NO. 03-4465
(joint appeal)

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

IN RE DIET DRUGS (Phentermine/Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
Sheila Brown, et al. v. American Home Products Corporation
Civil Action No. 99-20593
MDL DOCKET NO. 1203
PTO 3085

BRIEF OF APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS

1. *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liability Litigation*; MDL Docket No. 1203; in the United States District Court for the Eastern District of Pennsylvania, Philadelphia Division.

2. The undersigned counsel of record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Appellants:

Shanne Webb-Cochran, Renai Kuykendall, Willa Sartin, Dawn Stewart, Joanne Valenti, and other class members who ingested fen-phen and who suffer, or will suffer, from elevated pulmonary hypertension that is not secondary to valvular heart disease but does not meet the Settlement Agreement criteria for primary pulmonary hypertension.

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STATEMENT OF RELATED CASES

Pursuant to 3D CIR. LOC. R. 28.1(a)(ii), Appellants state that to their knowledge No. 03-4465 is the only appeal taken from PTO 3085. A consolidated appeal, No. 03-3401/03-3402, has been taken from PTO 2929 (JA3:622-34), which denied a motion to determine the inadequacy of representation for downstream opt-out class members. PTO 2929 held that the opt-outs were forbidden from collaterally attacking the fen-phen settlement; and, further, that their representation was adequate. A motion to consolidate the present appeal with No. 03-3401/03-3402 will be filed. Another consolidated appeal, No. 03-3650/03-3741, has been taken from PTO 2958, which denied the disqualification of class counsel. (JA3:635-50).

Additional appeals have been taken from other district court orders in the MDL 1203 diet drug litigation and are pending before this Court. Appellants are aware of the following such appeals:

02-2345
02-3529
02-3941
02-4020/02-4021/02-4074 (consolidated; individual briefing)
02-4022
02-4073
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This Court's previous decisions with respect to MDL 1203 are reported at: 30 Fed. Appx. 27, 2002 WL 272351 (3d Cir. Feb. 26, 2002); 282 F.3d 220 (3d Cir. 2002); 275 F.3d 34 (3d Cir. 2001) (table); and 263 F.3d 157 (3d Cir. 2001) (table).

* Oral argument was held on December 10, 2003 (Ambro, Fuentes, Chertoff, Circuit Judges).

JURISDICTIONAL STATEMENT

The district court (Bechtle, J.), assigned to preside over the MDL 1203 diet drug litigation, asserted jurisdiction over the litigation under 28 U.S.C. §§ 1332 and 1407, and approved a class action settlement. *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liability Litig.)* (JA2:327 (PTO 1415)).

This Court has jurisdiction over the appeal under 28 U.S.C. § 1291. The appeal is timely: PTO 3085 was signed on October 24, 2003, and entered on October 27, 2003. The joint notice of appeal was filed on November 13, 2003.

STATEMENT OF THE ISSUES[1]

1. Certain absent class members, such as Appellants, suffer from, or will suffer from, elevated pulmonary hypertension that is not secondary to valvular heart disease but does not meet the Settlement Agreement's criteria for primary pulmonary hypertension. Those class members were not represented separately during negotiations between class counsel and Wyeth that resulted in the Settlement Agreement.

   The Settlement Agreement extinguishes all claims that Appellants could have brought regarding their condition of elevated pulmonary hypertension Did the district court err in holding that Appellants were adequately represented at the time the class was certified and the settlement was approved?

2. Is the proper remedy for such inadequate representation to hold that Appellants cannot be bound, as a matter of due process, to the class action Settlement Agreement?

[1] The above issues were presented in filings in support of Appellants' motion to determine inadequacy of representation for primary pulmonary hypertension and pulmonary hypertension class members. (Docket Nos. PP #203921 (07/07/03); #203991 (08/04/03)). The issues were also raised in the hearing held October 1, 2003. (JA4:1313-23, 1347-54).

STATEMENT OF THE CASE

This appeal arises from the MDL 1203 diet drug litigation and involves a collateral challenge to the fen-phen settlement brought by Appellants Shanne Webb-Cochran, Renai Kuykendall, Willa Sartin, Dawn Stewart, and Joanne Valenti. Webb-Cochran, *et al.*, appeal on behalf of themselves and other absent class members who ingested fen-phen and who suffer, or will suffer, from elevated pulmonary hypertension (PH) that (1) is not secondary to valvular heart disease (VHD); but (2) does not meet the criteria for primary pulmonary hypertension (PPH) included in the Settlement Agreement.[2]

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[2] Three other individuals (Rita Dix, Donna Franz and Judy Davis) ingested fen-phen and suffer from PPH as defined by Settlement Agreement criteria. They had been parties to the motion to determine inadequacy of representation for primary pulmonary hypertension and pulmonary hypertension class members, which gave rise to this appeal. (Docket No. PP #203921 (07/07/03)). But on October 10, 2003, two weeks before PTO 3085 (the subject of the present appeal (JA1:1-6)) was issued, the district court addressed the issue of PPH claims in PTO 3065. (JA3:651-62).

PTO 3065 dealt with a motion in which Wyeth had asked the district court to enforce the Settlement Agreement against PPH victims, by enjoining the introduction of evidence of VHD in PPH cases tried in state courts. In an earlier order, the court had imposed certain evidentiary restrictions in cases involving PPH plaintiffs. *See* PTO 2867 (JA3:607-11). In PTO 3065, however, the court denied the motion to prohibit evidence on grounds that PPH claims are carved out of the fen-phen settlement, thus allowing claimants to present evidence to the extent permitted by various state courts. Since Wyeth did not appeal the district court's order in PTO 3065, Rita Dix, Donna Franz and Judy Davis are not parties to the present appeal.

Appellants contend that their due process rights were violated because they were not adequately represented by class counsel at the time the class was certified and the settlement was approved. Therefore, they argue, they are not bound by the terms of the Settlement Agreement and should be permitted to pursue their own claims outside the fen-phen settlement.

Specifically, the appeal addresses the propriety of Memorandum and Pretrial Order (PTO) No. 3085 (PTO 3085) (JA1:1-6), in which the district court held that class members with elevated pulmonary hypertension (elevated PH) were adequately represented during settlement negotiations between class counsel and Wyeth. PTO 3085 so held even though no class member with elevated PH was named as a class representative, no class or subclass was defined for those with elevated PH, but elevated PH claims were nonetheless extinguished under the terms of the fen-phen settlement. Elevated PH plaintiffs are not entitled to receive benefits from the settlement and are not permitted to sue outside the settlement. The treatment of elevated PH class members demonstrates that the settlement suffers from the same kinds of intra-class conflicts and notice problems that had

doomed the settlements in *Georgine, Amchem,* and *Ortiz*.[3] Appellants maintain that the court's holding is legally erroneous.

