UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**3:09-md-02100-DRH-PMF**
	)	**MDL No. 2100**

This Document Relates To:

PLAISANCE v. BAYER CORP., et al. **No. 3:09-cv-20108-DRH-PMF**

BAYER'S MEMORANDUM IN SUPPORT OF
MOTION TO STRIKE OR DISMISS CLASS ALLEGATIONS

Plaintiff Cindy Plaisance, a Louisiana resident, has filed a putative personal injury class action that, on its face, fails the preponderance and superiority requirements of Rule 23(b)(3), and the adequacy requirement of Rule 23(a). Indeed, the complaint appears to be nothing more than a placeholder – a thinly veiled and improper attempt to obtain *American Pipe*[1] tolling on YAZ® and Yasmin® personal injury claims. For instance:

- Plaintiff purports to represent a nationwide injury class, but defines the class differently in different parts of her complaint. *Compare* First Amended Class Action Complaint (Plaisance D.E. 23) ("Compl.") ¶¶ 11, 21 (defining class to include persons with all allegedly YAZ or Yasmin-related injuries), *with id.* ¶ 105 (limiting class to persons who allegedly suffered deep vein thrombosis ("DVT")).

- Plaintiff also purports to represent classes for each of the 50 states and the District of Columbia, on the theory that a Louisiana resident can serve as a stand-in class representative for each of the states, until plaintiffs' lawyers come up with putative class representatives who are members of the putative statewide classes. *Id.* ¶¶ 24-74, 112, and p. 8, n.2.

- Plaintiff tries to paper over choice of law problems by pleading claims under the common law (which Louisiana does not follow), *id.* ¶¶ 117-247, alleging that Louisiana law applies to all claims, *id.* ¶ 105, and then cataloguing the various state laws that might govern the claims of other class members, *id.* ¶¶ 248-97.

[1] *Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 554 (1974).

None of the putative classes can be certified. Individual issues of fact predominate concerning each putative class member's medical history and use of YAZ or Yasmin and bar certification of any of the proposed classes. Individual issues of law also bar certification of any nationwide class. Overwhelming management problems are clear from a quick reading of the complaint and show that plaintiff-by-plaintiff litigation is superior. Further, the named plaintiff is a manifestly inadequate class representative.

Each of these obstacles to certification is clear from the face of the complaint and the myriad decisions denying class certification in pharmaceutical product liability cases. There is no need for discovery to conclude that an injury class cannot be certified in this litigation. This Court is empowered to address class certification at the earliest practicable time. Fed. R. Civ. P. 23(c)(1)(A); 23(d)(1)(D). That time should be now. The Court therefore should strike the class allegations contained in paragraphs 11-74, 98-116, and 299 of the complaint. Ms. Plaisance can then proceed as an individual plaintiff, should she wish to do so.

THE COMPLAINT

Plaintiff alleges that she suffered a blood clot and deep vein thrombosis or DVT as a result of taking the oral contraceptives YAZ and/or Yasmin. Compl. ¶¶ 42, 108.

Class definition(s) and representative(s). Initially, plaintiff asserts that the action is brought "on behalf of all persons residing in the United States who purchased YAZ®/Yasmin® . . . ." *Id.* ¶ 11. The complaint repeatedly lists myriad injuries for which plaintiff and the putative injury class seek compensation –

> including, inter alia, *heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gall bladder disease and/or sudden death*, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff Plaisance's and the Personal Injury Class'

> inability to use any form of prescription contraception for the duration of their life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

Id. ¶ 18 (italics added); *see also id.* ¶¶ 21, 88-95, 98-99.

Having repeatedly alleged that the putative class suffered this array of injuries, plaintiff then pleads that she will seek certification of a nationwide class of persons who suffered DVTs. *Id.* ¶ 105. In the alternative, plaintiff seeks certification of separate classes for the 50 states and the District of Columbia, limited to persons who suffered DVTs. *Id.* ¶ 106. For 49 of the states and the District of Columbia, the name of the statewide class representative is "Intentionally left blank." *Id.* ¶¶ 24-74. Plaintiff asserts that she can act as a surrogate representative of these classes, until plaintiffs who actually would be members of the statewide classes turn up:

> Plaintiff Plaisance, as representative for the national class, acts as a surrogate for those state classes (defined above) for which there is yet a nominal class representative plaintiff, i.e., a headless class. By interlineation, plaintiff will cause to have substituted appropriate class representatives as their claims are filed and transferred to MDL 2100 pursuant to 28 U.S.C. § 1407.

