Blain v. Smithkline Beecham Corp.

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MEMORANDUM OPINION

In moving to certify this product liability action against the manufacturer of the antidepressant drug Paxil as a national class action, the plaintiffs seek to represent all persons whose children under age eighteen committed or attempted to commit suicide while using the drug. The gist of the plaintiffs' claims is that despite its specific knowledge of Paxil's association with the increased risk of suicidality in pediatric patients, the defendant GlaxoSmithKline ("GSK") failed to warn doctors, the medical community and the public of this danger.[1] The plaintiffs seek a class trial on three issues relating to liability: (1) whether Paxil can cause suicidality in pediatric patients; (2) whether GSK knew or should have known that it can; and (3) whether GSK failed to adequately warn of the danger. Opposing certification, GSK argues that the plaintiffs cannot satisfy the commonality, typicality and adequacy requirements of a class action under Federal Rule of Civil Procedure 23(a), nor can they establish the predominance and superiority elements of Rule 23(b)(3).

A class action is not an appropriate vehicle for litigating the issues in this case. The plaintiffs fail to meet the typicality and adequacy prongs of Rule 23(a). Typicality is wanting because the individual circumstances of the named plaintiffs are markedly different from those of the putative class members and GSK can raise unique defenses to almost each class member's claim. These same differences result in interests so divergent that the named plaintiffs are inadequate representatives of the absent class members. Finally, the predominance and superiority requirements of Rule 23(b)(3) are lacking - predominance because the proposed common issues are overwhelmed by the differences among the factual and legal issues affecting individual causation, damages and defenses; and, superiority because the proposed class would be unmanageable in light of the choice-oflaw conflicts that are resolved in favor of each individual's home state. In essence, the plaintiffs have failed to define a class capable of ascertaining membership without individualized fact-finding. Therefore, the motion for certification will be denied.

I. Background

Paxil[2] was first approved for sale in the United States in December of 1992 for the safe and effective treatment of depression in adults.[3] By the early 2000s, the FDA expanded approval to include treatment of obsessive compulsive disorder, social anxiety disorder and generalized anxiety disorder in adults; and, it approved a new controlled-release formulation, called Paxil CR, to treat depression.[4] Paxil has never been approved for treatment of any condition in children.[5] Nonetheless, physicians may prescribe Paxil "off-label"[6] for an "unapproved" population, such as children or adolescents,

without FDA knowledge or approval.[7] Since 1997, drug manufacturers have been permitted to disseminate information about "off-label" uses for their drugs generated by independent sources, including medical journal articles, textbooks and participation in medical conferences. The manufacturer must disclose both its interest in the drug and the fact that the use has not been approved by the FDA. The information must not be false or misleading. See 21 U.S.C. §§ 360aaa (2006); Wash. Legal Found. v. Henney, 128 F. Supp. 2d 11 (D.D.C. 2000).

From 1992 through 2004, the "PRECAUTIONS" section in the Paxil prescribing information, in relevant part, stated: "Safety and effectiveness in children have not been established."[8]

On October 15, 2004, after the FDA completed a review of pediatric clinical data for all SSRIs and other antidepressants, it required all manufacturers of SSRIs to include on the drug label the following "Black Box" warning:

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.

Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS and PRECAUTIONS - Pediatric use.) Pooled analysis of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.[9] Beginning in January of 2005, defendant GSK complied with this FDA directive and updated its label accordingly.[10]

The plaintiffs allege that between 1998 and 2001, GSK conducted at least three placebo-controlled studies of Paxil for pediatric depression which showed that the drug is ineffective in the treatment of pediatric depression and is associated with a high increased risk of suicidal events. The plaintiffs claim that "as [the results of] these studies became known to GSK, the company reacted by seeking to hide the data from the public," and failed to "publish its analysis of the suicidality risk associated with the pediatric use of Paxil until 2006."[11] In addition, the plaintiffs assert that despite these studies showing that Paxil was neither safe nor effective in the treatment of pediatric depression, GSK began a marketing campaign to promote Paxil as safe and effective for such treatment.[12] GSK's promotion of Paxil for an off-label use, according to the plaintiffs, was false, misleading and not based upon independently developed data.

II. Proposed Class Definition

The plaintiffs are moving for certification of the following class:

All persons (or if such person is deceased or under the age of majority, that person's legal representative) in the United States who committed suicide, attempted to commit suicide, or engaged in other self-injurious behavior while under the influence of the prescription drug Paxil and who were under the age of 18 at the time of the person's suicide, attempted suicide, or self-injurious act at any time after December 29, 1992.[13]

III. Legal Standards for Class Certification

To be certified, a class must satisfy all four requirements of Rule 23(a) and must fit one of the provisions of Rule 23(b). The plaintiffs must demonstrate that: (1) the size of the class is so numerous that joinder of all members is impracticable; (2) there are questions of law and fact common to the class; (3) the claims or defenses are typical of the class; and (4) the representatives will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a)(1)-(4). Additionally, the proposed class action must be one of the types recognized by Rule 23(b). Here, plaintiffs have moved for certification only under subsection (b)(3), which requires a finding that common questions of law or fact predominate over questions affecting only individual class members, and that a "class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3).

The burden is on the plaintiffs to demonstrate that a class should be certified. Johnston v. HBO Film Mgmt., Inc., 265 F.3d 178, 183 (3d Cir. 2001); Baby Neal v. Casey, 43 F.3d 48, 55 (3d Cir. 1994). Though the plaintiffs need not establish the merits of their case at the class certification stage and the substantive allegations of the complaint must be taken as true, Chiang v. Veneman, 385 F.3d 256, 262 (3d Cir. 2004) (citing Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974)), the court must conduct a rigorous analysis to determine the suitability of resolving the issues in a class action. Because certification and the merits are intertwined, this analysis necessitates a factual inquiry. Beck v. Maximus, Inc., 457 F.3d 291, 297 (3d Cir. 2006) (citing Newton, Merrill Lynch, Fenner & Smith, Inc., 259 F.3d 154, 167 (3d Cir. 2001)). As the United States Supreme Court recognized in Coopers & Lybrand v. Livesay, 437 U.S. 463 (1978):

Evaluation of many of the questions entering into determination of class action questions is intimately involved with the merits of the claims. The typicality of the representative's claims or defenses, the adequacy of the representative, and the presence of common questions of law or fact are obvious examples. The more complex determinations required in Rule 23(b)(3) class actions entail even greater entanglement with the merits.

