IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
This Document Relates To: ALL CASES	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO ALL REMAINING PLAINTIFFS

ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019
Tel. No. (212) 836-8000

- and-

601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
Tel. No. (202) 942-5000

LOWENSTEIN SANDLER LLP
One Lowenstein Drive
Roseland, NJ 07068
Tel. No. (973) 597-2500

Attorneys for Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services, Inc., and Sanofi-Synthelabo LLC

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Cases **Page(s)**

STATUTES, RULES AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

The Court should grant summary judgment in all remaining MDL cases because Plaintiffs' claims are preempted by federal law and lack the necessary admissible expert support.

Throughout the long course of the litigation, Plaintiffs' liability theories remained obscure. Their complaints threw together a "kitchen sink" of allegations that Plavix was supposedly too costly, not efficacious, and that Defendants downplayed its risks. Concerned they needed to understand better Plaintiffs' vague liability theories before key prescribing doctor depositions, Defendants secured an agreed order requiring Plaintiffs to disclose experts in opposition to learned intermediary motions ***before*** those depositions. But that deadline came and went, and Plaintiffs served no report. Despite scores of prescriber depositions, Plaintiffs' scattershot questioning ***still*** revealed no core theory of failure to warn.

At long last, Plaintiffs served their merits expert opinions late this summer. Plaintiffs have therefore now disclosed their core liability theories in the form of three "generic" experts whose opinions apply to all cases. They had literally years to prepare these experts and to put their "best foot forward." But far from supporting their cases, what these experts' opinions make clear is that, at the most fundamental level, Plaintiffs' claims in this litigation are both legally invalid and unsupported by the evidence.

First, federal law preempts Plaintiffs' claims. Plaintiffs' expert opinions boil down to a disagreement with the FDA— FDA supposedly "got it wrong" when it approved Plavix and got it wrong when it wrote and approved its initial label. Plaintiffs' core liability theory is premised on their sole labeling expert Dr. Tackett's opinion that the FDA-approved label was inadequate from the "get-go." *See* Ex. A to the Certification of Jocelyn A. Wiesner ("Wiesner Cert.") (Dep. of Dr. Randall ("Tackett Dep.")) at 67:11-23; 68:18-70:1; 73:13-74:3; 74:10-75:2; 85:5-86:11; 111:17-112:11; 118:5-19; 124:8-125:16. But the U.S. Supreme Court has drawn a clear distinction between labeling changes that a manufacturer can make unilaterally based on new information, and labeling that FDA must pre-approve. The former category may escape

preemption. *See Wyeth v. Levine*, 555 U.S. 555, 572–73 (2009) (rejecting preemption because company could have changed the label unilaterally based on new information); *In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 280 (3d Cir. 2017) (same). But the latter does not. The Supremacy Clause does not permit a state tort claimant to second-guess labeling that FDA must pre-approve before a drug goes to market. *See In re Celexa & Lexapro Mktg. & Sales Prac. Litig.*, 779 F.3d 34, 41–43 (1st Cir. 2015) (claims relating to FDA initial approval rather than newly acquired information were preempted); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 178 (S.D.N.Y. 2016) (failure-to-warn claims based on initial label preempted).

Nor can Plaintiffs recover in tort based on a theory that FDA should never have approved Plavix, which is what Plaintiffs' expert biostatistician Dr. Lemuel Moyé says. FDA has repeatedly found Plavix to be safe and effective based on its own scientific analyses of clinical trial data. Dr. Moyé acknowledges that FDA considered all the evidence, including arguments that he himself made against approval, but believes FDA just drew the risk/benefit calculus incorrectly. Wiesner Cert. Ex. B (Dep. of Dr. Moyé ("Moyé Dep.")) at 20:3-7; 26:23-27:23; 36:3-22; 42:7-46:11. But if Plaintiffs' tort theory were correct, the only way Defendants could avoid liability would be to re-design or simply "stop selling" Plavix despite FDA's approval. Allowing such a claim to proceed would create an irreconcilable conflict between state and federal law. *See Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2475-77 (2013) (state law duty to re-design generic drug preempted because "the altered chemical would be a new drug that would require its own NDA" and because it is "chemically incapable of being redesigned"); *id.* at 2477 & n.3 ("stop selling" rationale not a basis to avoid preemption); *Yates v. Ortho-McNeil Janssen Pharm. Inc.*, 808 F.3d 281, 293 (6th Cir. 2015) (applying *Bartlett* to branded drugs).

Second, Plaintiffs' claims lack required evidentiary support. The heart of these cases is Plaintiffs' failure to warn allegations. Here, putting aside preemption, Dr. Tackett's opinions are unreliable and therefore inadmissible. As set forth in further detail in Defendants' separate motion to exclude his testimony, Dr. Tackett (who is not a medical doctor and has never worked

for FDA) bases his opinions not on the methods of science or application of his expertise, but on *ipse dixit* that has no foundation in the evidence. Without supporting expert proof, Plaintiffs' failure to warn claims are doomed.

Dr. Moyé's opinion that Plavix's risks outweighs its benefits is similarly inadmissible, as Defendants demonstrate in their separate motion to exclude his testimony. His opinion is an island unto itself, admittedly running directly counter to FDA and the entire medical community. To the extent Plaintiffs intended his testimony to support their design defect claims, such claims must similarly fail.

In sum, Plaintiffs' expert opinion confirms that their cases are fundamentally at odds with federal law and lack basic evidentiary support. As a result, this litigation must now come to an end.

STATEMENT OF FACTS

A. Plavix® and Its Labeling

Plavix® inhibits blood platelets from forming clots, and it is widely prescribed to reduce the risk of heart attacks or strokes in certain patients. Because it functions by inhibiting blood clots, Plavix®, like all antiplatelet therapies, also increases the risk of bleeding.

