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IN RE: DIET DRUG LITIGATION : SUPERIOR COURT OF NEW JERSEY
: LAW DIVISION: BERGEN COUNTY
: MASTER DOCKET NO.: BER-L-7718-03

: Civil Action

OPINION

REBECCA JOLIN-WANTY, : Docket No. BER-L-5668-03MT

Plaintiff, :

v. :

WYETH, INC., :

Defendant. :

BETTY TORRENCE : Docket No. BER-L-2570-04MT

Plaintiff, :

v. :

WYETH, :

Defendant. :

Robert J. Brennan, Esq. and Daniel K. Winters, Esq., Porzio, Bromberg & Newman, P.C., and Anand Agneshwar, Esq., Arnold & Porter, LLP, appearing on behalf of defendant Wyeth Corporation.

Walsh, J.S.C.

Two (2) drugs, both appetite suppressants, fenfluramine – marketed as Pondimin® – and dexfenfluramine – marketed as Redux™ (collectively “phen-fen”), were widely sold in the United States prior to 1997.¹ In 1997, data surfaced suggesting a link between the use of these drugs and valvular heart disease. In July 1997, the United States Food and Drug Administration (“FDA”) issued a public health advisory and in September 1997, American Home Products Corporation (“AHP”) removed both drugs from the market.

In the wake of the Pondimin® and Redux™ market withdrawals, some 18,000 individual lawsuits and over 100 putative class actions were filed in the federal and state courts. In December 1997, the Judicial Panel for Multidistrict Litigation transferred all the federal actions to the United States District Court for the Eastern District of Pennsylvania, creating Multidistrict Litigation 1203 (“MDL 1203”). *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, 282 F.3d 220, 226-227 (3d Cir. 2000).

¹ The term phen-fen, which is usually written fen-phen, refers to the use of fenfluramine or dexfenfluramine in combination with phentermine. For purposes of this Opinion, phen-fen will refer only to fenfluramine or dexfenfluramine, whether used in combination with phentermine or not.

In November 1999, the plaintiffs and Wyeth Corporation (“Wyeth”), the successor of AHP, agreed to a tentative settlement which anticipated a nationwide class (the “CAS”). The proposed class included all persons in the United States, as well as their representatives and dependents, who had taken either or both Pondimin® and Redux™. The CAS received “Final Judicial Approval” on January 3, 2002, when all appeals were resolved or exhausted.

Under the CAS, certain class members who satisfied specific medical criteria and procedural requirements were entitled to opt-out and thereafter could bring a lawsuit against Wyeth.² By May 3, 2004, which was the cut-off date for most of these opt-outs, approximately 50,000 individuals had opted-out of the CAS and had commenced litigation in various states. The Chief Justice of the New Jersey Supreme Court, by Order dated July 17, 2003, consolidated all the New Jersey phen-fen opt-out cases for case management before this Court.

Over 5,800 phen-fen cases are now before this Court for supervision. One of the questions which needs to be addressed is whether trials of some of these cases should be consolidated pursuant to R. 4:38-1. The Court advised the parties that it intended to select approximately twenty (20) cases for trial in January 2005 and that it was likely that it would consolidate several cases from that group in a single trial.

² The opt-out procedure is not relevant for purposes of this Opinion. Details about the opt-out procedures and challenges available to Wyeth are discussed in In re: Diet Drug Litigation, BER-L-7718-03 (Law Div. April 13, 2004) (slip op at 5-9).

The Court raised these issues with the plaintiffs and Wyeth during the April 16, 2004 case management conference and solicited their positions particularly as to consolidation. The Court heard the parties at length during the June 28, 2004 case management conference.³ At that time, Wyeth urged this Court to try the individual cases and not to consolidate them for trial claiming prejudice. As a fall-back position, Wyeth suggested that the Court create three (3) groups “of one, two and three plaintiffs respectively,” believing that these trials would provide “empirical evidence to the parties and the Court as to whether the efficiencies of joint trials outweigh the potential prejudice to Wyeth” and thus would guide the Court’s course with respect to succeeding trials. The plaintiffs, on the other hand, found no significant problems in the consolidation of the cases before the Court “into trial clusters of five cases each” which they proposed.

For the reasons that follow, the Court believes that “common question[s] of law or fact arising out of the same transaction or series of transactions” exist here. In short, the common issues here present circumstances where the judicial economy achieved through a single trial involving several plaintiffs significantly outweighs the alternative of repetitive trials of individual cases. Specifically, the Court will consolidate the following five (5) cases for trial to commence on January 3, 2005:

³ The parties were permitted to make further submissions after the June 28, 2004 hearing and did so. Baron & Budd filed a Memorandum and an Affidavit and Certification on July 15, 2004 on behalf of the plaintiffs and Wyeth filed a position paper response on August 2, 2004. The Court has considered these submissions.

1. Rebecca Jolin-Wanty (“Jolin-Wanty”), L-5668-03MT
2. Betty Torrence (“Torrence”), L-2570-04MT
3. Terri Greer (“Greer”), L-6653-03MT
4. Vicki Napier (“Napier”), L-6847-03MT
5. Juanita Rose (“Rose”), L-7078-03MT⁴

In doing so, the Court rejects Wyeth’s claim that the jury will be confused to Wyeth’s prejudice and in this Opinion provides specific safeguards to insure that each of the cases consolidated for trial will receive individual treatment and consideration by the jury.

I

R. 4:38-1 controls the consolidation of different actions in the Superior Court. It provides that “[w]hen an action is pending in the Superior Court, and another action involving a common question of law or fact arising out of the same transaction or series of transactions is pending . . . the Superior Court on . . . its own motion . . .” may consolidate them. The decision as to whether cases should be consolidated is left to the discretion of the trial court. *Rendine v. Pantzer*, 141 N.J. 292, 311 (1995); *Judson v. Peoples Bank & Trust Co. of Westfield*, 17 N.J. Super. 143, 145 (Ch. Div. 1951). The authority reflected in **R.** 4:38-1 has been used by both the Appellate Division and the New Jersey Supreme Court to consolidate trials in product liability actions brought by separate plaintiffs against

⁴ These five (5) cases will be backed-up by six (6) cases; Loreen Robinson, L-7566-04MT; Penelope Pence, L-7080-03MT; Magalene Todd, L-2569-04MT; Wanda Flynn, L-2556-04MT; Rhonda Curry, L-6849-03MT; and Deborah Nault, L-6654-03MT. In the event any of the five (5) selected cases are settled prior to the trial date, that or those cases will replace the settled cases ready for trial.

the same defendant where common issues of fact and law existed. *Batson v. Lederle Laboratories*, 290 N.J. Super. 49, 55 (App. Div. 1996), *aff'd*, 152 N.J. 14, 17 (1997) (consolidated trial on all issues in two (2) tetracycline tooth staining cases).