On July 7, 2003, Appellants filed a motion and supporting memorandum in the district court, contesting the adequacy of their representation by class counsel at the time the class was certified and the fen-phen settlement approved. (Docket No. PP #203921 (07/07/03)). Appellants' motion was later joined by thousands of additional class members represented by ninety law firms in twenty-nine states. (Docket No. PP #203991 (08/04/03)).

It is undisputed that the ingestion of fen-phen causes medical conditions of differing severity, ranging from relatively mild to fatal. Additionally, the medical conditions caused by fen-phen are known to become progressively worse over time.

At the more innocuous end of the fen-phen spectrum lie those class members whose conditions have not risen and will not rise to the level of "FDA Positive" valvular heart disease (VHD), as defined in the Settlement Agreement. In the mid-range are class members who suffer from varying degrees of FDA Positive VHD; and who may also suffer from pulmonary hypertension secondary to their valvular heart disease.

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[3] In those cases, as well as in other decisions, the Supreme Court and this Court have repeatedly held a class action settlement not binding upon absent class members unless it was negotiated and approved consistent with due process.

By contrast, at the severe end of the range of fen-phen conditions are individuals diagnosed with primary pulmonary hypertension (PPH), a life-threatening disease for which there is presently no cure. Closely aligned with PPH victims are Appellants and other similarly situated class members, who suffer or will suffer from elevated pulmonary hypertension but do not have valvular heart disease. Although their pulmonary hypertension is not secondary to VHD, Appellants and others have not been diagnosed with "primary" pulmonary hypertension, as that condition is defined in the Settlement Agreement. Their pulmonary artery pressure measurements, however, come close to those included in the Agreement's definition of PPH.

As a result of class counsel's negotiations with Wyeth, the fen-phen settlement's subclasses were structured according to class members' knowledge of whether they had FDA Positive valvular heart disease as of a certain date. Based on that knowledge, or lack thereof, five discrete subclasses, each with a separate representative, were created. PPH victims were not represented during negotiations because the Settlement Agreement provides a PPH carve-out and thus affords no settlement benefits for PPH claimants. Therefore, those individuals are free to sue Wyeth in state courts, subject to limitations imposed by each court.

Also not represented during the negotiations were Appellants and class members like them with elevated PH. In addressing PPH victims, the district court

found that the Settlement Agreement "provides no option for them to receive direct [*i.e.*, matrix] benefits from the Trust." (JA3:655-57 (PTO 3065)). In this respect, Appellants and those with elevated PH are like those with PPH. But because Appellants do not quite meet the PPH threshold of pulmonary artery pressure, the Settlement Agreement provides that Appellants (unlike PPH claimants) may not pursue their claims against Wyeth outside the fen-phen settlement. Therefore, the settlement extinguishes all claims of Appellants and others like them with elevated PH. (JA2:402-04 (PTO 1415)).

After Appellants' motion and all subsequent briefing (Docket Nos. PP #203921 (07/07/03); #203991 (08/04/03); #203994 (08/04/03); #207 (08/04/03)), the district court held a hearing on October 1, 2003. (JA4:1294-1473). Its order denying Appellants' motion, PTO 3085, was issued October 24, 2003, and entered on October 27, 2003. (JA1:1-6). This appeal follows.

STATEMENT OF FACTS

1. The Serious Diseases Caused by Fen-Phen

Because the Court is familiar with the background of the fen-phen litigation and settlement, *see In re Diet Drugs*, 282 F.3d 220 (3d Cir. 2002),[4] the relevant facts will be addressed here only briefly. Beginning in 1989, Wyeth (formerly

[4] That appeal, unlike this one and No. 03-3401/03-3402 (consolidated) did not involve a challenge to the adequacy of representation.

known as American Home Products, or AHP, (JA3:824 (Agreement)), manufactured and marketed a pair of appetite suppressants under the trade names Pondimin and Redux (the "fens"). Until removed from the market in 1997, the fens were prescribed alone or in combination with a third drug, phentermine (not at issue here). Approximately six million Americans took fen-phen from 1995 to 1997 alone. (JA2:339-41 (PTO 1415)).

The diet drug litigation arose because the ingestion of Pondimin and/or Redux results in serious, and sometimes fatal, diseases. Epidemiological studies have determined that fen-phen causes valvular heart disease, or VHD, a condition in which the normal structure and/or function of the heart valves is disrupted. The result is valvular regurgitation, in which blood "regurgitates" backward through the diseased heart valves. (*Id.* at 357). VHD is undisputably a "progressive" condition — *i.e.*, it gets worse over time.[5]

In addition to causing VHD, fen-phen has been linked conclusively with elevations in pulmonary artery pressure. The district court found that a causal relationship has been established between fen-phen use and primary pulmonary hypertension, or PPH, which is a "relentlessly progressive," rare, and inevitably

[5] As the district court found, "once significant valvular regurgitation exists, it tends to beget more severe regurgitation in a significant subset of patients." (*Id.* at 359-60; *see also id.* at 365, 371, 376, 441; JA5:1486, 1488-89, 1536 (Tr. fairness hearing 05/02/00)).

fatal disease affecting pulmonary circulation. (JA2:371-74 (PTO 1415)). In medical terms, PPH is a diagnosis of exclusion — an elevation of pulmonary artery pressure without a demonstrable cause, such as valvular heart disease, a congenital heart defect, or other condition. (JA2:374 (PTO 1415); JA5:1625-26 (Tr. fairness hearing 05/03/00)). According to the IPPHS (International Primary Pulmonary Hypertension Study), individuals using fen-phen for three months have a risk of developing PPH that is twenty-three times that of the general population. (JA2:372-73 (PTO 1415)).