FDA first approved Plavix in 1997 for use as monotherapy (*i.e.*, without another drug) in patients with recent heart attack or stroke or diagnosed peripheral arterial disease ("PAD") on the basis of the CAPRIE trial, which showed that Plavix is more effective than aspirin in preventing future heart attacks, strokes, and vascular events.[1] After studies demonstrated other clinical benefits, FDA approved Plavix for dual therapy with aspirin for the treatment of patients with particular types of acute coronary syndrome ("ACS") in 2002 based on the CURE trial (which showed a benefit in patients with ACS without ST-segment elevation)[2] and in 2006 based on the

[1] *See* Wiesner Cert. Ex. C (November 17, 1997 FDA Approval Letter and attached approved labeling).

[2] *See* Wiesner Cert. Ex. D (February 27, 2002 FDA Approval Letter and attached approved labeling).

CLARITY and COMMIT trials (which showed a benefit in patients who have myocardial infarction with ST-segment elevation).[3]

These approvals were garnered only after FDA's exhaustive review. To gain FDA approval for a drug entering the market for the first time, a drug manufacturer must submit a new drug application ("NDA"). *See* 21 C.F.R. § 314.1 *et seq*. NDAs must include "full reports of [all clinical] investigations which have been made to show whether . . . such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). In evaluating the data, FDA must determine whether the NDA contains information sufficient to establish that the drug meets FDA's efficacy and safety requirements. 21 C.F.R. § 314.105. Each time a manufacturer seeks a new indication for a drug, it must submit a supplemental NDA. *See* 21 C.F.R. § 314.70(b). FDA goes through a similarly thorough review of the clinical evidence to determine whether to approve the medicine for subsequent indications. *Id.*; *see also* 21 U.S.C. § 355(a) and (d).

Following its approval, Plavix has become a mainstay of antiplatelet therapy. Dual therapy of Plavix plus aspirin has been for many years the standard of care for treatment of patients with ACS, as well as with the placement of stents (medical devices that are commonly implanted to keep patients' arteries open but that can also trigger clotting). For more than a decade, leading medical consensus organizations have recommended Plavix in these and other clinical settings, and they continue to do so today.[4]

---

[3] *See* Wiesner Cert. Ex. E (August 17, 2006 FDA Approval Letter and attached approved labeling).

[4] *See, e.g.*, Ezra A. Amsterdam, et al., *2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes*, 64 J. AM. C. CARDIOLOGY e139, e162, e167 (2014); Patrick T. O'Gara et al., *2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction*, 61 J. AM. C. CARDIOLOGY e78, e92 (2013); Glenn N. Levine, et al., *2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease*, 68 J. AM C. CARDIOLOGY 1082, 1091 (2016); Walter N. Kernan, et al., *Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack*, 45 Stroke 2160, 2198-99 (2014); Jeffrey L. Anderson, et al., *Management of Patients with Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations*, 61 J. AM. C. CARDIOLOGY, 1555, 1561 (2013).

Because Plavix works by inhibiting clots which can cause heart attacks or strokes, it necessarily increases bleeding risks. FDA thoroughly reviewed the extent of Plavix's bleeding risk as part of its assessment of the drug's safety profile. *See, e.g.*, Wiesner Cert. Ex. F (FDA medical officer's safety review noting "Disorders of hemostasis [*i.e.*, blood clotting] were of course given special attention") at PLAVNDA0104744–747. And the risk of bleeding has been disclosed in Plavix's labeling since the drug first entered the market. From day one, the label disclosed bleeding risks in the "CONTRAINDICATIONS" section; the "PRECAUTIONS" section (including under the bold subheading "GI Bleeding" and "Information for Patients"); and the "ADVERSE REACTIONS" section. As approved by the Food and Drug Administration ("FDA"), the initial 1997 Plavix label states as follows:

> **CONTRAINDICATIONS**
>
> The use of PLAVIX is contraindicated in the following conditions:
>
> ***
>
> - Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.
>
> * * *
>
> **PRECAUTIONS**
>
> **General**
>
> As with other anti-platelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 7 days prior to surgery.
>
> *GI Bleeding:* PLAVIX prolongs the bleeding time. In CAPRIE, PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0%, vs. 2.7% on aspirin. PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions (such as aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDS) should be used with caution in patients taking PLAVIX.

See 1997 Plavix label (Ex. C).

In describing to physicians what information should be provided to patients, the "PRECAUTIONS" section also specifically warns about Plavix's bleeding risk:

> **Information for Patients**
>
> Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking PLAVIX before any surgery is scheduled and before any new drug is taken.

Id.

Plavix's bleeding risks are discussed yet again in the "ADVERSE REACTIONS" section of the label, including the precise rates observed for GI bleeding, hospitalization, and intracranial hemorrhage:

> **ADVERSE REACTIONS**
>
> . . . . The clinically important adverse events observed in CAPRIE are discussed below:
>
> *Hemorrhagic*: In patients receiving PLAVIX in CAPRIE, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

Id.

As new studies emerged, the further bleeding data was added to the label. *See, e.g.*, 2002 Label (Ex. D) (including incidence of bleeding in the CURE dual therapy study). But the label included this core information concerning the drug's bleeding risk from the first day the companies marketed the product.

B. The Litigation to Date.

The Plavix litigation began in 2006 when Plaintiffs filed 24 cases before this Court. By the time discovery was done, only six of those Plaintiffs remained, the rest having been

voluntarily dismissed by Plaintiffs or the Court. The Court then dismissed the six remaining Plaintiffs' claims on summary judgment based on prescribing doctor testimony.[5]

Plaintiffs did not respond to these results by recognizing their claims lacked merit and walking away. Instead, they filed thousands of additional cases across the country raising the exact same claims. The Judicial Panel on Multidistrict Litigation coordinated hundreds of those cases here in the District of New Jersey. During the "second round" of litigation, Defendants expended substantial efforts defending the cases. They produced more than 10 million additional pages of documents and presented 21 company witnesses and 17 sales representatives for deposition. This "generic" company discovery is now complete.