Consolidation of mass tort cases for management and trial is common in our state and federal courts. *Johnson v. Celotex Corp.*, 899 F.2d 1281, 1285 (2d Cir. 1990), *cert. denied*, 498 U.S. 920 (1990) (question is whether risks for prejudice and possible confusion are overborne in asbestos cases by the risk of inconsistent adjudications of common factual and legal issues, the burden on the parties, witnesses and available judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits against a single one, and the relative expense to all concerned of the single-trial versus a multiple-trial alternative); *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1495-1497 (11th Cir. 1985) (court approved consolidation of four (4) asbestos cases finding the trial judge took measures to insure that the jury was not confused); *In re Norplant Contraceptive Product Liability Litig.*, 168 F.R.D. 579, 580-581 (E.D. Tex. 1996) (Norplant® cases combined for trial); *In re Eastern and Southern Districts Asbestos Litigation*, 772 F. Supp. 1380, 1387 (E.D. & S.D.N.Y. 1991) (consolidated trial on all issues as to sixty-four (64) plaintiffs suing six (6) defendants over asbestos exposure at the Brooklyn Navy Yard), *aff'd in part, rev'd in part sub nom.*, *In re Brooklyn*

Navy Yard Asbestos Litig., 971 F.2d 831 (2d Cir. 1992).⁵ As the United States Court of Appeals for the Second Circuit noted, when it approved the consolidation for trial of four (4) plaintiffs' cases involving asbestos against multiple defendants:

Consolidation is a valuable and important tool of judicial administration. This is especially true when the courts are overwhelmed with huge numbers of cases which involve substantially the same questions of fact, as happens when large numbers of plaintiffs allege that they have developed similar illnesses in reaction to a particular toxic substance. . . . In such circumstances, consolidation permits the . . . court to furnish trials in hundreds, even thousands of cases it might otherwise not reach for many years. If carefully and properly administered . . . consolidation is also capable of producing, with efficiency and greatly reduced expense for all parties, a fairer, more rational and evenhanded delivery of justice.

It requires little imagination to recognize that without consolidation the courts are simply incapable of handling litigation of such volume. The waste of time and expense involved in empaneling separate juries to decide the same sorts of questions over and over again is staggering. This is all the more true when one recognizes that each

⁵ The Maryland Court of Special Appeals reached a conclusion similar to that of the Second Circuit. *ACandS, Inc. v. Abate*, 710 A.2d 944, 956 (Md. App. 1998) (approving consolidated trial of all issues related to claims of five (5) plaintiffs against eleven (11) defendants). In *Abate*, *supra*, the Maryland Court of Special Appeals described a scenario that necessarily follows if such cases are individually tried:

After only a brief introduction to asbestos litigation one recognizes that the same medical studies, medical journal articles, workers' compensation claims, third-party suits, depositions of witnesses, transcripts of court testimony, minutes of meetings, correspondence, and other exhibits are produced against the same defendants in trial after trial throughout the nation. Indeed, the documents have been photocopied so many times for an ever-expanding distribution among members of the plaintiffs and defense bars that the copies introduced into evidence are nearly illegible.

Id.

As the *Abate* Court emphasized in approving a consolidated trial, “[a]bsent unusual circumstances, it is senseless to repeat the presentation of the same evidence against the same defendants in successive, individual trials or mini-consolidations.” *Id.*

successive jury must be educated by expert witnesses to understand the toxicity of asbestos fibers, the etiology of asbestos-induced diseases, the state of the art regarding the industry's knowledge of these dangers through the years, and the economic issues involving loss of services and future income that recur so frequently in these cases.

Consorti v. Armstrong World Industries, Inc., 72 F.3d 1003, 1006 (2d Cir. 1995), *vacated on other grounds sub nom.*, *Consorti v. Owens-Corning Fiberglass Corp.*, 518 U.S. 1031 (1996) (citation omitted).

There is no doubt that the over 5,800 cases before this Court present common issues of fact and law. The question of whether Pondimin® and/or Redux™ are associated with increased levels of mitral and/or aortic valvular disease in the population will be one of the focal points in these trials. Certainly, the proofs as to the basic medical issues, as well as general causation and liability, will be virtually identical in each of these phen-fen cases. Of course, many of the witnesses will be identical as well. One would expect the plaintiffs to call epidemiologists, cardiologists, toxicologists, and experts on warnings and on FDA regulatory issues. No doubt, Wyeth will counter these witnesses with similar experts expressing different opinions.

Professor John C. Coffee of Columbia University, a well-known commentator on class and mass tort actions and a witness at the fairness hearings in MDL 1203, said exactly that:

I think in this case we have class cohesion because of the existence of very obvious common facts. We have basically two diet drugs as opposed to a range of

different asbestos-carrying products, whether in the naval field or constructions industries. We have basically one kind of product, two drugs. We have basically one producer. . . . We basically have one kind of injury. You can break it down. But it's a valvular heart injury that we are talking about in these cases as opposed to a broad spectrum of injuries that asbestos exposure can cause pleural scars to asbestosis to mesothelioma to lung cancer. And we basically have one scientific theory of what the causation is. . . . We also have some common legal theories. We have a negligence theory. In my judgment, negligence theories have a high degree of commonality. They don't vary greatly from state to state in terms of the prima facie case that the plaintiff has to put on. Common legal theories about the conduct of AHP. What did it do? What did it know? When did it know it? Those are questions about whether it had a duty to warn, whether it had knowledge of side effects of developing knowledge, and whether it violated a legal duty. We also have common medical evidence here. The medical evidence is quite developed, and it's not going to vary from class member to class member. Information about either the defendant or the science is going to be the same no matter where this action was brought, no matter who the class member raising these claims are.