Id. ¶ 112.

Plaintiff also lists 26 putative "common issues," *id.* ¶ 109, and alleges that certification under Rule 23(c)(4)(A) may be appropriate "with respect to particular issues set forth above or to be developed in the course of the litigation," *id.* ¶ 114.

Claims and controlling law. The complaint also is inconsistent in its treatment of the law. Plaintiff asserts claims for negligence, strict product liability, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud and deceit, and seeks compensatory and punitive damages, medical monitoring, and attorneys' fees. *Id.* ¶¶ 117, 130, 155, 167, 179, 192, 205, 213, 299. All of these claims are pled under the common law.

However, plaintiff allegedly was injured in Louisiana, *id.* ¶¶ 42, 106(xix), which does not follow the common law. *See* La. Rev. Stat. Ann. § 9:2800.52 (Louisiana Products Liability Act establishes "the exclusive theories of liability for manufacturers for damage caused by their products"). Moreover, she alleges that the claims of the putative nationwide class should be resolved "through the unitary application of Louisiana law," asserting that "as long as no out-of-state plaintiff gets less protection under its states' laws and Defendants are subject to Louisiana law, there should be no objection to the unitary application of Louisiana law." Compl. ¶ 105.

Later in the complaint, plaintiff includes a section titled "Ascription of Claims," which may be intended to plead the law that would apply to each of the putative statewide classes. *Id.* ¶¶ 248-97. Some of these allegations contain question marks. *See, e.g., id.* ¶ 270 (Michigan law); *see also id.* ¶ 266 (question marks in paragraph concerning Louisiana law).

ARGUMENT

This Court should strike or dismiss plaintiff's class allegations. Courts can strike class allegations when "the issues are plain enough from the pleadings." *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 160 (1982); *accord Buckmaster v. Wyman*, No. 05-C-0166, 2006 WL 1785845, at *5 (E.D. Wis. June 23, 2006) (Griesbach, J.) (striking class allegations); *Miller v. Motorola, Inc.*, 76 F.R.D. 516, 518 (N.D. Ill. 1977) (Flaum, J.) (same); *Bd. of Educ. v. Climatemp, Inc.*, Nos. 79 C 3144 & 79 C 4898, 1981 WL 2033, at *2 (N.D. Ill. Feb. 20, 1981) (Leighton, J.) (same). This rule previously has been applied by an MDL court to strike putative class claims in pharmaceutical product liability litigation. *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 208 F.R.D. 625, 634 (W.D. Wash. 2002) (Rothstein, J.) ("*PPA*"). *See also* Fed. R. Civ. P.

23(d)(1)(D) (empowering courts to "require that the pleadings be amended to eliminate allegations about representation of absent persons. . . .").[2]

Plaintiff's class allegations should be stricken because, on the face of the complaint and under controlling law, she cannot establish predominance, superiority or adequacy. *E.g.*, *Stubbs v. McDonald's Corp.*, 224 F.R.D. 668, 674 (D. Kan. 2004) (Vanbebber, J.) ("The burden of showing that each element of Rule 23 has been met remains with the party seeking class treatment, even if the opposing party raises the viability issue"); *In re PPA*, 208 F.R.D. at 630 (burden on plaintiff); *Lumpkin v. E.I. du Pont de Nemours & Co.*, 161 F.R.D. 480, 481 (M.D. Ga. 1995) (Fitzgerald, C.J.) (plaintiff must make a prima facie showing that Rule 23 has been met). Delay for class discovery would waste the resources of the Court and the parties. *See Lumpkin*, 161 F.R.D. at 481 (striking class allegations where "awaiting further discovery will only cause needless delay and expense"). *See generally* Fed. R. Civ. P. 23(c)(1)(A) (requiring class certification decisions to be made "[a]t an early practicable time").[3]

I. PLAINTIFF CANNOT ESTABLISH THAT COMMON ISSUES PREDOMINATE.

The class claims should be stricken because plaintiff cannot establish that "questions of law or fact common to class members predominate over any questions affecting

