ARNOLD & PORTER KAYE SCHOLER

Anand Agneshwar
+1 212.836.8011 Direct
Anand.Agneshwar@apks.com

November 22, 2017

VIA ECF AND E-MAIL

The Honorable Freda L. Wolfson
United States District Court for the
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: Supplemental Letter Briefing in *In re Plavix Marketing, Sales Practices, & Products Liability Litigation (No. II)*, MDL No. 2418

Dear Judge Wolfson:

In response to Plaintiffs' submission, Defendants are tempted to say *res ipsa loquitur* and leave it at that. After repeated requests, the Court allowed Plaintiffs one last chance to identify evidence that Defendants could have made a post-approval CBE label change. Yet Plaintiffs manage to cite only two paragraphs from Dr. Tackett's 205-paragraph, 53-page report. They do not cite Dr. Moyé's report at all. Both doctors were deposed for a full day, yet Plaintiffs do not cite their depositions. And they ignore the Court's admonition to submit quotes and not paraphrase the evidence.

Instead, Plaintiffs spend most of their supplemental brief re-arguing their position that claims based on Plavix's initial label are not preempted. Despite a nearly three-hour argument during which Plaintiffs' counsel repeatedly looked in vain for a citation to support their initial labeling theory, two-and-a-half days after argument they still cannot find any citations that support their position. Instead, they provide a mishmash of pre-

Mensing cases, including dissenting opinions, design defect cases,[1] and post-approval cases[2]—none of which involved claims that an initial label was deficient.

Though we are tempted not to respond at all, we briefly address Plaintiffs' arguments. ***First***, Plaintiffs' citations to Dr. Tackett's unsworn report are not ***evidence*** sufficient to survive summary judgment. *See, e.g.*, *Fowle v. C & C Cola*, 868 F.2d 59, 67 (3d Cir. 1989) ("The substance of this [expert's] report was not sworn to by the alleged expert. Therefore, the purported expert's report is not competent to be considered on a motion for summary judgment."); *Liebling v. Novartis Pharm. Corp.*, 2014 WL 12576619, at *1 (C.D. Cal. Mar. 24, 2014) ("[I]t is well established that unsworn expert reports are inadmissible and cannot be used to create a triable issue of fact for purposes of summary judgment.").[3] Plaintiffs could have called Dr. Tackett to testify at the hearing or elicited needed testimony at his deposition, and did neither. Plaintiffs' failure to cite to admissible evidence to support a post-approval theory is fatal to their argument.

Second, Plaintiffs' two citations do not in any case point to newly acquired post-approval information to support a unilateral CBE change.

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1 *Tobin v. Astra Pharm. Prods. Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993); *Hill v. Searle Labs., Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (dicta during discussion of comment k).

2 *See In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d 776, 779, 783 (E.D. La. 2007) (post-approval data concerning cardiovascular events); *In re Zyprexa Prod. Liab. Litig.*, 489 F. Supp. 2d 230, 248-49, 276-77 (E.D.N.Y. 2007) (post-approval data concerning weight gain, hyperglycemia, and diabetes); *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 670-71, 676 (E.D. Ky. 2006) (new evidence of cancer risk); *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678, 680-81, 685-86 (E.D. Pa. 2006) (same); *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, 2006 WL 2819046, at *2, *7, *13 (D.N.J. Sept. 29, 2006), rev'd sub nom. *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, judgment vacated*, 556 U.S. 1101 (2009) (post-approval association with suicidality); *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1173 (W.D. Wash. 2006) (same); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 (D. Neb. 2006) (same); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 728, 731 (D. Minn. 2005) (same); *Zikis v. Pfizer, Inc.*, 2005 WL 1126909 *2-3 (N.D. Ill. May 9, 2005) (same); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 880, 886 (E.D. Tex. 2005) (same); *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085, 1089, 1094 (C.D. Cal. 2000) (same); *Eve v. Sandoz Pharm. Corp.*, 2002 WL 181972 at *3 (S.D. Ind. Jan. 28, 2002) (citing availability of CBE as a basis to deny preemption); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1033-34, 1038 (S.D. Ill. 2004) (same); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1296, 1301, 1303 (D. Minn. 1988) (failure-to-warn of post-approval cases of Pelvic Inflammatory Disease).

3 *See also Arce v. 1704 Seddon Realty Corp.*, 89 A.D. 3d 602, 603 (N.Y. App. Div. 2011) ("The report of plaintiff's expert was unsworn and therefore, did not constitute competent evidence sufficient to raise an issue of fact."); *Dickerson v. Murray*, 2016 WL 1613286, at *3 (Del. Super. Ct. Mar. 24, 2016) ("Both parties have submitted expert reports . . . . [but] only Defendants' expert was deposed, and unsworn statements cannot be considered"); *Helldorfer* Order at 2 (Ex. H to Rooney Decl.) (sustaining objection to admissibility on summary judgment of unsworn prescriber declaration).

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- Paragraph 180. Dr. Tackett's citation to the 2009 Effient label is not new post-approval evidence that ***Plavix*** causes more bleeding than previously known. *See* 21 C.F.R. § 314.3(b) (defining "newly acquired information" to require that it "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA"). It is Dr. Tackett's way of trying to show that other drugs mention bleeding risks in the Warnings section, and therefore Plavix's initial label should have too.[4]

- Paragraph 181. The email from Dr. Blumenthal is not newly acquired scientific data about Plavix. It is simply an internal discussion. To the extent Plaintiffs are suggesting that the MATCH study, which was the subject of the email, is new evidence, that gets them nowhere. After becoming confused about what his report said about MATCH, Dr. Tackett testified he was ***not*** criticizing the MATCH labeling, *see* Tackett Dep. at 173:20-177: 22, 178:18–179:4, and he offers no opinion that MATCH justified different placement of the pre-existing bleeding information.

Finally, Plaintiffs disregarded the Court's request to submit no later than Friday, November 17 references to specific paragraphs in Dr. Moyé's report that they intended to offer as "background" testimony concerning clinical studies. The Court therefore should exclude Dr. Moyé's testimony in its entirety.

Respectfully Submitted,

Anand Agneshwar /HD

Anand Agneshwar

cc: Daniel Pariser
Shayna Sacks
Jennifer Liakos
Hunter Shkolnik
Debra Humphrey
Michael Werner

[4] *See* Tackett Report at ¶ 180 ("A comparison to labels of other antiplatelet and anticoagulant drugs demonstrate stronger warnings concerning bleeds ***with the initial approved labeling***. . . . This would strongly suggest that if submitted as part of the label by BMS/Sanofi, the FDA would have approved a label that had bleeding in the Warning section.") (emphasis added); Tackett Dep. at 134:19-22 ("And so all of those [drugs, including Effient] were anticoagulants, and I think that their warnings for bleeding were much stronger than what came out with Plavix ***to begin with***.") (emphasis added).

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

I, **DAVID FAUVRE**, hereby certify that on November 22, 2017 a true and correct copy of Defendants' Supplemental Letter Briefing in *In re Plavix Marketing, Sales Practices, & Products Liability Litigation (No. II)*, MDL No. 2418 was filed electronically with the Clerk of the United States District Court and forwarded electronically to all counsel.

I certify under penalty of perjury that the foregoing is true and correct.

DATED: November 22, 2017

Respectfully submitted,

David Fauvre /HD

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

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

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 Co., Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo LLC