Wyeth endorsed Professor Coffee's testimony as it sought support for approval of the CAS. The Court agrees with Professor Coffee that the fact pattern in all these phen-fen cases reflects the homogeneity of the litigation. In fact, no serious student of mass tort case management could say otherwise.⁶

⁶ Wyeth suggests that consolidation of these phen-fen cases is inappropriate because phen-fen litigation as a mass tort has not matured. The Manual on Complex Litigation states that "mature torts" such as asbestos or the Dalkon Shield are ripe for consolidation, yet mass torts with fewer prior verdicts should be litigated in smaller units until general causation, typical injuries and levels of damages are established. See Manual for Complex Litigation, 3rd Ed. at 322 (1995).

A dominant concern when considering whether to consolidate cases for trial is the identity of the parties. The presence of multiple parties on both sides of a consolidated case's caption clearly complicates the proceedings. Here, however, Wyeth is the only defendant. *See Illinois Central R.R. v. Travis*, 808 So. 2d 928, 934-936 (Miss. 2002). There will be no confusion as to which party the plaintiffs believe is liable and all the relevant evidence will be directed to implicating or exonerating this defendant. Wyeth has not seriously contended that there will be confusion in this regard, nor could it.

II

Wyeth concedes that the decision as to whether to consolidate is committed to a trial court's sound discretion but claims that the phen-fen cases before this

Phen-fen litigation has been in the state and federal courts since 1997. Both scholars and courts recognize that a mass tort has a life cycle. *See e.g. McGovern, An Analysis of Mass Torts for Judges*, 73 TEX. L. REV. 1821, 1841-1845 (1995). A mass tort reaches maturity when "there has been full and complete discovery, multiple jury verdicts, and a persistent vitality in the plaintiffs' contentions. Typically, at the mature stage, little or no new evidence will be developed, significant appellate review of any novel legal issues has been concluded, and at least one full cycle of trial strategies has been exhausted." *Id.* at 1843 (quoting McGovern, *Resolving Mature Mass Tort Litigation*, 69 B.U. L. REV. 659, 659 (1989)). Asbestos litigation, which has been around for decades, is a typical "mature tort." In those cases, the courts have had ample opportunity to evaluate medical, scientific and other factual issues relating to asbestos exposure. Alternatively, Propulsid claims have been classified as "immature torts" because "scientific, legal, and factual issues related to 'immature torts' are novel and unsettled." *Id.* at ¶ 26. Aggregation is less appropriate in "immature torts" because "enough trials have [not] occurred so that the contours of various types of claims within the . . . litigation are known. . . ." *See In re Bristol-Myers Squibb Co.*, 975 S.W.2d 601, 603 (Tex. 1998); *Janssen Pharmaceutica, Inc. v. Armond*, 866 So.2d 1092 (Miss. 2004) (reversing an order consolidating Propulsid cases with fifty-six (56) plaintiffs against forty-two (42) physicians because there was no single transaction or occurrence).

The diet drug litigation probably is not a "mature tort." But it is not an "immature tort" either. Voluminous discovery in tens of thousands of cases has been had since 1997. Scientific, legal and factual issues relating to the type of injury – valvular regurgitation – and causation are not novel. In these circumstances, a court should focus on whether there is homogeneity among the cases it is considering for consolidation. As will be seen, such homogeneity exists here.

Court are so disparate that consolidation here would be an abuse of that discretion.⁷

The significant case differences exist, according to Wyeth, and include: (1) the use of different drugs (Pondimin® or Redux™, or both) with different labeling during their periods of use; (2) the use by the plaintiffs of the diet drugs for different lengths of time; (3) the use of these diet drugs when Wyeth's knowledge or alleged knowledge of the potential risks may have differed; (4) the receipt of diet drug prescriptions from different doctors, each of whom made individualized prescribing judgments as learned intermediaries; (5) the different medical histories and ages of plaintiffs; (6) the different injuries and symptoms suffered by the

⁷ Appellate courts are reluctant to disturb trial court decisions involving consolidation where active case management is underway. This is true even where the cases under management are heterogeneous. For example, in *In re Bristol-Myers Squibb Co.*, 975 S.W.2d 601 (Tex. 1998), the trial court had consolidated nine (9) breast implant plaintiffs and twelve (12) defendants where the medical devices were produced by three (3) different manufacturers. In declining to reverse the trial court's consolidation order, the Texas Supreme Court acknowledged that:

1. breast implant litigation then was not mature tort;
2. the existence of "learned intermediaries," who were responsible for implanting the devices and providing the warnings given to them by the manufacturers varied from patient to patient, product to product;
3. some of the plaintiffs received implants from only one manufacturer while others received implants from more than one;
4. implants differed from manufacturer – silicone gel, saline, or both;
5. some implants were coated with polyurethane, which allegedly degraded into potential carcinogenic chemicals, while others did not;
6. the plaintiffs suffered an assortment of ailments, including atypical neurological disease, systemic connective tissue disease, flu-like symptoms, and scores of other maladies as well as "local injuries" such as scarring, capsular contracture, and chest pains;
7. breast implant litigation did not appear to involve a cluster of related conditions or diseases with similar etiologies;
8. evidence regarding causation as to each product and ailment materially differed; and
9. "state-of-the-art" evidence would differ depending on when the plaintiff received the implant.

Id. at 603-604. Despite these differences, the Texas Supreme Court concluded that the record did not demonstrate sufficient prejudice, to support a finding that the trial court abused its discretion. *Id.* at 605; See also *In re Ethyl Corp.* 975 S.W.2d 606 (Tex. 1998) (consolidating twenty-two (22) asbestos cases against five (5) defendants where there were multiple worksites, the workers engaged in a variety of occupations, the dates and length of exposure varied and the diseases suffered were diverse).

The individual issues presented here are far less convoluted than the breast implant and asbestos cases just discussed.

plaintiffs; and (7) the different damage and risk-benefit profiles of the plaintiffs. The Court believes on the record before it that Wyeth's concerns it will be prejudiced, whether taken singly or considered as a whole, lack merit.