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[2] *See Bennett v. Nucor Corp*, No. 3:04CV00291, 2005 WL 1773948, at *2 (E.D. Ark. July 6, 2005) (Wright, C.J.) (relying on Rule 23(d)(1)(D) in striking class allegations); *Thompson v. Merck & Co.*, No. C.A. 01-1004, 2004 WL 62710, at *2 (E.D. Pa. Jan. 6, 2004) (Weiner, J.) (same); *Stubbs*, 224 F.R.D. at 674-75 (same); *Ross-Randolph v. Allstate Ins. Co.*, No. DKC 99-3344, 2001 WL 36042162, at *4 (D. Md. May 11, 2001) (Chasanow, J.) (same).

[3] Delay may prejudice Bayer and generate unnecessary motion practice if plaintiffs attempt to claim *American Pipe* tolling, which should not be available based on this manifestly deficient class complaint. *See, e.g.*, *Cunningham v. Ins. Co. of N. Am.*, 530 A.2d 407, 495 (Pa. 1987) (Flaherty, J.) ("Providing notice of the mere possibility of an actionable claim, by filing a patently non-justiciable class action suit, cannot be regarded as sufficient to toll the statute of limitations. To hold otherwise would be to render the statute of limitations so diluted in its effect as to skirt the clear legislative policy expressed therein, and would encourage plaintiffs to sleep on their rights in the hope that officious intermeddlers, who lack standing, will institute actions on their behalf.").

only individual members" of the class. Fed. R. Civ. P. 23(b)(3). The Seventh Circuit repeatedly has held that putative products liability classes do not satisfy Rule 23(b)(3). *E.g.*, *In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1015, 1018-19 (7th Cir. 2001) (rejecting a nationwide class and suggesting that state-based classes would fail) ("*Bridgestone*"); *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1304 (7th Cir. 1995) (issuing mandamus to reverse class certification in a blood products case) ("*RPR*"); *see also Thorogood v. Sears, Roebuck & Co.*, 547 F.3d 742, 745-46 (7th Cir. 2008); *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 674 (7th Cir. 2001) ("few warranty cases ever have been certified as class actions—let alone as nation-wide classes").

The predominance of individual issues of fact and law is particularly clear in pharmaceutical product liability cases like this one. *Miller v. Janssen Pharmaceutica Prods., L.P.*, No. 05-cv-4076-DRH, 2007 WL 1295824, at *7-8 & n.3 (S.D. Ill. May 1, 2007) ("Courts generally refuse to certify nationwide classes in cases involving personal injury, products liability and breaches of warranty.").[4] A few of the predominant individual issues of fact and law are discussed below.

[4] *See, e.g.*, *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-1968, 2010 WL 2102330, at *18 (S.D. W. Va. May 25, 2010) (Goodwin, C.J.); *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 396-97 & n.8 (S.D.N.Y. 2008) (Keenan, J.) ("courts almost unanimously have rejected class certification in pharmaceutical products liability actions"); *In re Prempro Prods. Liab. Litig.*, No. 4:03CV1507, 2007 WL 951878, at *1 (E.D. Ark. Mar. 28, 2007) (Wilson, J.) (noting "the long line of product liability MDLs that have rejected class certification in pharmaceutical drug cases"); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 460-61 (E.D. La. 2006) (Fallon, J.); *Zehel-Miller v. AstraZeneca Pharms., LP*, 223 F.R.D. 659, 663-64 (M.D. Fla. 2004) (Conway, J.) (denying class certification and noting that "[i]f Plaintiffs had not withdrawn their personal injury damages claims, little discussion would be necessary," as "(c)lass certification under Rule 23(b)(3) would be indisputably inappropriate, since individual issues would overwhelm any common questions"); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 203 (D. Minn. 2003) (Davis, J.) ("Many courts presiding over similar products liability case involving prescription drugs have denied similar requests for class certification."); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 65-66 & n.35 (S.D.N.Y. 2002) (Kaplan, J.) (collecting cases); *In re Propulsid Prods. Liab. Litig.*,