The latency period for PPH can be substantial. Class counsel's expert, Dr. Robyn J. Barst, testified at the fairness hearing, which resulted in the approval of the settlement, that "five to six years is a latency period during which time the patient is more likely than not to develop primary pulmonary hypertension due to appetite suppressant ingestion." (JA5:1632 (Tr. fairness hearing 05/03/00)). Some three years later, on October 20, 2003, Dr. Barst signed a supplemental declaration and expert report stating in part the following to the district court:

> It is my opinion to a reasonable degree of medical certainty that there is a potential latency of ten or more years between the last date on which a patient is exposed to Diet Drugs and the date at which the patient develops the first symptoms of what is ultimately diagnosed as PPH.

(JA4:1247 (declaration and supplemental expert report)). *See also Smith v. Wyeth-Ayerst Labs. Co*., 278 F.Supp.2d 684, 693-97 (W.D.N.C. 2003) (finding reliable

scientific evidence to support the conclusion that there is a significant period of latency between exposure to diet drugs and the development of the first symptoms of PPH).

2. Background to the Fen-Phen Settlement

Based on the deleterious health effects of fen-phen, some 18,000 lawsuits and more than 100 class actions were filed against Wyeth and others throughout the U.S. (JA2:343 (PTO 1415)). In early 1998, the Judicial Panel on Multidistrict Litigation transferred all pending federal cases to the Eastern District of Pennsylvania. *In re Diet Drugs*, 990 F. Supp. 834 (J.P.M.L. 1998) (MDL Docket No. 1203).

In October 1999 negotiations between Wyeth and class counsel resulted in a complaint proposing a consolidated settlement class action in *Brown v. American Home Products Corp.*, No. 99-20593. (JA2:346-49, 377 (PTO 1415)). The *Brown* third amended class action complaint (JA4:954-96) encompasses claims of valvular heart disease brought by persons who had taken fen-phen. (*Id.* at 955-61). It does not include individuals with elevated PH or PPH.

Following negotiations, Wyeth and class counsel entered into a proposed settlement and executed a Settlement Agreement. (JA3:671-828 (Agreement)).[6] The district court granted preliminary approval and conditionally certified a nationwide class under FED. R. CIV. P. 23(b)(3). (JA2:316-25, 349 (PTOs 997, 1415)). After hearings on its fairness and adequacy conducted in May 2000 (JA5:1474-1971; JA6:1972-2393), the court approved the fen-phen settlement in PTO 1415. (JA2:326-488). Separate settlements with Wyeth led to withdrawal of all appeals from the approval. *See* 275 F.3d 34 (3d Cir. 2001).

3. Structure of the Fen-Phen Settlement

a. Settlement Benefits or Opt-Out Rights for Members of the *Brown* Subclasses

i. Intra-Settlement Benefits

The fen-phen settlement was structured to provide certain financial benefits for class members who chose to remain in the settlement. To receive intra-settlement benefits, individuals who took Pondimin and/or Redux were placed in subclasses. The settlement's principal financial benefits are reserved for "matrix level" conditions, which are forms of FDA Positive VHD. (JA3:713-29 (Agreement); JA2:383-85 (PTO 1415)).

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[6] To date, the Settlement Agreement has been amended six times, from November 18, 1999 to January 10, 2003. (*Id.* at 671). This brief refers to the operative terms of the Agreement as amended.

The *Brown* settlement class is divided into five separate subclasses, each with its own representation. (*Id.* at 377-78). Subclass lines are defined by a class member's knowledge by September 30, 1999, of whether he or she suffered from FDA Positive valvular heart disease; and the length of time the class member had ingested fen-phen.

Class members are divided mainly between two subclasses. Members of subclass 1 did not know that they had FDA Positive VHD as of September 30, 1999; subclass 2 members did know of their diagnosis.[7] Subclasses 1 and 2 are further subdivided based on the length of time class members had taken the diet drugs. In each subclass, one representative was named on behalf of persons who took the fens for sixty days or less (subclasses 1(a) and 2(a)), and one for those who took the fens for sixty-one days or more (subclasses 1(b) and 2(b)). (*Id.*).

The settlement also creates a third subclass, also with its own class representative. Subclass 3 comprises those members of subclass 1 who were diagnosed with a condition known as "mild mitral regurgitation" (generally by January 3, 2003, the end of the settlement's screening period). (JA3:683 (Agreement); JA2:378, 381 (PTO 1415)).

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[7] As class counsel explained at the fairness hearing, the defining characteristic of subclass one is that "people . . . don't know whether they are FDA Positive or not." (JA5:1523 (Tr. fairness hearing, 05/02/00)).

ii. Opt-Out Rights

Also under the terms of the Settlement Agreement, class members suffering from FDA Positive VHD may choose to exercise their intermediate or back-end ("downstream") rights to opt out of the fen-phen settlement and not to receive intra-settlement matrix benefits. Downstream opt-outs are entitled to pursue claims against Wyeth subject to a number of restrictions, including a prohibition against the seeking of punitive damages. The claims that downstream opt-outs may pursue are termed "settled claims," and are defined in the Settlement Agreement as follows:

> "Settled Claims" shall mean any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the purchase, use, manufacture, sale, dispensing, distribution, promotion, marketing, clinical investigation, administration, regulatory approval, prescription, ingestion, and labeling of Pondimin® and/or Redux™

(JA3:689-90 (Agreement)).[8]

b. Carve-Out for PPH Claimants

The district court described the terrible disease of primary pulmonary hypertension in its order certifying the *Brown* settlement class:

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[8] The Settlement Agreement limits the claims brought by downstream opt-outs and "Sixth Amendment opt-outs." (JA2:732-40 (Agreement)). Those individuals who elected to opt out of the settlement by March 30, 2000 (before the class was certified), are termed "initial opt-outs." Not being part of the class, initial opt-outs are permitted to sue Wyeth without restriction. (*Id.* at 731-32).

> PPH is a relentlessly progressive disease that leads to death in virtually all circumstances. The only approved treatment for the disease involves the administration of a drug known as Prostacyclin ("Flolan"), which must be administered continuously through an intravenous pump. Flolan is not a cure for the disease. If it is used successfully, it can reduce the patient's symptoms and delay death for a few years. Administration of the drug is accompanied by a high incidence of serious complications. The drug can cause death if administered to patients who do not suffer from PPH . . . .
>
> * * *
>
> A diagnosis [of PPH] is accompanied by enormous psychological trauma to the patient because it is a virtual death sentence.
>
> * * *

(JA2:372 (PTO 1415)).