A.

The Drug Used and the Period of Use

Wyeth complains that the five (5) plaintiffs selected for trial used different drugs. Jolin-Wanty and Torrence took ReduxTM, while Greer, Napier and Rose took Pondimin[®].⁸ Wyeth, however, fails to indicate what, if any, significance this information should play in the trial. The labeling of Pondimin[®] and ReduxTM demonstrates that the clinical pharmacology of both drugs is similar as well as their safety profile. On July 24, 1997, Wyeth sent a "Dear Doctor" letter which warned the healthcare community of valvular disease associated with the use of either Pondimin[®] or ReduxTM. That letter, in part, indicated that:

We are writing to advise you of labeling changes being developed with the U.S. Food and Drug Administration (FDA) for two Wyeth-Ayerst products, Pondimin[®] (fenfluramine hydrochloride) tablets C-IV and ReduxTM (dexfenfluramine hydrochloride capsules) C-IV. The revised labeling is the result of heightened concern regarding potential side effects which have been reported with concomitant use of fenfluramine and phentermine ("fen/phen").

⁸ Torrence and Napier took Phentermine in connection with Pondimin[®] and ReduxTM, but Wyeth fails to explain why this should confuse the jury or prejudice Wyeth.

A boxed warning will be added to the physician and patient labeling discussing a potentially serious and unusual form of valvular heart disease which has been reported in patients taking fenfluramine and phentermine. The symptoms of this disease may include dyspnea, reduced exercise tolerance and/or lower extremity edema. If patients develop these symptoms during therapy or develop a new heart murmur, physicians are advised to perform a complete cardiovascular evaluation.

The labeling for dexfenfluramine (Redux) will also include new warning language because it is a related chemical compound to fenfluramine.

Evidence of a causal relationship between the treatment of obesity with fenfluramine and phentermine combination therapy and valvular heart disease is inconclusive. Wyeth-Ayerst is initiating scientific studies to supplement currently available data.

The warning will also contain information from the current labeling on the small risk of developing primary pulmonary hypertension (PPH), an often-fatal disorder which has been associated with the use of prescription weight loss medications. PPH has symptoms which are similar to those of cardiac valvular disease. (Emphasis added.)

In short, while these chemical compounds may differ, Wyeth has failed to explain how that fact complicates the evidence and/or injects prejudice into such a joint trial. The Court believes, based on the record before it, that the chemical differences between Pondimin® and Redux™ are relatively insignificant and will play little or no role in the trial of this case.

Wyeth also complains that the plaintiffs “used the diet drugs during different periods of time” and claims that “[t]hese differences in periods of use are significant because Pondimin and Redux did not have the same labeling and because the labeling for each drug changed over time.” Wyeth says these differences “can be very relevant to the failure to warn, learned intermediary and proximate cause issues.” On the record here the Court disagrees.

The plaintiffs here took these drugs in 1996 and 1997. All the plaintiffs, with the possible exception of Greer, took them on or after August 17, 1996. Wyeth concedes that it did not warn about the possible association of valvular disease until July 24, 1997. So too, the warning concerning the possible association of pulmonary hypertension and phen-fen was in effect when each of these plaintiffs was taking diet drugs. If any differences in the respective product liability of Pondimin® and Redux™ exist, Wyeth did not point it out and, in any case, would have little overall significance here. In reality, Wyeth had a duty to list side effects associated with either Pondimin® and Redux™ in the labeling of the other. 21 C.F.R. § 201.57(g)(1).

B.

Use for Different Periods of Time and Wyeth’s Knowledge About Potential Risks During Those Period

The five (5) plaintiffs took phen-fen for varying periods. Greer took Pondimin® for about one (1) year. The other plaintiffs took one or the other diet

drug from between three (3) and six (6) months. Wyeth claims these differences in the duration of use are significant because the epidemiological evidence indicates that the risk of developing valvular regurgitation can vary depending on duration of use. See e.g., J. Jollis, et al., *Fenfluramine and Phentermine and Cardiovascular Findings Effect of Treatment Duration on Prevalence of Valve Abnormalities*, 100 CIRCULATION 2071, 2074 (May 2000) (finding that the risk of developing aortic regurgitation as a result of Pondimin® or Redux™ use is strongest for individuals who took the drugs for six (6) months or more and that the rate of aortic regurgitation in individuals who took the drugs for three (3) months or less was not statistically different from the rate of aortic regurgitation in the background population).

Even if the Court were to accept Wyeth's scientific argument as fact, only one (1) plaintiff took diet drugs for a period exceeding six (6) months. Wyeth cannot seriously argue that the jury could not easily separate Greer's more lengthy use of Pondimin® from that of the other plaintiffs. This argument may have greater significance in other phen-fen cases, though the Court believes this issue can be dealt with by use of the jury aids which are discussed later in this Opinion.

But here, the Court rejects Wyeth's concern that the jury in this consolidated phenfen case could not easily consider this difference, if it found it to be significant.⁹

As a corollary to this argument, Wyeth complains that when different periods of drug use by plaintiffs are combined in a consolidated case, Wyeth's alleged knowledge as to Pondimin® or Redux's™ danger may be different. Obviously, a manufacturer can only be held responsible for what it knew or should have known "given the scientific, technological, and other information available when the product was distributed; or in other words, did he have actual or constructive knowledge of the danger?" *Feldman v. Lederle Laboratories*, 97 N.J. 429, 452 (1984).

While this argument may have significance in some consolidated cases, it seems to have little relevance here. Pondimin® and Redux™ appear to have been used by all these plaintiffs during the narrow timeframe 1996 and 1997. The record here is devoid of information which supports a "state of the art" defense which Wyeth might mount as to only some of these plaintiffs. Accordingly, this

⁹ As the plaintiffs correctly note, "Wyeth has succinctly stated . . . [that]: 'the risk of developing aortic regurgitation as a result of Pondimin® and Redux™ use is strongest for individuals who took the drugs for six months or more and that the rate of aortic regurgitation in individuals who took the drugs for three months or less was not statistically different from the rate of aortic regurgitation in the background population.'" J. Jollis, et al., Fenfluramine and Phentermine and Cardiovascular Findings Effect of Treatment Duration on Prevalence of Valve Abnormalities, 100 CIRCULATION 2071, 2074 (May 2000). The plaintiffs observe, as does the Court, that "the jury can understand the effects of less than three months versus six months or more in assessing the risk of developing aortic regurgitation." Compare *Johnson v. Celotex Corp.*, 899 F.2d at 1285 (consolidating cases where one (1) plaintiff had been exposed for three (3) years from 1942 to 1945 while another plaintiff had been exposed for twenty (20) years from 1946 to 1966).

philosophical concern of Wyeth's should await factual support. Here it is not present.

