process protections necessary for the Settlement Agreement to bind them. Therefore, these Appellants cannot now challenge the adequacy of their representation yet again by bringing this collateral attack.

**B. Elevated Pulmonary Hypertension**

The second group of Appellants, those with PH, also cannot bring a collateral attack on the class settlement at this stage in the litigation. This is for the same fundamental reason as the downstream opt outs – the issues raised here were raised by class members at the fairness hearing and rejected by the District Court. The District Court heard extensive testimony concerning various conditions and their connection to diet drug use and approved the exclusion of PH from the Settlement Agreement. PTO 1415 Memorandum at 29-41. In fact, the District Court specifically treated PH as a symptom of many heart conditions, rather than a separate

injury caused by diet drugs in its detailed discussion of the medical evidence. PTO 1415 Memorandum at 28-9, 32, 37, 39. Further, the District Court approved the Settlement Agreement's definition of PPH, a serious lung disease that these Appellants argue is based on a flawed definition that wrongly excludes them. PTO 1415 Memorandum at 37-41.

As discussed above, the District Court heard and rejected arguments that representation was not adequate for those with differing conditions. PTO 1415 Memorandum at 113-5. The District Court specifically found that class members had "meaningful opt out rights," unlike the class members in Amchem. PTO 1415 Memorandum at 114. In addition, beyond the District Court's consideration of these issues at the fairness hearing, the District Court has already heard and rejected collateral challenges by various class members based on these same arguments. See PTO 2383

(appointing special master to administer screening of class members who meet requirements for PPH delineated in PTO 1415), PTO 2623 (concluding that moving class members do not meet definition of PPH, denying argument that definition of PPH should be expanded, and finding that class members' due process rights were not violated by the Settlement Agreement).

Thus, the District Court not only addressed the issues raised here by the PH Appellants at the fairness hearing, but has also subsequently addressed the adequacy of their representation and due process protections. As such, this group of Appellants has received the due process protections necessary for them to be bound by the class settlement and cannot relitigate those issues here.

**C. Post-Screening Deadline Diagnoses**

The third group of Appellants, who were diagnosed



after the screening deadline expired, face a similar problem as the first two sets of Appellants. Again, fairness of notice and adequacy of representation have already been litigated.<sup>4</sup>

#### The District Court's approval of the Settlement

Agreement concluded that the notice provided was more than

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<sup>4</sup> As a threshold matter, the jurisdiction of the District Court over the third group of Appellants is disputed. The Appellants argue that the District Court had no independent basis of jurisdiction over them because they brought their suit challenging the Settlement Agreement in New York. This argument is without merit. Appellants brought suit in New York state court and Wyeth removed the case to federal court. The MDL panel then transferred the case to the District Court. The case law, generally, supports the position that the MDL transfer gave the District Court jurisdiction. See, e.g., In re Auto Refinishing Paint Antitrust Litig., 358 F.3d 288, 197 n.11 (3d Cir. 2004). PTO 1415 gives the District Court continuing jurisdiction over “this action and each of the Parties, including [Wyeth] and the class members, to administer, supervise, interpret and enforce the settlement in accordance with its terms.” PTO 1415 at 8. In addition, this Court has already rejected a similar argument by other diet drugs class members. See In re Diet Drugs, 282 F.3d 220, 230 (3d Cir. 2002), (denying petition for writ of mandamus).

adequate. In fact, it appears from the record that these Appellants received actual notice. In addition, these Appellants are essentially relying on the same “futures” argument that was thoroughly considered and rejected by the District Court, as discussed above. PTO 1415 Memorandum at 113-5. Also, as discussed above, the District Court considered and rejected the suggestion that there were disabling intraclass conflicts that compromised the adequacy of representation. PTO 1415 Memorandum at 113-4.

Finally, these Appellants are attempting to factually challenge the District Court’s conclusion that VHD is not latent. This challenge is clearly inappropriate as it is not a component of a due process challenge, appropriate for collateral attack. See Orthopedic Bone Screw, 350 F.3d at 364-65 (holding that a collateral challenge to class settlement’s terms is foreclosed). This claim could be

properly raised in a Rule 60(b) motion with new evidence supporting the claim, if such evidence exists. Appellants do note that they have filed a Rule 60(b) motion with the District Court, but that the motion has been stayed pending the outcome of other litigation. Regardless of that fact, the District Court's finding regarding the non-latent nature of VHD should not be considered in this appeal.

**V. Conclusion**

All three sets of Appellants have had a full and fair opportunity to be heard and have already raised and litigated the challenges they argue here. It can be said “that the procedure adopted, fairly insures the protection of the interests” of these parties, who are properly bound by the Settlement Agreement. Hansberry, 311 U.S. at 42. Thus, all three groups of Appellants cannot collaterally challenge the class settlement here and the District Court will be affirmed.