Yet the second round of litigation proved a repeat of the first. After conducting more than 200 depositions of plaintiffs, spouses and physicians, ***only one*** of the 117 cases randomly selected for discovery across the litigation is left standing today. Plaintiffs' counsel voluntarily dismissed or withdrew as counsel almost every case. The courts then dismissed four of the five remaining cases on summary judgment based on prescribing doctor testimony: the California Court granted summary judgment in three cases, and this Court granted summary judgment in one other, *Hopkins*. *See* Wiesner Cert. Ex. G (Order Granting Defs. Mot. for Summ. J. as to Pls. Salsedo & O'Dwyer ("Salsedo/O'Dwyer Order"), *Plavix Prod. & Mktg. Cases*, JCCP No. 4748 (Cal. Super. Ct. June 29, 2017)); *Id.* Ex. H at 4 (Order Granting Defs.' Mot. for Summ. J. as to Pl. John Helldorfer ("Helldorfer Order"), *Plavix Prod. & Mktg. Cases*, JCCP No. 4748 (Cal. Super. Ct. Sept. 11, 2017)); Order Granting Defs. Mot. for Summ. J. as to Pl. Hopkins, 2017 WL 3531684 (D.N.J. Aug. 17, 2017).[6] In the single remaining Discovery Pool case across all

[5] *See Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556 (D.N.J. 2013) (Texas law); *Begley v. Bristol-Myers Squibb Co.*, 2013 WL 144177 (D.N.J. Jan. 11, 2013) (Illinois law), *aff'd* 544 F. App'x 120 (3d Cir.); *LaBarre v. Bristol-Myers Squibb Co.*, 2013 WL 144054 (D.N.J. Jan. 11, 2013) (Florida law), *aff'd* 544 F. App'x 120 (3d Cir.); *Carr-Davis v. Bristol-Myers Squibb Co.*, 2013 WL 322616 (D.N.J. Jan. 28, 2013) (Missouri law); *Mattson v. Bristol-Myers Squibb Co.*, 2013 WL 1758647 (D.N.J. Apr. 24, 2013) (California law); *Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291 (D.N.J. Jan. 7, 2013) (Alabama law).

[6] The California Court also granted Defendants' motion for summary judgment as to Plaintiff Silvia Alvarado, which Plaintiffs did not oppose. Order Granting Defs. Mot. for Summ.

jurisdictions (the *Thorpe* case), a summary judgment motion remains pending. *See* Defs.' Br. in Supp. of Mot. for Summ. J. as to Pl. Thorpe, Dkt. No. 59-2.

Expert discovery on litigation-wide issues is now complete. Plaintiffs served reports from three experts who address "generic" issues which apply across all cases. Plaintiffs' labeling expert, Dr. Tackett, opines that bleeding information should have appeared in the "Warnings" section of the Plavix label or in a "black box." Dr. Tackett acknowledges that FDA knew about Plavix's bleeding risk from day one. He simply disagrees with FDA's decision to approve the label.

Plaintiffs also disclosed the opinions of Dr. Lemuel Moyé, who opines that FDA should never have approved Plavix because its risks outweigh its benefits. Dr. Moyé was the lone dissenter in the FDA Advisory Committee's 10-1 vote in favor of approving Plavix. In this litigation, he once again disagrees with FDA.[7]

A joint hearing is scheduled for November 15-16, 2017, to address the admissibility of these experts' testimony and to resolve case-wide dispositive motions. The Court should accordingly address the fundamental deficiencies in Plaintiffs' legal theories and expert opinions and should grant summary judgment in all MDL cases.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW

Plaintiffs' disclosure of their litigation-wide generic experts finally reveals the true nature of their legal claims. Plaintiffs' lone expert who offers any opinion to support their claims that Defendants failed to warn has explained why the Plavix label is supposedly deficient. His answer: from day one, the FDA-approved label should have included bleeding in the

---

J. as to Pl. Alvarado ("Alvarado Order"), *Plavix Prod. & Mktg. Cases*, JCCP No. 4748 (Cal. Super. Ct. October 11, 2017).

[7] Plaintiffs have one other "generic" expert, Dr. Schneller. Defendants have not at this juncture moved to exclude the opinions of Dr. Schneller since they are largely supportive of Plavix and contradict Plaintiffs' other experts' opinions.

"Warnings" rather than "Precautions" section. Their expert on the Plavix clinical studies, Dr. Moyé, opines that (contrary to FDA's approval) the science shows Plavix does more harm than good. These core theories of liability are preempted by federal law.

A. Plaintiffs' Failure-To-Warn Claims Are Preempted

Plaintiffs' principal liability theory in this litigation is failure-to-warn. Dr. Tackett, their sole expert on the topic of warnings, opines that the bleeding information should have been in the "Warnings" section of the label or in a black box.[8] Plaintiffs' claim is not that FDA was unaware of any pertinent bleeding information when it approved the label. Dr. Tackett just thinks the agency "got it wrong." *See* Tackett Dep. (Ex. A) at 108:23–110:22. Federal law preempts such second-guessing of FDA's decisions approving an initial drug label.

The question for "impossibility" preemption is whether the company could have complied with both a state law requirement demanding a different label ***and*** federal law imposing certain labeling requirements. In a duo of recent cases, the Supreme Court has framed the question as this: If the company could ***unilaterally*** make the change that plaintiffs believe was required under state law, there is no conflict between state and federal law and therefore no preemption in most cases. If the company instead was required to obtain FDA approval before making change, then the claim is preempted.[9]

---

[8] *See* Tackett Dep. (Ex. A) at 69:13–70:1 (Q: Is it fair to say that your placement criticism of bleeding -- bleeding warnings is really the main thrust of your opinion here today? A: . . . [Y]es, the placement there . . . that's the main thrust is the placement of it, yes. Q: "[T]hose [language criticisms] are really secondary less important than the placement issue in your mind? A: I think the placement is more important to get the information to the clinicians."); *id.* at 118:10–19 (admission that if warning about excessive bleeding was in a black box, the label would be sufficient notwithstanding his other language criticisms); *id.* at 111:17–112:11 (admission that critique of intracranial bleeding language was really a placement issue); *id.* at 125:2-125:16 (same admission as to critique of language in precautions section); *id.* at 132:23-133:6 (witness not aware of any incorrect data in the label).