C.

Receipt of Diet Drug Prescriptions from Different Physicians

The five (5) plaintiffs here appear to have received their diet drug prescriptions from a limited number of physicians located in three (3) states. New Jersey, like the overwhelming number of other states, subscribes to the learned intermediary doctrine -- that is the pharmaceutical company's duty is to warn the physician rather than the patient. *Niemiera by Niemiera v. Schneider*, 114 N.J. 550, 559-561 (1989). Wyeth argues that these prescribing physicians might have reacted differently to warnings even if Wyeth had warned as the plaintiffs would have wished. While the Court, and perhaps the parties, have limited information about the prescribing physicians at this time, there appear to be no notable differences as to warning information which would threaten the fairness of a consolidated trial.

Moreover, New Jersey has adopted a heeding presumption, meaning it is presumed that the prescribing physician would have provided an adequate warning to plaintiffs if it were provided to him or her by Wyeth.

We conclude that the heeding presumption in failure-to-warn cases furthers the objectives of the strong public policy that undergirds our doctrine of strict products liability. The heeding presumption accords with

the manufacturer's basic duty to warn; it fairly reduces the victim's burden of proof; and it minimizes the likelihood that determinations of causation will be based on unreliable evidence. Consequently, we now hold that with respect to the issue of product-defect causation in a product-liability case based on a failure to warn, the plaintiff should be afforded the use of the presumption that he or she would have followed an adequate warning had one been provided, and that the defendant in order to rebut that presumption must produce evidence that such a warning would not have been heeded.

Coffman v. Keene Corp., 133 N.J. 581, 602-603 (1993).

Wyeth has not suggested evidence from any of the prescribing physicians that if confronted with a warning about valvular heart disease, he or she would have ignored that warning and prescribed Pondimin® and Redux™ anyway.¹⁰ And, in the Court's view, it is doubtful that such testimony will be forthcoming.

D.

Different Injuries and Symptoms

Wyeth expresses concern that the five (5) plaintiffs here claim injury to different valves and allege different symptoms arising from those conditions. Some of the plaintiffs allege mitral regurgitation, some allege aortic insufficiency and others allege injury to both valves. It also worries that the plaintiffs will

¹⁰ New Jersey requires when pharmaceutical companies directly advertise their prescription drug products to patients, they must provide adequate warnings directly to the patient. *Perez v. Wyeth Laboratories, Inc.*, 161 N.J. 1 (1999). This Opinion takes no position as to whether the duty to warn in these phen-fen cases should be directed to the physician, the patient, or both.

present different symptoms and injuries allegedly resulting from valvular disease to the jury which would have the effect of confusing it.

The Court finds this argument to have little weight. All the plaintiffs have valvular heart disease. Whether the damage is mild or moderate, the disease process is the same. Review of the fact sheets prepared for the five (5) plaintiffs here does not disclose any obvious differences in symptoms or injuries, but the Court cannot say on this record that they do not exist. Assuming they do, that is beside the point.

As noted, the injury is valvular heart disease. The general medical evidence no doubt will demonstrate the varying degrees and nuances of valvular heart disease along with symptoms persons may experience. Obviously, the jury will have to distinguish this information if it chooses to award damages. But that will always be true in any consolidated trial.

Courts addressing this issue have expressed confidence in the jury's ability to separate these types of issues. *See e.g., Todd-Stenberg v. Dalkon Shield Claimants Trust*, 56 Cal. Rptr. 2d 16, 18 (Cal. Ct. App. 1996) (approving the consolidating of six (6) cases, three (3) of which were jointly tried, where "a large portion of the trial would be devoted . . . to how PID occurs, whether it can be caused by the use of Dalkon Shield, and what other factors might cause or

contribute to the disease”); *Consorti*, 72 F.3d at 1006. Plainly, the similarities here overwhelm the individual differences presented in each plaintiff’s case.

E.

Different Medical Histories and Ages

No doubt Wyeth may, in some cases, present evidence of alternative causation presumably based in part on each plaintiff’s age and medical history. Some of the scientific literature supports Wyeth’s view that age is an important factor in the prevalence of valvular disease in the United States population -- “background regurgitation in the general population increases with age.” J.P. Singh, et al., *Prevalence and Clinical Determinants of Mitral, Tricuspid, and Aortic Regurgitation*, (The Framingham Heart Study), 83 AM. J. OF CARDIOL. 897, 900-901 (1999). But it turns out that the oldest plaintiff here is fifty-eight (58) years old (Torrence). The literature referred to by Wyeth indicates no significant association between valvular heart disease and persons under sixty (60) years old.¹¹

Wyeth also can be expected to point to other “pre-existing conditions” that are associated with an increased risk of valvular regurgitation” such as hypertension, which also are discussed in Singh, et al., *Prevalence and Clinical*

¹¹ The plaintiffs differ in ages with the youngest being thirty (30) years old (Jolin-Wanty) and the oldest fifty-eight (58) (Torrence). The other plaintiffs are thirty-four (34) (Rose), thirty-five (35) (Napier) and forty-seven (47) (Greer). It is doubtful that a plaintiff’s age would cause Wyeth significant prejudice under any circumstances. Plainly, a jury can keep a litigant’s age in mind.

Determinants of Mitral, Tricuspid, and Aortic Regurgitation, (The Framingham Heart Study), 83 AM. J. OF CARDIOL. 897, 900-901 (1999). Review of the five (5) plaintiffs' "fact sheets" shows that only one (1) (Greer) suffers from hypertension. These "fact sheets" disclose few other significant adverse health factors though that could clearly change with further discovery.

