SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 1

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IN RE: PLAVIX PRODUCTS LIABILITY LITIGATION Index No. 776000/2013

Decision and Order

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Hon. Martin Shulman, J.S.C.

Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services, Inc. and Sanofi-Synthelabo LLC (collectively, "B-MS" or "Defendant") have filed three motions, to wit: (1) to preclude the generic testimony of Dr. Randall Tackett ("Dr RT"), plaintiffs' warning label expert (motion sequence 1); (2) to preclude the generic testimony of Dr. Lemuel Moyé ("Dr LM"), plaintiffs' causation expert (motion sequence 2); and (3) to obtain summary judgment as a matter of law dismissing the remaining New York plaintiffs' ("NY Plaintiffs") claims in this drug products liability litigation (motion sequence 3). NY Plaintiffs have filed an omnibus affirmation in opposition to these motions. Motion sequences 1, 2 and 3 are consolidated for disposition.

Brief Background and History of the Litigation

In 1997, B-MS began "manufactur[ing] and market[ing] the drug Plavix, an antiplatelet prescription widely prescribed to prevent heart attacks and strokes." *Davidson v Bristol-Myers Squibb Co.*, 2011 WL 13234404, *1, 2011 US Dist LEXIS 154340, *2 (SD Ill, Sept. 30, 2011, No. 10-CV-970-MJR). United States District Court Judge Freda L. Wolfson, who presides over multiple Plavix cases in the Multi-District Court Litigation ("MDL"), succinctly summarized the following background in a number of decisions (*see illustratively*, *Armantrout v Bristol-Myers Squibb (In re Plavix Mktg.,*

Sales Practices & Prods. Liab. Litig.[NO. II]), 2017 WL 3531684, *1-2, 2017 US Dist LEXIS 13134, *4-7 [D NJ, Aug. 17, 2017, Civ. No. 13-4521 (FLW)]):

> Plavix . . . was initially approved by the United States Food and Drug Administration ("FDA") for use as monotherapy, i.e., taken without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral arterial disease . . . Thereafter, the FDA approved Plavix for dual therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").
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> Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, it is well known that Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, its labeling included certain information on that risk. . . [T]he drug label[1] provided:
>
> CONTRAINDICATIONS
>
> The use of PLAVIX is contraindicated in the following conditions:
>
> * * *
>
> • Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.
>
> * * *
>
> PRECAUTIONS
>
> General
>
> [PLAVIX] prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intraocular). If a patient is to undergo elective

[1] Except for very minor changes, the format and content of the Plavix label as a package insert remains essentially the same since this drug was commercially introduced in 1997.

surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.

Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment (see ADVERSE REACTIONS).

GI Bleeding: In CAPRIE[2], PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CURE,[3] the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). 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 should be used with caution in patients taking PLAVIX.

* * *

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.

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[2] CAPRIE is an acronym referencing a randomized, blinded clinical trial conducted, among various goals, to learn the risks of bleeding in the administration of **C**lopidogrel (Plavix is its brand name) versus **A**spirin in **P**atients at **R**isk of **I**schemic **E**vents (https://www.wikijournalclub.org/wiki/CAPRIE).

[3] CURE is an acronym referencing a clinical trial that studied the therapeutic effects of **C**lopidogrel administered to patients with **U**nstable angina to prevent **R**ecurrent **E**vents (https://www.ncbi.nlm.nih.gov/pubmed/11102254).

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at 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.

. . .

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3). There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%) and fatal bleeding (0.2%), was the same in both groups.

In patients receiving both PLAVIX and aspirin in CURE, the incidence of bleeding is described in Table 3.

(Pagination, footnote and court record references omitted).

On this record, NY Plaintiffs never challenged the fact that from the inception of this drug product liability litigation in 2006, to date, plaintiffs in other jurisdictions have not been prevailing against Defendant with their theories of liability (*see* B-MS's Memorandum of Law in Support of Summary Judgment Motion ["Def-SJ Memo"] at pp 7-9). Notably, in multi-state and MDL litigations, plaintiffs' counsel have exchanged the same generic expert witness reports, wherein Dr RT opined that instead of placing the bleeding risk information in the Plavix initial label's "Precautions" section, the FDA should have placed this information either in the Plavix label's "Warnings" section or

formatted same as a "black box" warning.[4] Dr RT further acknowledged that the FDA knew of the bleeding risks associated with Plavix prior to approving this drug, but has taken issue with this federal agency's inceptual approval of the Plavix label's format and content prior to its commercial launch. As to causation, Dr LM, evidently the "lone dissenter in the FDA Committee's 10-1 vote in favor of approving Plavix . . ." (Def-SJ Memo at p 9), has steadfastly opined that the FDA should never have approved Plavix because it does more harm than good.