[9] *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) ("[t]he question for 'impossibility' is whether [defendant] could ***independently*** do under federal law what state law requires of it") (emphasis added) (citations omitted); *see also In re Celexa & Lexapro Mktg. & Sales Prac. Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) ("The line *Wyeth* and [*Mensing*] thus draw [is] between changes that can be ***independently*** made using the CBE regulation and changes that require prior FDA approval . . . .") (emphasis added); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015) ("The Court [in *Mensing*] thus limited [*Wyeth*] to situations in which the

For example, in *Wyeth v. Levine*, the Court declined to find impossibility preemption when the manufacturer could have changed its label unilaterally after learning of new information. 555 U.S. 555, 568–73 (2009). The Court relied on a regulation permitting manufacturers to make "Changes Being Effected" ("CBE") labeling revisions without FDA preapproval. *See id.* at 568 ("There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval."). That regulation permits label changes to, among other thing, "add or strengthen a contraindication, warning, precaution, or adverse reaction" on the basis of "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii)(A). The Court therefore held that "[t]he CBE regulation permitted Wyeth to ***unilaterally*** strengthen its warning, and the mere fact that FDA approved Phenergan's label does not establish that it would have prohibited such a change." *Wyeth*, 555 U.S. at 573 (emphasis added).

A few years later, in *PLIVA, Inc. v. Mensing*, the Court addressed preemption when a generic company could not unilaterally change the label through the CBE process. Plaintiffs argued that, even if the company could not unilaterally change the label, it could have urged FDA to require a label change, thereby setting in motion a chain of events that ultimately would have resulted in a change. *See* 564 U.S. 604, 620 (2011). The Court rejected Plaintiffs' bid to escape a conflict between state and federal law by speculating about what the FDA would or would not have done in such circumstances. *See id.* at 622. The Court broadly held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which in turn is dependent on the exercise of judgment by a federal agency, that party cannot ***independently*** satisfy those state duties for pre-emption purposes." *Id.* at 623-24 (emphasis added). While *Mensing* involved a generic drug, the linchpin of its decision was the

---

manufacturer can, 'of its own volition, … strengthen its label in compliance with its statutory duty'…") (citing *Mensing*, 564 U.S. at 623-24); *In re Lipitor Mktg., Sales Prac., & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 769–70 (D.S.C. 2016) ("The U.S. Supreme Court has held that if a drug manufacturer must obtain FDA approval to take action to comply with state law, then the state law is preempted.") (citing *Mensing*, 564 U.S. at 604).

company's inability to change labeling unilaterally, not whether the drug was generic or branded. *See id.*

After *Levine* and *Mensing*, courts across the country have followed this analytical framework when addressing impossibility preemption in branded pharmaceutical cases. In *In re Celexa*, for example, the First Circuit dismissed a consumer protection claim against a branded manufacturer for presenting misleading information about a clinical study in its drug label. *See* 779 F.3d at 41. The Court explained that "a necessary step in defeating [the defendant's] preemption defense is to establish that . . . [the defendant] could have corrected [the labeling deficiency] using the CBE regulation." *See id.* The Court then assessed plaintiffs' allegations, and decided that plaintiffs never alleged any "newly acquired information" obtained post-approval that could justify a CBE. *See id.* at 42–43. Defendant could therefore not unilaterally change the label, and plaintiffs' claim was preempted.

Similarly, in *Utts v. Bristol-Myers Squibb Co.*, plaintiffs claimed that the anticoagulant drug Eliquis inadequately warned of bleeding. After a thorough review of the Supreme Court's preemption opinions, the court reasoned that "read holistically, [those decisions] indicate[] that federal law preempts all ***pre-FDA approval*** failure to warn and design defect claims for branded prescription medication." 226 F. Supp. 3d 166, 179 (S.D.N.Y. 2016) (emphasis added). The court explained that plaintiffs' claimed inadequacies in that case all related to the initial label, not later-acquired information and therefore were preempted. *See id.* at 184; *see also In re Lipitor*, 185 F. Supp. 3d at 769–70 ("To the extent that Plaintiffs claim Lipitor's label should have included different statements about Lipitor's efficacy for primary prevention based on the ASCOT data," which was the study FDA relied on to approve Lipitor and its initial label, "those claims are preempted."). The Court accordingly dismissed the claims as preempted.[10]

[10] The *Utts* Court initially dismissed the claims with leave to amend. Defendants then filed another motion to dismiss, which the Court granted and dismissed the claims with prejudice. *See Utts v. Bristol-Myers Squibb Co. (Utts II)*, — F.3d —, 2017 WL 1906875 (S.D.N.Y. May 8, 2017).

The Third Circuit's recent decision in *In re Fosamax Products Liability Litigation* represents the other side of the Supreme Court's dichotomy. In that post-approval case, defendants indisputably could have utilized the CBE process but they argued it was futile because "clear evidence" showed that FDA would have rejected it. *See* 852 F.3d 268, 274, 280 (3d Cir. 2017) (citing *Wyeth*, 555 U.S. at 571) ("[T]he primary question in this appeal is whether, prior to September 2010, the FDA would have rejected an attempt . . . to unilaterally amend the Fosamax label (via a CBE submission) to include a warning about the risk of atypical femoral fractures."). Ultimately, the Court held it was a question for the jury whether a CBE would have been futile.[11]

This case falls squarely within the *Mensing*, *Celexa*, and *Utts* line of cases. Plaintiffs' failure-to-warn case turns on Dr. Tackett's opinion that the Plavix label was deficient from the "get-go," and that the initial deficiency carried over into later versions of the label. *See* Tackett Dep. (Ex. A) at 125:2–16. But Dr. Tackett agrees that Defendants could not make a unilateral labeling change during the initial approval process. *See id.* at 183:8-13; *see also* 21 C.F.R § 355(b)(1)(F), § 314.50(c)(2)(i) (FDA's approval of a new drug application includes approval of the label's text). He further admits that FDA was aware of the bleeding risk (which is part of Plavix's mechanism of action) from the start. *See* Tackett Dep. (Ex. A) at 67:11–70:16, 101:12-102:2; 106:20-107:11. And Dr. Tackett does not point to any new information he asserts should have triggered a CBE. His opinion boils down to this—FDA just made a mistake in approving the initial label. This is exactly the type of "second guess of an FDA judgment" that federal preemption was meant to avoid. *See In re Celexa*, 779 F.3d at 41.[12] Because their core theory of

[11] It is questionable whether the case properly decided that the "clear evidence exception" should be decided by the jury and not the Court. The case held that the jury should determine what the FDA would or would not have done, precisely the type of inquiry the Supreme Court said was *not* for the jury in *Mensing*. But that issue has no bearing on this case, which indisputably is focused on what the company should have done prior to FDA approval.