Id. at 469 n.12 (quoting 15A Charles Alan Wright et al., Federal Practice & Procedure § 3911, at 485

n.45). Nonetheless, the court may not determine the merits of the plaintiff's case. Eisen, 417 U.S. at 177-78. Thus, we must look beyond the complaint and consider the substantive elements of the plaintiffs' cases. See Newton, 259 F.3d at 166.[14]

IV. Sufficiency of the Class Definition

Some courts have focused on the sufficiency of the class definition itself before embarking on an analysis of the Rule 23(a) requirements. They have refused to certify classes where a determination of the merits of each individual's claims would have been necessary to determine class membership. Kline v. Sec. Guards, Inc., 196 F.R.D. 261, 267-68 (E.D. Pa. 2000); Forman v. Data Transfer, Inc., 164 F.R.D. 400, 403 (E.D. Pa. 1995); Black v. Premier Co., No. Civ. A. 01-4317, 2002 WL 32122658, at *5 (E.D. Pa. Sept. 13, 2002) (Baylson, J.).

Because the same considerations in evaluating the sufficiency of the class definition are implicated in the commonality, typicality and adequacy of representation analyses, and courts are charged with analyzing all of the Rule 23(a) factors anyway, the sufficiency of the class definition can be assessed in the context of the Rule 23(a) analysis without engaging in a redundant exercise.

Suffice to say at this point that the proposed definition cannot work as a vehicle for a class action. The reasons why the class definition in this case does not pass the test are detailed in the following discussion of the Rule 23(a) requirements.

V. The Four Requirements of Rule 23(a)

A. Numerosity

GSK does not challenge numerosity. There are presently fifty-six people that are potential members of the putative class. In addition, based on GSK's own clinical trial data and statistical analysis,[15] the plaintiffs estimate that there are potentially 7,000 children who committed or attempted suicide while taking Paxil each year during the class period.[16]

Thus, the numerosity requirement is satisfied.

B. Commonality

Commonality requires that the plaintiffs share a question of law or fact with the prospective class members. The commonality threshold is low. So long as the named plaintiffs share at least one question of fact or law with the grievances of the prospective class, the existence of individual facts and circumstances will not defeat commonality. Baby Neal, 43 F.3d at 56.

The plaintiffs propose three questions they contend are common to all members of the putative class:

1. Whether Paxil can cause a pediatric patient to develop suicidality ("General Causation");

2. Whether, and when, GSK knew or should have known that Paxil is associated with suicidality in pediatric patients (GSK's Knowledge"); and

3. Whether Paxil's label, promotion, and advertising were adequate during the class period to apprise the medical community of Paxil's true risks ("Failure to Warn Claim").[17]

1. General Causation

The plaintiffs contend that there are two separate causation inquiries: can Paxil cause suicide or suicidality, and did Paxil cause the suicide or suicidality in the particular plaintiff.[18] They propose that the first issue, general causation, be decided on a class wide basis, leaving specific causation to be determined at each individual's trial.

The two parts of the causation issue cannot be separated. Answering the question whether Paxil can cause suicidality in pediatric patients is only the starting point in the causation inquiry. The answer to the first part reveals only who are potential members of the class. It is the answer to the second part, that is, who suffered harm as a result of the drug, that defines the class. Thus, whether the drug did cause the individual plaintiff's suicidality is the determinative question for class membership.

The answer to the specific causation question depends upon a number of individualistic factors, such as: the patient's diagnosis; the dosage taken; the duration of treatment; the patient's age and physical characteristics; the patient's family, mental and medical histories; and whether the patient previously suffered from suicidality. Such a plaintiff-specific analysis dominates the causation inquiry.[19] Thus, causation does not provide a common question.

2. GSK's Knowledge

Whether and when GSK knew or should have known that Paxil is associated with suicidality in pediatric patients is common to the putative class. The individual facts of each member's case, no matter how different, do not affect what and when GSK learned about the incidence of pediatric suicidality and Paxil.[20]

Therefore, because the determination of GSK's knowledge requires no individual proof and will apply to all members, it is a question common to the class.[21]

GSK argues that what GSK knew about Paxil and pediatric patients changed over time because the science was evolving; and, as a result, what duty it had and what was an adequate warning changed.[22]

Consequently, according to GSK, to determine the adequacy of a warning when each member's cause

of action accrued would entail a varying inquiry.[23]

The question of what knowledge GSK had regarding Paxil's association with suicidality in pediatric patients and when it had the knowledge are common questions for the class. If the substance of the warning changed over the years in response to changing knowledge, the differences could be accounted for by defining subclasses corresponding to the relevant periods. Therefore, contrary to GSK's assertion, individual adjudications would not be necessary to ascertain what GSK knew and when.

3. Failure to warn

Plaintiffs argue that the jury's findings on the failure to warn issue will be common to all members of the class because:

A jury can compare what GSK said regarding pediatric suicidality in Paxil's label, advertising and promotion with what GSK knew about pediatric suicidality. A jury may find that GSK adequately warned of this risk at all times through the class period or that at a certain time, Paxil's warning became adequate after previously being inadequate . . . The common finding may effect [sic] class members in different ways depending on when a class member may have been prescribed Paxil or whether a class member's doctor was already aware of the information. However, the fact that a common liability finding may affect class members differently does not render the issue individual.[24]