B-MS's ARGUMENTS

Federal Preemption

To advance its federal preemption argument, B-MS makes the following points:

- Implicitly relying on generic expert Dr. RT's opinion, one of NY Plaintiffs' core liability theories presumably rests on a claimed inadequacy of Plavix's warning label essentially criticizing the location of bleeding risks information on the label. Significantly, this warning expert makes no claim that the FDA was unaware of the relevant research data, analyses, etc., as to bleeding risks before it approved Plavix;

- Indisputably, because Defendant was introducing a new drug to the marketplace, federal law not only required this drug manufacturer to obtain FDA approval before marketing and selling Plavix, but B-MS was also required to obtain FDA's approval of the exact text of the warning as to both format and content;

- It has been argued that B-MS should have been able to unilaterally and independently make labeling revisions as Dr RT's opinion inferentially suggests to satisfy a state law duty (i.e., placement of information is key to allegedly heighten a dispensing clinician's awareness of the bleeding risk) and still be in compliance with federal law;

[4] A black box warning is a "type of warning that appears on the package insert for certain prescription drugs, so called because the US Food and Drug Administration specifies that it is formatted with a 'box' or border around the text."(https://en.wikipedia.org/wiki/boxed_warning).

- Nor has it been shown that Defendant acquired new information about the bleeding risks of taking Plavix, post-FDA approval, to justify "mak[ing] 'Changes Being Effected' ("CBE") labeling revisions without FDA pre-approval . . .", relying on a federal CBE regulation (Def-SJ Memo at p 10);

- NY Plaintiffs' claims are also preempted as they alleged another core theory of liability which presumably rests on Dr LM's causation opinion that the bleeding risk of taking Plavix outweighs its benefits as an anti-clotting drug. In other words, Dr LM implies that "to avoid state tort liability, Defendant[ ] must re-design or simply 'stop selling' Plavix despite FDA's approval. Allowing such . . . claim[s] to proceed to trial would create an irreconcilable conflict between state and federal law . . ." (Def-SJ Memo at p 14);

- Notably, precedential federal case law has repeatedly applied the preemption doctrine to bar state drug design defect claims against branded drug manufacturers because any design change to foreclose state tort liability (i.e., altering an FDA approved drug's initial chemical composition) would in effect create a new drug requiring a new FDA application for approval. *Id.* Federal case law has also rejected Dr LM's solution to simply pull Plavix from the market; and

- On summary judgment, dismissal of NY Plaintiffs' failure-to-warn and design defect claims is warranted absent admissible expert support to sustain either core theory of liability as well as any of their pleaded "tag-along" claims (e.g., derivative claims pleading statutory consumer fraud, breach of warranty, etc.) (Def-SJ Memo at pp 16-22).

Preclusion of Warnings Expert's Opinion

In B-MS's Memorandum of Law in Support of Motion to Exclude the Testimony of Dr. Randall Tackett ("RT Memo") Defendant highlights that this generic expert's reports, deposition testimony and affidavits proffered in the varied states' lawsuits and in the MDL litigation, never found the Plavix label information inaccurate or incomplete, but simply took issue with the "FDA's informed and expert judgment as to where to place the bleeding information in the label . . ." (RT Memo at p 1). In addition to

seeking the exclusion of Dr RT's inadequate warning opinion on federal preemption grounds, *supra*, Defendant also urges the court to soundly reject Dr RT's *ipse dixit* opinion because this purported warnings expert: is not a physician licensed to practice medicine and, thus, was never professionally or legally capable of relying on any drug label to write prescriptions;[5] admits the FDA has the discretion or "guidance" to determine where this bleeding risk should go on the Plavix label and has a "final say" about its format and content (Dr RT Dep at 99:9-16 and 101:16-18); has a doctorate in pharmacology, yet lacks scientific or regulatory expertise to design, develop, test or evaluate the adequacy of a drug label warning; supports his inadequate warning opinion on his self-perceived interpretation of one internal B-MS email from one of Defendant's employees seemingly questioning the sufficiency of the Plavix warning label, an interpretation disabused by that employee's deposition testimony to the contrary (Exhibit G to RT Motion); is solely critical of Defendant's otherwise accurate information about the serious bleeding side effects not being placed under the "Warnings" section or within a "black box", despite the fact that this bleeding risk information was printed in the "Contraindications," "Precautions," and "Adverse Reactions" sections of this FDA pre-approved label; never applied any scientifically recognized methodology or produced any scientific evidence-based data to prove that