[12] Plaintiffs' claim that Defendants should have added a "black box" is preempted for the further reason that, because of its special significance, a black box warning ***always*** requires FDA preapproval. *See* Tackett Dep. (Ex. A) at 89:19–90:16; 21 C.F.R. § 201.57(e) ("Special problems, particularly those that may lead to death or serious injury, ***may be required by the Food and Drug Administration***, to be placed in a prominently displayed box") (emphasis

labeling inadequacy is accordingly preempted as a matter of law, the Court should dismiss Plaintiffs' failure-to-warn claims.

B. Plaintiffs' Claims That Plavix's Risks Outweigh Its Benefit Are Preempted

Plaintiffs also claim, based on Dr. Moyé's testimony, that Plavix's risk outweighs its benefits and that FDA should therefore never have approved the drug. *See* Moyé Dep. (Ex. B) at 20:11-21:7. It is less clear what legal theory this arguments supports. The only plausible claim connected to this opinion is design defect, yet Plaintiffs have not seriously defended their design defect claims in response to Defendants' summary judgment motions in the MDL and California. But in whatever clothes this liability theory is dressed, it is also preempted. The implication of Dr. Moyé's opinion is that, to avoid state tort liability, Defendants must re-design or simply "stop selling" Plavix despite FDA's approval. Allowing such a claim to proceed to trial would create an irreconcilable conflict between state and federal law. *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2476-77 (2013) (state law duty to re-design generic drug preempted because "the altered chemical would be a new drug that would require its own NDA" and because it is "chemically incapable of being redesigned"); *id.* at 2477 ("stop selling" rationale not a basis to avoid preemption); *Yates v. Ortho-McNeil Janssen Pharm. Inc.*, 808 F.3d 281 (6th Cir. 2015) (applying Bartlett to branded drugs).

This result follows from the Supreme Court's decision in *Mutual Pharmaceuticals Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013). There, the Court found a New Hampshire design defect claim brought against a generic manufacturer to be preempted. To prevail under New Hampshire law, plaintiffs had to show that the risk of the product outweighed its benefit. *See id.* at 2474. But the only way the manufacturer could meet that standard would be to re-design the drug. *See id.* ("A drug's usefulness and its risk of danger are both direct results of its chemical design…."). Doing so was impossible, the Court held because any change in design would make

---

added); Wiesner Cert. Ex. I (44 Fed. Reg. 37,434, 37,448 (June 26, 1979)) ("to ensure the significance of boxed warning in drug labeling, they are ***permitted only when specifically required by FDA***") (emphasis added).

the product a new drug requiring prior FDA approval. *Id.* at 2475. Nor could the Defendants comply with both state and federal law by ceasing to sell the drug. The Court held that a drug manufacturer "is not required to cease acting altogether to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.*

Courts have repeatedly applied *Bartlett* to find that design defect claims against branded drug manufacturers preempted. *See, e.g.*, *Yates*, 808 F.3d at 293 (design defect claim against manufacturer of branded birth control preempted); *Gustavesen v. Alcon Labs., Inc.*, 2017 WL 4374384 (D. Mass. Sept. 29, 2017) (design defect claims against both brand name and generic drug manufactures preempted).[13]

Yates v. Ortho-McNeil Janssen Pharmaceuticals, Inc. is emblematic. There, the plaintiff alleged that a brand name birth control drug was defectively designed and that the manufacturer should have changed the dosage of estrogen to reduce the risks. *Yates*, 808 F.3d at 298. But the Sixth Circuit explained that the branded defendant could not change the dosage of estrogen without first seeking FDA approval. *Id.* (changes to the drug formulation are "major changes" that require pre-approval under 21 C.F.R. § 314.70). Thus, such claims were "clearly preempted." *Id.* The Sixth Circuit also rejected plaintiff's argument that defendants could have

[13] *See also Utts v. Bristol–Myers Squibb Co.*, No. 16cv5668(DLC), 2016 WL 7429449, at *12 (S.D.N.Y. Dec. 23, 2016) (finding too speculative plaintiff's claim that "defendants had a pre-approval duty to submit a differently designed drug for FDA approval" and thus dismissing design defect claim with prejudice); *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 832-34 (W.D. Tenn. 2016) (relying on *Yates* to grant motion to dismiss where plaintiff claimed defendants had a "duty to design the drug differently before FDA approval"); *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028, at *4 (N.D. Ala. Mar. 21, 2016) (dismissing design defect claim because "any [FDA] approved drug, whether through the NDA or ANDA process, cannot be altered without the FDA's prior permission, rendering compliance with both state and federal law impossible"); *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014) (holding that New York law design defect claim was "preempted as a matter of law"); *Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1014 (E.D. Mo. 2014) (finding design defect claim preempted where redesign required by state law would be "a major change requiring prior FDA approval"); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 875 (N.D. Ohio 2014) (granting summary judgment on design defect claim because "[c]reating an alternative design would, by its very essence, require changing the composition of the drug, which is prohibited by federal law").

submitted a differently designed drug to FDA for initial approval, finding that such "pre-approval" design defect claims amount to little more than the "stop selling" rationale the Supreme Court rejected in *Bartlett*. *Id.* at 300.