What GSK knew and what it warned are questions common to all. Who was to receive the warnings and how the warnings were to be given, however, are not common because they are informed by requirements that vary from state to state. The adequacy of GSK's warnings regarding the risk of suicidality in pediatric patients is governed by different state laws. In jurisdictions where the learned intermediary doctrine applies, GSK may have no duty to warn individual users, depending on each individual plaintiff's physician's knowledge of the risks of prescribing Paxil to pediatric patients. In several jurisdictions, a physician's decision to use a manufacturer's device in an off-label manner does not per se subject the manufacturer to liability, even if it knows of the off-label use. Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 439 (E.D. Pa. 2004) (dismissing negligence claim based on a manufacturer "allowing" a physician to use a medical device in an off-label manner when it knew the FDA had only approved it for a different use); Cox v. Depuy Motech, Inc., No. 95-CV-3848-L, 2000 WL 1160486, at *8-9 (S.D. Cal. Mar. 29, 2000). In at least one jurisdiction, the manufacturer has no duty to warn of risks associated with off-label uses of its drug, making a finding on the adequacy of a warning irrelevant. See Robak v. Abbott Labs., 797 F. Supp. 475, 476 (D. Md. 1992). In other jurisdictions, a manufacturer can be liable for failure to warn of risks of off-label use of its product if that use accounted for a significant portion of the manufacturer's sales of the drug. See, e.g., Miles Labs., Inc. v. Superior Court, 184 Cal. Rptr. 98, 103 (Cal. Ct. App. 1982). In some jurisdictions, the intervening negligence of a physician precludes the manufacturer's liability for failure to warn. See Peterson v. Parke Davis & Co., 705 P.2d 1001, 1003 (Colo. Ct. App. 1985); Reeder v. Hammond, 336

N.W.2d 3, 5-6 (Mich. Ct. App. 1983).

Seeking to answer the question of the "adequacy" of GSK's warnings would require the application of different legal principles to too many individual claims. Thus, this issue fails to meet the Rule 23(a)(2) requirement of commonality.

In sum, the only proposed common issue that meets the commonality prong is the one regarding GSK's general knowledge of the risk of suicidality in pediatric patients. Because the plaintiffs are required to share only one question of fact or law with the grievances of the prospective class, they overcome the commonality hurdle of 23(a)(2).

C. Typicality

The typicality prong of Rule 23(a) requires that the claims or defenses of the plaintiffs are typical of the class. Fed. R. Civ. P. 23(a)(3). Typicality requires a strong similarity of legal theories to ensure that the class representatives' pursuit of their own goals will work to benefit the entire class. Barnes v. Am. Tobacco Co., 161 F.3d 127, 141 (3d Cir. 1998); Jones v. GPU, Inc., 234 F.R.D. 82, 97 (E.D. Pa. 2005). It entails an inquiry as to whether "the named plaintiff's individual circumstances are markedly different or the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based." Baby Neal, 43 F.3d at 57-58 (quoting Eisenberg v. Gagnon, 766 F.2d 770, 786 (3d Cir. 1985)). Moreover, "[w]here the defendant can raise unique defenses to each plaintiff's claim, typicality may not exist if the defenses could threaten to become the focus of the litigation." Jones, 234 F.R.D. at 98. At the same time, "factual differences will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members, and if it is based on the same legal theory." Baby Neal, 43 F.3d at 58 (quoting Hoxworth v. Blinder, Robinson & Co., 980 F.2d 912, 923 (3d Cir. 1992)). Unlike the commonality requirement, however, typicality requires more than just "one unifying factual or legal question." In re Paxil, 212 F.R.D. at 550.

An examination of the numerous factual and legal differences between the two representatives themselves, and among them and the class members reveals how marked the differences are. These differences overwhelm any similarities, defying typicality.

The plaintiffs present Pamela Blain as typical of the class of parents who had a child commit suicide while under the influence of Paxil and who claim that Paxil was the proximate cause of death. They proffer Tonya Brooks as typical of the class of plaintiffs who attempted to commit suicide or engaged in other self-injurious behavior while under the influence of Paxil, which behavior was proximately caused by taking Paxil.

As alleged in the complaint and the motion for class certification, Pamela Blain, a Kansas citizen, is the personal representative of the estate of her son Trevor, who allegedly committed suicide at age

eleven after taking Paxil for thirty-three days. She purports to represent family members who have lost a child due to a "Paxil-induced" suicide. Trevor, who was eleven years old, died in December of 2000, two weeks after attempting suicide by hanging.[25] His parents had divorced when he was young, and he had fears and anxiety about attending school.[26] In early 2000, his pediatrician diagnosed Trevor with separation anxiety and referred him to a psychiatrist. The doctor's diagnoses were separation anxiety and depression.[27] Several months later, in October of 2000, the psychiatrist prescribed between 10 and 20 mg/daily of Paxil.[28] Soon after he began taking Paxil, Trevor experienced angry outbursts, insomnia, increased fidgetiness, and a detached appearance. Approximately one month later, he attempted suicide by hanging in a laundry room in his home and died two weeks later.[29]

According to GSK, prior to taking Paxil, Trevor was "terrified' of attending school, afraid of his father, and highly anxious and depressed. He also had an extensive family history of mental health issues. Both his parents and his sister had been prescribed antidepressants for anxiety and depression, and his sister had attempted suicide.[30] GSK also suggests that based on the police investigation into the cause of Trevor's death, the episode may have been an accident or prank, and not an attempted suicide.[31]

A nurse practitioner working under the supervision of a psychiatrist provided Trevor with Paxil. The nurse and the doctor had received the Paxil warnings that were in effect in 2000, and the nurse gave Trevor's mother a copy of the package insert.[32] Trevor's mother testified that if she had known Paxil had not been approved for pediatric patients (which the package label stated at the time), she would not have allowed her son to take it. Neither the nurse nor the psychiatrist recalls any GSK representative discussing or otherwise promoting the use of Paxil in the pediatric population.[33]

Tonya Brooks is a Texas resident who, at age seventeen, attempted suicide after taking Paxil for 144 days. She seeks to represent those children who attempted suicide while "under the influence of Paxil." Tonya was sixteen years old when she saw a television commercial encouraging people who were uncomfortable in social settings to talk to their doctor about getting Paxil.[34] Because she felt uncomfortable in large crowds, she asked her family doctor if Paxil would help.[35] After diagnosing her with social anxiety disorder, her doctor prescribed between 12.5 and 25 mg/daily of Paxil CR.[36] Soon after taking Paxil, Tonya cut her wrist and leg with a razor blade multiple times, and covered the marks with clothing. She experienced increased anxiety, anger, agitation, and hostility; and became emotionally abusive to friends and family.[37] Five months later, in June of 2004, plaintiffs allege that Tonya attempted to commit suicide by swallowing large amounts of Paxil and Ambien, a prescription sleep aid. Although she survived, she was in a serious car accident the next day while still "under the influence of the medication she had taken."