A. Individual Issues of Fact Predominate.

Individual issues of fact predominate regardless of whether the proposed class is nationwide or statewide, and regardless of whether the class covers an array of injuries or DVTs. Here, as in other pharmaceutical product liability MDLs, "the existence of predominating individual issues of fact alone renders all of the proposed classes unsuitable for class certification." *In re PPA*, 208 F.R.D. at 633 (striking class allegations); *accord In re Fosamax*, 248 F.R.D. at 391 (there are "too many individual questions of fact particular to each class member's claim"); *In re Vioxx*, 239 F.R.D. at 461 ("courts have almost invariably found that common questions of fact do not predominate in pharmaceutical drug cases"). In particular:

Causation-in-fact is individualized. The question of whether any absent class member sustained an injury caused by YAZ or Yasmin can only be determined on an individual basis. *Miller*, 2007 WL 1295824, at *6 ("proof of injury and causation also would require individualized expert testimony"). This will require an examination of each person's medical history, including pre-existing conditions and use of other medications, and an evaluation of potential alternate causes for the alleged injury. In addition, the class members ingested different products — YAZ and/or Yasmin — for different periods of time. *In re Vioxx*, 239 F.R.D. at 462 (noting "the highly individualized inquiry of whether Vioxx specifically caused the injury alleged by each plaintiff in light of his or her medical history, family history, other risk factors, and use of the drug"). Consequently, "[a]n assessment of specific causation . . . necessarily dissolves into a myriad of individualized causation inquires." *In re PPA*, 208 F.R.D. at 631-32;

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208 F.R.D. 133, 143-44 (E.D. La. 2002) (Fallon, J.). *See also* Advisory Committee Notes to Rule 23(b)(3) Amendments, 39 F.R.D. 69, 103 (1966) (mass tort cases are "ordinarily not appropriate" for class treatment because they present "significant questions, not only of damages but of liability and defenses to liability . . . affecting the individuals [class members] in different ways").

accord In re Rezulin, 210 F.R.D. at 66 ("the individualized nature of the causation inquiries is not surprising").

Legal causation and application of the learned intermediary doctrine is individualized. YAZ and Yasmin are prescription medicines. To establish legal causation on failure-to-warn and certain other claims, a plaintiff must show that her doctor would not have prescribed the medicine if it had carried an "adequate" warning. *In re Norplant Contraceptive Prods. Litig.*, 955 F. Supp. 700, 704-05, 709 (E.D. Tex. 1997) (Schell, C.J.), *aff'd*, 165 F.3d 374 (5th Cir. 1999) (Jolly, J.). That determination turns on facts unique to each plaintiff and each prescriber, including how the doctor balances the risks and benefits of the medicine for that particular patient and the particular doctor's prescribing practices. *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577, 589 (S.D. Ohio 2003) (Spiegel, J.) (denying class certification based on "the existence of individual Learned Intermediaries"); *In re Baycol*, 218 F.R.D. at 205-06 (application of the learned intermediary doctrine is an individual issue). Moreover, under the learned intermediary doctrine, information that a particular prescriber obtained from sources other than the pharmaceutical company, such as medical literature, scientific conferences, lectures and seminars, and other doctors, may be relevant. *In re St. Jude Med., Inc.*, 522 F.3d 836, 839 (8th Cir. 2008) (Colloton, J.) (reversing class certification and noting that "[p]hysicians learned about [the product] in different ways . . . . Any trial thus would require physician-by-physician inquiries into each doctor's sources of information").

Because determination of legal causation and application of the learned intermediary doctrine can only be made on a case-by-case basis based on facts unique to that patient and prescriber, these individual issues of fact predominate. *See In re Propulsid*, 208 F.R.D. at 143 (denying class certification and noting that "knowledge of the treating physicians

may be of great importance to this case"); *see also In re Rezulin*, 210 F.R.D. at 67 (denying class certification and noting that "whether an individual plaintiff's doctor received any warnings . . . and whether he or she heeded those warnings" were of "central importance").

Fraud and warranty claims are individualized. Plaintiff's claims that Bayer fraudulently or negligently misrepresented the safety and efficacy of YAZ and Yasmin and that Bayer breached express or implied warranties are not amenable to class resolution. Compl. ¶¶ 155, 167, 179, 192, 205, 213. These claims all require "individual inquiries of each class member with respect to the materiality of the statements, whether the members saw [the statements], and what caused the members" or their physicians to use or prescribe YAZ and/or Yasmin. *Sanders v. Apple Inc.*, 672 F. Supp. 2d 978, 991 (N.D. Cal. 2009) (Fogel, J.) (striking fraud and warranty class allegations); *accord Ross-Randolph*, 2001 WL 36042162, at *6 (striking fraud class allegations because questions of reliance require individualized inquiries). For instance, plaintiff alleges that certain television advertisements that ran in 2003, 2008 and 2009 misled plaintiffs. Compl. ¶ 87. But whether a plaintiff saw that advertising, and whether it related to the specific medicine she took (YAZ or Yasmin) or the reasons that she was prescribed the medicine, can be determined only on an individual basis. A plaintiff who took Yasmin from 2006-2007 might not have seen, much less relied upon, the 2003, 2008 and 2009 advertisements mentioned in the complaint.

Remedies are individualized. None of the remedies sought by plaintiff can be adjudicated on a classwide basis.

- *Compensatory damages.* Adjudication of a named plaintiff's claim for compensatory damages would prove nothing with respect to the valuation of claims of any other person in a putative class. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, Civ. A. 93-7074, 1995 WL 273597, at *11 (E.D. Pa. Feb. 22, 1995) (Bechtle, J.) ("the measure of damages will be dependent almost exclusively on individual factors"); *see also In re Bridgestone*, 288 F.3d at 1020

(noting that multiple trials are "needed for accurate evaluation of mass tort claims"). Even if the class were limited to plaintiffs who suffered DVTs, that would encompass a wide range of alleged injuries, some transient, some with allegedly long-lasting effects. *In re PPA*, 208 F.R.D. at 631 ("whether that individual suffered an injury, when the injury occurred, the type of injury suffered, and the number of occurrences of injury" all present individual issues). Accordingly, these damages would require adjudication on a plaintiff-by-plaintiff basis. *Id.*

- *Mental anguish.* The complaint is replete with claims for mental anguish and prospective mental anguish. *E.g.*, Compl. ¶¶ 21-22, 299. "[C]laims for mental anguish and pain and suffering . . . necessarily involve a determination of whether and how each class member was personally affected." *Thompson*, 2004 WL 62710, at *4 (striking class allegations).

- *Punitive damages.* The complaint seeks punitive damages that must, as a matter of constitutional law, bear a relationship to compensatory damages awarded to a particular plaintiff. *E.g.*, *BMW of N. Am. v. Gore*, 517 U.S. 559, 580-81 (1996). Plaintiff cannot avoid the individual nature of this inquiry by asking the Court to apply a multiplier to all cases, because the information available to Bayer changed during the more-than five years covered by the proposed class definitions. *In re Baycol*, 218 F.R.D. at 215; *see also Thompson*, 2004 WL 62710, at *4 (striking punitive class allegations).

- *Medical monitoring.* The complaint seeks medical monitoring as a remedy. Compl. ¶¶ 18, 299. But medical monitoring is available in most states only to provide care that the plaintiff would not otherwise receive. *In re Baycol*, 218 F.R.D. at 211-12. Accordingly, it would be necessary to track each class member's prior medical care to determine whether any additional monitoring would be required. *See id.* at 212 ("individual issues will undermine the cohesion of the medical monitoring class"); *see also In re St. Jude Med., Inc.* 425 F.3d 1116, 1122 (8th Cir. 2005) (Riley, J.) (reversing certification of a medical monitoring class and noting that "medical monitoring is highly individualized").

In short, this is not a case in which an absent class member's damages involve a simple mathematical calculation; damages are a separate jury issue that can only be determined on a plaintiff-by-plaintiff basis. *Mantolete v. Bolger*, 767 F.2d 1416, 1424-25 (9th Cir. 1985) (Tang, J.) (affirming order striking class allegations because the propriety of relief required "an inquiry into the individuals' medical and work history"); *see also Advanced Acupuncture Clinic, Inc. v. Allstate Ins. Co.*, No. 07-4925, 2008 WL 4056244, at *13 (D.N.J. Aug. 26, 2008) (Pisano,

J.) (striking class allegations because the "reasonableness and necessity of medical bills" required "individualized evaluation"); *Ross-Randolph*, 2001 WL 36042162, at *6 (striking class allegations because "whether a particular medical procedure is necessary" requires "individual determination").

The examples above are just some of the individual issues of fact that would have to be adjudicated separately for each member of any putative class. These individual issues predominate and bar certification of any of the proposed classes.

B. Individual Issues of Law Predominate.

Individual issues of law bar certification of any nationwide class. Plaintiff asserts "that the unitary application of Louisiana law" can solve this problem. Compl. ¶ 105. The short and complete answer to this assertion is the Seventh Circuit's decision in *RPR*, issuing a writ of mandamus to vacate a class certification order that proposed to adjudicate certain issues applying general negligence law. *In re RPR*, 51 F.3d at 1300 (finding violation of *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938)); *see also In re Bridgestone*, 288 F.3d at 1017-18.

Under choice of law rules in Louisiana, where this case was filed (Plaisance D.E. 1, 4),[5] "the substantive law of the plaintiffs' home states will apply to the merits" of each class member's claim. *In re Vioxx Prods. Liab. Litig.*, 478 F. Supp. 2d 897, 905-06 (E.D. La. 2007) (Fallon, J.) (applying Louisiana choice of law rules and selecting the law of each plaintiff's home state in a pharmaceutical product liability action); *see also* La. Civ. Code art. 3542. That is

[5] Louisiana choice of law rules govern the complaint. *See Chang v. Baxter Healthcare Corp.*, 599 F.3d 728, 732 (7th Cir. 2010); *see also In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F. Supp. 2d 932, 936 (D. Minn. 2007) (Frank, J.) (filing an amended complaint in the MDL does not impact choice of law). Even if Illinois's choice of law rules governed, these rules also would require application of the law of each plaintiff's home state. *Clay v. Am. Tobacco Co.*, 188 F.R.D. 483, 497 (S.D. Ill. 1999) ("A proper application of the Illinois choice of law princip[le]s, however, demonstrates that the laws of each of the 47 states would have to be applied.").

consistent with the conclusion of other MDL courts, holding that the law of the state where each class member allegedly was injured applies and that substantive differences in state law "swamp any common issues and defeat predominance." *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 741 (5th Cir. 1996) (Smith, J.); *accord, e.g., In re Bridgestone*, 288 F.3d at 1015 ("state laws about theories such as those presented by our plaintiffs differ, and such differences have led us to hold that other warranty, fraud, or products-liability suits may not proceed as nationwide classes").

Similarly, the law governing punitive damages varies significantly from state to state. *See Mack v. Gen. Motors Acceptance Corp.*, 169 F.R.D. 671, 678-79 (M.D. Ala. 1996) (Thompson, C.J.) (citing *BMW*, 517 U.S. 559 (1996)). In particular, states apply different standards, burdens of proof, and procedures; some states cap punitive damages while others prohibit such awards with respect to pharmaceutical products approved by the FDA. *E.g.*, *BMW*, 517 U.S. at 568 ("States necessarily have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case."); Ohio Rev. Code Ann. § 2307.80(c)(1); Utah Code Ann. § 78B-8-203. These substantial differences make class treatment impossible. *See Mack*, 169 F.R.D. at 678-79.

C. Plaintiff's Proposed Common Issues Do Not Predominate and Cannot Be Certified Under Rule 23(c)(4).

Paragraph 109 of the complaint lists 26 putative common issues that purportedly predominate for purposes of a Rule 23(b) class or could be tried under a Rule 23(c)(4) class. These issues neither predominate nor support certification of an issue class.

First, the putative common issues presume application of a universal legal standard. This is wrong for the reasons given above. The question of whether a product is defective, Compl. ¶ 109(a), or whether a defendant is strictly liable, *id.* ¶ 109(j), or negligent, *id.* ¶ 109(n), can only be decided under the law applicable to the claims of each putative class

member. Similarly, "Whether Defendants concealed adverse information from Plaintiff Plaisance and the Personal Injury Class," *id.* ¶ 109(c), depends on Bayer's duty, if any, to warn patients (as opposed to physicians) under the law applicable to each class member's claims. Thus, individual issues of law predominate.

Second, individual issues of fact predominate with respect to the putative common issues. For example:

- "Whether Defendants' failed to give adequate and timely warning," *id.* ¶ 109(b), would depend in part on the facts known at the time a particular class member was taking YAZ or Yasmin and what her doctor knew about the risks and benefits of the medicine.

- "Whether Defendants' conduct constitutes negligence," *id.* ¶ 109(n), "depend[s] on individual facts — whether there is a breach of duty or the foreseeability of harm will depend on what Defendants knew or should have known at the time [the drug] was prescribed and whether Defendants acted reasonably based on the knowledge it had at that time." *In re Baycol*, 218 F.R.D. at 208.

- "Whether Defendants violated applicable state consumer protection laws", Compl. ¶ 109(d), would depend on whether a misrepresentation or omission to a particular class member or her doctor was the proximate cause of her decision to purchase YAZ or Yasmin. *E.g.*, *De Bouse v. Bayer AG*, 922 N.E.2d 309, 316 (Ill. 2009) (Garman, J.).

In short, plaintiff's general questions of knowledge and liability are "clearly overwhelm[ed]" by the "number of individual questions posed." *In re PPA*, 208 F.R.D. at 632-33; *accord In re Old Kent Mort. Co. Yield Spread Premium Litig.*, 191 F.R.D. 155, 163 (D. Minn. 2000) (Doty, J.) (striking class allegations where liability turned on "transaction-specific inquires").

Third, plaintiff cannot brush aside her predominance problems by seeking certification of one or more questions under Rule 23(c)(4). Certification under Rule 23(c)(4) is improper if "noncommon issues are inextricably entangled with common issues, or . . . the uncommon issues are too unwieldy or predominant to be handled adequately on a class action basis," or if adjudication of common issues would not advance the litigation. *Rink v.*

Cheminova, Inc., 203 F.R.D. 648, 669 (M.D. Fla. 2001) (Lazzara, J.); *Harding v. Tambrands Inc.*, 165 F.R.D. 623, 632 (D. Kan. 1996) (Theis, J.); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 209 F.R.D. 323, 351 (S.D.N.Y. 2002) (Scheindlin, J.); *In re Tetracycline Cases*, 107 F.R.D. 719, 727 (W.D. Mo. 1985) (Roberts, J.); *see also Castano*, 84 F.3d at 745 n.21 (broad use of 23(c)(4) "would eviscerate the predominance requirement of rule 23(b)(3)"). Plaintiff's claims here arise out of circumstances individual to each putative class member. *See In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1084-85 (6th Cir. 1996) (Suhrheinrich, J.); *In re Baycol*, 218 F.R.D. at 209; *In re Rezulin*, 210 F.R.D. at 66-68; *In re PPA*, 208 F.R.D. at 632-33; *Neely v. Ethicon, Inc.*, No. 1:00-CV-00569, 2001 WL 1090204, at *10-11 (E.D. Tex. Aug. 15, 2001) (Heartfield, J.); *In re Orthopedic Bone Screw*, 1995 WL 273597, at *10-11. Because plaintiff's common liability issues are intertwined with individual fact issues, Rule 23(c)(4) certification is inappropriate.

II. CLASS TREATMENT IS NOT SUPERIOR.

Class certification also should be denied because class certification is not superior to individual adjudication of any personal injury claims arising from the use of YAZ or Yasmin. The same individual issues of fact described above would make any nationwide class or statewide unmanageable.[6] *See generally In re Bridgestone*, 288 F.3d at 1018 (reversing certification of a nationwide product liability class and cautioning: "Lest we soon see a Rule 23(f) petition to review the certification of 50 state classes, we add that this litigation is ***not manageable*** as a class action ***even on a statewide basis***" (emphasis added)).

Even if some form of class trial could be devised – and it could not – hundreds or thousands of individual trials would be required to adjudicate the individual claims of class

[6] These problems would be multiplied for nationwide classes, where individual issues of law would create further management problems.

members. This would defeat the purpose of class certification: to "achieve economies of time, effort, and expense." Advisory Committee Notes to Rule 23(b)(3) Amendments, 39 F.R.D. at 102; *accord Cunningham Charter Corp. v. Learjet Inc.*, 258 F.R.D. 320, 334 (S.D. Ill. 2009) (noting that "the Court would be left to conduct individualized mini-trials"); *Miller*, 2007 WL 1295824, at *6 (noting that "the Court would have to conduct mini-trials for each would-be class member"); *see also In re Baycol*, 218 F.R.D. at 209 ("certification under (c)(4) will not make the case more manageable, as application of the laws of 51 jurisdictions will infuse complexity into a class trial, and individual trials will still be required to determine issues of causation, damages, and applicable defenses. As a result, a class trial will not materially advance this litigation").

As the sheer number of YAZ and Yasmin personal injury actions pending in this MDL and in state courts indicates, injured consumers have an interest in controlling their own claims and can economically prosecute their claims on an individual basis. Fed. R. Civ. P. 23(b)(3)(A). Accordingly, there is no need for a class action. *In re Bridgestone*, 288 F.3d at 1020 (concluding alleged efficiencies from class litigation are "elusive" where underlying claims are sizeable enough to be prosecuted individually); *In re RPR*, 51 F.3d at 1299-1300 (a class action "need not be tolerated when the alternative exists of submitting an issue to multiple juries constituting in the aggregate a much larger and more diverse sample of decision-makers"); *see also Castano*, 84 F.3d at 748 ("The most compelling rationale for finding superiority in a class action—the existence of a negative value suit—is missing in this case"). Because plaintiff cannot establish that the putative classes are manageable, much less superior, those classes cannot be certified and the class claims should be stricken from the complaint.

III. PLAINTIFF CANNOT ADEQUATELY AND FAIRLY REPRESENT THE INTERESTS OF THE ALLEGED CLASSES.

Finally, class certification should be denied because, on the face of her complaint, plaintiff is not an adequate representative of any of the proposed putative classes.

First, if plaintiff is seeking to represent class members with different injuries, *see* Compl. ¶ 42, she is an inadequate representative as a matter of law. *See Bennett*, 2005 WL 1773948, at *3 (striking class allegations because plaintiff could not adequately represent class members with different injuries); *Stubbs*, 224 F.R.D. at 674-75 (same); *Miller*, 76 F.R.D. at 518 (same). Persons with different alleged injuries have different interests. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 626 (1997) (reversing certification and noting the "diversity" of alleged diseases within the putative class).

Second, plaintiff cannot represent a nationwide class because she is neither an adequate nor typical representative of persons whose claims arise under the laws of different states. *Cunningham*, 258 F.R.D. at 329.

Third, plaintiff cannot adequately represent classes from states other than Louisiana because she is not a member of those classes, as defined in her complaint. Compl. ¶ 106. *See Amchem*, 521 U.S. at 625-26 (noting that a class representative must be part of the class). Plaintiff's proposal—that 50 putative statewide class actions go forward with a facially inadequate stand-in representative until another class representative turns up—would violate the due process rights of absent class members in those states. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 812 (1985) (due process requires that the named plaintiff "at all times adequately represent the interest of the absent class members); *Hansberry v. Lee*, 311 U.S. 32, 45 (1940) (a representative whose "substantial interests are not necessarily or even probably the same as those

whom they are deemed to represent, does not afford that protection to absent parties which due process requires").

Fourth, plaintiff is not even an adequate representative of a Louisiana class of persons who allegedly suffered DVTs. All of her claims are subject to dismissal because they are pled under the common law, which Louisiana does not recognize. *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002) (King, C.J.) ("negligence, strict liability, and breach of express warranty are not available as theories of recovery against a manufacturer, independent from the LPLA"); *Lacey v. Bayer Corp.*, No. Civ.A. 02-1007, 2002 WL 1058890, at *2 (E.D. La. May 24, 2002) (Porteous, J.) (dismissing "plaintiff's claims of negligence, fraud, misrepresentation, negligence and reckless misrepresentation, conspiracy and strict liability"); *Jefferson v. Lead Indus. Ass'n*, 930 F. Supp. 241, 245 (E.D. La. 1996) (Vance, J.) ("breach of implied warranty or redhibition is not available as a theory of recovery for personal injury"), *aff'd*, 106 F.3d 1245 (5th Cir. 1997) (per curiam).

Finally, the sheer number of individual personal injury suits concerning YAZ and Yasmin "call into question Plaintiff[']s ability to adequately represent the interests of other class members. The right and desire of other potential plaintiffs to control their own litigation and pursue independent actions are important considerations which defeat the propriety of class certification." *Lumpkin*, 161 F.R.D. at 482 (striking class allegations).

CONCLUSION

Because plaintiff's personal injury class cannot be certified in any of its proposed forms, this Court should strike or dismiss plaintiff's class allegations with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2010, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

s/ Susan A. Weber