[5] *See*, Dr RT's September 29, 2017 Deposition Transcript ("Dr RT Dep") as Exhibit A to Caterina Aff in Support of Motion to Preclude Dr. Randall Tackett's Testimony ("RT Motion"), at 7:6-24.

prescribing clinicians "would overlook the extensive bleeding information found throughout the Plavix label if not included in the 'Warnings' section[6] . . ." (RT Memo at p 15); offers additional, unsupported opinions as to the inadequacy of Plavix's warning label about risks other than bleeding which are not relevant to these cases; lacks the qualifications and expertise to show that Defendant's "motive, intent and/or state of mind . . ." ostensibly discerned from B-MS's internal documents is proof of Defendant's liability for an alleged inadequate warning label for Plavix (RT Memo at p 21); and impermissibly bolsters his opinion with information contained in certain promotional material, information about government enforcement actions against B-MS and information about post-marketing safety surveillance, all of which have absolutely no relevance to NY Plaintiffs' claims.

Preclusion of Causation Expert's Opinion

At the outset of B-MS's "Introduction" set forth in its Memorandum of Law in Support of Motion to Exclude the Testimony of Dr. Lemuel Moyé ("LM Memo"), Defendant similarly argues Dr LM's causation opinions are preempted by federal law. B-MS also contends there are additional bases for precluding Dr LM's causation opinion that Plavix's bleeding risk outweighs its benefit as an anti-clotting agent (its mechanism of action helps reduce heart attacks and strokes): Dr LM fails to articulate any relevant,

[6] Significantly, the FDA conducted physician focus groups and learned that physicians did not make "meaningful distinctions" between a drug label's discrete "Warnings" and "Precautions" sections and ultimately proposed a new regulation to combine the information contained in each section under "one heading entitled 'Warnings/Precautions'. . ." (December 22, 2000 FDA Proposed Rule published in the Federal Register at 81084-81092 as Exhibit H to RT Motion).

established principles or employ any generally accepted scientific methodology to support his subjective, conclusory opinion challenging the safety and/or efficacy of Plavix (parenthetically, this expert offers no opinion as to adequacy or accuracy of the Plavix labeling information, either as to its format or content); the bulk of Dr LM's opinions address his concern about the individual variability of response ("VOR") to Plavix (e.g., "Studies . . . [of] carriers of a certain variant of a liver enzyme, known as a cyp2c19 [allele] do not metabolize the drug completely . . . [yet] admits that VOR is an issue only . . . [if a] patient is a carrier of . . . [this variant enzyme]. . ." [LM Memo at p 9])(bracketed matter added), and this drug's efficacy is wholly irrelevant to these bleeding side effects cases involving non-carrier plaintiffs; Dr LM candidly acknowledges his opinions questioning the safety of Plavix are not generally accepted in the medical community;[7] this causation expert can neither cite to any peer-reviewed or other publication sharing his views that the FDA should never have approved Plavix, nor cite to any peer-reviewed or other publication actually questioning Plavix as a safe treatment option to prevent heart attacks and strokes (Dr LM Dep at 215:8-11 and 213:23-214:6); Dr LM was incapable of persuading a single FDA Advisory Committee member to share this lone dissenter's viewpoint that Plavix is not safe (Dr LM Dep at 36:3-37:11); although disagreeing with the results or conclusions of certain clinical trials, nonetheless, Dr LM acknowledges that renowned and universally respected cardiologists and scientists conducted these trials which generated supportive data as

[7] *See*, Dr LM's September 22, 2017 Deposition Transcript ("Dr LM Dep") as Exhibit A to Caterina Aff in Support of Motion to Preclude Dr. Lemuel Moyé's Testimony ("LM Motion") at 215:12-15.

to the efficacy of Plavix as a safe anti-clotting agent (*for example, see* LM Dep at 73:10-76:17); and without a shred of evidence, Dr LM speculates that despite the data gathered during the past 20 years demonstrating that Plavix is a safe and effective drug as to its intended uses, he "fears" this drug does more harm than good grounded on an unproven supposition that patient incidents of adverse effects of bleeding from taking this drug are under-reported (Dr LM Dep at 25:24-26:15).

