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VIA ECF and ELECTRONIC MAIL
The Honorable Freda L. Wolfson
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *In Re: Plavix Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, MDL No. 2418

Dear Judge Wolfson:

Please accept this letter brief on behalf of Plaintiffs in response to Your Honor's request at the November 15, 2017, hearing.

Plaintiffs stand by its arguments that the initial label is not pre-empted and therefore Plaintiffs' failure to warn and related claims must survive. Courts have considered this exact question and have overwhelmingly upheld that FDA approval of a new drug application does not preempt state tort suits."[1] See, *Reigel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (*Justice Ginsburg*,

[1] This proposition is further supported in Tobin v. Astra Pharmaceutical Prods., Inc., 993 F. 2d 528, 537–538 (CA6 1993); Hill v. Searle Labs., 884 F. 2d 1064, 1068 (CA8 1989); In re Vioxx Prods. Liability Litigation, 501 F. Supp. 2d 776, 788– 789 (ED La. 2007); In re Zyprexa Prods. Liability Litigation, 489 F. Supp. 2d 230, 275–278 (EDNY 2007); Weiss v. Fujisawa Pharmaceutical Co., 464 F. Supp. 2d 666, 676 (ED Ky. 2006); Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678, 685–687 (ED Pa. 2006); McNellis ex rel. DeAngelis v. Pfizer, Inc., No. Civ. 05–1286 (JBS), 2006 WL 2819046, *5 (D. NJ, Sept. 26, 2006); Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 968 (Neb. 2006); Laisure-Radke v. Par Pharmaceutical, Inc., 426 F. Supp. 2d 1163, 1169 (WD Wash. 2006); Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 732 (Minn. 2005); Zikis v. Pfizer, Inc., No. 04 C 8104, 2005 WL 1126909, *3 (ND Ill., May 9, 2005); Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876, 885–886 (ED Tex. 2005); Eve v. Sandoz Pharmaceutical Corp., No. IP 98–1429–C–Y/S, 2002 WL 181972, *1 (SD Ind., Jan. 28, 2002); Caraker v. Sandoz Pharmaceuticals Corp., 172 F. Supp. 2d 1018, 1044 (SD Ill. 2001); Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1087 (CD Cal. 2000); Kociemba v. G. D. Searle & Co., 680 F. Supp. 1293, 1299–1300 (Minn. 1988). But see 71 Fed. Reg. 3933–3936 (2006) (preamble to labeling regulations discussing FDA's recently adopted view that federal drug labeling requirements preempt conflicting state laws); In re Bextra & Celebrex Marketing Sales Practices & Prod. Liability Litigation, No. M:05–1699 CRB, 2006 WL 2374742, *10 (ND Cal., Aug. 16, 2006); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 537–538 (ED Pa. 2006); Needleman v. Pfizer Inc., No. Civ. A. 3:03–CV–3074–N, 2004 WL 1773697, *5 (ND Tex., Aug. 6, 2004); Dusek v. Pfizer Inc., No. Civ. A. H–02–3559, 2004 WL 2191804, *10 (SD Tex., Feb. 20, 2004). But cf. 73 Fed. Reg. 2853 (2008) (preamble to proposed rule).

dissenting) (where the Court was considering a product pre-emption case based on the 510(k) approval process) and *Wyeth v. Levine*, 555 U.S. 555 (2009) (*Justice Alito, dissenting) (discussing the NDA application process and why the process should not be different from Reigel*).

This argument is exemplified in established precedent regarding pharmaceutical products in *Wyeth v. Levine*, 555 U.S. 555 (2009), *PLIVA Inc. v. Mensing*, 564 U.S. 604, (2011) and *In re Fosamax Alendronate Sodium Prods. Liab. Litig.*, 852 F.3d 268, and has been upheld by all courts except one – a 2016 opinion by Judge Denise Cote of the Southern District of New York in *Utts v. Bristol-Myers Squibb Co*.

Should Your Honor nevertheless find that the initial label is pre-empted, as to Your Honor's request for post-approval data cited within Plaintiffs' expert reports or deposition transcripts, please see the following:

> Line 180: A comparison to labels of other antiplatelet and anticoagulant drugs, including those with the same mechanism of action, demonstrate that there was information available to Defendants to consider and submit to the FDA to support the position that bleeding should have been included in the warning section. Specifically, "in 2009, Effient, a drug with the same mechanism of action as Plavix, was approved. Its initial approved label contained a black box warning regarding bleeding. It was not until 2011 that Plavix included a warning for general bleeding, and then only in the Warnings section of the label."
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> Line 181: Dr. Mel Blumenthal, Bristol-Myers Squibb Company's Executive Director of Clinical Design & Evaluation, in an April 2004 email, recognized that the label was weak regarding bleeding. "Yet, the bleeding warning was not changed until 2011, nor were doctors informed of this by Dear Doctor or Dear Healthcare Professionals letters."

We appreciate Your Honor's consideration of this matter.

Respectfully submitted,

Shayna E. Sacks

cc:
Anand Agneshwar, Esq.
Daniel Pariser, Esq.