But the point to be made here is that there always will be differences in the health profiles of multiple plaintiffs. The relevant question is whether Wyeth will suffer significant prejudice on that account. On this record, the answer is plainly no. Where differences exist between the plaintiffs, Wyeth will call it to the attention of the jury. As will be discussed, the jury will be given the necessary tools to help it separate these facts and individualize its verdict.

F.

The Risk-Benefits of Phen-fen

Finally, Wyeth worries that each plaintiff's tolerance for risk in conjunction with each plaintiff's need and personal desire to lose weight will cause jury confusion. There is no doubt that each plaintiff wished to lose weight and took phen-fen for that purpose. Wyeth suggests that some plaintiffs may have taken phen-fen to lose weight while other plaintiffs did so for health reasons. The distinction approaches the metaphysical. Plainly, Wyeth marketed Pondimin® and Redux™ as weight loss drugs. As Wyeth's April 30, 1996 Press Release

indicating the approval of Redux™ by the FDA makes clear, Redux™, like Pondimin®, is indicated “for management of obesity, including weight loss and maintenance of that weight loss.” The Press Release announces:

**NEW WEAPON IN WAR AGAINST FAT
Redux™ Cleared for Marketing by FDA**

Wyeth-Ayerst Laboratories, a division of American Home Products Corporation (NYSE:AHP), and Intemeuron Pharmaceuticals, Inc. (NASDAQ:IPIC) announces clearance from the U.S. Food and Drug Administration (FDA) to market REDUX™ (dexfenfluramine hydrochloride capsules) C-IV. The first weight loss drug to be cleared in more than 20 years. REDUX marks an important milestone in America’s war on fat. REDUX, when combined with reduced-calorie diet, is indicated for the management of obesity, including weight loss and maintenance of that weight loss. The safety and effectiveness of REDUX beyond 1 year have not been determined at this time.

REDUX is recommended for obese patients with an initial body mass index (BMI) of at least 30 kg/m² (which is approximately 30% over desirable weight) or a BMI of at least 27 kg/m² (which is approximately 20% over desirable weight) in the presence of other risk factors (e.g., hypertension, diabetes or hyperlipidemia).

* * * *

“REDUX is a new treatment option for many obese Americans who struggle to lose weight and keep it off. While losing weight is often difficult, so is maintaining that weight loss,” said Marc Deitch, M.D., Senior Vice President of Medical Affairs and Medical Director of Wyeth-Ayerst. “Having an effective weight loss and maintenance drug helps an individual

complement a diet and improve his or her chances of achieving long-term success.”

Wyeth also contends that some plaintiffs may exhibit different tolerance levels for various risks. Of course, it is claimed that none of the plaintiffs knew that Wyeth’s diet drugs were associated with increased risk of valvular heart disease. Moreover, under the “learned intermediary” defense that Wyeth has indicated it will rely upon, each plaintiff’s tolerance level is irrelevant since the doctor, not the plaintiff, would have been receiving the risk information and would have the final say as to whether the drug was right for the plaintiff. In any case, even without the “learned intermediary” defense, plaintiffs are entitled to the heeding presumption discussed in *Coffman*, at 602-603. While Wyeth may introduce evidence that a given plaintiff would routinely ignore safety warnings, the Court believes it is not likely to do so. In any event, such information would be minimally relevant. *Sharpe v. Bestop, Inc.*, 314 N.J. Super. 54, 77 (App. Div. 1998), *aff’d*, 158 N.J. 329 (1999) (“defendant may *only* introduce rebuttal evidence of plaintiff’s failure to heed warnings if such evidence rises to the level of *habit or routine practice*”) (emphasis added).

III

Wyeth injects the scientific method into the consolidation calculus arguing that empirical evidence establishes that the consolidation of several plaintiffs for trial makes it “significantly more likely . . . [that a jury will] find Wyeth liable

and/or to award higher damages. . . .” Wyeth submits the Affidavit of Irwin A. Horowitz, a Professor of Psychology at Oregon State University to buttress that conclusion.¹²

¹² Dr. Horowitz is a Professor of Psychology at Oregon State University, and has served in this capacity for ten (10) years. Previously, he served as a Research Professor and the Director of the Social/Developmental program. Professor Horowitz received his Ph.D. in Social Psychology from Michigan State University in 1966. He is a fellow of the American Psychological Association, the American Psychological Society and the American Psychology and Law Association. He is also a member of the American Judicature Society.

Professor Horowitz has devoted a substantial portion of his career to researching, writing and teaching about social psychology and the law, with a primary focus on juror information processing in civil trials involving multiple plaintiffs and criminal trials where the defendant is charged with multiple offenses.

As part of his work, Professor Horowitz and a colleague, Professor Kenneth S. Bordens, conducted several controlled simulated trial studies to explore the effects of consolidating multiple plaintiffs in a single trial on damage awards and liability determinations. A number of these studies were funded by grants from the National Science Foundation. Typically, the studies involved more than 100 (up to approximately 700) simulated jurors who were jury eligible in the local jurisdiction. Simulated jurors were randomly assigned to one of the conditions of the experiment(s). Typically, mock jurors were asked to view or listen to a case involving one or multiple plaintiffs (the number of multiple plaintiffs depended on the particular experiment). Judgments then were made either individually or as deliberating groups, depending on the experiment. To create a control group for each plaintiff, several jurors heard the claim of a subset of simulated plaintiffs and decided the issues of compensation and liability separately for those plaintiffs. The study protocols also had other randomly selected jurors or juries judge trials in which, depending on the experiment, manipulated the following variables: (1) the number of plaintiffs in each case; (2) consolidating plaintiffs claiming different levels of injury; (3) informing jurors that the trial plaintiffs represented numerous non-trial plaintiffs; and (4) increasing the complexity of the trial by either increasing the information load, increasing the number of witnesses, changing whether evidence favored one side or could go either way or increasing the technicality of the language used during the trial.