NY PLAINTIFFS' OPPOSITION

In his affirmation in opposition to B-MS's respective motions to preclude Dr RT and Dr LM from testifying in the New York Plavix litigation and for summary judgment dismissing the New York claims, NY Plaintiffs' counsel essentially argues as follows:

- Unlike in the California and MDL litigations, NY Plaintiffs have not yet designated their expert witnesses pursuant to CPLR §3101(d) in these actions to support their core theories of liability;

- Because Dr RT and Dr LM have served as veteran, designated experts in all the Plavix litigations outside of New York, to allow Defendant to unilaterally deem (impliedly designate) Dr RT and Dr LM to be NY Plaintiffs' expert witnesses here in New York and strike their respective testimony, would be "both antithetical to the adversary process and procedurally premature . . . (Werner Opp Aff at ¶ 8). Stated more sharply, there is no basis to "forc[e] NY Plaintiffs to adopt designation of these two experts from other litigations, by other plaintiffs, in another jurisdiction, at another time, and under different circumstances" (*id.*, at ¶10);

- Case Management Order No. 6 ("CMO 6")(Exhibit 3 to Werner Opp Aff), applicable only to plaintiffs selected to be part of the discovery pool in the New York Plavix Litigations ("Discovery Pool cases"), contains an Expert Discovery Section with successive time deadlines for the parties' respective designations, report exchanges and depositions of expert witnesses only in Trial Pool cases, i.e., Discovery Pool cases not otherwise disposed of as a result of earlier dispositive motions or dismissed on other grounds as set forth in CMO 6;

- Since all of the Discovery Pool cases have been dismissed, B-MS cannot simply circumvent CPLR § 3101(d) and rely on the CMO 6 Expert Discovery Section to deem Dr RT and Dr LM as designated expert witnesses in the remaining NY Plaintiffs' cases;

- B-MS and counsel for plaintiffs with claims in other jurisdictions never reached any agreement to deem the reports of Dr RT and Dr. LM "which addressed generic/litigation-wide issues . . . to apply to all cases . . ." (see email exchange as Exhibit 4 to Werner Opp Aff), and the same can be said regarding the use of these generic expert witnesses' depositions taken in the MDL and California litigations (Exhibits 5 and 10 to Werner Opp Aff);

- Defendant's federal preemption argument cannot be sustained at this juncture because NY Plaintiffs have not yet designated trial expert witnesses, and even if sustained, whether there is federal preemption of a state law failure-to-warn claim is a fact question for a jury; and

- By disregarding the deposition transcripts of Dr RT and Dr LM, the court is left with Defendant's summary judgment motion bereft of admissible evidence and must deny Defendant summary judgment in these remaining New York actions.

B-MS's REPLY

B-MS's reply urges the court to discount NY Plaintiffs' opposition because: (1) it rests solely on a procedural claim of prematurity without substantively challenging any of Defendant's arguments; (2) ignores an informal, tacit agreement between the parties in the New York Plavix Litigations that a planned joint hearing would be conducted in the MDL with at least three state court judges joining US District Court Judge Wolfson to adjudicate the generic liability issues common to the federal and state court Plavix litigations after hearing the parties' respective generic experts' testimonies; (3) NY Plaintiffs' counsel, as common counsel in the MDL, in the "eleventh hour" chose not to call Dr RT and Dr LM, similarly situated plaintiffs' generic expert witnesses, who have

offered their expert opinions in other jurisdictions and gave their respective depositions approximately 45 days before the scheduled joint hearing (Exhibit C to Caterina Aff in Support of Reply); (3) NY Plaintiffs' technical, procedural argument is disingenuous because their core theories of liability in these bleeding side effects cases have not changed during the many years of litigation, and NY Plaintiffs have had full and fair opportunities over this ensuing period to develop and competently prove these theories against a backdrop of certain indisputable commonalities in the MDL, New York and other states' Plavix litigations, to wit; almost identical pleadings; respective, common counsel for the parties;[8] common, core theories of liability; respective, identical generic experts; non-case specific expert opinions; etc.; and (4) except for delaying the inevitable "day of reckoning," NY Plaintiffs never sought or attempted to justify any CPLR §3212(f) basis for a continuance (e.g., more time to garner different expert evidence to corroborate newly acquired information disclosed in opposition to summary judgment).