Under the Settlement Agreement the criteria to be met for a diagnosis of PPH are the following:

> a. For a diagnosis based on examinations and clinical findings prior to death:
>
> (1) (a) Mean pulmonary artery pressure by cardiac catheterization of $\geq$ 25 mm Hg at rest or $\geq$ 30 mm Hg with exercise with a normal pulmonary artery wedge pressure $\leq$ 15 mm Hg; or
>
> (b) A peak systolic pulmonary artery pressure of $\geq$ 60 mm Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or
>
> (c) Administration of Flolan to the patient based on a diagnosis of PPH with cardiac catheterization not done due to increased risk in the face of severe right heart dysfunction; and

(2) Medical records which demonstrate that the following conditions have been excluded by the following results:

(a) Echocardiogram demonstrating no primary cardiac disease . . .; and

(b) Left ventricular dysfunction . . .; and

(c) Pulmonary function tests demon-strating the absence of obstructive lung disease . . . and the absence of greater than mild restrictive lung disease . . .; and

(d) Perfusion lung scan ruling out pulmonary embolism; and

(e) If . . . the lung scan is indeterminate or high probability, a pulmonary angiogram or a high resolution angio computed tomography scan demonstrating absence of thrombo-embolic disease; and

(3) Conditions known to cause pulmonary hypertension . . . have been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension.

-OR-

b. For a diagnosis made after the individual's death:

(1) Autopsy demonstrating histopathologic changes in the lung consistent with primary pulmonary hypertension and no evidence of congenital heart disease . . . as documented by a Board-Certified Pathologist; and

(2) Medical records which show no evidence of alternative causes as described above for living persons.

* * *

> This definition of PPH . . . is intended solely for the purpose of describing claims excluded from the definition of Settled Claims . . . .

(JA3:684-86 (Agreement)).

The Settlement Agreement carves out an exception for claims "based on PPH." Therefore, PPH plaintiffs may file suit against Wyeth with no restrictions:

> Notwithstanding the foregoing, Settled Claims do not include claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH; provided, however, that if a Class Member receives settlement benefits from Fund B, he/she may not bring a lawsuit based upon a claim for PPH, unless the Class Member was diagnosed with PPH before the Class Member had left-sided heart valve abnormalities (other than those which produce trivial, clinically insignificant left-sided regurgitation) or Endocardial Fibrosis.
>
> * * *

(*Id.* at 689-90).

Thus, the Doppler echocardiogram provision of the PPH definition carves out a class member from the Settlement Agreement **if and only if** he or she has peak systolic pulmonary artery pressure of at least 60 millimeters (mm) of mercury (Hg) at rest. If systolic pulmonary artery pressure is **less than** 60 mm Hg, as measured by an echocardiogram, then the class member's claims will not be excluded from the Settlement Agreement's general release — even if he or she suffers from elevated PH as a result of using diet drugs, and even if medical records exclude other conditions. In other words, a patient with pulmonary artery pressure of 40 mm Hg or 50 mm Hg, or even 59 mm Hg, as measured by a

Doppler echocardiogram, will have any relevant legal claims pertaining to that condition extinguished under the Settlement Agreement unless and until she meets the criteria for PPH set forth in the Agreement.

Yet a peak systolic pressure of 60 mm Hg, as measured by echocardiogram, is not necessarily a prerequisite to a **medical** diagnosis of PPH or of pulmonary hypertension. For example, the Surveillance of North American Pulmonary Hypertension study ("SNAP") — one of the leading studies to establish a link between diet drugs and pulmonary hypertension, as well as between diet drugs and PPH — defined pulmonary hypertension as pulmonary artery systolic pressure greater than 35 millimeters of mercury, as measured by echocardiography or by catheterization.[9] Patients with pulmonary hypertension that was not secondary to valvular heart disease and was not associated with HIV were categorized as having PPH. Thus, Appellants would have qualified as having PPH for purposes of the SNAP study, although not for purposes of the Settlement Agreement. The SNAP study concluded, on the basis of a prospective surveillance study on 579 patients diagnosed with pulmonary hypertension at twelve large referral centers in North

[9] *See* Stuart Rich, *et al.,* "Anorexigens and Pulmonary Hypertension in the United States: Results from the Surveillance of North American Pulmonary Hypertension," 117 Chest (J. Amer. College of Chest Physicians) 870 (2000). (JA4:1144).

America between September 1, 1996, to December 31, 1997, that diet drugs are causally related to PPH.[10]

Class counsel's expert, Dr. Robyn Barst, testified at the fairness hearing preceding approval of the Settlement Agreement: "[I]f you are diagnosing pulmonary hypertension then I do not feel you need a peak systolic pulmonary artery pressure accurately measured by echo of 60 to demonstrate pulmonary hypertension." (JA5:1625 (Tr. fairness hearing 05/03/00)). Rather, the "minimum level accurately measured by echocardiography" to diagnose PH is "at least 35 millimeters of mercury." *Id.* In fact, Dr. Barst testified that she was monitoring a group of patients with possibly elevated PH as a result of diet drugs, even though they did not meet the definition of PPH in the Settlement Agreement:

> There [is] a small group of patients that have been exposed to the fenfluramines before they were referred to me for further evaluation. Outside echocardiograms raised the possibility that they had elevated pulmonary artery pressures by echocardiography. When they first came to see me after they had stopped taking the fenfluramines, our initial evaluations did not demonstrate that they had pulmonary hypertension by echocardiography . . . . An overall risk benefit for these patients, I felt we should follow them up to five to six years which is a latency period, during which time the patient is more likely than not to develop primary pulmonary hypertension due to appetite suppression ingestion.

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[10] (JA4:1146) ("In summary, this study supports the findings of previous reports that fenfluramines are risk factors for PPH. Their quick withdrawal from the United States market may well have aborted an incipient epidemic in the United States . . . .").

(*Id.* at 1632).

c. No Settlement Benefits, No Opt-Out Rights and No Carve-Out for Appellants

Because of the PPH carve-out negotiated by Wyeth and class counsel, PPH claimants were not placed in a subclass. Therefore, they were not represented during settlement negotiations. None of the class or subclass representatives had been diagnosed as suffering from PPH or elevated PH, nor does the Settlement Agreement provide any benefits for those suffering from PPH or elevated PH. Rather, because PPH is excluded from the list of "settled claims," the Agreement allows PPH-diagnosed victims the option of suing Wyeth in state courts.