According to Professor Horowitz, when these variables were manipulated, the facts relating to the common plaintiffs across the trials remained the same. At the close of the simulated trials, jurors were asked to decide the issues of compensation and liability for each plaintiff. Jurors were also asked to complete a variety of cognitive measures (e.g., memory, attributions of responsibility). In those studies in which juries were the focus of the analysis, as opposed to individual jurors, Professor Horowitz taped and analyzed the jury deliberations. The damage awards, liability verdicts, and the various cognitive measures obtained in trials consolidating the cases of several plaintiffs were then compared to the results obtained when each plaintiff received a separate trial. The data from these studies were analyzed with statistical methods to determine whether any differences obtained in the various study groups were significant.

Ultimately, the data from these studies served as the basis of seven (7) articles by Professor Horowitz and collaborators concerning the likelihood that prejudice and juror confusion may accompany consolidation. These articles include: I. Horowitz, K. Bordens, The Consolidation of Plaintiffs: The Effects of Number of Plaintiffs on Jurors’ Liability Decisions, Damage Awards and Cognitive Processing of the Evidence, 85 J. OF APPLIED PSYCHOL. 909 (2000); I. Horowitz, K. Bordens, The Effect of Outlier Presence, Plaintiff Population Size, and Aggregation of Plaintiffs on Simulated Civil Jury Decisions, 12 L. & HUM. BEHAV. 209 (1988); I. Horowitz, K. Bordens, The Limits of Sampling and Consolidation in Mass Tort Trials: Justice Improved or Justice Altered?, 22 L. & PSYCHOL. REV. 43 (1998); I. Horowitz, K. Bordens, Information Processing In Joined and Severed Trials, 13 U. OF APPLIED SOC. PSYCHOL. 351 (1983); I. Horowitz, K. Bordens, Mass Tort Civil Litigation: The Impact of Procedural Changes on Jury Decision Making, 81 J. OF APPLIED PSYCHOL. 757 (1996); I. Horowitz, E. Victor, K. Bordens, and M. Bourgeois, The Effects of Trial Complexity on Jurors’ Construction of Evidence, 86 J. OF APPLIED PSYCHOL. 641 (2001).

Specifically, Wyeth claims that Professor Horowitz's research findings provide empirical support for the notion that consolidating these plaintiffs at trial is likely to cause jurors to confuse the evidence relating to individual plaintiffs thereby resulting in substantial prejudice to Wyeth. In one (1) experiment, Professor Horowitz notes that when four (4) or more plaintiffs were consolidated, jurors were significantly impeded in their ability to separate the evidence applicable to each plaintiff. I. Horowitz, K. Bordens, *The Consolidation of Plaintiffs: The Effects of Number of Plaintiffs on Jurors' Liability Decisions, Damage Awards, and Cognitive Processing of Evidence*, 85 J. OF APPLIED PSYCHOL. 909, 916 (2000). Professor Horowitz's research has also shown that juries are significantly more likely to find defendants liable and/or to award higher damages when a trial involves multiple plaintiffs. *Id.* at 916. A similar trend was also observed with respect to juror attribution of responsibility to defendants -- as the number of plaintiffs increased, jurors were more likely to attribute greater responsibility to defendants. *Id.* at 917.

Wyeth also claims that Professor Horowitz's research raises another concern -- that of the "outlier" plaintiff. Simulated civil trials by Professor Horowitz and his colleagues have shown that the presence of an outlier plaintiff (defined as a plaintiff whose injuries are more severe than those of the other plaintiffs) can cause jurors to find the defendant more blameworthy, resulting in higher damage awards.

I. Horowitz, K. Bordens, *The Effects of Outlier Presence, Plaintiff Population Size and Aggregation of Plaintiffs on Simulated Civil Jury Decisions*, 12 L & HUM. BEHAV. 209 (1998). In some mock jury studies, according to Professor Horowitz, participants commented that they inferred that all of the plaintiffs would eventually suffer the same injury as an outlier plaintiff.

The Court finds Professor Horowitz's research and findings to be credible and the concerns he expresses about consolidated multiple plaintiff trials to be entitled to serious consideration. But as already noted, the product liability claims here are quite homogenous. While some legitimate concerns about confusion are raised, they are not of the magnitude suggested by Wyeth and the Court is confident that the trial safeguards which will shortly be discussed will allow the jury to consider the five (5) plaintiffs' claims and to render fair verdicts as to each of them and as to Wyeth. Wyeth's concerns in these regards are discussed in turn.

A.

There Are No "Outliers" in The Consolidated Cases Selected

Professor Horowitz has written that the existence of an "outlier," a more seriously injured plaintiff in the consolidated groups, might cause the jury to infer "that all plaintiffs would eventually develop the injuries claimed by the most severely injured plaintiff." But the record fails to show that any of these five (5) plaintiffs is a likely outlier. They all have valvular disease but none have had

valve replacement surgery. While the Court doubts that the inclusion of such a plaintiff would create the outlier concern expressed by Professor Horowitz, it already has indicated that the valve replacement cases would, for the time being, be separately tried. It is also anticipated that plaintiffs with primary pulmonary hypertension, a significantly more serious medical condition, will not be joined with plaintiffs having only valvular disease. Since it cannot seriously be argued that any outliers exist among these five (5) plaintiffs, any concerns about outliers should await factual support that they are present.

B.

The Plaintiffs Are Homogeneous

Professor Horowitz based the conclusions made with respect to the consolidation here on the assumptions that Wyeth asserts about the heterogeneous nature of the plaintiffs. The assumptions Professor Horowitz has been asked to make by Wyeth, however, are not supported by the record before this Court. As already noted, the plaintiffs here have much in common. When cases are combined some differences inevitably will exist. The question is whether those differences imperil the fairness of this consolidated trial.

On this score, the plaintiffs have submitted the Affidavit of Professor Peter Blanck, the Charles M. and Marion Kierscht Professor of Law and Professor of

Psychology and of Public Health at the University Iowa.¹³ Professor Blanck

concludes that:

[C]onsolidating or aggregating five plaintiffs into one trial group for purposes of this litigation need not inherently bias or prejudice the jury's verdicts. Procedural and substantive safeguards are available to eliminate or mitigate to harmless levels potential bias or prejudice. These safeguards and trial techniques include the Court ensuring jurors' comprehension through jury aids, consolidating the plaintiffs in homogeneous or similar groups, and excluding an outlier (i.e., non-typical) case. In its June 29 (sic, 28), 2004 case management conference, this Court suggested such procedural and substantive safeguards that may eliminate or mitigate potential unfairness claimed to be associated with consolidation (e.g., eliminating outliers, grouping cases in a homogeneous fashion, and assisting juries in separating and comprehending facts).

Professor Blanck's conclusions are buttressed by Robert B. Hirschhorn ("Hirschhorn"), a jury and trial consultant.¹⁴ Hirschhorn concludes that the differences that exist among plaintiffs where "two, four or even ten plaintiffs" are

¹³ Professor Blanck's credentials are impressive. He is a social psychologist and attorney by education, training, and experience. He presently holds an endowed chair at the University of Iowa School of Law (Charles M. and Marion Kierscht Professor of Law), and is a University Professor at the University of Iowa. He also serves as Director of Law, Health Policy & Disability Center at the University of Iowa College of Law.

He received a Ph.D. in Social Psychology from Harvard University and J.D. from Stanford Law School. He served as Chair of the American Psychological Association's Committee on Standards in Research, and was a Fellow at Princeton University's Woodrow Wilson School and a Mary Switzer Scholar.

As a Professor and researcher, Professor Blanck has focused his attention on disability civil rights law, social science research methods, judge and jury decision-making processes, and contract law. He co-authored with Professor Michael Saks an article in the *Stanford Law Review* where they examined the unrecognized benefits of consolidating or aggregating cases in mass tort litigation, in circumstances similar to the present litigation. Michael Saks and Peter Blanck, Justice Improved: The Unrecognized Benefits of Aggregation and Sampling in the Trial of Mass Torts, 44 *Stan L. Rev.* 815 (1992).

¹⁴ Robert B. Hirschhorn is an attorney and jury consultant by education, training, and experience. He received a B.A. in Government and International Relations from Clark University in 1978, and a J.D. from St. Mary's University School of Law in 1981 and has acted as a jury and trial consultant for twenty (20) years.

consolidated in one (1) trial would “not prejudice Wyeth, create [a] significantly increased risk of [a] verdict for Plaintiffs, and/or result in higher damage awards.”

This Court agrees with Professor Blank and Hirschhorn that these remarkably similar five (5) cases, when consolidated for trial, will not impair Wyeth’s right to the fair trial. To insure that the differences that do exist will not prejudice Wyeth, the Court intends to take steps at trial which it will now turn to.

C.

Tools to Aid the Jury Will Minimize Any Prejudice

Professor Horowitz’s simulated mock trials were conducted without jury aids. Professor Horowitz admitted that in one of his simulations mock jurors asked to take notes, but those requests were denied. *See* Irwin A. Horowitz & Ken Bordens, *The Consolidation of Plaintiffs: The Effects of Number of Plaintiffs on Juror’s Liability Decisions, Damage Awards, and Cognitive Processing of Evidence*, 35 JOURNAL OF APPLIED PSYCHOLOGY, 909, 917 (2000). Professor Horowitz acknowledges that permitting notetaking would have permitted the jurors to “keep better track of the individual plaintiffs. . . .” *Id.*; *see e.g.*, Lynne Forster Lee, Irwin Horowitz & Martin Bourgeois, *Effects of Notetaking on Verdicts and Evidence Processing in a Civil Trial*, 18 LAW AND HUMAN BEHAVIOR, 567, 576 (1994).

Hirschhorn has expertise in the art of jury selection and has published several articles dealing with this subject and trial dynamics. Accepting the variables Professor Horowitz mentioned, such as age, medical history, drug use, duration of use, symptoms, and the extent of injuries, Hirschhorn believes that the jury will have no problem sorting through the evidence. Hirschhorn suggests that to help jurors keep information separate, the Court might wish to provide some aids. Hirschhorn suggests:

- (a) providing the jury a four-inch notebook with dividers containing specific facts for each plaintiff;
- (b) allowing the jury to take notes during the trial;
- (c) allowing the jurors to write down questions of a particular witness; and
- (d) referring to fact specific evidence with a color-code, alpha-code, or number-code by plaintiff.

Hirschhorn also suggests that the Court “provide separate jury charges with separate instructions to eliminate any prejudice that may occur from jurors comparing the extent of each plaintiff’s injuries.” Separate jury charges allow the jury to consider the evidence regarding each plaintiff individually, which Hirschhorn believes will eradicate any prejudice that may result from consolidation.

Professor Blanck concurs in these views. He believes that jury aids can help jurors separate the evidence and eliminate minor heterogeneity that may well exist in a consolidated trial group.

Appellate and trial courts which have considered these issues agree that concerns about jury confusion can easily be remedied by the trial judge. In *Todd-Stenberg v. Dalkon Shield Claimants Trust*, 56 Rptr. 2d 16, 18 (Cal. Ct. App. 1996), the appellate court sustained the consolidation of six (6) cases, three (3) of which had proceeded to trial. In doing so, the appellate court noted that the trial court had taken steps to minimize potential jury confusion: “[t]he jury was given a separate binder of evidence and separate chronologies prepared on each plaintiff.” See also *In re Eastern & Southern Districts Asbestos Litig.*, 772 F. Supp. 1380, 1388 (E.D. & S.D.N.Y. 1991).

This Court intends to permit the jury to take notes and to ask questions in this consolidated trial. **R.** 1:8-8(b) and (c). The Court will meet with the parties to discuss additional trial safeguards but has already indicated that separate materials will be given to the jury about each plaintiff. Color-coding the evidence may be a valuable tool as well. The specific safeguards which the Court will adopt will be the subject of a separate Order after the parties have had an opportunity to be heard on potential specific measures.

IV

For the reasons set forth in this Opinion, the Court finds that the consolidation of these five (5) plaintiffs for trial will serve the ends of justice by producing a fair outcome with efficiency and greatly reduced expense to the parties. R. 4:38-1 exists precisely for that reason. Wyeth's concerns of prejudicial confusion in such a procedure are overblown here and in the few instances where the concern has merit can easily be dealt with through the tools discussed in this Opinion.

An Order is enclosed with this Opinion.

CHARLES J. WALSH, J.S.C.

CJW/len