The same result applies here. The core of Dr. Moyé's opinion is that Plavix's risks supposedly outweigh its benefits. But the only way Defendants could avoid liability imposed on the basis of such a view is to change the makeup of the drug or stop selling it altogether. Defendants cannot be held liable in tort for selling an FDA-approved product or declining to seek FDA approval to re-design it. *See Bartlett* 133 S. Ct. at 2471; *Yates* 808 F.3d at 298. For these reasons, Plaintiffs' defect claims -- and any other claims based on Dr. Moyé's opinion that Plavix causes more harm than good -- are preempted.

II. PLAINTIFFS' CLAIMS MUST BE DISMISSED BECAUSE THEY LACK ADMISSIBLE EXPERT TESTIMONY

A. Plaintiffs Have No Admissible Expert Testimony To Support Failure To Warn Claims.

"Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Brill v. Guardian Life Ins. Co. of Am.*, 142 N.J. 520, 533 (1995) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). Where the non-moving party bears the burden of proof at trial, the movant fulfills its summary judgment burden by merely "point[ing] out to the district court that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325.

Here, Plaintiffs do not have the proof needed to sustain their failure-to-warn claims. The most fundamental element of any failure-to-warn claim in a prescription drug case is that a drug's label is deficient.[14] Plaintiffs bear the burden of proof on this issue.[15]

[14] *See, e.g., LaBarre v. Bristol-Myers Squibb Co.*, 544 Fed. Appx. 120, 125 (3d Cir. 2013) (explaining that to prevail on a failure to warn claim, "a plaintiff must prove… that the warnings accompanying the item were inadequate") (Florida law); *Koken v. Black & Veatch Const., Inc.*, 426 F.3d 39, 45 (1st Cir. 2005) ("A products liability action for failure to warn requires a three-part analysis" including "whether the actual warning on the product, if any, was inadequate") (quotations and citation omitted) (Maine law); *Jeter v. Brown and Williamson Tobacco Corp.*,

The sufficiency of prescription drug labeling is an issue that requires expert testimony. *See, e.g.*, *LaBarre*, 2013 WL 144054, at *9 ("Plaintiff has not presented any other expert testimony. Based on this reason alone, Plaintiff's failure-to-warn claim fails under Florida law."), *aff'd* 544 F. App'x at 125 ("[S]ummary judgment is appropriate on a failure to warn claim if a plaintiff has not proffered expert testimony on the adequacy of the warnings"); *Begley*, 2013 WL 144177, at *5-6 (under Illinois law, "a plaintiff must present expert testimony to establish that a warning is inadequate" because "only a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate") (internal quotation omitted).[16] A lay jury cannot be expected to understand on its own the medical and

---

113 Fed. App'x. 465, 467 (3d Cir. 2004) ("a plaintiff in a failure to warn case must establish that . . . a warning of a particular product was either lacking or inadequate") (Pennsylvania law); *Mulhall v. Hannafin*, 45 A.D. 3d 55,58 (N.Y. App. Div. 2007) ("To succeed on their failure-to-warn claim, plaintiffs were required to prove that the product did not contain adequate warnings. . . ."); *Daniel v. Fisons Corp.*, 138 Ohio App. 3d 104, 109 (Ohio App. 2000) (drug manufacturer may be held liable "where the manufacturer has failed to provide an adequate warning"); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W. 3d 87, 94 (Tex. App. 2000) ("[i]n any failure to warn case, the plaintiff must show . . . that the warning was defective"); *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112 (Cal. 1996) (plaintiff must prove "defendant did not adequately warn of a particular risk"); Restatement (Third) of Torts: Products Liability § 6(a); Restatement (Second) of Torts § 402A, cmt. j (1965) ("In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning"); Francis C. Amendola, et al., 72A C.J.S. Products Liability § 33 ("The duty of a supplier to warn of possible dangers arising from the use of its products requires the giving of a warning which is adequate under the circumstances").

[15] *See, e.g.*, 72A C.J.S. Products Liability § 229 ("A products liability plaintiff has the burden to establish a duty to warn, to establish a failure to warn, and to prove proximate causation of loss resulting from the failure to warn."); *LaBarre*, 544 Fed. App'x. at 124 (Florida law); *Koken*, 426 F.3d at 45 (Maine law); *Solomon*, 916 F. Supp. 2d at 563 (Texas law); *Jeter*, 113 Fed. App'x. at 467 (Pennsylvania law); *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112 (Cal. 1996); *Mulhall v. Hannafin*, 45 A.D. 3d at 61-62; *Michel v. Minn-Dak Co.*, 2002 WL 31689352, at *2 (Minn. App. 2002); *Christison v. Biogen Idec Inc.*, 199 F.Supp.3d 1315, 1319 (D. Utah 2016) (Utah law).

[16] *See also Grobelny v. Baxter Healthcare Corp.*, 341 Fed. App'x. 803, 807 (3d Cir. 2009) (perceiving "no error" with district court's ruling that "expert testimony was required to demonstrate the inadequacy of the warnings" provided with intravenous immunoglobulin treatment) (New Jersey law); *Beaudette v. Louisville Ladder, Inc.*, 462 F.3d 22, 27 (1st Cir. 2006) (affirming summary judgment because "expert testimony is required for [plaintiffs'] failure to warn claim" involving warnings attached to a ladder) (New Hampshire law); *Christison v. Biogen Idec Inc.*, 199 F.Supp.3d 1315, 1319 (D. Utah 2016) (granting summary judgment where plaintiffs failed to provide expert testimony regarding adequacy of drug label) (Utah law); *Calisi v. Abbott Labs.*, 2013 WL 5441355 (D. Mass. Sept. 27, 2013) (granting summary judgment for defendant where plaintiff's only expert as to adequacy of warnings

scientific evidence behind a drug's risk profile and the FDA regulatory history of the product, and apply that knowledge to assess whether a label designed for medical doctors to use in prescribing drugs adequately discloses those risks.[17]

Here, Plaintiffs have no competent expert evidence to support their failure-to-warn claims. Their only expert witness on labeling, Dr. Tackett, offers one basic theory of why the Plavix label is inadequate: that bleeding did not appear in the "Warnings" section of the label or in a "black box." But for the reasons further detailed in Defendants' motion to exclude his testimony, this opinion is not admissible.