Finally, Defendant argues that having met its *prima facie* burden to support its federal preemption argument on a developed factual record, even without the generic experts' opinions, NY Plaintiffs' failure to substantively challenge same must constitute their concession warranting summary judgment dismissing the remaining NY Plaintiffs' actions.

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[8] Varied counsel, admitted *pro hac vice* in the New York Plavix litigations, served as common counsel to plaintiffs in other jurisdictions and defended generic expert witnesses, Dr RT and Dr LM, at their depositions. Notably, counsel for the NY Plaintiffs informally participated in same (*see* B-MS's Reply Memorandum of Law at p 5).

ANALYSIS AND DECISION

Mutual Pharm. Co., Inc. v Bartlett, 570 US 472, 476 (2013)("Bartlett") sets forth the regulatory scheme for FDA pre-approval before a drug manufacturer commercially markets a brand-name drug:

> Under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C.§301 et seq., drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce §355(a). In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). An NDA is a compilation of materials that must include "full reports of [all clinical] investigations," §355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source," 21 CFR §§314.50(d)(2) and (5)(iv) (2012). The NDA must also include "the labeling proposed to be used for such drug," 21 U.S.C. §355 (b)(1)(F); 21 CFR §§314.50(c)(2)(I), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 CFR §§314.50(d)(5); §314.50(c)(2)(ix). The FDA may approve an NDA only if it determines that the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. §355(d). In order for the FDA to consider a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000).
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> The process of submitting an NDA is both onerous and lengthy. See Report to Congressional Requesters, Government Accountability Office, Nov. 2006, New Drug Development, 26 Biotechnology L. Rep. 82, 94 (2007) (A typical NDA spans thousands of pages and is based on clinical trials conducted over several years).

An earlier US Supreme Court opinion, principally addressing the liability of a generic drug manufacturer, emphasized that FDA approval requires "costly and lengthy clinical testing. §§ 355(b)(1)(A), (d); see also D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed. 2008) . . ." *PLIVA, Inc. v Mensing*, 564 US 604, 612 (2011). Relevant to the court's legal analysis, in pre-approving a new brand-name drug as to its content[9] and label[10], the FDA's "views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment (citation omitted)." *Id.* at 613.

At their inception, the NY Plaintiffs' standard short-form complaints (e.g., Exhibit A to Caterina Aff in Support of Summary Judgment Motion), which were deemed to have fully incorporated the allegations contained in the master long-form complaint, made no claim that B-MS fraudulently (or even negligently) concealed any information about the risk of bleeding side effects or acted deceitfully in any way to obtain FDA

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[9] "The determination whether a [new] drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations. . ." and is "peculiarly suited to initial determination by the FDA . . ." (*see, Weinberger v Bentex Pharms., Inc.*, 412 US 645, 653 [1973][bracketed matter added]).

[10] "The drug manufacturer must also submit 'the labeling proposed to be used for such drug.' *Id.* §355(b)(1)(F); 21 C.F.R. §314.50(c)(2)(I). The application must include the proposed label's text 'with annotations to the information in the [drug application] that support the inclusion of each statement [on the label].' 21 C.F.R. §314.50(c)(2)(i). In order to approve an NDA . . . the FDA must determine, 'based on a fair evaluation of all material facts,' that the proposed label is not 'false or misleading in any particular.' 21 U.S.C.§355(d)(7); 21 C.F.R. §314.125(b)(6). After approval, the manufacturer may distribute the drug without violating federal law as long as it uses the FDA-approved label. See 21 U.S.C. §331[c], 333(a) & 352(a), [c] . . ." (*see, Marcus v Forest Labs., Inc. (In re Celexa & Lexapro Mktg. & Sales Practices Litig.)*, 779 F3d 34, 36 [1st Cir 2015]).

approval, on which it relied, and/or breached any express warranties as to the efficacy of Plavix as a therapeutic anti-clotting agent. The NY Plaintiffs typically pleaded the claim that Plavix, prescribed as monotherapy (without aspirin), caused them to suffer a side effect of gastrointestinal bleeding and that Defendant failed to adequately warn about this bleeding risk.

In B-MS's Fourth Affirmative Defense pled in its Answer to Master Complaint (Exhibit B to Caterina Aff in Support of Summary Judgment Motion), NY Plaintiffs were on notice that B-MS would be aggressively relying on the learned intermediary doctrine[11] to defend against their failure-to-warn claims. While the Discovery Pool cases were being litigated, CMO 6 imposed an August 1, 2016 deadline (Exhibit C to Caterina Aff in Support of Summary Judgment Motion) for NY Plaintiffs to serve expert reports to sufficiently oppose anticipated summary judgment motions of dismissal grounded on this defense. That deadline passed without NY Plaintiffs proffering any warning label expert (or, for that matter, any causation expert to support their pleaded claim that Plavix was unsafe). Indisputably, after numerous depositions of prescribing physicians were conducted, all of whom attested to being fully aware of Plavix's

[11] In its seminal decision, *Martin v Hacker*, 83 NY2d 1, 9 (1993), the Court of Appeals, mindful of a drug manufacturer's serious responsibility to a patient-consumer, aptly determined that a drug manufacturer fulfilled its duty to warn by "giving adequate warning through the prescribing physician, not directly to the patient (citations omitted) . . ." In this vein, it is "the physician's function [as an informed intermediary] to evaluate a patient's needs, [read the warning label to] assess the risks and benefits of [the] available drug[ ], and then advise the patient of its risks and possible side effects . . . and it is the physician who owes a duty to balance the risks against the benefits of the . . . [proposed medication treatment[ ] and to prescribe . . . [the drug] and supervise . . . [its] effect[ ] . . ." (bracketed matter added) (*see, Abrams v Bute*, 138 AD3d 179,187 [2d Dept], *lv denied* 28 NY3d 910 (2016) (internal citations and quotations omitted).

bleeding risks, NY Plaintiffs in the Discovery Pool cases and plaintiffs in the MDL and in other state courts "voluntarily dismissed or the courts granted summary judgment in every one of the 117 cases randomly selected for discovery throughout the country. . ." (B-MS's Reply Memorandum of Law at p 4; *see also*, Def-SJ Memo at pp 7-8).

During the ensuing 12 years of litigation, Dr RT and Dr LM, as plaintiffs' veteran, generic experts, issued comprehensive reports proffered in the MDL (*see illustratively*, Exhibits M and N to Caterina Aff in Support of Summary Judgment Motion) and in other jurisdictions. NY Plaintiffs' counsel, as common counsel to those plaintiffs, relied on these expert reports and defended this Dynamic Duo's opinions (either during their depositions or in summary judgment motion practice) in support of their core theories of liability in those cases.

After years of litigation in the MDL and other jurisdictions, B-MS's motions now attempt closure in the New York Plavix Litigations. Now is the time for NY Plaintiffs to either "prove it, or lose it." (*Black Star Farms, LLC v Oliver*, 600 F3d 1225, 1232 [9th Cir 2010]), and at this juncture, NY Plaintiffs cannot simply resort to a CPLR § 3101(d) procedural technicality[12] to avoid substantively challenging Defendant's generic *in limine* motions to preclude generic experts, Dr RT's and Dr LM's respective deposition

[12] CPLR §3101(d)(1)(i) states that upon request, a party is required to "identify each person whom the party expects to call *as an expert witness at trial* . . ." (emphasis added). In his dissenting opinion, Associate Justice Edward D. Carni astutely observed that this notice provision expressly "require[s] the disclosure of experts retained for the purpose of providing testimony at the time of trial[,] . . . [and] simply does not require the disclosure of experts or consultants that are retained and utilized by a party for purposes other than providing trial testimony. . ." (bracketed matter added) (*see, Construction by Singletree, Inc. v Lowe*, 55 AD3d 861, 865 [2d Dept 2008]).

testimony[13] and its overarching summary judgment motion seeking dismissal of the remaining NY Plaintiffs' cases. Nor did NY Plaintiffs' Opposition invoke CPLR §3212(f) to justify a continuance for further discovery to corroborate any facts to controvert Defendant's record evidence and arguments.

An award of summary judgment is appropriate when no issues of fact exist. *See* CPLR 3212(b); *Sun Yau Ko v Lincoln Sav. Bank*, 99 AD2d 943 (1st Dept, 1984), *aff'd*, 62 NY2d 938 (1984); *Andre v Pomeroy*, 35 NY2d 361 (1974). In order to prevail on a motion for summary judgment, the proponent must make a *prima facie* showing of entitlement to judgment as a matter of law by providing sufficient evidence to eliminate any material issues of fact. *Winegrad v New York Univ. Med. Ctr.*, 64 NY2d 851, 853 (1985); *Alvarez v Prospect Hosp.*, 68 NY2d 320, 324 (1986). Indeed, the moving party has the burden to present evidentiary facts to establish his cause sufficiently to entitle him to judgment as a matter of law. *Friends of Animals, Inc. v Associated Fur Mfrs., Inc.*, 46 NY2d 1065 (1979).

While the moving party has the initial burden of proving entitlement to summary judgment (*Winegrad v New York Univ. Med. Ctr.*, 64 N.Y.2d 851 [1985]), once such proof has been offered, in order to defend the summary judgment motion, the opposing party must "show facts sufficient to require a trial of any issue of fact." CPLR 3212(b); *Zuckerman v City of New York*, 49 NY2d 557, 562 (1980); *Freedman v Chemical*

[13] Pursuant to CPLR 3117(a)(3), with notice and related due process concerns fully satisfied, B-MS can safely use the depositions of these generic, out-of-state witnesses for any purpose against the NY Plaintiffs (B-MS's Reply Memorandum of Law at p 5).

Constr. Corp., 43 NY2d.260 (1977); *Friends of Animals, Inc. v Associated Fur Mfrs., Inc.*, 46 NY2d 1065 (1979).

Notwithstanding NY Plaintiffs' Opposition to the contrary, federal preemption presents a question law. *See Devlin v Transportation Communications Intl. Union*, 173 F3d 94, 98 (2d Cir 1999) (summary judgment appropriate to decide ERISA preempts New York law). Morever, in searching the record, this court finds that B-MS has met its prima facie burden by submitting sufficient evidence which eliminated all material issues of fact warranting a determination on a question of law.

On this record, NY Plaintiffs' Opposition does not challenge B-MS's full compliance with the federal regulatory scheme to obtain approval of Plavix. Relevant to Defendant's *in limine* motion to preclude Dr RT's generic warning label opinion plaintiffs proffered in other jurisdictions and which NY Plaintiffs do not now disclaim, Judge Curtis E. A. Karnow, the Coordinating Superior Court Judge in the California Plavix Litigations, succinctly summarized that opinion as essentially attacking the initial FDA approved label, because:

> (1) prescription drug labeling is hierarchical such that a risk is emphasized by placing it in the "Warnings" section and de-emphasized by placing it in the "Precautions" section; and (2) the bleeding risk attendant to the use of Plavix is so serious that it should be disclosed at the "Warnings" level or even higher [as a black box warning] based on the pharmacology of the drug and its side effects. (Bracketed matter added)

In re Plavix Product & Marketing Cases, 2017 WL 6812239, *2 (Cal. Super., San Francisco County, Dec. 1, 2017, No. CJC1300478).

In its opening paragraph discussing the "Federal Preemption Doctrine," the court in *Utts v Bristol-Myers Squibb Co.*, 226 F Supp3d 166, 178 (SDNY 2016), stated:

> The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v Nat'l Foreign Trade Council*, 530 U.S. 363, 372, 120 S.Ct. 2288, 147 L.Ed.2d 352 (20002). State law is preempted by federal law when: (1) Congress intends federal law to "occupy the field," or (2) where state law conflicts with a federal statute. *Id.* (citation omitted).
>
> Conflict preemption exists "where it is impossible for a private party to comply with both state and federal law." *Id.*

Then citing to a trilogy of U.S. Supreme Court opinions which addressed the issue of conflict preemption involving state drug product liability cases against drug manufacturers, to wit, *Wyeth v Levine*, 555 US 555 (2009), *PLIVA, Inc. v Mensing*, *supra* and *Bartlett*, *supra*, the *Utts* court concluded "this case law, read holistically, indicates that federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication." *Id.* at 178.