Class counsel and Wyeth structured the *Brown* settlement to exclude PPH victims. Their negotiations did not, however, account for individuals like Appellants who do not suffer from valvular heart disease; and whose pulmonary hypertension is elevated, but nonetheless slightly below Settlement Agreement criteria for defining PPH.[11]

Appellants and others thus (1) did not receive separate representation, as did VHD claimants; (2) were not included in an elevated PH subclass; (3) are not

[11] Appellants Webb-Cochran, *et al.*, have all been diagnosed with elevated PH. Their pulmonary artery pressures range from 45 mm Hg to 52 mm Hg, somewhat below the ≥60 mm Hg required by the Settlement Agreement to qualify for the PPH carve-out. (Docket No. PP #203921 (memo, 07/07/03) at 5-6).

entitled to receive matrix benefits within the settlement; (4) are not entitled to exercise downstream opt-out rights and pursue "settled claims" against Wyeth outside the settlement; and, (5) were not carved out of the settlement, and thus could not sue Wyeth, as could PPH claimants. Therefore, as a result of negotiations between class counsel and Wyeth, Appellants and other class members like them have had their claims extinguished by the fen-phen settlement. Yet they have received no benefits under the settlement.

SUMMARY OF ARGUMENT

The district court erred in holding in PTO 3085 that Appellants were bound by the Settlement Agreement in this case. The Agreement eliminated any claims for elevated pulmonary artery pressure unless the claims met its definition of PPH — *i.e.*, a pulmonary artery pressure of 60 mm Hg, as measured by electrocardiography. Yet no class or subclass representative suffered from elevated PH unconnected to valvular heart disease. No class or subclass was defined on the basis of elevated PH. Accordingly, Appellants were denied adequate representation during the negotiations that resulted in the settlement abolishing their claims.

The Supreme Court's decisions in *Amchem Prods., Inc. v. Windsor* and *Ortiz v. Fibreboard Corp.*, and this Court's decision in *Georgine v. Amchem Prods., Inc*., clearly recognize the due process requirement that all absent class members

with distinct and potentially conflicting interests be provided with separate subclass representation if they are to be bound by a class action settlement. In this case, the subclasses in question consisted of members with widely varied diagnosed, undiagnosed, and then-future medical conditions. These conditions created divergent and frequently directly opposed interests that made adequate representation impossible. No separate representation was provided for persons such as Appellants, who, as a result of fen-phen exposure, have developed PH unconnected to valvular heart disease. As a result, these class members' interests were sacrificed wholesale — providing an object lesson in the wisdom and necessity of the *Georgine/Amchem* principle.

Although the *Brown* class action settlement provided no benefits whatsoever for the diagnosis, treatment, or compensation of PH, it entirely extinguished all PH-based claims unless and until they qualify as PPH under the Settlement Agreement. Appellants were left empty-handed and with no recourse to the courts for the significant, life-threatening injuries they have suffered. This result is plainly unconstitutional. Appellants must be released from the settlement and permitted to pursue the remedies available to them under state law.

The district court's rationale for PTO 3085 — that there is no evidence linking fen-phen to PH — is unsustainable. The district court itself has repeatedly recognized that fen-phen can cause elevations of pulmonary artery pressure.

Appellants' pulmonary artery pressure does not meet the Settlement Agreement's definition of PPH (60 mm Hg as measured by electrocardiography). But their pressure **does** qualify as PPH for purposes of the authoritative SNAP study, which established a causal link between fen-phen use and elevations of pulmonary artery pressure exceeding 35 mm Hg, as measured by electrocardiography. Accordingly, Appellants' claims are well supported by leading science.

In any event, the district court's rationale for its order impermissibly rested on the merits of Appellants' claims. At this stage of the proceedings, Appellants seek simply an opportunity to present evidence regarding their PH claims to the appropriate forum. It is premature to decide the merits of their claims. And nothing about the merits of their claims could possibly justify binding Appellants to a class action settlement in which they were inadequately represented.

STANDARD OF REVIEW

Adequacy of representation is a legal determination that is subject to de novo review. *See Dow Chem. Co. v. Stephenson*, 273 F.3d 249, 256 (2d Cir. 2001), *aff'd by an equally divided Court*, ___ U.S. ___, 123 S. Ct. 2161 (2003). Moreover, the requirement that absent class members be adequately represented demands "undiluted, even heightened attention in the settlement context." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997). Therefore, in reviewing the propriety of the district court's order, this Court must apply a

"heightened due process scrutiny" standard. *See, e.g., Patel v. Zemski*, 275 F.3d 299, 310 (3d Cir. 2001).

ARGUMENT

I. The Constitution Requires, at a Minimum, Separate Representation for Absent Class Members with Conflicting Interests.

In *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591 (1997), and *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), the Supreme Court firmly established the rule that class members with potentially conflicting interests must be divided into subclasses, each receiving separate representation. *See Ortiz*, 527 U.S. at 856. In the absence of such subdivision, the requirement of adequacy of representation imposed by FED. R. CIV. P. 23 and the Due Process Clause cannot be met, and absent class members therefore cannot be bound by a class action settlement. In *Georgine v. Amchem Prods., Inc.*, which was affirmed by the Supreme Court in *Amchem*, this Court recognized the fundamental problem making it impossible for one class representative to represent a class of plaintiffs who might, in the future, develop any of a number of different medical conditions, or none at all:

> [T]he course of each plaintiff's future is completely uncertain. . . . [S]ome plaintiffs may ultimately contract mesothelioma, some may get asbestosis, some will suffer less serious diseases, and some will incur little or no physical impairments . . . . It is simply impossible to say that the legal theories of named plaintiffs are not in conflict with those of the absentees or that the named plaintiffs have incentives that align with those of absent class members.

83 F.3d at 632 (citations omitted).

Likewise, in *Amchem,* the Supreme Court found that differences among class members spawned disabling intra-class conflicts: "In significant respects, the interests of those within the single class are not aligned. Most saliently, for the currently injured, the critical goal is generous immediate payments. That goal tugs against the interest of exposure-only plaintiffs in ensuring an ample, inflation-protected fund for the future." 521 U.S. at 626.

This Court reached a similar conclusion in *Barnes v. American Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998), denying class certification on the basis that variations in medical conditions and other aspects of class members' individual circumstances made it impossible for a single class representative to represent their interests adequately. The Court opined, "[A]ddiction, causation, the defenses of comparative and contributory negligence, the need for medical monitoring and the statute of limitations present too many individual issues to permit certification . . . . These disparate issues make class treatment inappropriate." *Id.* at 143.

Absent adequate representation, it is unconstitutional to bind absent class members to a class action settlement. *See Hansberry v. Lee*, 311 U.S. 32, 40 (1940) (holding that, subject to an exception for class action suits with constitutionally adequate representation, "[i]t is a principle of general application in Anglo-American jurisprudence that one is not bound by a judgment in personam in a litigation in which he is not . . . a party"); *see also Phillips Petroleum v. Shutts*,

472 U.S. 797, 812 (1985) (holding that "the Due Process Clause of course requires that the named plaintiff at all times adequately represent the interests of absent class members"). Because absent class members are constitutionally entitled to collaterally attack a finding that they were adequately representation, *see, e.g., In re Real Estate Title & Settlement Servs. Antitrust Litig.*, 869 F.2d 760, 769 (3d Cir. 1989), *cert. denied*, 493 U.S. 821 (1989), the district court's adequacy determinations at the time of class certification are not controlling here. *See also Taunton Gardens Co. v. Hills,* 557 F.2d 877, 878 (1st Cir. 1977) ("[I]t is well settled that the court that certifies a class action cannot predetermine the *res judicata* effect of the judgment, which can be tested only in a subsequent action.") (internal quotations and citations omitted).

II. Appellants' Interests Conflicted with Those of Other Class Members and Demanded Separate Subclass Representation

Appellants suffer from elevated PH, a condition that they allege is a separately compensable medical condition, as well as a precursor to the always-fatal PPH. Because PPH develops progressively over time as pulmonary blood pressure rises — that is, since blood pressure must pass through the range categorized as "PH" in order to go from normal levels on the one hand to "PPH" levels on the other — it is **always** preceded by levels of PH similar to those currently suffered by Appellants. Indeed, under some medical definitions, such as

the authoritative SNAP study, Appellants already may be classified as suffering from PPH.

Therefore, at the time of settlement, Appellants had (and still have) an extremely significant interest in providing resources for the **immediate** monitoring and management of this medical condition. This interest was clearly distinct from that of any of the class representatives with FDA Positive valvular heart disease, who are by definition at no risk of developing PPH, and from those with no medical conditions at all. Appellants were nonetheless lumped in a subclass — persons who had not been diagnosed with FDA Positive VHD — that encompassed people with **undiagnosed** VHD (who were at no risk of developing PPH), people with no illness whatsoever, and people with PH and PPH. In addition to the wide variation in the medical conditions at the time of the settlement, subclass members varied in terms of the **future** course of their conditions, which were unpredictable — a classic "futures" problem making it impossible to provide constitutionally adequate notice or representation.

The conflict among these distinct interests is made obvious by the results of the settlement negotiation: with no one representing the specific interests of PH victims, they were entirely excluded from settlement benefits and their PH claims extinguished unless and until their pulmonary artery pressure meets the Settlement Agreement definition of PPH. It is precisely the likelihood of class members'

interests being disregarded in this manner that underlies the *Amchem* rule: representation cannot be constitutionally adequate when persons with a wide variety of medical conditions are lumped into one undifferentiated class.

A. The Class Was Plagued by Conflicts

Because Appellants had not been diagnosed with FDA Positive VHD at the time of the settlement, they were each lumped into one of the two "no-FDA-Positive-diagnosis" subclasses (1(a) or 1(b)), depending on whether they had taken fen-phen for more or less than sixty days.[12] Each of these subclasses was plagued by conflicts of interest that made its representation by a single subclass representative constitutionally inadequate. Indeed, at the time of the settlement, the interests of members of each "no-FDA-positive-diagnosis" subclass varied along at least three axes: their then-current knowledge of their medical conditions; their actual medical conditions; and the future course of their conditions.

First, the fact that none of the class members had received an FDA-positive VHD diagnosis did **not** mean that they were similarly situated — even from the perspective of their own knowledge at the time. In fact, subclasses 1(a) and 1(b)

[12] Appellants Webb, Kuykendall, and Sartin were also included in subclass 3, which overlaps with subclasses 1(a) and 1(b) and includes class members with mild mitral regurgitation. (Docket No. PP #203921 (memo, 07/07/03) at 5-6). Subclass 3 encompasses the same types and degree of variation in all respects as do subclasses 1(a) and 1(b), other than, obviously, the presence or absence of diagnosed mild mitral regurgitation at the time of the settlement.

included those persons who had received **negative** VHD diagnoses; those who had been diagnosed with PH not meeting the Settlement Agreement's definition of PPH (who were nonetheless entitled to compensation and who required immediate medical attention); those who had been diagnosed with PPH; those who had received negative diagnoses for PH and PPH only; those who had received negative diagnoses for VHD, PH, and PPH; those diagnosed with and without mild mitral regurgitation;[13] and those persons who had received no positive or negative diagnoses of any fen-phen related conditions.

Each of these groups had different incentives, some of which were squarely opposed to one another. For example, those who had received negative VHD diagnoses faced a comparatively lower risk of developing VHD, but therefore faced a higher-than-average (within the subclass) risk of developing PPH, since the two are mutually exclusive conditions. Their incentive was therefore to minimize payments for VHD and maximize them for PH and PPH medical monitoring and damages. Those class members who had received negative PH and PPH diagnoses were at comparatively less risk of developing either, and had an incentive to maximize VHD payments and minimize PH/PPH payments. Those who had been diagnosed with PH were at **much** higher risk of developing PPH (as defined by the

[13] Although persons with mild mitral regurgitation were separately represented in subclass 3, they were also included in subclasses 1(a) and 1(b), adding to the disabling conflicts in those subclasses.

Settlement Agreement), due to the progressive nature of the disease, and faced medical harms from pulmonary hypertension as well. Their overwhelming — indeed, life-or-death — incentive was therefore to seek immediate medical care and monitoring for PH so as to prevent a progression to PPH.

In addition to the variation in members' then-present diagnoses, these subclasses encompassed an even wider range in **actual** medical conditions: in addition to persons with PH, PPH, mild mitral regurgitation, and no ailments, they also encompassed persons suffering from (though not yet diagnosed with) all of the different varieties of FDA Positive VHD in all degrees of severity. Thus, in addition to conflicts among class members' **actual** interests paralleling those outlined above with respect to their **perceived** interests, there existed an even more profound conflict: persons who were already suffering from FDA Positive VHD were at **no risk**, by definition, of developing PPH; and therefore had no interest in seeking benefits either for PPH itself or for the monitoring and treatment of precursor conditions (*i.e.*, elevated PH), but every interest in devoting all of the settlement funds to the treatment of VHD.

Finally, the conflicts of interest plaguing the subclasses at the time of the settlement appear starkest of all when the **subsequent** course of their disease development is taken into account. Since the settlement, some subclass members have (like Appellants) been diagnosed with PH; others with PPH; many others

with each of the various forms of FDA Positive VHD; and most with no illness at all. Those who were already diagnosed with PH, PPH, and mild mitral regurgitation have seen their diseases progress at various rates; some PPH victims have already passed away. Members of the subclasses thus face widely varying medical needs, some of which are totally ignored by the settlement (such as those of Appellants), and others of which are provided for in different degrees. At the time of the settlement, then, subclass members faced widely different futures and thus had sharply conflicting interests in terms of the proper allocation of resources and remedies in the settlement.

B. Appellants' Interests Were Neither Protected by the Terms of the Settlement Nor Adequately Represented by the Appointed Subclass Representative

In the decision under review, the district court never so much as addressed the existence, nor the disabling nature, of any of the conflicts of interest discussed here. Indeed, its cursory one-paragraph treatment of Appellants' argument that PH victims were inadequately represented relied solely on the proposition that PH victims have no claim at all because their condition is not linked to diet drugs. (JA1:5). This proposition is discussed below in Section C. Appellants first address, however, two of the district court's holdings as to other class members' collateral attacks on the settlement that might arguably bear on their own inadequacy challenge.

First, in addressing the contention that class members with PPH were inadequately represented, the court held that the terms of the settlement made the question of whether PPH claimants were adequately represented irrelevant; they did not need to be represented because the settlement did not bind them in any way (contrary to Wyeth's reading of it). (JA1:1-5). The court did not contend, nor could it, that the PPH carve-out in the Settlement Agreement also prevents the settlement from interfering with the interests of class members, like Appellants, who suffer from sub-PPH levels of PH.

It is true that should Appellants' current conditions progress to the point that they meet the Settlement Agreement's definition of PPH, they will then be free to pursue their state law claims unbound by the settlement. This possibility falls far short of protecting their interests, however. Appellants have quite literally a life-or-death interest in preventing that very progression from occurring; they now seek payments from Wyeth that will enable them to afford the best possible medical care and monitoring to avoid that outcome. Obviously, any remedy they could seek after developing PPH could not possibly be equivalent. Moreover, to the extent that state tort law provides a remedy for PH-related harms prior to progression to full-fledged PPH, the settlement extinguishes plaintiffs' right to seek that remedy (as Appellants are seeking to do here).

Second, in PTO 2623, also addressing the representation of PPH victims, the district court stated, "Because all class members face the same, albeit remote, possibility of developing PPH in the future, we believe that the interests of class members regarding the PPH definition were properly represented at the time of the negotiations, notwithstanding that there was no specific PPH subclass." (JA3:520 n.9 (PTO 2623)). That is, the court concluded that subclass members were similarly situated, and therefore adequately represented, because they equally lacked knowledge of the future development of their medical conditions.

For three reasons, this supposed shared ignorance (and shared risk) does not obviate the conflict within the subclasses with respect to the future development of PH (or PPH, for that matter). First, as discussed in Section A, subclass members' known medical conditions at the time of the settlement varied widely, and these differences produced significant differences in their expectations — that is, their known risks — regarding the likelihood of developing PH. Some members of the subclass, in fact, **already knew** they had PH or PPH. The subclasses were defined in terms of knowledge only of FDA Positive status (*i.e.*, of a *VHD* diagnosis), not PH/PPH status.

Second, there is no legal basis for the district court's assumption that only known disease status at the time of the settlement is relevant to the determination of whether disabling conflicts exist. To the contrary, this Court and the Supreme

Court have always focused on conflicts of "interest," not conflicts of "incentives." Class members' **actual** current and future medical conditions are at least as important as their **perceived** current conditions for the purpose of determining what their interests are. That is, indeed, the basic nature of the "futures" problem that concerned the Court in *Amchem*. In *Georgine*, for example, this Court held that adequate representation was impossible because "the course of each plaintiff's future [was] completely uncertain," and focused on the widely varied nature of the conditions that they could "ultimately contract." 83 F.3d at 632. Similarly, in *Stephenson v. Dow Chem. Co.*, 273 F.3d 249 (2d Cir. 2001), the Second Circuit held that class members who discovered their Agent Orange-related injuries too late to bring a claim or seek settlement benefits were not adequately represented. *Id.* at 260. These decisions foreclose the district court's logic that, since all members of the class risked the latent development of injuries, such future injuries could never have been the basis of an adequacy of representation challenge.

Third, the district court's logic, which makes class members' ignorance a defense against an adequacy of representation challenge, would turn on its head the requirement of constitutionally adequate notice. Due process requires that notice be provided "in a meaningful time and in a meaningful manner." *Peralta v. Heights Med. Ctr., Inc.*, 485 U.S. 80, 86 (1988). In *Amchem*, the Supreme Court agreed with the Third Circuit that notice to absent class members who were

unaware of their medical conditions at the time of the settlement was "highly problematic" as a constitutional matter. 521 U.S. at 628. *Amchem* makes clear that this problem is not cured by class members' mere knowledge that they were **exposed** to a dangerous product, if they lack knowledge as to the **effects** of that exposure, nor by Rule 23-compliant notice that a settlement has been reached:

> Many persons in the exposure-only category, the Court of Appeals stressed, may not even know of their exposure, or realize the extent of the harm they may incur. Even if they fully appreciate the significance of class notice, those without current afflictions may not have the information or foresight needed to decide, intelligently, whether to stay in or opt out.

521 U.S. at 628 (agreeing with the Third Circuit's analysis);[14] *see Georgine*, 83 F.3d at 633 ("[C]lass members who know of their exposure but manifest no physical disease may pay little attention to class action announcements. Without physical injuries, people are unlikely to be on notice that they can give up causes of action that have not yet accrued. [And], even if class members find out about the class action and realize they fall within the class definition, they may lack adequate information to properly evaluate whether to opt out of the settlement."); *Stephenson*, 273 F.3d at 260-61 & n.10.

[14] *Amchem*'s statements regarding notice, although dicta, constitute reasoned analysis of the Supreme Court and should not be ignored by this Court. *See In re McDonald*, 205 F.3d 606, 612-13 (3d Cir. 2000).

The district court's defense of the adequacy of class members' representation on common-ignorance grounds essentially amounts to an assertion that all subclass members were equally lacking in the "information and foresight needed to decide, intelligently, whether to stay in or opt out."

That reasoning obviously runs afoul of the notice requirement. This Court and others have thus consistently recognized that shared ignorance of class members is a reason for denying, not granting, class certification. *See, e.g., Scott v. University of Delaware*, 601 F.2d 76, 89 (3d Cir. 1979), *cert. denied*, 444 U.S. 931 (1979) ("[W]e do not think that future faculty members, whose possible claims are only speculative and can only be formulated in a highly abstract and conclusory fashion, should provide, and possibly be prejudiced by, membership in the class which [the plaintiff] seeks to represent."); *Shults v. Champion Int'l Corp.*, 821 F. Supp. 520, 524 (E.D. Tenn. 1993) ("No settlement that precludes future, unknown causes of action can be considered fair, reasonable, or in the best interests of the class as a whole."), *appeal dismissed*, 35 F.3d 1056 (6th Cir. 1994); *Yandle v. PPG Indus., Inc.*, 65 F.R.D. 566, 572 (E.D. Tex. 1974); *Foster v. Bechtel Power Corp.*, 89 F.R.D. 624, 627 (E.D. Ark. 1981); *Freeman v. Motor Convoy, Inc.*, 68 F.R.D. 196, 200 (N.D. Ga. 1975). Indeed, class counsel in this case have recognized the same point with respect to PPH claimants, noting that the lack of knowledge as to

which class members — all facing the same risk ex ante — would actually develop PPH was the very reason PPH claims were carved out of the settlement:

> Given the potential and significant period of latency between ingestion of Diet Drugs and the development of PPH, Class Members diagnosed with PPH subsequent to the dissemination of the class notice would have had no basis to determine whether they suffered from PPH and, if so, to assess the effect of the settlement on their claim and to make a decision on whether to opt-out or object to the settlement. There is a real question as to whether it is fundamentally fair, in a due process sense, to enter a class judgment foreclosing an individual from litigating a significant personal injury claim arising from an injury that was latent at the time that the class notice issued, particularly where the settlement provides no compensation for the latent injury when it ultimately manifests itself.

(Docket # 493 (memorandum of class counsel, as amicus curiae, in opposition to Wyeth's motions for injunctions against PPH claimants, 10/27/03 at 8)); *see also id.* at 9 ("Thus, there is a very significant question as to whether a class action judgment can lawfully bind an individual with respect to the litigation of any claim based on a substantial physical injury that was latent at the time the class notice issued consistent with the constitutional guarantee of procedural due process."); *id.* at 9 ("[W]hen the settlement here was presented to the Court for consideration and approval, the parties repeatedly made the point that the instant settlement . . . did not purport to resolve claims arising from any potentially latent disease. This point proved crucial to the Court's decision to approve the settlement.") (citations omitted).

The conditions suffered by Appellants are equally latent; indeed, they already qualify as PPH under the definition of the SNAP study. PH claims should have been excluded from the settlement just as PPH claims were; the same concerns identified by class counsel demand that Appellants be released from the settlement.

C. The District Court's Holding that Diet Drugs Do Not Cause Elevated PH Is Improper and Incorrect.

The sole stated basis for the district court's rejection of Appellants' inadequacy argument, expressed in a perfunctory one-paragraph discussion, was that their medical condition was not caused by diet drugs. The district court acknowledged that "[t]he medical testimony and articles in the record before this court set forth evidence of the causal connection between fen-phen and PPH, as well as between fen-phen and left-sided valvular heart disease (VHD)." (JA1:5). "Other than those two conditions, which involve secondary pulmonary hypertension, there is nothing before us that fen-phen causes other diseases or conditions related to PH." (*Id.*) "There is no requirement that subclasses be established for hypothetical groups of class members." (*Id.*)

The court's reasoning was demonstrably faulty. There is nothing "hypothetical" about Appellants. They suffer from elevated PH, ranging from 45 mm Hg to 52 mm Hg. They allege that their conditions are caused by fen-phen, and they rely in part on the authoritative SNAP study, for purposes of which their

conditions would have been classified as "PPH." Using this definition, SNAP documented a causal relationship between diet drugs and pulmonary hypertension. Even class counsel's expert, Dr. Barst, recognized that primary pulmonary hypertension can be demonstrated by an echocardiogram reading of 35 mm Hg or higher; and in her own practice has continued to provide medical surveillance to patients, like Appellants, who ingested diet drugs but do not qualify as having PPH under the Settlement Agreement's definition. The district court's conclusion that Appellants could not demonstrate injury or causation is wrong.

Moreover, the district court improperly prejudged the merits of Appellants' claims. The issue before the court was adequacy of representation, not the substance of Appellants' claims against Wyeth. Appellants seek only a forum in which their claims may be heard, free from the bar of the Settlement Agreement. If Wyeth is correct that Appellants cannot establish causation or injury linked to diet drugs, then it will be entitled to prevail in whatever court ultimately adjudicates Appellants' claims. But it puts the cart before the horse to argue (as Wyeth does) that it was permissible to deny Appellants adequate representation during the Settlement Agreement negotiations because their claims lack merit in any event. The merits of Appellants' claims have never been considered, and it is improper to bar the door of the courthouse by reference to the Settlement

Agreement. As a matter of due process, Appellants' claims cannot have been extinguished by that Agreement.

CONCLUSION

PTO 3085 should be reversed and this Court should direct the granting of Appellants' motion to determine the inadequacy of representation for class members with pulmonary hypertension.

Respectfully submitted,

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I certify that two copies of the Brief of Appellants have been provided to all parties, as described below on January 20, 2004.

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CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type-volume limitations of FED. R. APP. P. 32(a)(7)(B) because the brief contains 8,199 words, exclusive of the exempted portions in FED. R. APP. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface and typestyle requirements FED. R. APP. P. 32(a)(5) and 32(a)(6) because the brief has been prepared in proportionally spaced typeface using Microsoft Word 2000 in Times New Roman 14-point type for text and footnotes.

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CERTIFICATE OF ADMISSION

Pursuant to 3D CIR. LOC. R. 28(3)(d), the undersigned certifies that at least one of the attorneys whose names appear on the brief is a member of the bar of this Court.

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