Putting aside preemption, Dr. Tackett's opinions are not reliable, but sheer *ipse dixit* untethered to the evidence. Absent competent expert proof, Plaintiffs' failure-to-warn claims must be dismissed.

---

contained in Humira label was excluded) (Massachusetts law); *Jones v. Synthes USA Sales, LLC*, 2010 WL 3311840, at *10 (D.N.J. Aug. 19, 2010) (granting summary judgment where plaintiffs failed to provide expert testimony because expert testimony was "crucial to their inadequate warning claim") (New Jersey law); *Foltz v. Smith & Wesson Corp.*, 2009 WL 2596598, at *3-4 (N.D. Tex. Aug. 20, 2009) (granting summary judgment because "expert testimony is required to determine what warnings, if any, should be included" in firearm labeling case) (Texas law); *Montagnon v. Pfizer, Inc.*, 584 F. Supp.2d 459, 463 (D. Conn. 2008) (granting motion for summary judgment where plaintiff proferred no expert testimony as to adequacy of drug warnings) (Connecticut law); *Lundy v. Conoco Inc.*, 2006 WL 3300397, at *3 (S.D. Miss. Nov. 10, 2006) ("On the issue of whether expert testimony is required to support a failure to warn/inadequate warnings claim, federal courts applying Mississippi law, have found that such testimony is a prerequisite on all strict liability claims.") (Mississippi law); *Burton v. Danek Medical, Inc.*, 1999 WL 118020, at *8 (E.D. Pa. March 1, 1999) (explaining that "[g]enerally, expert testimony is required to determine the adequacy of the warning provided to the medical community by the manufacturer of a prescription product" and granting summary judgment where no such expert testimony was proffered) (Pennsylvania law); *In re Zoloft Litigation*, 2017 WL 665299, at *11 (W.Va. Cir. Ct. Feb. 15, 2017) (granting summary judgment for defendants because plaintiffs had failed to proffer expert testimony as to inadequacy of Zoloft label);.

[17] *See, e.g., Dion v. Grad. Hosp. of Univ. of Pa.*, 360 Pa.Super. 416, 425-26 (Pa. 1987) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. The terms and applications of a warning on such a drug, in order to have meaning, must be explained to the jury. This is a subject 'so distinctively related to some science, profession, business or occupation as to be beyond the ken of the average layman.'") (quoting McCormick on Evidence 33 (E. Cleary, 3d ed. 1984); *see also LaBarre*, 2013 WL 144054, at *4 ("'[P]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.'") (quoting *Buckner v. Allergan Pharms.*, 400 So. 2d 820, 822 (Fla. 5th DCA 1981).

B. Plaintiffs' Have No Admissible Expert Testimony To Support Design Defect Claims.

Plaintiffs' theory of design defect, if they have one, is unclear. Defendants are aware of no complaint that even pleads a specific theory of design defect liability. But no matter its precise contours, Plaintiffs cannot hope to present a design defect case based on complex scientific evidence concerning the risks and benefits of the drug, such as interpretation of cardiology clinical trials, to a jury without the help of an expert.[18]

Here, Plaintiffs proffer only one expert who even purports to give testimony that could possibly support a design defect claim, Dr. Moyé. Dr. Moyé opines that Plavix's bleeding risk outweighs its efficacy, and that FDA accordingly should never have approved the drug. Moyé Dep. (Ex. B) at 15:22-16:1; 20:11-21:1. But this opinion is also inadmissible for the reasons set forth in Defendants' motion to exclude his testimony. *See* Defs.' Brief in Supp. of Mot. to Exclude Dr. Lemuel Moyé. In addition to preemption, his subjective view that the drug's risks

[18] *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d 136, 159 (3d Cir. 2000) (acknowledging that "expert evidence is generally required in a products liability case where a defect is alleged" unless the defect is obvious and within the comprehension of the average juror) (Pennsylvania law); *Kline v. Zimmer Holdings, Inc.*, 2015 WL 4077495, at *1 (W.D. Pa. July 6, 2015) (holding that "expert testimony must be presented to establish the design defect and failure to warn claims" in a case involving an allegedly defective hip replacement component) (Pennsylvania law); *Payne v. C.R. Bard, Inc.* 2014 WL 1887297, at *2 (M.D. Fla. May 12, 2014) ("Expert testimony is generally necessary to prove that a complex product like a medical device is defective.") (Florida law); *Show v. Ford Motor Co.*, 697 F.Supp.2d 975, 983 (N.D. Ill. 2010) ("[P]roducts liability cases that involve complex products beyond a lay jury's understanding require expert testimony.") (Illinois law); *Justice v. Ford Motor Co.*, 2012 WL 2513495, at *3 (N.D. Ga. June 27, 2012) (noting a "typical requirement [under Georgia law] that in a complex products liability case a plaintiff must produce an expert who states that the product was defectively designed. . . .") (Georgia law); *Laspesa v. Arrow Int'l, Inc.*, 2009 WL 5217030, at *5 (D. Mass. Dec. 23, 2009) (plaintiffs must provide expert testimony to prove a design defect "when the product's mechanisms are technical and complex" and applying this rule to the context of a medical device) (Massachusetts law); *Toms v. J.C. Penney Co.*, 2007 WL 2893052, at *4 (D.N.J. Sept. 28, 2007) ("It is well-settled law that where the allegedly defective product involves a complex instrumentality, a plaintiff is required to provide expert testimony.") (New Jersey law); *Kallassy v. Cirrus Design Corp.*, 2006 WL 1489248, at *4 (N.D. Tex. May 30, 2006) (granting summary judgment for failure to proffer expert testimony in defective aircraft case and explaining that "Texas courts have required expert testimony to prove defect where the defect involves technical matters beyond the general experience of the jury.") (Texas law); *Fulton v. Pfizer Hosp. Prods. Group, Inc.*, 872 S.W.2d 908, 912 (Tenn. App. 1993) ("[T]he product in dispute is a technically complex medical device. Therefore, expert testimony is required [to show that the product was defective].").

outweigh its benefits is, to put it mildly, an outlier opinion that is unsupported by reams of clinical evidence. Dr. Moyé admits that his view is not generally accepted; Plaintiffs' own cardiologist expert disagrees with him; and Dr. Moyé's litigation-driven view conflicts with his own earlier peer-reviewed, published statement that Plavix is valuable therapy. *See id.* at 9-12. Once Dr. Moyé's inadmissible opinions are excluded, Plaintiffs' design defect claims must therefore also be dismissed.