To the extent Dr RT's generic warning label opinion suggests that B-MS should have been able to unilaterally and independently make labeling revisions to strengthen the warning to purportedly satisfy a state law requirement, this pre-supposes B-MS could have done so without FDA approval which is not the case here implicating the "impossibility preemption" doctrine, i.e., conflict preemption where it is impossible for Defendant to comply with both state and federal law (*see PLIVA, Inc. v Mensing*, 564 US at 623-624 ["[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise

of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes . . ."]). Parenthetically, on this record NY Plaintiffs have not produced any evidence that Defendant was in possession of "newly acquired information" after the FDA approved Plavix in 1997 which would have enabled Defendant to make any unilateral changes to the Plavix warning label without further FDA approval. (*Cf.*, *Wyeth*, *supra*, 555 US at 572-573). Based on the foregoing, this court must exclude Dr RT's generic label warning opinion; and grant B-MS summary judgment dismissing the NY Plaintiffs' failure to warn claims because these claims are federally preempted and lack evidentiary support.

As discussed earlier, plaintiffs in the MDL and in other jurisdictions proffered Dr LM as their generic expert who essentially offers a general causation opinion that Plavix was defectively designed as a new, anti-clotting drug, and that the risk of bleeding outweighs its therapeutic benefit in reducing incidents of strokes and heart attacks. In a similar vein, NY Plaintiffs have also not disclaimed this generic expert's general causation opinion. Except for resting on a CPLR §3101(d) trial expert witness notice provision, NY Plaintiffs' Opposition does not substantively challenge any of Defendant's arguments seeking to preclude the generic, general causation expert's opinion as either being preempted by federal law or otherwise lacking any scientific basis to prove NY Plaintiffs' core liability theory that Plavix is unsafe.

Based on the foregoing reasoning, NY Plaintiffs' design defect claims are also federally preempted. *Utts*, *supra*. Dr LM's opinion seemingly would require Defendant to either re-design this drug after the FDA approved its chemical composition (content)

or stop selling it. If Defendant did the former to avoid state tort liability, it would be creating a new drug requiring an NDA and FDA approval. Moreover, to have stopped selling Plavix, as this generic expert suggests, to "escape the impossibility of complying with both its federal and state law duties . . . [would be] incompatible with . . . [US Supreme Court] pre-emption jurisprudence." (bracketed matter added) (*Bartlett*, 570 US at 488). *See also*, *Yates v Ortho-McNeil-Janssen Pharms. Inc.*, 808 F3d 281, 300 (6th Cir 2015).

Alternatively, Dr LM's conclusory, general causation opinion that Plavix does more harm than good must be excluded because his views admittedly achieved no consensus in relevant medical and scientific communities, i.e., at a minimum, it did not meet the *Frye* test (*Frye v U.S.*, 293 F 1013 [DC Cir 1923]). Against a backdrop of admissions in his deposition testimony *inter alia* that Plavix enjoys widespread approval as a safe and therapeutic drug (see B-MS's Reply Memorandum of Law at pp 11-12), this generic expert offers no "'controlled studies, clinical data, medical literature, peer review [of his own publication, if any] or [other valid medically and scientific] supporting proof . . ." of his general causation opinion (*Matter of Bausch & Lomb Contact Lens Solution Prod. Liab. Litig.*, 87 AD3d 913 [1st Dept 2011], *lv dismissed* 19 NY3d 845 [2012]); *see generally, Parker v Mobil Oil Corp.*, 7 NY3d 434 [2006] and *Cornell v 360 W. 51st St. Realty, LLC*, 22 NY3d 762 [2014]). It is readily apparent on this record that Dr LM's opinion is "grounded on a consensus of one." (*Matter of New York City Asbestos Litig. [Bernard v Brookfield Props. Corp.]*, 984 NYS2d 633, 2013 NY Slip Op 52269[U], at *7 [Sup Ct, NY County 2013]).

Accordingly, this court must also exclude Dr LM's causation opinion, and grant B-MS summary judgment dismissing the NY Plaintiffs' design defect claims because these claims are federally preempted and lack evidentiary support.

For the foregoing reasons, it is

ORDERED that Defendant's motions (motion sequences 1 and 2) to preclude testimony from Dr. Lemuel Moyé and Dr. Randall Tackett are granted in their entirety; and it is further

ORDERED that Defendant's motion for summary judgment (motion sequence 3) is granted in its entirety and the complaints of the remaining New York Plaintiffs in these coordinated actions are dismissed. The Clerk is directed to enter judgment in favor of defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services, Inc. and Sanofi-Synthelabo LLC accordingly.

This constitutes this court's decision and order.

Dated: New York, New York
August 22, 2018

Hon. Martin Shulman, J.S.C.