Three days later, Tonya gouged a three-inch deep hole in her leg. After she ceased taking Paxil, her suicidal and self-mutilation desires quickly subsided.[38]

According to GSK, when Tonya was hospitalized for her suicide attempt, she tested positive for PCP and amphetamines. She told her doctor that she did not really intend to kill herself but had mistakenly taken too many pills.[39] GSK suggests multiple other possible causes for Tonya's behavior. It points to Tonya's "tumultuous childhood," her extensive family history of anxiety, depression and alcohol abuse, and her fear of crowds and panic attacks. She also may have bipolar disorder, which, GSK asserts, could be the cause of her behavioral changes that occurred after she started taking Paxil.[40]

Tonya is the only pediatric patient for whom Dr. Lin, her family physician, ever prescribed Paxil. Before prescribing Paxil for Tonya, Dr. Lin had received two "Dear Healthcare Provider" letters from GSK about the FDA's ongoing analysis of pediatric suicidality data. Accordingly, she was aware that Paxil was not approved for pediatric use.[41]

Just as there are between the two plaintiffs, there are numerous critical factual and legal differences among the putative class members that preclude typicality. Each class member took varying doses of Paxil, for varying indications, at various times, at different developmental stages and for different durations. Each has different medical, psychosocial, and pharmaceutical histories. The prescribing physicians for each had different specialties, varying levels of knowledge about Paxil and other SSRIs, different clinical experience with Paxil and similar medications for pediatric patients, and varying levels of contact with the patient. Based on these differences, GSK can potentially raise unique defenses to each plaintiff's claim.

Any similarity in legal theories among the named plaintiffs and the proposed class of plaintiffs is eclipsed by the individualistic defenses GSK can raise to each plaintiff's claim. "Where the defendant can raise unique defenses to each plaintiff's claim, typicality may not exist if the defenses could threaten to become the focus of the litigation." Jones, 234 F.R.D. at 98. The danger is that the class representatives will be preoccupied with meeting and defeating those defenses unique to them at the expense of those issues that they share with the class members, a problem also implicating adequacy. Therefore, because the individual circumstances of each of the named plaintiffs are so markedly different from each other and those of the absent class members, the plaintiffs have failed to meet the typicality requirement.

D. Adequacy of Representation

Rule 23(a)(4) aims to protect the interests of the class. There are two parts to this test. The first goes to the competency of counsel, and the second to the plaintiffs' motivation and ability to protect the interests of the other class members.

The first part of the adequacy requirement is not at issue. GSK does not contest counsel's competency to prosecute a class action. Class counsel have litigated other class actions, have over a decade of experience with cases involving SSRIs, and are presently counsel of record in other class

actions involving Paxil.[42]

The second prong of the adequacy of representation requirement, which GSK does challenge, tends to merge with the commonality and typicality requirements of Rule 23(a). Jones, 234 F.R.D. at 98. As previously determined, the plaintiffs have failed to meet the typicality requirement. The same factual and legal differences among the named plaintiffs and the unnamed class members that defeat typicality render plaintiffs inadequate representatives of the putative class. The divergent interests and circumstances will impair the plaintiffs' ability to adequately protect the interests of the class members. Therefore, the plaintiffs have failed to satisfy the second part of the adequacy requirement.

VI. Rule 23(b)(3) - Predominance and Superiority

Meeting the four requirements of 23(a) satisfies only part of the certification test. The action must also qualify as one of the types of class actions described in Rule 23(b). In this case, plaintiffs have moved for certification under subsection (b)(3), which requires that common questions of law or fact predominate over questions affecting only individual class members, and that a "class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). Thus, the plaintiffs must satisfy both the predominance and the superiority aspects of Rule 23(b)(3).

In determining whether the action fits within Rule 23(b)(3), the Rule specifically directs the court to consider the interest of class members in individually controlling the litigation, the status of ongoing litigation brought by members of the class, the desirability of concentrating the litigation in the particular forum, and likely management difficulties. Fed. R. Civ. P. 23(b)(3)(A)-(D). In the end, it is the interests of the individual members in controlling their own litigation that drives the certification decision on predominance. The superiority analysis focuses on the advantages and disadvantages of using the class-action device in relation to other litigation methods.

A. Predominance and Rule 23(c)(4)(A)

There are two views of the interplay between the predominance requirement and subsection 23(c)(4), which provides that: "[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues." One is that Rule 23(c)(4)(A) may be used to certify a class regardless of whether the claim as a whole satisfies Rule 23(b)(3)'s predominance requirement. See Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996). The other view is that only after the predominance requirement of 23(b)(3) is satisfied may common issues be certified pursuant to 23(c)(4). The latter approach considers Rule 23(c)(4) as a procedural tool to sever common issues for trial and not as a vehicle to reach certification. Arch v. Am. Tobacco Co., 175 F.R.D. 469, 496 (E.D. Pa. 1997) (quoting Castano v. Am. Tobacco Co., 84 F.3d 734, 745 n.21 (5th Cir. 1996)).

The plaintiffs urge adoption of the former position. They contend that even if common questions do

not predominate over individual questions, the court may isolate the common issues and perform the predominance evaluation solely with respect to their proposed common issues.[43] I disagree.

The better view is that issue certification under 23(c)(4)(A) does not obviate the need to evaluate predominance. In other words, a predominance determination is a prerequisite to certification under Rule 23(b)(3). Indeed, the 1966 Advisory Committee Notes so instruct, stating that only where predominance exists can the class action device be used. Fed. R. Civ. P. 23(b)(3) Advisory Committee's Note. Using subsection 23(c)(4) to certify a putative class that is otherwise improper for certification would bypass the 23(b)(3) predominance requirement. Castano, 84 F.3d at 745 n.21; Arch, 175 F.R.D. at 496. While some courts have noted that the purpose of Rule 23(c)(4) is to provide "some flexibility in separating the distinct issues and classes within the case in order to fashion a case suitable for class action treatment . . . and give courts the discretion necessary to advance judicial economy," those concerns have always been trumped when "the common issues are inextricably tied to the individual issues." In re Paxil, 212 F.R.D. at 543. Therefore, only after the court has found that the cause of action satisfies the predominance requirements of Rule 23(b)(3) may it certify common issues pursuant to Rule 23(c)(4)(A). See Arch, 175 F.R.D. at 496.

B. Predominance and Rule 23(b)(3)

In a class action brought under Rule 23(b)(3), common questions of law or fact must predominate over questions affecting only individual members and must be a significant part of the individual cases. The predominance inquiry is "far more demanding" than the commonality requirement of Rule 23(a). Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623-24 (1997).

Subdivision [23](b)(3) encompasses those cases in which a class action would achieve economies of time, effort, and expense, and promote uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results. . . .

It is only wh[en] predominance exists that economies can be achieved by means of the class-action device.

Fed. R. Civ. P. 23(b)(3) Advisory Committee's Note.

Predominance poses a problem for certification in drug product liability cases. See, e.g., In re Prempro Prods. Liab. Litig., 230 F.R.D. 555, 567 (E.D. Ark. 2005); Zehel-Miller v. AstraZenaca Pharm., L.P., 223 F.R.D. 659, 663 (M.D. Fla. 2004); In re Baycol Prods. Litig., 218 F.R.D. 197, 204 (D. Minn. 2003); In re Paxil Litig., 212 F.R.D. 539, 551 (C.D. Cal. 2003); In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 65-68 (S.D.N.Y. 2002); In re Propulsid Prods. Liab. Litig., 208 F.R.D. 133, 144 (E.D. La. 2002). Individual issues in such cases invariably overwhelm common ones. This case is no different.

As the court stated in In re Paxil in finding no Rule 23(b)(3) predominance: [I]ndividual questions of

fact regarding causation nevertheless subvert any benefits to be gained through a class action proceeding. Whether, and to what extent, Paxil causes discontinuation symptoms varies from patient to patient. Not only do individual physiologies affect the causation issues, but so too do the underlying illnesses and medical history of each individual plaintiff. 212 F.R.D. at 551. See also Georgine v. Amchem Prods., Inc., 83 F.3d 610, 628-29 (3d Cir. 1996) (finding no 23(b)(3) predominance where each plaintiff's exposure to product and lifestyle differed from one another in material respects, and manufacturers could raise varying defenses to each individual class member's claim), aff'd sub nom., Amchem Prods. v. Windsor, 521 U.S. 591 (1997); In re Orthopedic Bone Screw Prods. Liab. Litig., MDL No. 1014, No. Civ. A. 93-7074, 1995 WL 273597, at *10-11 (E.D. Pa. Feb. 22, 1995) (Bechtle, J.) (finding lack of predominance where "there are simply too many individual issues with respect to causation, liability and damages," including different defenses to be raised against different plaintiffs).

For the same reasons typicality and adequacy are lacking, so is predominance. The number and complexity of the questions that must be resolved to determine liability in each individual's case predominate over any common questions. For instance, the psychological and medical histories, the pharmacological regimens, the roles of the physician and the physical characteristics in each individual's case vary. Depending on the individual's home state, GSK's defenses may or may not be applicable, or may be applied differently. In short, determining liability in each case will require an individual fact intensive inquiry that will minimize any common questions.

C. Superiority

Not only do the plaintiffs fail to satisfy the predominance prerequisite, they cannot meet 23(b)(3)'s superiority requirement which requires the plaintiffs to prove that a "class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). The superiority analysis assesses the advantages and disadvantages of using the class-action device in relation to other methods of litigation. The Rule itself suggests various factors to consider in making this assessment: the interest of class members in individually controlling the litigation, the state of ongoing litigation brought by class members, the desirability of concentrating the litigation in the particular forum, and likely management difficulties. Id.[44]

1. Material Advancement of the Litigation

Litigating the proposed common issues will involve scientific evidence, voluminous documents, a multitude of witnesses and volumes of discovery. According to the plaintiffs, many class members cannot individually afford the expense of proving a prescription drug product liability case. This argument overlooks the fact that most, if not all, cases of this type are litigated on a contingency fee basis. Consequently, the individual plaintiff need not bear the cost of proceeding during the pendency of the case.

In addition, given the multitude of different circumstances and defenses among the class members, each individual trial will consume a significant portion of each individual's case. Hence, if costs were prohibitive, the expense of litigating a case would impede each individual in any event.

As seen in considering typicality, the most significant portion of the litigation parsing out causation will take place in the context of each individual's claim where liability will consume the fact-finding process. Even though the issues proposed by the plaintiffs must be tried in each trial, it may be more beneficial for a jury to assess the individual claims in the context of these issues. Hence, although it may be more convenient for counsel to pool resources, class treatment will not materially advance the litigation.

2. Class Members' Interest in Individually Controlling their Lawsuit

Although it may be more efficient for counsel and the court to try the issue of general causation in a class trial, it would sacrifice the individual plaintiff's interest in controlling the litigation. Any hope of efficiency would be subverted by the individual and unique circumstances of each member's case which are inextricably intertwined with the general causation issue.

Whether putative class members have a significant interest in individually prosecuting their own separate lawsuits is affected by the financial stakes involved in each individual's case. The greater the damages in one's claim vis-a-vis others' claims, the greater the interest the individual has in controlling the litigation. The lesser the potential damages, the less the interest is because separate suits may be impracticable. See Fed. R. Civ. P. 23(b)(3) Advisory Committee's Note.

Here, the individual claims are for wrongful death or serious personal injuries.

Consequently, because the potential value of each individual's claim is high, each has a compelling interest in controlling strategic decisions throughout the litigation and having those decisions made by the attorney of his or her choice. The highly personal and emotional implications in each case militate against surrendering individual choices and decisions in the litigation. Therefore, the strong interest class members have in controlling their own lawsuits disfavors certification.

3. The Extent of Existing Litigation

The existence of individual lawsuits filed in jurisdictions outside of the forum generally weighs against certification. See Turner v. Murphy Oil USA, Inc., 234 F.R.D. 597, 610 (E.D. La. 2006); Cent. Wesleyan Coll. v. W.R. Grace & Co., 143 F.R.D. 628, 640 (D.S.C. 1992) (stating that the inquiry under this portion of Rule 23(b)(3) is aimed at determining whether there is so much pre-existing litigation that a class would be unproductive), aff'd, 6 F.3d 177 (4th Cir. 1993); Dirks v. Clayton Brokerage Co. of St. Louis, Inc., 105 F.R.D. 125, 137 (D.C. Minn. 1985); In re Elec. Data Sys. Corp. Sec. Litig., 226 F.R.D. 559, 571 (E.D. Tex.), aff'd sub nom., Feder v. Elec. Data Sys. Corp., 429 F.3d 125 (5th Cir. 2005); cf. In

re Reliant Energy ERISA Litig., Civ. A. H-02-2051, 2005 WL 2000707, at *4 (S.D. Tex. Aug. 18, 2005) (finding that the absence of other litigation concerning the putative claims indicates that the individual class members have little interest in pursuing independent actions). To overcome this principle and the fact that there are many similar suits pending elsewhere in various stages of litigation, the plaintiffs point out that the plaintiffs in those other cases are represented by either plaintiffs' counsel or one other law firm - the Pogust firm.[45] The cases being prosecuted by plaintiffs' counsel are in the early stages. Those filed by the Pogust firm have had general discovery. In those cases, little expert discovery has been conducted and no dispositive motions have been decided.

On one hand, the state of the other litigation seems to favor certification because the parties have not invested a substantial amount of litigation time and class certification will not result in overlapping and redundant discovery and motion practice. On the other hand, certification is not favored because there are no dispositive rulings that will interfere with the presentation of each individual's case. Hence, the existing litigation factor is neutral.

4. Manageability of Proposed Class and Choice-of-Law Impediments

In examining the manageability of the proposed class, two factors are considered: the manageability of the plaintiffs' proposed trial plan, and whether there are choice-of-law conflicts in a putative nationwide class. In re Prempro, 230 F.R.D. at 562. Choice-of-law principles present a significant problem for class certification in this case. Conflicts among the laws of the various jurisdictions render a class action as proposed by the plaintiffs unmanageable.

A federal court sitting in diversity must apply the choice-of-law rules of the forum state. Berg Chilling Sys., Inc. v. Hull Corp., 435 F.3d 455, 462 (3d Cir. 2006). Accordingly, Pennsylvania law applies here.

Pennsylvania uses a two-step process to resolve choice-of-law questions. First, the court must determine whether there is a real conflict. Second, if there is an actual conflict, the court must then decide which state has the greater interest in applying its law.

If after applying the respective law of each state to the same set of facts the result is the same, there is no conflict. Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 839 n.20 (1985). In other words, there is no conflict where the application of either state's law renders the same result. Berg Chilling, 435 F.3d at 462. A true conflict, on the other hand, exists when the governmental interests of both jurisdictions would be impaired if their law were not applied. Lacey v. Cessna Aircraft Co., 932 F.2d 170, 187 (3d Cir. 1991).

If there is a true conflict, the court proceeds to the second step and decides which state has the greater interest in the application of its law. LeJeune v. Bliss-Salem, Inc., 85 F.3d 1069, 1071 (3d Cir. 1996) (citing Cipolla v. Shaposka, 267 A.2d 854, 855 (Pa. 1970)). This flexible inquiry uses the

Restatement (Second) of Conflict of Laws as a guide to evaluate the significance of the contacts or relationship of the states to the parties and the dispute. See Berg Chilling, 435 F.3d at 463; Garcia v. Plaza Oldsmobile Ltd., 421 F.3d 216, 220 (3d Cir. 2005). After characterizing the nature of the issue as founded in contract, tort or a hybrid, the court uses the appropriate Restatement section identifying the most relevant contacts for that type of action to assess which state has the more significant relationship and contacts to the issue. Berg Chilling, 435 F.3d at 463, 467; Garcia, 421 F.3d at 220. The contacts are weighed qualitatively within the context of the competing policies and interests of each state. Berg Chilling , 435 F.3d at 467-68; In re Estate of Agostini, 457 A.2d 861, 871 (Pa. Super. Ct. 1983) (citing Cipolla, 267 A.2d at 856). After balancing the respective governmental policy interests of the affected states, the court applies the law of the state having the greater interest in the determination of the issue. Garcia, 421 F.3d at 219-20.

The plaintiffs acknowledge that there are actual conflicts among the various jurisdictions' laws. Accordingly, I proceed directly to the greater interest analysis.

Because this action sounds in tort, section 145 of the Restatement (Second) of Conflict of Laws guides the analysis. That provision dictates that the law of the state which has the most significant relationship with the occurrence and the parties applies, and lists the following factors to consider: where the injury occurred, where the injury-producing conduct occurred, the domiciles of the parties, and the place where the parties' relationship is centered. Restatement (Second) of Conflict of Laws § 145 (1971).

Turning to this case, in light of these factors, I now evaluate the contacts and relationship to the issue of liability - the issue implicated by the plaintiffs' proposed common questions. Each putative class member suffered the injury in his or her home state. The tortious conduct took place not only in Pennsylvania but in every state, including each class member's home state, where Paxil was delivered, marketed and taken. Although GSK is a Pennsylvania corporation headquartered here, each plaintiff is presumably domiciled in his or her state. The parties' relationship is not centered in Pennsylvania. Most if not all contacts with the class members, such as marketing, prescribing and taking the drug, were in the home states. Thus, the state having the most significant contacts and relationship to the liability issue is each class member's home state.

There is no way to apply Pennsylvania law to part of the liability determination, as proposed by the plaintiffs, without disregarding the comity afforded the other states whose interests are in protecting their citizens from tortious harm caused within their boundaries. A state's interest in fixing liability for tortious harm caused within its boundaries goes to its interests in protecting its citizens and regulating conduct there. Of course, Pennsylvania has an interest in regulating its citizens' labeling practices.[46] When that conduct reaches and has consequences beyond the state's borders, it affects citizens of other states. When it does, the foreign state's interest in protecting its citizens outweighs Pennsylvania's regulatory concerns.

To circumvent the conflicts between the differing states' product liability and negligence laws, the plaintiffs urge the court to invoke depecage, a principle that applies the laws of different states to different issues in the same case. Berg Chilling, 435 F.3d at 462. Specifically, they contend that the court should apply Pennsylvania law to their proposed common issues of general causation, GSK's knowledge and its failure to warn: and then the law of each individual class member's home state will be applied to specific causation and damages. Thus, the plaintiffs are proposing to apply Pennsylvania law to determine general causation, and each class member's home state's law to determine specific causation and damages.

The Third Circuit has not applied depecage to multi-state class action claims. Nor has it applied different states' laws to less than a complete element of the claim, as plaintiffs are proposing we do here. Depecage applies one state law to one entire claim and a different state law to another claim in the same case. See, e.g., Berg Chilling, 435 F.3d at 463, 468 (applying Pennsylvania law to successor liability claim and applying New Jersey law to contract claim); Zavecz v. Yield Dynamics, 179 F. App'x 116 (3d Cir. 2006) (upholding district court's finding that California law applied to contractual attorneys' fees award claim and Pennsylvania law applied to the tort law conversion claim).

The plaintiffs are actually asking that Pennsylvania law be applied to only a part of the liability equation. However, the issue of liability cannot be determined piecemeal. It must be decided by taking into consideration all parts of the question, including defenses.

Plaintiffs assert that because the proposed common questions are so narrow, the differences in the state laws are "inconsequential." On the contrary, as an unexhaustive survey shows, the variances in the laws of the various jurisdictions are hardly inconsequential. In some states, a plaintiff may recover; and, in another state, depending on the applicability of certain legal principles, she may not based upon the same or similar facts. For example, some states, like California, apply a strict liability standard to prescription drug manufacturers for failure to warn of known or reasonably scientifically knowable risks; others, like Pennsylvania, recognize negligence as the only basis of recovery in cases involving prescription drugs where a failure to provide a sufficient warning is alleged; and some, for instance, Florida and Nebraska, have treated comment k to section 402A of the Restatement (Second) of Torts as an affirmative defense to a prescription drug strict liability claim. See Carlin v. Superior Court, 920 P.2d 1347, 1350-52 (Cal. 1996); Hahn v. Richter, 673 A.2d 888, 890-91 (Pa. 1996); Adams v. G.D. Searle & Co., 576 So. 2d 728, 731-33 (Fla. Dist. Ct. App. 1991); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000).

Differences in affirmative defenses also exist. For example, in some states, assumption of the risk is a complete defense to a products liability claim; in others, it involves a comparative fault analysis; and, in yet others, pure comparative fault is used. Castano, 84 F.3d at 742 n.15. The learned intermediary doctrine applies in some and not in other states.

Similarly, state laws differ with respect to the duty to warn and the adequacy of the warning. State

laws vary in how much knowledge a manufacturer must have before a duty to warn arises. There are differences with respect to whether warnings are required for the off-label use of a drug. Some states require no warning, see Robak v. Abbott Labs., 797 F. Supp. 475, 476 (D. Md. 1992), while others have varying levels of requirements for adequate warning of an off-label use. Miles Labs., Inc. v. Superior Court, 184 Cal. Rptr. 98, 100 (Cal. Ct. App. 1982) (manufacturer liable for failure to warn of risks of off-label uses of its product if the manufacturer knew or should have known of the off-label use and that use accounted for a significant portion of the manufacturer's sales of the drug); Peterson v. Parke Davis & Co., 705 P.2d 1001, 1003 (Colo. Ct. App. 1985); Reeder v. Hammond, 336 N.W.2d 3, 5-6 (Mich. Ct. App. 1983) (intervening negligence of a physician precludes the manufacturer's liability for failure to warn of risks of off-label use). Negligent infliction of emotional distress claims vary greatly among the states. Some states require a physical impact or physical contact (see, e.g., Hammond v. Cent. Lane Commc'ns Ctr., 816 P.2d 593, 596-97 (Or. 1991); Deutsch v. Shein, 597 S.W.2d 141, 145-46 (Ky. 1980); and others do not recognize the cause of action at all (see, e.g., Allen v. Walker, 569 So. 2d 350, 352 (Ala. 1990)). These differences among the states' laws are illustrative and not exhaustive.

Plaintiffs propose two trial plans. In one plan, they state that the court can conduct a class trial as to only the common issues without including any issues that overlap with a class member's individual case. Each class member will return to his or her home state for a trial on the remaining disputed issues.[47] In a second plan, plaintiffs propose to try each of the two named plaintiffs' cases to verdict on liability and damages. Using jury interrogatories, the three proposed common issues can be decided and bind all other members of the class in their separate trials to be conducted in the individual's original forum.[48] The plaintiffs offer no suggestion as to how the verdicts in the plaintiffs' cases would not be infected by the individual facts and issues that are unique to them to ensure that the absent class members would not be affected.

The plaintiffs have not demonstrated that their proposed class action is superior to other available methods. As a threshold matter, the plaintiffs have failed to devise a method of determining class membership without individualized fact finding. Because an overwhelming number of individual issues would remain unresolved for each class member, adjudication of the proposed common issues would not materially advance a disposition of the case as a whole. Moreover, the proposed class will be unmanageable because there is no way to apply the varied state laws and, at the same time, guarantee procedural fairness.

5. Appropriateness of Forum

The only factor favoring this forum is that GSK is headquartered here. Because many defense witnesses and documents are in this forum, it may be more convenient for GSK. Yet, the defendant opposes certification and has moved for the transfer of the plaintiffs' cases.

The law governing liability and damages will be controlled by the individual member's home state's jurisprudence. Furthermore, although there are some liability witnesses in Pennsylvania, witnesses

essential to proving liability and damages in each individual's cases are located in those other jurisdictions. Thus, the forum factor does not lend to certification.

Conclusion

The proposed class does not satisfy the typicality and adequacy requirements of Rule 23(a), nor the predominance and superiority requirements of Rule 23(b)(3). Therefore, the motion for class certification will be denied.

1. They assert claims of wrongful death/negligence (count I); negligent pharmaco vigilance (count II); strict liability (count III); breach of express warranty (count IV); fraud (count V); survival (count VI); negligent infliction of emotional distress (count VII); loss of consortium and loss of income (count VIII).

2. Paxil is a member of the class of drugs called Selective Serotonin Re-uptake Inhibitors ("SSRIs"), which is a type of antidepressant. Joint Stipulation of Uncontested Facts ("Jt. Stip.") ¶ 1. Zoloft and Prozac are examples of other SSRIs. Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion for Class Certification ("Pls.' Mem.") at 3.

3. Jt. Stip. ¶¶ 1-2.

4. Id. ¶¶ 5-7.

5. Id. ¶ 11.

6. The term "off-label" refers to the use, prescription or marketing of an FDA-approved drug for an unapproved use, such as, in an unapproved population, or for a condition other than for what it has been approved. Steven R. Salbu, Off-Label Use, Prescription and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy, 51 Fla. L. Rev. 181, 188-89 (1999).

7. Jt. Stip. ¶¶ 12-13.

8. Id. ¶¶ 3, 8, 9.

9. Id. ¶ 10.

10. Id.

11. Pls.' Mem. at 10, 13.

12. Id. at 14. The promotional methods GSK allegedly used include physician education, ghost-writing a purportedly "independent" medical journal article, and sponsoring lectures and posters. Id. at 15-19.

13. Compl. ¶ 33.

14. The parties conducted limited factual discovery to develop a context for evaluating their respective positions on certification. See Order, Civ. A. No. 06-1247 (June 21, 2006) (Doc. No. 39).

15. GSK's analysis of the Paxil clinical trial data found a 3.4% rate of a "suicide event" for pediatric patients taking Paxil. Pls.' Mem. at 27 (citing Alan Apter, M.D., et al., Evaluation of Suicidal Thoughts and Behaviors in Children and Adolescents Taking Paroxetine, 16 J. Child & Adolesc. Psychopharm. 77 (2006)).

16. Pls.' Mem. at 27-28.

17. The plaintiffs have abandoned most of the common questions they had proposed for certification in their complaint. See Compl. ¶ 37(a) - (m); Pls.' Mem. at 1.

18. Pls.' Reply Mem. at 4.

19. In mass tort cases, courts have routinely refused to certify common questions of general causation. See, e.g., In re "Agent Orange" Prod. Liab. Litig., 818 F.2d 145, 164-65 (2d Cir. 1987); Dalkon Shield IUD Prods. Liab. Litig. v. A.H. Robins, Co., 693 F.2d 847, 853 (9th Cir. 1982); In re Prempro Prods. Liab. Litig., 230 F.R.D. 555, 570 (E.D. Ark. 2005); In re Paxil Litig., 212 F.R.D. 539, 546-47 (C.D. Cal. 2003); Neenan v. Carnival Corp., 199 F.R.D. 372, 376-77 (S.D. Fla. 2001); Emig v. Am. Tobacco Co., 184 F.R.D. 379, 390 (D. Kan.1998); Barnes v. Am. Tobacco Co., 176 F.R.D. 479, 500-01 (E.D. Pa. 1997); Arch v. Am. Tobacco Co., 175 F.R.D. 469, 488 (E.D. Pa. 1997); Kurczi v. Eli Lilly & Co., 160 F.R.D. 667, 677 (N.D. Ohio 1995).

20. Pls.' Reply Mem. at 5.

21. Pls.' Mem. at 29.

22. Tr. of oral argument on Pls.' Mot. for Class Certification, Nov. 15, 2006 ("Hr'g Tr.") at 48-49.

23. GSK's Brief in Opposition to Plaintiffs' Motion for Class Certification ("GSK's Mem.") at 30-32.

24. Pls.' Reply Mem. at 5-6.

25. Compl. ¶ 42.

26. Pls.' Mem. at 21.

27. Id.

28. Jt. Stip. ¶¶ 66, 71.

29. Pls.' Mem. at 21-22.

30. GSK's Mem. at 18-19.

31. Id. at 21.

32. Id. at 19-20.

33. Id.

34. Pls.' Mem. at 22.

35. Id.

36. Jt. Stip. ¶¶ 67, 72.

37. Pls.' Mem. at 22.

38. Id. at 23.

39. GSK's Mem. at 14, 18.

40. Id. at 15, 16.

41. Id. at 15-17.

42. Pls.' Mem. at 32-33.

43. Pls.' Mem. at 35-36.

44. Although the plain language of Rule 23(b)(3) directs the court to consider these factors in evaluating both predominance and superiority, in a majority of cases, the courts consider these factors solely with respect to making a determination of superiority. Moore's Federal Practice, §§ 23.44[1], 23.46[2][a] (3d ed. 2006).

45. The Pogust firm and its clients consent to the class action. Pls.' Mem. at 39.

46. Plaintiffs argue that Pennsylvania has the greater interest in applying its laws to the general liability issues, such as "general causation" and "labeling decisions," because it has a strong interest in regulating its corporate citizens, pointing out that GSK's decisions regarding warnings, marketing, testing and distribution of Paxil occurred in Pennsylvania at its headquarters.

47. Pls.' Mem. at 2-3.

48. Id. at 49-50; Hr'g Tr. at 8-9.