C. Plaintiffs' Remaining "Tag-Along" Claims Also Fail

Plaintiffs allege a myriad of other claims in their complaints that are essentially derivative of their failure-to-warn or design defect claim. For example, they assert negligence, fraud, statutory consumer fraud, and/or breach of warranty claims. *See, e.g.*, Compl., *Brown, et al. v. Bristol-Myers Squibb Co., et al.*, No. 3:14-cv-05410, Dkt. No. 1 (D.N.J. Aug. 28, 2014); Compl., *Evans, et al. v. Bristol-Myers Squibb Co., et al.*, No. 3:14-cv-07342, Dkt. No. 1 (D.N.J. Nov. 3, 2014); Compl., *Armantrout, et al. v. Bristol-Myers Squibb Co., et al.*, No. 3:13-cv-04521, Dkt. No. 1-1 (D.N.J. July 2, 2013). No matter the guise in which they are presented, the factual basis of these claims is fundamentally the same: that Defendants allegedly downplayed the drug's bleeding risks. Indeed, this Court and others have routinely held that such "tag-along" claims must fail along with the principal failure-to-warn claims.[19] These claims can accordingly

[19] *See In re Plavix Mktg., Sales Practices & Prod. Liab. Litig. (No. II)*, No. 13-4521 (FLW), 2017 WL 3531684, at *13 (D.N.J. Aug. 17, 2017) ("Because all the underlying substantive claims fail, summary judgment is appropriate as to the loss of consortium claim, as well.") (New York law); *Mattson v. Bristol-Myers Squibb Co.*, 2013 WL 1758647, at *5 (D.N.J. Apr. 24, 2013) (California law) ("Plaintiff's negligence claim is nothing more than a restatement of her defective manufacturing and failure-to-warn claims."); *Carr-Davis v. Bristol-Myers Squibb Co.*, 2013 WL 322616 (D.N.J. Jan. 28, 2013) (same) (Missouri law); *Begley v. Bristol-Myers Squibb Co.*, 2013 WL 144177 (D.N.J. Jan. 11, 2013) (holding that plaintiff's design defect, manufacturing, and negligence claims were premised on Defendants' alleged failure to warn, and correspondingly failed) (Illinois law), *aff'd* 544 F. App'x 120 (3d Cir.); *LaBarre v. Bristol-Myers Squibb Co.*, 2013 WL 144054 (D.N.J. Jan. 11, 2013) (same) (Florida law), *aff'd* 544 F. App'x 120 (3d Cir.); *Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556 (D.N.J. 2013) (holding that because "Plaintiff is unable to establish any triable issue with respect to his failure-to-warn claim, Plaintiff's design claim correspondingly fails" and similarly holding that "Plaintiff's negligence claim is nothing more than a restatement of his defective design, defective manufacturing, and failure-to-warn claims") (Texas law); *Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291 (D.N.J. Jan. 7, 2013) (holding that plaintiff's design defect, manufacturing, and negligence claims were premised on Defendants' alleged failure to warn, and correspondingly

fare no better without expert proof.[20] They are both preempted and lack the expert support needed to reach a jury.

* * *

Finally, although the basic theories and expert support underlying all of Plaintiffs' claims are the same, Defendants recognize that Plaintiffs have pleaded various claims in numerous different complaints under many different state laws. But whichever state law applies and no matter how it is pleaded, Defendants do not believe that Plaintiffs can seriously maintain that they could try these cases with no expert support. Otherwise they would not have disclosed generic experts in the litigation cases to begin with. We have accordingly not undertaken to supply the Court with a comprehensive 50-state survey and individualized analysis of every complaint. If Plaintiffs identify any cases they nevertheless believe could proceed bereft of experts, they should say so in their Opposition. If the Court believes it necessary or helpful to assess this issue on a state-by-state basis, Defendants respectfully suggest the Court provide for supplemental briefing.

CONCLUSION

For the foregoing reasons, Defendants respectfully seek summary judgment as to all claims in the litigation.

---

failed) (Alabama law); *Holland v. Hoffman-La Roche, Inc.*, 2007 WL 4042757 (N.D. Tex. Nov. 15, 2007) (dismissing plaintiff's design defect claim because plaintiff's failure to warn claim failed) (Texas law); *Motus v. Pfizer*, 196 F. Supp. 2d 984, 999 (C.D. Cal. 2001) (granting summary judgment on failure-to-warn claim and then dismissing claims for negligence, strict liability, fraud, and breach of warranty because the latter claims were "premised to some extent on the allegation [that defendant's] failure to warn caused her injuries") (California law); *Martin v. Hacker*, 83 N.Y.2d 1, 8 n.1 (N.Y. 1993) ("Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent.") (citation omitted); *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 62 (N.Y. App. Div. 1979) ("[r]egardless of the descriptive terminology used to denominate the cause of action . . . where the theory of liability is failure to warn, negligence and strict liability are equivalent").

[20] Plaintiffs' manufacturing defect claims must also be dismissed. Plaintiffs do not even purport to present expert evidence supporting those claims. Nor did they pursue them in discovery.

Dated: October 16, 2017

Respectfully submitted,

By: /s/ Gavin J. Rooney

Gavin J. Rooney
Naomi D. Barrowclough
LOWENSTEIN SANDLER LLP
One Lowenstein Drive
Roseland, NJ 07068
Tel. No. (973) 597-2500
grooney@lowenstein.com

Anand Agneshwar
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
Tel. No. (212) 836-8000
Fax No. (212) 836-8689

Daniel S. Pariser
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
Tel. No. (202) 942-5000

Attorneys for Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC