IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: BUDEPRION XL MARKETING & SALES LITIGATION	MDL No. 2107
THIS DOCUMENT APPLIES TO: ALL ACTIONS	09-md-2107

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

March 26, 2010

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INTRODUCTION

Twenty-five years ago, Congress amended the Food Drug & Cosmetics Act ("FDCA") to streamline the process for the Food & Drug Administration's ("FDA's") review and approval of generic drug applications, in order to encourage manufacturers to develop safe, effective, and affordable alternatives to brand-name drugs. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (citing H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647). These amendments, known as the Hatch-Waxman amendments, greatly sped up generic-drug approvals by allowing for their approval without independent safety and efficacy testing, if FDA concluded that the generic drug was as safe and effective as the brand drug on whose safety and efficacy testing the generic could rely. Pursuant to this well-established process, FDA approved the marketing of defendants' extended release bupropion hydrochloride products (the "Generic Products") as a generic equivalent of the brand drug Wellbutrin XL, and has repeatedly re-affirmed that determination since the products have been on the market.[1] Using this lawsuit, plaintiffs now directly challenge the exclusive role Congress assigned FDA to accomplish the Hatch-Waxman Act's objectives.

The conflict between plaintiffs and FDA arises because all of plaintiffs' claims depend on one contention: that the defendants' generic drug products are "less effective at treating depression and more prone to cause adverse events" than the brand drug, Wellbutrin XL. Compl. ¶ 74. That contention, which lies at the core of all plaintiffs' claims, conflicts directly with FDA's express determination that the Generic Products and Wellbutrin XL are equivalent. FDA's equivalence finding means the Generic Products are just as safe and as effective as Wellbutrin XL, and that the generic and brand drugs are interchangeable for *all* therapeutic purposes. FDA, *Facts About Generic Drugs* (emphasis added) (Ex. 1).[2] Before approving these

[1] Defendant Impax Laboratories, Inc. ("Impax") manufactures the Generic Product at 150mg and 300mg strengths, under an approved abbreviated new drug application. Defendant Teva Pharmaceuticals U.S.A., Inc. ("Teva") sells the 300mg Generic Product, and Impax sells the 150mg Generic Product.

[2] Available at http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM173825.pdf (last visited Mar. 2, 2010). The Court may, of course, consider documents on a motion to dismiss that are in the public record or are otherwise matters of which it may take judicial notice such as government publications, government documents reflecting agency action, and pleadings from other

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generic drugs, FDA necessarily determined that the very differences between the Generic Products and Wellbutrin XL about which plaintiffs now complain did not affect the generics' equivalence to the brand product. The issues raised by plaintiffs are, thus, "intertwined with the adequacy of the agency's bioequivalency guidelines" and determinations. *Astellas Pharma US, Inc. v. FDA*, 642 F.Supp.2d 10, 21 (D.D.C. 2009). The approval process required FDA to consider differences in, for example, Tmax and dose dumping, *i.e.*, the very things plaintiffs claim are not disclosed. After the approval, FDA evaluated the complaints about the Generic Products on which plaintiffs have based their claims. In that review, FDA concluded that defendants' products did not cause the kinds of conditions about which plaintiffs now complain, and reaffirmed its determination that the Generic Products are as safe and effective as Wellbutrin XL. *See* FDA, *Review of Therapeutic Equivalence Generic Bupropion XL 300 mg & Wellbutrin XL 300 mg* (Ex. 2) [hereinafter "FDA Review"].[3] Thus, Plaintiffs and FDA—the sole expert agency charged by Congress with making bioequivalence determinations—cannot both be right.

Recognizing the conflict between their claims and FDA's equivalence determination, plaintiffs have tried to label their case as one about a "failure to warn." But this is not a personal injury case where a plaintiff seeks damages for injuries resulting from an undisclosed risk that FDA never considered or ruled on. And none of the "failure to warn" cases concerns alleged differences between a brand and a generic product. Here, plaintiffs' fundamental complaint is with FDA's decision to approve the Generic Products and allow them to remain on the market as equivalents of Wellbutrin XL. If Plaintiffs' allegations were right, and the Generic Products were not as safe and effective as the brand drug, then FDA could not allow the Generic Products to remain on the market as generic equivalents. 21 U.S.C. § 355(e). Plaintiffs, however, seek to impose state-law obligations purportedly requiring defendants to disclose certain differences between the Generic Products and Wellbutrin XL, even though FDA has necessarily determined

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cases. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Papasan v. Allain*, 478 U.S. 265, 269 n.1 (1986); *Blue Tree Hotels Inv. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004). The Court may also consider on a motion to dismiss documents that are referenced in plaintiffs' complaint or integral to their claims. *See U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002).

[3] Available at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm153270.htm (last updated Sept. 18, 2009).

that all those differences are immaterial. Requiring such representations would conflict directly with FDA's determination that, as an equivalent generic, the Generic Products are "*the same as a brand-name drug in: dosage, safety, strength, quality, the way it works, the way it is taken, and the way it should be used*." FDA, *Facts About Generic Drugs* (emphasis added) (Ex. 1), *see also Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996); 67 Fed. Reg. 65448, 65452 (2002); 60 Fed. Reg. 32982, 32983 (1995).

Because, in exercising its exclusive authority to determine bioequivalence, FDA has determined that the Generic Products are as safe and effective as Wellbutrin XL, plaintiffs' allegations to the contrary—on which their Complaint entirely depends—fail to state a claim.[4]

REGULATORY BACKGROUND

I. FDA Has An Exclusive Congressional Mandate To Determine Whether A Generic Drug Is As Safe And Effective As A Brand Drug.

The FDCA establishes the procedure for obtaining approval to market pharmaceuticals, including both brand-name drugs and generics, in the United States. *See* 21 U.S.C. § 355. Brand-name drug manufacturers (*i.e.*, non-generics) must file a New Drug Application ("NDA") that contains extensive scientific and clinical data demonstrating the safety and effectiveness of the proposed new drug. *See id*. § 355(b)(1). Under the Hatch-Waxman Act, generic drug manufacturers must submit an Abbreviated New Drug Application ("ANDA"). The ANDA does not contain the generic's own safety and efficacy data; instead, it relies on data provided in the brand-name drug's NDA. *See Eli Lilly and Co. v. Medtronic, Inc*., 496 U.S. 661, 676 (1990); *see* 21 U.S.C. § 355(j)(2). An applicant's ANDA, therefore, must establish the proposed generic drug's bioequivalence to the previously approved drug, consistent with FDA regulations. 21 U.S.C. § 355(j); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). If a generic drug is bioequivlant to a brand drug, it means that the generic drug is the

[4] Because CMO #3 required plaintiffs to file a "Consolidated Amended Complaint," and because plaintiffs represented that their complaint would "contain . . . all claims that exist in this case" and that "rulings are *res judicata* as it may affect any other complaint in the future or existing, you know, anywhere in MDL 2107," 1/21/2010 Hrg. Tr. at 5, the fact that plaintiffs have named their complaint an "Administrative Class Action Complaint" should make no difference for purposes of this motion. Dismissal of plaintiffs' live complaint on any grounds would require dismissal of all underlying actions in this MDL proceeding.

"therapeutic" equivalent of that brand drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. §§ 320.1(c), 320.24 (a), (b). FDA has explained that

> "A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same."

FDA, *Facts and Myths about Generic Drugs* (emphasis added) (Ex. 3).[5] Thus, a bioequivalent generic has the same safety and efficacy as the brand drug. *See, e.g.*, *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). As FDA explained in adopting its regulations implementing the Hatch-Waxman Act, a generic approved through the ANDA process must have the same safety and efficacy as the brand drug, because any differences in safety or efficacy would disqualify the generic from being approved under the ANDA process. *Abbreviated New Drug Application Regulations*, 57 Fed. Reg. 17950, 17953 (Apr. 28, 1992). Thus, products that are bioequivalent—and thus "therapeutically equivalent"—are the "same" as a matter of federal law; they are equally safe and effective. *See, e.g.*, 67 Fed. Reg. at 65452;[6] 60 Fed. Reg. at 32983;[7] FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations*, 30th ed., at vii (the "Orange Book")[8]; FDA Review.

FDA has explained in everyday terms what it means when it determines that a generic drug is bioequivalent (and thus therapeutically equivalent) to a brand drug: the generic drug is "*the same as a brand-name drug in: dosage, safety, strength, quality, the way it works, the way it is taken, and the way it should be used*." FDA, *Facts About Generic Drugs* (emphasis added)

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[5] Available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (page last updated Feb. 19, 2010).

[6] "We consider drug products to be therapeutically equivalent if they are pharmaceutically equivalent and can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. A major premise in the ANDA approval system is that the ANDA drug is therapeutically equivalent to the brand-name or 'reference listed drug.' In assessing whether the active ingredients in the reference listed drug and the generic drug product are the 'same,' and would support a determination of therapeutic equivalence, we have concluded that, in certain instances, the generic drug's active ingredient does not have to have the exact physical form as the reference listed drug's active ingredient …." 67 Fed. Reg. at 65452.

[7] "[T]he approval of an abbreviated application is based on a showing that the generic drug is equivalent to the innovator drug on certain key chemical and pharmacologic parameters, and, thus, will be therapeutically equivalent to the innovator drug. . .throughout the shelf life of the generic product." 60 Fed. Reg. at 32983.

[8] Available at http://www.fda.gov/downloads/Drigs/DevelopmentApprovalProcess/UCM071436.pdf

(Ex. 1); *see also* 21 U.S.C. § 355(j)(2)(A)(iii). "When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency." FDA, *Facts and Myths about Generic Drugs* (emphasis added) (Ex. 3). "FDA requires generic drugs to have the same quality and performance as the brand name drugs." *Id*. Indeed, FDA makes clear to the public that its approval of a generic drug means that drug is just as safe and just as effective as the brand drug. *See, e.g.*, Ex. 4, Ex. 5.[9] Once approved as a generic product based on the brand product's safety and efficacy testing, federal law requires that the generic carry the same label, except for certain, limited exceptions.[10] 21 U.S.C. § 355(j)(2)(A)(v); *see also id*. §§ 355(j)(2)(A)(i), (iv); 21 C.F.R. § 314.150(b)(10); 57 Fed. Reg. at 17953, 17961; FDA Office of Generic Drugs, *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling* (May 2000) (Ex. 8) [hereinafter "*Guidance for Industry*"].

Nonetheless, differences not material to safety and efficacy may exist between a generic and brand drug. A generic drug does not have to look the same or taste the same as the brand drug. *See* 67 Fed. Reg. at 65452; FDA, *Facts About Generic Drugs* (emphasis added) (Ex. 1). Nor do they have to use the same drug delivery mechanism. *See* 21 C.F.R. § 320.1(c); *Pfizer Inc. v. Shalala*, 1 F.Supp.2d 38, 42, 47 (D.D.C. 1998), *aff'd in part, rev'd in part on ripeness grounds*, 182 F.3d 975 (D.C. Cir. 1999); Br. of FDA in *Astellas Pharma US, Inc. v. FDA*, No. 1:09-cv-01511 (D.D.C.) (filed Aug. 12, 2009), at 6 (Ex. 7). Indeed, the Hatch-Waxman Act presumes that generics manufacturers will develop drugs that are equivalent to a brand drug for therapeutic purposes, but have other differences that allow the generic to avoid infringing the brand drug's patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[11] However, a drug that is less safe, less

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[9] Available at FDA, *Consumer Education: Generic Drugs*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm169209.htm

[10] "Labeling" is a term of art meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The term includes materials distributed by the manufacturer when it supplements or explains materials sent with the drug. *See, e.g.*, *Kordel v. United States,* 335 U.S. 345, 349-50 (1948).

[11] Thus, the fact that Impax's non-infringement arguments in patent litigation with the brand-drug company "lauded the numerous differences between the release mechanisms," does not, as Plaintiffs' suggest, mean that the products must be materially different. Compl. ¶ 63. FDA could not have approved the Generic Products as bioequivalent

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effective, or fails to perform the same way as the brand drug is not bioequivalent and cannot be approved by FDA as a generic. If FDA determines at any point that a generic varies from the brand drug in active ingredients, rate of administration, dosage form, or strength, FDA *must* conclude that the generic is not equivalent and thus it either cannot be approved on that basis, or its approval must be revoked. 21 C.F.R. § 320.1(c), (d); *see also Pfizer*, 1 F.Supp.2d at 41 n.3.

Federal law charges FDA with the exclusive statutory responsibility and authority for assessing the equivalence of generic drugs. *See id*. §§ 355(j)(1), 355(j)(2)(A)(iv), 355(j)(4)(F). As such, FDA "thoroughly reviews the sufficiency of the ANDA's information" in determining whether to approve a generic drug. *Pfizer*, 1 F. Supp. 2d at 41. Although federal law defines what it means for a generic drug to be "bioequivalent" to a previously approved drug, *id*. § 355(J)(8)(B)(i), it specifically grants FDA broad discretion to select appropriate methods and standards for demonstrating bioequivalence, *id*. § 355(j)(7)(A)(i). Pursuant to that authority, FDA has promulgated standards for assessing bioequivalence, which also establishes *therapeutic equivalence*. 57 Fed. Reg. at 17950; Orange Book at vii-viii. FDA determines which studies it will require applicants to conduct in particular cases by evaluating which tests it believes are best-suited to compare the amount of drug delivered by the two products at the drug's particular site of action, based on "the purpose of the study, the analytical methods available, and the nature of the drug product." 21 C.F.R. § 320.24(a).

Following approval, FDA has an ongoing obligation to monitor generic drugs for any concerns about their equivalence to brand products that might arise from patients' experiences. FDA requires generic drug manufacturers to submit quarterly adverse event reports detailing any complaints with their drugs, including claims that the generic drug is not as effective as the brand drug. 21 C.F.R. § 314.80. If FDA believes that patient experience shows the generic drug not equivalent to the brand, it must withdraw approval for the ANDA. *See* 21 U.S.C. §§ 355(e); 355c(a)(2); *see also* 21 C.F.R. § 201.10(c)(2). A party dissatisfied with FDA's actions, either

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unless the differences were immaterial. Brand companies have previously made virtually identical arguments to FDA and in APA challenges to FDA approval without success. *See Pfizer Inc. v. Shalala*, 1 F.Supp.2d 38, 47 n.9 (D.D.C. 1998).

before or after approval can file an administrative complaint, known as a Citizen's Petition and, if appropriate, seek judicial review under the Administrative Procedures Act ("APA"). *See Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10 (D.D.C. 2009).

Granting FDA exclusive authority to decide generic drug equivalence arose from a need to move away from state-specific determinations. Before Hatch-Waxman, states would ask the FDA to prepare lists of equivalent brand and generic drugs, but "it became apparent that FDA could not serve the needs of each state on an individual basis." Orange Book at i. FDA recognized that "providing a single list based on common criteria would be preferable to evaluating drug products on the basis of differing definitions and criteria in various state laws." *Id.* Hence, FDA created its "list of all prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations" for generics. *Id*. FDA provides codes (such as "AB-rated") that reflect whether it has determined that the drug products are "expected to have the same clinical effect and safety profile" and are thus interchangeable. *Id.* at iv. These codes may be used by pharmacists and physicians to determine whether a generic is substitutable for the brand drug. *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394, at *1 (E.D. Mich. Mar. 2, 2010) (citing 21 U.S.C. § 355(j)(7)(A)).

II. FDA Determined That The Generic Products Are As Safe And Effective As The Brand Drug, Wellbutrin XL.

Following the procedures described above, FDA has determined expressly that the Generic Products are equivalent to Wellbutrin XL on three occasions: in its detailed, mandatory pre-approval ANDA review process; in deciding a Citizens' Petition—an administrative complaint—submitted by the brand drug-maker, Biovail; and after considering the post-marketing adverse events that form the basis of plaintiffs' complaint.

Impax filed an ANDA and an amendment to its ANDA seeking approval to market the Generic Product—bupropion hydrochloride extended release tablets, 150 mg and 300 mg as equivalents of Wellbutrin XL. That ANDA is a 3600-page submission that included specific data comparing the Generic Products to Wellbutrin XL. In particular, Impax's ANDA included specific information from limited human trials showing the blood levels of the Generic Products and brand drug's active ingredient—bupropion hydrochloride—in volunteers who took the

Generic Products. The ANDA results provided FDA all the information about these blood levels that FDA needed in determining whether the Generic Products were bioequivalent to, and thus as safe and effective as Wellbutrin XL.

On December 15, 2006, FDA approved Impax's ANDA for the 300 mg strength. *See* Dec. 15, 2006 FDA Approval of Impax's Bupropion XL ANDA at 3 (Ex. 7).[12] In so doing, FDA affirmed that "*the drug is safe and effective for use as recommended in the submitted labeling*" and is "bioequivalent *and, therefore, therapeutically equivalent*" to the brand-name, reference listed drug, Wellbutrin XL. *Id.* at 1-2 (emphasis added). FDA could have reached that conclusion *only if* it concluded (1) the Generic Products are as safe and effective as the brand, 57 Fed. Reg. at 17960; and (2) the generic did not require any warnings different from the brand product. 57 Fed. Reg. at 17953.

FDA also conducted an additional review of the Generic Products prior to approval, in order to respond to a Citizens' Petition that the brand-drug maker, Biovail, filed pursuant to 21 C.F.R. § 10.30. *See* Dec. 20, 2005 Biovail Citizen Petition (Ex. 8). The Biovail Citizens' Petition asserted that FDA abused its discretion by not requiring more extensive bioequivalence trials. In particular, Biovail argued that "bioequivalence studies … should be conducted at steady-state evaluating the performance of the dosage form based on AUC, Cmax, Cmin," and that further testing to "ensure the absence of 'dose dumping' if the drug is consumed with alcohol," should be required. *Id*. at 1. And much like plaintiffs, Biovail also argued that if the generic's label "refer[red] to specific test results or other scientific findings" for Wellbutrin XL found on the brand label, it would be "false or misleading" unless the generic product itself also satisfied those particular conditions. *See id*. at 5.

FDA carefully considered Biovail's Citizen Petition and, approximately one year later issued a detailed letter-decision granting in part and denying in part Biovail's requests. *See* Dec.

[12] Thereafter, Impax began delivering its 300 mg bupropion drug products to Teva for commercial marketing under the trade name "Budeprion XL." Compl.¶ 116-17. FDA subsequently gave final approval to Impax for the 150 mg strength, which Impax markets. Compl.¶ 116.

14, 2006 FDA Response to Biovail Citizen Petition at 6-8 (Ex. 9); *see also* Br. of FDA in *Biovail Corp. v. U.S. FDA*, No. 06-1487 (D.D.C.), at 13-15 (Ex. 10). FDA explained, *inter alia*, that once it determined that the Generic Products were bioequivalent to Wellbutrin XL and meet all the other requirements for ANDA approval, the Wellbutrin XL labeling, including equivalence and seizure information, were applicable to the generic extended-release product. *Id*. at 6-7.[13]

Biovail filed an action in the U.S. District Court for the District of Columbia under the APA, seeking to enjoin FDA from approving all generic bupropion products. The court denied all relief, finding that "it is well-accepted that 'the plain language of the Hatch-Waxman Amendments, their legislative history, and their interpretation by FDA all require manufacturers of generic drugs to copy the labeling of pioneer drugs "near-verbatim" to obtain ANDA approval.'" *Biovail Corp. v. U.S. FDA*, 519 F.Supp.2d 39, 48 (D.D.C. 2007). The court noted that because FDA's rejection of Biovail's assertions and approval of generic bupropion XL "rests squarely on the FDA's evaluation of scientific data within its area of expertise, [it is] entitled to a high level of deference." *Id*. at 47 (internal quotations omitted).

Following its original approval and Biovail's unsuccessful challenge, FDA again reaffirmed its finding that the Generic Products are as safe and effective as Wellbutrin XL. FDA studied post-marketing reports on 85 individuals who reported undesirable effects when switching from Wellbutrin XL to the 300 mg Generic Product (sold under the trade name Budeprion XL 300 mg). The agency expressly considered "whether the reported lack of efficacy and/or new onset side effects in these patients … suggests a problem with the generic product, *i.e.*, lack of bioequivalence to the branded product, or have some other explanation." *See* FDA Review (Ex. 2). FDA found there was no support for "a conclusion that the reported lack of antidepressant effect and new onset side effects are the result of differences between the two

[13] The agency noted that it considered the results of in vitro dissolution studies to evaluate the possible effect of alcohol when determining whether to approve each ANDA. *Id*. at 13. FDA agreed with Biovail that, in assessing the bioequivalence of generic bupropion HCl extended-release tablets to Wellbutrin XL, ANDA applicants should conduct a "fed" bioequivalence study (drug administered shortly after a meal), in addition to a "fasted" study (drug administered under fasting conditions), to demonstrate the absence of a "food-effect" on the release of the active ingredient in the generic product. FDA Biovail CP Response at 8. Impax conducted the required studies to obtain approval.

products"—allegations identical to those Plaintiffs make here. *Id.* at 3. In its review, FDA specifically considered whether the difference in the time it takes for the drug's active ingredient to reach maximum concentration in the user's bloodstream (Tmax) might have any relationship with the reported lack of efficacy or new onset side effects or both. FDA observed that the "Tmax was examined *but is not required to be within any specified limits*." *Id*. (emphasis added). FDA observed that the "bupropion Tmax was faster for Teva's XL product (2-3 hours) than Wellbutrin XL (5-6 hours)," but that "[t]hese differences in Tmax …*were not considered clinically significant*." *Id*. (emphasis added). Thus, FDA concluded that "[t]he pharmacokinetic profiles of the generic and branded products *do not support a conclusion that the reported lack of antidepressant effect and new onset side effects are the result of differences between the two products*." *Id*. (emphasis added) FDA also stated that the number of complaints made regarding the Generic Products was well within the "expected" range, because the rate of the incidents, e.g. recurrence of depression, that led to those complaints was within the expected rates for patients receiving depression therapy generally.[14] As such, FDA specifically reaffirmed that "the generic form of bupropion XL 300 mg (Teva Pharmaceuticals)," *i.e.*, the 300 mg Generic Product, is "*bioequivalent and therapeutically equivalent to (interchangeable with) Wellbutrin XL 300 mg.*" *Id*. at 5 (emphasis added). Moreover, FDA concluded: "[T]he reported cases of worsening of symptoms following a switch are far more likely to be a consequence of the natural course of treated [depression] than of the small pharmacokinetic differences between the generic and branded product." *Id.*[15]

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[14] FDA explained, that in clinical trials, patients receiving depression therapy have a 5-8% recurrence rate, regardless of whether they change drugs. *Id.* at 4-5. FDA thus expects that, under normal circumstances, of the approximately 400,000 people taking the 300 mg Generic Product in 2007, some 20,000 to 32,000 would experience a recurrence of depression within 30 days of starting therapy with that Generic Product. *Id.* The 85 reported incidents were a tiny fraction of that expected number.

[15] In its 2008 Review, the FDA also dismissed any concern over the sufficiency of the original testing of the Generic Products, which was done only at the 150 mg strength, due to the risks associated with testing the 300 mg strength in healthy subjects. *Id.* at 2. Nonetheless, to address questions raised following the recent anecdotal commentary on the 300 mg Generic Product, Teva and Impax have voluntarily initiated a multiple dose, double blind, double dummy comparative bioavailability study. Defendants and FDA have been in discussions regarding this study for nearly two years—long before plaintiffs filed their initial complaints. Because of the safety concerns noted by FDA, the study will involve persons currently or previously treated with 300 mg Wellbutrin XL or a generic counterpart, limiting the population from which to recruit study participants. *See* Oct. 28, 2008 FDA Letter

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ARGUMENT

Plaintiffs' claims would allow state law to impose requirements on generic drug makers that conflict with FDA's determination that their drugs are equivalent to their brand counterparts. As such, plaintiffs' claims would interfere with FDA's express, affirmative decisions, taken pursuant to authority that Congress granted it under the Hatch-Waxman Act. Two equally compelling and independent federal-law doctrines—conflict preemption and primary jurisdiction—require dismissal here. Moreover, because plaintiffs' claims would impose upon defendants obligations inconsistent with FDA's directives, Rule 19 requires joining FDA as an indispensable party. Because FDA's sovereign immunity precludes joining it as a party, Rule 19(b) requires dismissal of plaintiffs' claims. Finally, plaintiffs fail to state a claim under state law and have failed to satisfy the basic pleading requirements of Rules 8 and 9(b).

I. Federal Law Requires Dismissal Of Plaintiffs' Claims.

A. Plaintiffs' Claims Are Preempted By The FDCA And FDA's Determination That The Generic Products Are As Safe And Effective As Wellbutrin XL.

To prevail on their claims, plaintiffs would have to prove that the Generic Products are not as safe and not as effective as Wellbutrin XL.[16] Otherwise, there could be no "material omissions" under plaintiffs' theory.[17] Yet, plaintiffs would have the Court ignore FDA's express determinations that the brand and Generic Products are bioequivalent and, thus, therapeutically equivalent and interchangeable with Wellbutrin XL. Allowing plaintiffs to proceed in the face of such a determination by FDA would both "'interfere with'" FDA's exclusive authority to

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(Ex. 11); Jan. 3, 2010 FDA Letter (Ex. 12); Jan. 29, 2010 Teva Letter to FDA (Ex. 13). That study and the resulting data will be provided to FDA, and are expected to provide further scientific support affirming FDA's determination that the Generic Products are as safe and effective as the brand product.

[16] *See, e.g.*, Compl. ¶ 46 ("less effective, more risky"), ¶ 52 ("less effective … more likely to cause certain dangerous side effects"), ¶ 55 ("experiencing adverse side effects"), ¶ 56 ("not effectively treating"), ¶ 71(j) ("different physiological and therapeutic effect"), ¶ 71(*l*) ("did not work the same"), ¶ 133 ("diminished effectiveness and increased adverse events"), ¶ 137 ("misled the public about the safety and efficacy"), ¶ 150(b) ("less effective and presented more risks").

[17] The materiality of all alleged representations or purported omissions is entirely dependent on the core premise that the Generic Products are not as safe and effective as Wellbutrin XL. Indeed, the only "reliance" alleged by plaintiffs is that they "believed [the Generic Products were] identical in all respects to Wellbutrin XL in term[s] of ease-of-use, effectiveness, and risk of side effects." Compl. ¶ 142; *see id.* ¶ 143. Even that allegation does not demonstrate reliance on anything other than the fact of the FDA's approval. *See* 21 U.S.C. § 355(j)(7)(A) (requiring FDA to maintain a database of brand drugs and their approved generic equivalents, known as the "Orange Book.").

determine that a generic drug is as safe and effective as a brand drug, and would be "'contrary to'" FDA's express findings of bioequivalence. *Hillsborough County, Fl. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1 (1824)). As such, plaintiffs' claims are preempted.

1. Plaintiffs' Claims Conflict With FDA's Finding That The Generic Products Are As Safe And Effective As Wellbutrin XL.

Plaintiffs' claims are all premised on the assertion that the Generic Products are not as safe and not as effective as Wellbutrin XL. *See* Compl. ¶¶ 46, 52, 55, 56, 71, 74, 133, 137, 150. But that premise conflicts with FDA's contrary findings both pre- and post-approval that they are bioequivalent, and thus just as safe and effective. Congress charged FDA with the responsibility for deciding whether a generic drug is bioequivalent, and thus therapeutically equivalent to, and interchangeable with, a brand drug. 21 U.S.C. § 355(j)(2), (3), (7); *see also* 21 C.F.R. § 320.24. And FDA is vested with exclusive authority under the FDCA on *how* to make those determinations. *See* 21 U.S.C. § 355(j)(4)(F), (7).

FDA specifically and repeatedly exercised that authority in determining and re-affirming that the Generic Products are bioequivalent to Wellbutrin XL. Plaintiffs' attempts to collaterally attack FDA's repeated determinations that the Generic Products are bioequivalent to Wellbutrin XL are thus preempted by federal law: allowing them to proceed would both "actually conflict" with FDA's specific equivalence determinations made pursuant to the FDCA, *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000), and would pose "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

First, bioequivalence is fundamentally a federal law concept. *See* 21 U.S.C. § 355(j)(8)(B)(i). The FDCA gives FDA broad discretion in selecting the methods and standards for demonstrating bioequivalence, *see id.* § 355(j)(7)(A)(i), and charges FDA with the exclusive statutory responsibility for assessing the bioequivalence of generic drugs, *see id.* § 355(j)(4)(F); *see also* 21 C.F.R. § 320.24(b)(6); *Somerset Pharms., Inc. v. Shalala*, 973 F.Supp. 443, 453 (D. Del. 1997). FDA's determination is entitled to preemptive effect. *See City of New York v. FCC*, 486 U.S. 57, 64 (1988); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54

(1982). California law is, thus, preempted to the extent that it would require a different determination—which is, of course, the predicate to plaintiffs' claims. *See* Compl. ¶¶ 1, 46, 51-53, 134. This is not a case where FDA has not "made an affirmative decision" about the issue in dispute. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009). Rather, FDA has addressed the exact issues raised by plaintiffs in finding the Generic Products to be bioequivalent to Wellbutrin XL and approving them for marketing.

Because FDA has determined that the Generic Products and Wellbutrin XL are bioequivalent, there is no room for claims that these drugs materially differ. Although FDA's finding that the Generic Products are as safe and effective as Wellbutrin XL is alone sufficient to preempt all of plaintiffs' claims, FDA has specifically rejected plaintiffs' subsidiary allegations as well. For example, plaintiffs assert that the Court may find, as a matter of California law, that it is a material omission or misrepresentation not to disclose that Tmax for the Generic Products and Wellbutrin XL differ. Compl. ¶ 71(a), (b). Yet, FDA concluded that "differences in Tmax for both bupropion and its active metabolite, however, were not considered clinically significant" and "would not lead to decreased effectiveness." FDA Review (Ex. 2). Likewise, plaintiffs contend it is a material omission not to disclose that taking the Generic Products with food "increases the total amount of the drug eventually released into the body," Compl. ¶ 71(c), but FDA found that any alleged differences "are not considered clinically relevant." FDA Review (Ex. 2). Plaintiffs claim it was a material omission not to disclose that the 300 mg product was not tested for bioequivalence. Compl. ¶ 71(d). Setting aside the fact that this is a grossly misleading statement (because the 300 mg product was only approved after Impax performed the testing required by FDA), FDA would not have permitted the kind of testing that plaintiffs' allegation implies. Rather, "[b]ecause of the potential risk of seizures at higher doses, the 300 mg strength was not studied. This practice is used when evaluating the pharmacokinetic profile of a drug in normal volunteers, especially when a drug's adverse effects increase with dose." FDA Review (Ex. 2). However, according to FDA, "[t]he pharmacokinetic profile is not expected to differ between 300 mg and 150 mg doses of bupropion," and thus the alleged

"failure" to directly test the 300 mg product is not material. *Id*. To the contrary, it would be reckless for a jury to effectively impose testing obligations that FDA considers unsafe.

Plaintiffs' allegations, thus, all relate to matters where FDA considered the "factual basis for the alleged duty to warn" and "reject[ed] it." *Fellner v. Tri-Union Seafoods*, 539 F.3d 237, 251 (3d Cir. 2008).[18] A judgment requiring the warnings plaintiffs seek to impose would conflict with FDA's contrary determination that the Generic Products are just as safe and just as effective as Wellbutrin XL. Indeed, the California Supreme Court has recognized the danger of applying California law where FDA had made an express determination about a drug. *See Dowhal v. Smithkline Beecham Consumer Healthcare*, 32 Cal.4th 910, 929 (2004). The court concluded that state-law civil claims under the Unfair Competition Law could not be used to impose a warning that contradicted FDA's express findings, made in the context of responding to a Citizen Petition. So too here.

Second, allowing plaintiffs to collaterally attack FDA's expert determinations of bioequivalence through state-law claims against generic drug manufacturers would also impermissibly undermine Congress's specific delegation of exclusive authority to FDA to determine *how* to measure bioequivalence—and with it, how to determine if a generic product is as safe and effective as the brand product. *See Perez v. Campbell*, 402 U.S. 637, 652 (1971) (state law is preempted where it "frustrates the full effectiveness of federal law"), *superseded by statute as stated in In re Saunders*, 105 B.R. 781 (Bankr. E.D. Pa. 1989).

Plaintiffs' approach would turn states and state courts into mini-FDAs, enabling states to effectively set a standard for generic drugs different from FDA's. However, Congress did not grant FDA discretion in determining equivalence only to have a state take it away. *See* 21 U.S.C. § 355(j)(7)(A)(i); 21 U.S.C. § 322(j)(2)(A); 21 C.F.R. §§ 320.1(c), 320.24(a), (b). If

[18] The Third Circuit's decision in *Colacicco v. Apotex, Inc.*. 521 F.3d 253 (3d Cir. 2008) is in accord, finding preemption where "the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires." *Id*. at 271-272. However, in accordance with its normal practice, the Supreme Court vacated all cases in which its holding in *Wyeth* might be implicated, to allow lower court consideration in the first instance. Although *Colacicco's* reasoning was entirely consistent with *Wyeth,* it was accordingly vacated and is now before the district court for reconsideration.

FDA determines a generic product to be bioequivalent to a brand product, it gives it an "AB" rating, and it may be marketed as therapeutically equivalent to the brand product. In order to accomplish Congress's overall objective, the Hatch-Waxman Act requires FDA to publish a list of all approved brand drugs ("new drugs") and approved generics, i.e. AB rated therapeutic equivalents, to those brand drugs. 21 U.S.C. § 355(j)(7)(A)(i)-(ii). The FDA publishes this list as the Orange Book. Orange Book, at i. The Orange Book is "a single list based on common criteria," that is intended to substitute for evaluating equivalence of "drug products on the basis of differing definitions and criteria in various state laws." *Id*. Because the approach that flows from plaintiffs' claims would effectively allow states to set their own equivalence standards, plaintiffs' claims "interfere[] with *the methods* by which the federal statute was designed to reach th[at] goal." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992); *see also Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). Thus, plaintiffs' claims are preempted. *Id.*

This was precisely the issue in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). There the Court concluded that the fact that automobile manufacturers had been given various options by the Department of Transportation in developing passive restraints precluded claims that would allow liability on the theory that a defendant had failed to use a particular passive restraint. Likewise here, Congress has given FDA broad discretion to exercise its scientific judgment in determining which equivalence tests a particular generic drug should satisfy. *See* 21 U.S.C. § 355(j)(7)(A)(i). Liability predicated on a different approach to determining the safety and effectiveness of the generic drug would interfere with that discretion. As in *Geier*, the FDA's exercise of discretion in determining what testing should be required to show equivalence does not set a minimum bar that can be raised by state tort law, it is the *sin qua non* of the entire federal regime for generic drugs. *See Geier*, 529 U.S. at 874. When FDA makes an equivalence determination under the standards it deems appropriate, it reflects the agency's decision *not* to require a different set of standards. *Id*. at 878-79. States may not second-guess that determination and impose liability without disrupting the entire regulatory regime. It made no difference in *Geier*, and it makes no difference here, that state and federal law ultimately shared

the same goal of ensuring safety. "To the extent a state law interferes with the manner in which Congress intended the federal law to operate, the state law is preempted even where the state and federal laws share common goals." *Pac. Merch. Shipping Ass'n v. Cackette*, No. CIV S-06-2791 WBS KJM, 2007 WL 2492681, at *5 (E.D. Cal. Aug. 30, 2007), *aff'd*, 517 F.3d 1108 (9th Cir. 2008).

At bottom, the Hatch-Waxman Act expressed Congress's intention to *encourage* the marketing of generic drugs that are approved by FDA as interchangeable with the brand drug—that was Congress's goal in adopting a streamlined approval process for generic drugs. Were plaintiffs to prevail, FDA approval of a generic as bioequivalent would no longer be enough and generic drug manufacturers would have to engage in the very kind of safety and efficacy testing that the Hatch-Waxman Act expressly rejects for generic drug approval. The result is undeniable: there would be fewer generic drugs developed for approval by FDA. State law "is preempted if its effect is to discourage conduct that federal legislation specifically seeks to encourage." *City of Morgan City v. S. La. Elec. Coop. Ass'n.*, 31 F.3d 319, 322 (5th Cir. 1994). The use of state law to second-guess FDA's determination that the Generic Products are as safe and effective as Wellbutrin XL unquestionably would undermine Congress's express delegation of exclusive authority to FDA to select the methods and standards for approving generic products as interchangeable with brand products, and discourage the marketing of approved products. Such an application of state law is, thus, preempted. *See, e.g.*, *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 & n.6 (2000); *Geier*, 529 U.S. at 869; *Gade*, 505 U.S. at 103.

Because plaintiffs' state law claims would prohibit marketing the Generic Products unless they included warnings and information that FDA deemed erroneous, unsupported, immaterial, or inconsistent with its determination of bioequivalence, state law must yield to the FDCA and FDA's determination that the Generic Products are bioequivalent to—and, thus, as safe and effective as—Wellbutrin XL. *See Geier*, 529 U.S. at 873, 881; *Gade*, 505 U.S. at 108.

2. *Wyeth v. Levine* Does Not Apply To This Case.

Wyeth v. Levine, 129 S. Ct. 1187 (2009), does not change the preemption analysis in this case. *Wyeth* involved the fundamentally different situation in a personal-injury failure-to-warn case where the plaintiff sought to recover for the drug company's failure to include on its label a risk *about which FDA had not made an affirmative decision*. It was in *that* context that the Supreme Court found that state law could complement FDA's drug safety efforts. Here, by contrast, FDA has considered—*and rejected*—the factual basis underlying the "warnings" sought by plaintiffs. *See id*. at 1191-92. Indeed, FDA has determined the Generic Products to be as safe and effective as the brand product. *See* Dec. 15, 2006 FDA Approval of Impax's Bupropion XL ANDA (Ex. 7); FDA Review (Ex. 2). Requiring a warning that the products are less safe or effective, or work in a materially different way, would contravene FDA's determination. Thus, there is "clear evidence that the FDA would not have approved [the] change" that plaintiffs seek. *Wyeth*, 129 S. Ct. at 1198. Here, FDA considered and rejected the factual bases on which plaintiffs' claims now rest. That decision forecloses plaintiffs' requests for warnings about alleged material differences in the generic and brand product. FDA's resolution of the issues raised by plaintiffs and its "affirmative decision" is, thus, entitled to preemptive force. *Wyeth*, 129 S. Ct. at 1199.[19]

B. FDA Has Primary Jurisdiction Over Plaintiffs' Claims.

Because plaintiffs' claims require "resolution of issues which, under a regulatory scheme have been placed within the special competence" of FDA, this case should also be dismissed in

[19] Other cases following *Wyeth* have addressed a different question: whether a generic manufacturer should be able to rely on a brand manufacturer's inaction in updating its label to include appropriate warnings *See Demahy v. Actavis*, 593 F.3d 428, 449 (5th Cir. 2010) (noting the law does not "harness liability on name brand manufacturers for all failure-to-warn claims"); *Mensing v. Wyeth Inc.*, 588 F.3d 603, 608, 612 (8th Cir. 2009) (holding "generic defendants could have at least proposed a label change that FDA could receive and impose uniformly on all metoclopramide manufacturers if approved"); *see also Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.* , 586 F.3d 500, 510 (7th Cir. 2009) (noting that whether the CBE regulation applies to generic labels is "an open question"); *but see, e.g.*, *Gaeta v. Perrigo Pharms. Co.*, No. C05-04115, — F.Supp.2d, — 2009 WL 4250640, at *4 (N.D. Cal. Nov. 24, 2009); *Morris v. Wyeth Inc.*, 642 F.Supp.2d 677, 684-685 (W.D. Ky. 2009); *Valerio v. Smithkline Beecham Corp.*, No. 08-60522-CIV, 2008 WL 3286976, at *7 (S.D. Fla. Aug. 7, 2008). These cases all involved warnings where, as in *Wyeth*, FDA had not previously made an affirmative decision rejecting the factual basis of the warning. These decisions are inapposite to the present case, where FDA has expressly rejected the factual basis for Plaintiffs' claims. Nor do any of these cases seek to impose different warnings on brands and generics that FDA has determined to be equivalent.

favor of FDA's primary jurisdiction. *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956). Primary jurisdiction applies in cases where there is a "need to resolve an issue that … has been placed by Congress within the jurisdiction of an administrative body having regulatory authority … pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that … requires expertise or uniformity in administration." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1115 (9th Cir. 2008); *MCI Telecomms. Corp. v. Teleconcepts, Inc.,* 71 F.3d 1086, 1105 (3d Cir. 1995); *Phone-tel Commc'ns, Inc. v. AT&T Corp.*, 100 F.Supp.2d 313, 316 n.3 (E.D. Pa. 2000).

That doctrine is particularly applicable here, where the issues plaintiffs raise—principally whether the Generic Products are as safe, as effective, and work in the same way as Wellbutrin XL—are squarely within FDA's province to decide. *See, e.g.*, *Sun Pharm.*, 2010 WL 746394, at *7; *Schwarz*, 586 F.3d at 508-09. Indeed, no "federal court has permitted … [a] challenge [to] generic-equivalency representations under the Lanham Act when the defending party markets a FDA-approved, Orange Book-listed generic version of the pioneer drug." *Sun Pharm*., 2010 WL 746394, at *7. It makes no sense that plaintiffs—who disclaim any personal injury claims—could use state law to do just that. Plaintiffs' claims under state law are no different from lack-of-equivalency claims under the Lanham Act.

Although plaintiffs now try to extricate their allegations from FDA's role in determining bioequivalence, they cannot do so given FDA's view on what it means for two drugs to be bioequivalent. As in *Sun Pharmaceuticals*, plaintiffs have "not pointed to any statement or advertisement that does not directly implicate the FDA's equivalency determination." *Sun Pharms*., 2010 WL 746394, at *7. Whether a generic drug is just as safe and just as effective as its brand drug is quintessentially a matter for the agency. As the Third Circuit observed, "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us." *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995); *see also A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995); *Henley v. FDA*., 77 F.3d 616, 621 (2d Cir. 1996); *Astellas*, 642 F.Supp.2d at 19. Moreover, when it comes to brand-generic equivalence, "the determination of *which* method is

the most 'accurate, sensitive, and reproducible' for measuring bioequivalence is a matter of scientific judgment, falling squarely within the FDA's discretion." *Somerset Pharms., Inc. v. Shalala*, 973 F.Supp. 443, 453 (D. Del. 1997); *see also Bristol-Myers Squibb Co. v. Shalala*, 923 F.Supp. 212, 217 (D.D.C. 1996). Yet here, plaintiffs ask the Court to decide whether the Generic Products are as safe and effective as the brand drug, which is a question for FDA, the agency with expertise and responsibility for deciding it. No matter how they try to style their claims (misrepresentations, omissions, fraud), plaintiffs are asking the Court to decide an issue that is "intertwined" with FDA's bioequivalence determinations, and thus for the agency to resolve. *Astellas*, 642 F.Supp.2d at 21.

Under plaintiffs' approach, parties ranging from dissatisfied patients to opportunistic competitors could use state law to collaterally challenge FDA's determination of bioequivalence. The primary jurisdiction doctrine exists to prevent precisely such circumvention and to preserve for FDA's review those challenges that could potentially disrupt the statutory scheme established by the Hatch-Waxman Act. There will always be some variance between therapeutically equivalent drugs—even between different batches of the same drug. The question is who decides whether the differences are material. In the case of generic drugs, Congress has expressly answered that question: FDA. This is, thus, a textbook case for application of the primary jurisdiction doctrine, which "seeks to produce better informed and uniform legal rulings by allowing courts to take advantage of an agency's specialized knowledge, expertise, and central position within a regulatory regime." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 673 (2003) (Breyer, J., concurring) (citing 2 Federal Procedure: Lawyers Edition § 2:337, p. 373 (2003)). This case should be dismissed and plaintiffs required to present their allegations, which all relate to the Generic Product's bioequivalence—and thus, the equivalence of its safety and effectiveness—to FDA.

1. The Determination Of Whether A Generic Drug Is As Safe And Effective As A Brand Drug Is Within FDA's Discretion And Expertise Pursuant To A Comprehensive Regulatory Scheme.

Plaintiffs not only ask the Court to ignore FDA's express determinations with respect to the Generic Products, they would also have the Court ignore FDA's primary role in determining

whether a generic drug is as safe and effective as a brand drug (inviting the Court to undertake that determination for itself). *See* Compl. ¶¶ 46, 52, 55, 56, 71, 74, 133, 137, 150. Indeed, to evaluate plaintiffs' claims, the Court—and ultimately a jury—would either have to apply FDA's regulations and standards, or substitute its own standard under California law, neither of which is appropriate because they would invade the FDA's primary jurisdiction. A federal court cannot supersede FDA's discretion by interpreting and applying FDA regulations to resolve private claims and, thus, claims implicating FDA's regulations and expertise are not cognizable. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990); *Rutherford v. United States*, 806 F.2d 1455, 1461 (10th Cir. 1986); *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980).

Courts have avoided substituting their own judgment for FDA's, as plaintiffs invite here, precisely because of FDA's expertise. *See, e.g.*, *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-654 (1973); *Nat'l Ethical Pharm. Ass'n v. Weinberger*, 365 F.Supp. 735 (D.S.C. 1973), *aff'd*, 503 F.2d 1051 (4th Cir. 1974); *Sun Pharm.*, 2010 WL 746394, at *6 ("[T]he Court defers to the FDA's expertise over these matters."). The issues of "equivalence" underlying plaintiffs' claims are complex, involve an exercise of scientific and technical judgment, and thus are not well-suited for judicial determination—one of the factors courts consider in determining whether primary jurisdiction requires dismissal. *See, e.g.*, *Phone-Tel*, 100 F.Supp.2d at 316 n.3 (considering "[w]hether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise"); *see also Henley,* 77 F.3d at 621; *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1376 (9th Cir. 1983) ("The basis for the grant of primary jurisdiction is the FDA's expertise in resolving technical and scientific questions."). And as the agency recently reiterated, "FDA's decision to approve a generic version of [a brand-name drug] and the methods it applied are governed by statute and falls squarely within the agency's scientific and technical expertise." Br. of FDA in *Astellas Pharma US, Inc. v. FDA*, at 1 (Ex. 14); *see also* Aug. 10, 2009 FDA Denial of Astellas Citizen Petition at 4-5 (Ex. 15). If plaintiffs have actual *scientific evidence* to show that the Generic Products are not as safe, not as effective, or do not work in the same way

as Wellbutrin XL, plaintiffs should present such evidence to FDA and petition the agency to withdraw its determination to the contrary.

Deference to FDA's primary jurisdiction is particularly appropriate here where the question of whether two products are bioequivalent—and thus equally safe and effective—is "a matter of scientific judgment, falling squarely within the FDA's discretion." *Somerset*, 973 F.Supp. at 453. Indeed, "the expressed desire of Congress, through the 1984 amendments [in the Hatch-Waxman Act], was that the FDA retain its historically wide discretion in defining showings of bioequivalence." *Bristol-Myers Squibb*, 923 F.Supp. at 217 (internal quotation omitted); *see also Schering Corp. v. Sullivan*, 782 F. Supp. 645, 651 (D.D.C. 1992) ("Congress did not intend to restrict the FDA's discretion to determine how the bioequivalence requirement is to be met."), *judgment vacated on mootness grounds by Schering Corp. v. Shalala*, 955 F.2d 1103 (D.C. Cir. 1993). Given FDA's discretion to determine what "method is the most 'accurate, sensitive, and reproducible' for measuring bioequivalence," *Somerset*, 973 F.Supp. at 453, it makes no sense for a court or jury to make its own determination on how to measure whether the generic is as safe and effective as the brand drug. Indeed, "[w]hether the question at issue is particularly within the agency's discretion" is another factor that supports dismissal in favor of FDA's primary jurisdiction. *Phone-Tel*, 100 F.Supp.2d at 316 n.3.

Plaintiffs allegations regarding the different delivery mechanisms used in the Generic Products and Wellbutrin XL also implicate the primary jurisdiction doctrine. Plaintiffs contend that the Generic Products use an "inferior" delivery mechanism that "makes [them] less effective in treating depression and more likely to cause certain dangerous side effects than the Brand Product." Compl. ¶¶ 51-52. That assertion is another matter to be determined by FDA. Brand companies frequently file Citizen Petitions asserting that their patented release technology is integral to the drug's performance, and asking FDA to require the use of the same release mechanism. That was precisely the issue before the court in *Pfizer*, 1 F.Supp.2d 38. There the brand company argued that because the generic "does not utilize an osmotic pump system to release its active ingredient" the generic was not the same dosage form as the brand and could not be properly classified as "extended release tablets." *Id*. at 42. Much like plaintiffs here, the

brand company warned about the dangers of "approv[ing] a generic form … that has a non-osmotic pump dosage" because "unsuspecting patients could be given a drug that has a different rate of release from that of [the brand drug] resulting in danger to users of the drug." *Id*. at 45 & n.7. The district court rejected this as "a bogus argument" because "FDA regulations already provide that the FDA will refuse to approve an ANDA if information shows that the inactive ingredients, such as a drug's release mechanism, make the product unsafe." *Id*. (citing 21 C.F.R. § 314.127(a)(8); 21 U.S.C. § 355(j)(3)(H)).[20]

Similarly, plaintiffs' allegations that defendants failed to warn "that a patient being switched from Wellbutrin XL to the Generic Products should be carefully monitored by his [or] her physician," or should "self-monitor," Compl. ¶¶ 71(g), 72, 77, 133, challenge FDA's finding that the Generic products and Wellbutrin XL are "interchangeable," and as such should be presented to FDA. This kind of warning obviously would serve to discourage generic substitution for the brand product. *See Astellas*, 642 F.Supp.2d at 21. In *Astellas*, the brand company sought to have FDA impose a similar warning and was rebuffed because "the current review process for ANDAs is adequate to assure the interchangeability of generic versions … with their branded counterparts," and thus there "was no need for the additional notices requested by the plaintiff." *Id*. The court affirmed FDA's determination, noting that the "'high degree' of deference afforded to the FDA in assessing scientific data applies to FDA's determinations regarding labeling requirements for drugs." *Id*. The court concluded that the challenges to representations of interchangeability were "*intertwined with the adequacy of the agency's bioequivalency guidelines*." *Id*. (emphasis added). So too here.

FDA's determination that a generic drug is as safe and effective as a brand drug is directly reviewable under the APA, and the agency's jurisdiction to make that determination and

[20] The court further observed that "[u]nder the current FDA regime, an ANDA sponsor therefore may submit an ANDA for a generic drug that has the same active ingredients … but a different formulation and, thus, a different release mechanism as the [brand] drug." *Pfizer*, 1 F.Supp.2d at 47. The court rejected the brand company's challenge to that regime because FDA's approach "makes sense. If, for instance, a generic tablet that does not use the osmotic pump can perform the same extended release functions as [the brand drug], and can perform them safely, then it is logical that the generic drug would be approved as a generic equivalent of [the brand drug]. What else would a generic drug be?" *Id*.

not have it collaterally challenged is "essential to [FDA's] effective operation." *Weinberger v. Hyson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). The heart of the Hatch-Waxman Act "designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created." *Id*. (addressing prior amendments to the FDCA). Plaintiffs' claims raise "complex chemical and pharmacological considerations." *Weinberger*, 412 U.S. at 654. Because plaintiffs' disagreement is fundamentally with FDA's determination, they must make use of the administrative scheme by exhausting remedies and then seeking relief from the agency under the APA, *see Carnohan*, 616 F.2d. at 1121-22, which is precisely what Biovail did, *see Biovail Corp.*, 519 F. Supp. 2d 39.

It would be anomalous for virtually identical claims to be reviewed under the deferential arbitrary and capricious standard of the APA, but for plaintiffs' claims to be able to proceed in a manner where a jury could make a *de novo* decision as to whether the Generic Products are as safe and effective as Wellbutrin XL. Yet, were the Court to allow plaintiffs' case to proceed in this forum, rather than dismissing in favor of FDA's primary jurisdiction, that is exactly what would happen. Instead of arguing to FDA that it should require additional testing to demonstrate bioequivalence with a brand drug, or that FDA should require additional warnings because of purported differences between the generic and brand product—claims raised in *Biovail*, *Astellas*, and *Pfizer* and a bevy of other cases[21]—parties will seek *de novo* review in court, *despite FDA's scientific conclusion that the Generic Products are as safe and effective as Wellbutrin XL*. Because of the technical and policy issues implicated by plaintiffs' claims, FDA's discretion in determining how to assess whether a generic product is as safe and effective as a brand product, and the deference due to FDA's scientific expertise, this Court should dismiss plaintiffs' claims in favor of FDA's primary jurisdiction.

[21] *See, e.g.*, *Warner-Lambert Co. v. Shalala*, 202 F.3d 326 (D.C. Cir. 2000); *Serono Labs, Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998); *Hill Dermaceuticals, Inc. v. U.S. FDA*, 524 F.Supp.2d 5 (D.D.C. 2007); *Bristol-Myers Squibb Co. v. Shalala*, 923 F.Supp. 212 (D.D.C. 1996); *Fisons Corp. v. Shalala*, 860 F.Supp. 859 (D.D.C. 1994); *Schering Corp. v. Sullivan*, 782 F.Supp. 645, 651 (D.D.C. 1992).

2. Adjudicating Plaintiffs' Claims Could Lead To Inconsistent Obligations, Disrupting FDA's Statutory And Regulatory Scheme.

FDA has a strong interest in employing uniform standards for evaluating disputes regarding its ANDA approvals, another factor counseling dismissal in favor of FDA's primary jurisdiction. *See Clark*, 523 F.3d at 1115; *Phone-Tel*, 100 F. Supp. 2d at 316 n.3 (courts consider "[w]hether there exists a substantial danger of inconsistent rulings"). Despite their disclaimers, plaintiffs' claims would require the Court to re-evaluate the determinations made by FDA in approving the Generic products for marketing as a generic version of the brand drug, without first giving FDA the benefit of considering plaintiffs' factual allegations. Because a comprehensive administrative scheme exists for obtaining regulatory and judicial review of FDA's decisions—including its bioequivalence determinations—through the filing of a Citizen Petition and subsequent challenge under the APA, any effort to obtain collateral review of issues intertwined with a bioequivalence determination amounts to an end-run around the regulatory scheme. Primary jurisdiction counsels that courts should defer to the regulatory scheme by abstaining under these circumstances, thereby avoiding the risk of conflicting decisions. *See Carnohan*, 616 F.2d 1120.

A court order prohibiting defendants from marketing these products or requiring the kinds of label warnings or so-called "corrective campaign" that plaintiffs seek would also create confusion in the medical community regarding appropriate use of the Generic Products and directly contradict FDA's recent communications regarding those products. *See Bernhardt v. Pfizer Inc.*, No. 00 Civ 4042 LMM, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000) (holding "[a]n order by this Court directing [the defendant manufacturer] to issue [communications describing its drug as inferior] would … creat[e] the potential for inconsistent direction concerning a serious medical ailment and how it is best treated."); *Sun Pharm.*, 2010 WL 746394, at *6 ("Furthermore, a decision in Plaintiff's favor would conflict with the valid FDA approval of Defendants' product."). Indeed, while plaintiffs would have the Court order defendants to send "Dear Doctor" letters, *see* Compl. ¶ 127, FDA specifically prohibits generic manufacturers from sending such letters without FDA approval. 21 U.S.C. § 355-1(i)(2); *Demahy v. Actavis, Inc.*, 593 F.3d 428, 444 (5th Cir. 2010) ("generic manufacturers cannot send

'Dear Doctor' letters without prior FDA approval"). And FDA, of course, would not approve of a letter that is inconsistent with its repeated findings of bioequivalence. Thus, the risk of inconsistent obligations is substantial.

In sum, to impose warning requirements that are inconsistent with FDA's findings—without first requiring plaintiffs to present any new evidence to FDA, allowing FDA to consider it, and then having judicial review of FDA's decision—would upset the comprehensive regime for generic drug approval established by Congress. By contrast, there is no undue prejudice to plaintiffs by requiring them to pursue and exhaust the administrative remedies available at FDA, particularly given the injunctive relief they seek with respect to product labeling and marketing. There is no threat of undue delay if the Court dismisses the action and directs plaintiffs to file a Citizen Petition pursuant to 21 C.F.R. § 10.30. *See Clark v. Actavis Group HF*, 567 F.Supp.2d 711, 719 (D.N.J. 2008). Furthermore, even if FDA cannot provide the exact relief plaintiffs seek, that does not weigh against applying the primary jurisdiction doctrine. *See, e.g.*, *Thompson v. Tex. Mexican Ry. Co.*, 328 U.S. 134, 151 (1946) (remanding an action for injunction and damages to agency despite claim the agency lacked the power to grant the relief sought); *Alberta Gas Chems., Ltd. v. Celanese Corp.*, 650 F.2d 9, 13-14 (2d Cir. 1981) (same).

C. FDA Is An Indispensable Party That Cannot Be Joined.

Plaintiffs' claims must also be dismissed because FDA is an indispensible party to the claims, but cannot be joined. FDA's approval of the Generic Products was contingent on its finding that they are "bioequivalent," and thus "therapeutically equivalent to" and "interchangeable with" Wellbutrin XL. Indeed, as described above, plaintiffs could not sell their product legally *without* representing that it is bioequivalent to and thus meets the same standards of safety and efficacy as Wellbutrin XL.[22] Were plaintiffs to prevail without FDA also before the Court—and therefore bound by the Court's judgment—defendants would face an impossible situation: comply with the Court's injunction but violate FDA's directive and the statutory and

[22] It is the bioequivalency finding that allows substitution of the Generic Products for Wellbutrin XL—substitution that would be permitted regardless of the warnings plaintiffs seek. *See, e.g.*, *Sun Pharm.*, 2010 WL 746394, at *1.

FDA requirements that a generic drug represent itself as completely equivalent to the brand, or comply with the FDA directive but face contempt for violating the Court's injunction. Because this conflict can be avoided only if FDA were bound to whatever judgment the Court entered, FDA must be a party to this action. *See* Fed. R. Civ. P. 19(a)(1)(B)(ii).

Plaintiffs, of course, have not named FDA as a party to this action, and FDA's sovereign immunity precludes its joinder, thereby requiring dismissal. Sovereign immunity bars suits against the federal government and its agencies absent express waiver, *see United States v. Testan*, 424 U.S. 392, 399 (1976), which is not implicated here. And as the Supreme Court recently made clear in applying Rule 19(b), "a case may not proceed when a required-entity sovereign is not amenable to suit." *Republic of Philippines v. Pimentel*, 128 S. Ct. 2180, 2191 (2008). The "sovereign immunity of the United States can justify dismissal for inability to join an indispensable party" even when "no alternative forum is available," unlike here. *Delano Farms Co. v. Cal. Table Grape Comm'n*, 623 F.Supp.2d 1144, 1170 (E.D. Cal. 2009). "If the United States is immune from suit and no waiver is available, the United States cannot be joined under Rule 19(a), and is an indispensable party under Rule 19(b)." *Id*. at 1164. Because FDA cannot be joined, but is an indispensable party, the case must be dismissed under Rule 12(b)(7).

II. Plaintiffs Fail To Plead Sufficiently Their State-Law Claims.

Because plaintiffs fail to plead sufficiently that defendants' alleged misrepresentations or omissions caused their purported injuries, and seek to improperly expand the applicability of the California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and California Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, *et seq.*, California law and the federal pleading standards further compel dismissal of all claims.[23]

A. Plaintiffs' Allegations Fail To Plead Reliance, Causation, Or Materiality.

[23] Plaintiffs' claims as pled cannot survive this motion to dismiss. As such, there is no need to address the extent to which California law applies here, because for purposes of this motion only, defendants assume that it applies; the complaint fails anyway. As described in note 4, *supra*, plaintiffs represented that their complaint would "contain . . . all claims that exist in this case" and that "rulings are *res judicata* as it may affect any other complaint in the future or existing, you know, anywhere in MDL 2107," 1/21/2010 Hrg. Tr. at 5. Dismissal of this complaint requires dismissal of all actions in this MDL proceeding.

California law is clear that to prevail under either the UCL or CLRA, plaintiffs must plead and prove causation, including the element of reliance. "The language of the UCL, as amended by Proposition 64 [in November 2004], makes clear that a showing of causation is required as to *each representative plaintiff*." *Laster v. T-Mobile USA, Inc.*, 407 F.Supp.2d 1181, 1194 (S.D. Cal. 2005); *see also In re Tobacco II Cases*, 46 Cal.4th 298, 314 (Cal. 2009). The same is true under the CLRA: "'Relief under the CLRA is specifically limited to those who suffer damage, making causation a necessary element of proof.'" *Buckland v. Threshold Enters., Ltd.*, 155 Cal.App.4th 798, 809 (Ct. App. 2007) (quoting *Wilens v. TD Waterhouse Group, Inc.*, 15 Cal.Rptr.3d 271, 276 (Ct. App. 2003)). Accordingly, "California requires a plaintiff suing under the CLRA for misrepresentations in connection with a sale to plead and prove she relied on a material misrepresentation." *Brownfield v. Bayer Corp.*, No. 2:09-cv-00444-JAM-GGH, 2009 WL 1953035, at *3 (E.D. Cal. July 6, 2009); *Pfizer, Inc. v. Superior Court*, No. B188106, 2010 WL 660359, at *6 (Ct. App. Feb. 25, 2010); *see also Caro v. Procter & Gamble Co.*, 18 Cal.App.4th 644, 668-69 (1993). Thus, plaintiffs must plead "actual reliance." *Pfizer*, 2010 WL 660359, at *5. Where "none of the named Plaintiffs allege that they saw, read, or in any way relied on the advertisements [nor] that they entered into the transaction as a result of those advertisements," their claims must be dismissed. *Laster*, 407 F.Supp.2d at 1194; *see also Johns v. Bayer Corp.*, No. 09CV1935 DMS (JMA), 2010 WL 476688, at *5 (S.D. Cal. Feb. 9, 2010). Indeed, as the California Court of Appeal has explained, "we do not believe a UCL violation may be established without a link between a defendant's business practice and the alleged harm…. The UCL provisions are not so elastic as to stretch the imposition of liability to conduct that is not connected to the harm by causative evidence." *In re Firearm Cases*, 126 Cal.App.4th 959, 981 (Ct. App. 2005).

Here, plaintiffs fall far short of alleging the required reliance or causation. *First*, insofar as plaintiffs' claims are based on alleged misrepresentations, plaintiffs fail to plead sufficiently *reliance* on any such misrepresentations. Indeed, with regard to the named plaintiffs, the complaint merely notes that each switched from Wellbutrin XL to the Generic Products without any averment as to their reason for switching. *See* Compl. ¶ 114 ("Mr. Richards continued to be

prescribed 'Wellbutrin XL 300-mg' by his physician, and took same up to and through January 2008, when he switched to the Impax Product (300mg)."); *id.* ¶ 115 ("Ms. Sackler was diagnosed and was prescribed Wellbutrin XL (150mg) in or around 2006. In or around 2008, Ms. Sackler began to utilize the Impax Product (150mg)."). The complaint is completely devoid of any allegation that any plaintiff saw, read, or heard any representation by defendants. Allegations that defendants made misrepresentations on their websites, *see e.g.*, Compl. ¶ 71(j)-(*l*), without any allegation that plaintiffs viewed the websites—much less relied on the statements thereon—are insufficient. These are the kinds of conclusory and deficient allegations that are insufficient to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Phillips v. County of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008). Moreover, insofar as plaintiffs allege that defendants made misrepresentations on their products' labels, *see, e.g.*, Compl. ¶ 71(a), plaintiffs could not have relied on such misrepresentations in choosing to purchase the Generic Products, as they would not have seen the prescription drug label insert before purchasing it—and they do not even allege awareness of the products' labeling prior to their purchasing decision. *See, e.g.*, *Gillette Co. v. Norelco Consumer Prods. Co.,* 946 F.Supp. 115, 135 (D. Mass. 1996); *Wilchombe v. Teevee Toons, Inc.*, 515 F.Supp.2d 1297, 1305-06 (N.D. Ga. 2007). In short, plaintiffs' complaint contains *no* allegations that any plaintiff purchased the Generic Products as a result of defendants' alleged misrepresentations and *no* allegations that any plaintiff saw, read, or heard any representation by defendants. To merely assert, as plaintiffs do, that had defendants disclosed the purported differences between the Generic Products and Wellbutrin XL, "pharmacies would not have wanted to sell it and … Consumers likewise would have avoided the Impax Product," Compl. ¶ 73, a mere paraphrase of the legal standard, is utterly deficient. *See, e.g.*, *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 227 (3d Cir. 2008). It is also not "plausible on its face," in that it is equally as likely that they would have relied on *the FDA's determination of bioequivalence* and granting of an AB-rating to the Generic Products. *See* 21 U.S.C. § 355(j)(7)(A) (requiring FDA to maintain a public database of brand drugs and their approved generic equivalents, known as the "Orange Book."); *Iqbal*, 129 S. Ct. at 1949;

Twombly, 550 U.S. at 570. Plaintiffs therefore cannot establish causation on the basis of alleged misrepresentations.

Second, plaintiffs' bare assertions that they "suffered injury in fact and lost money as a result of Defendants' omissions and false representations," Compl. ¶ 153, that they "would not have purchased but for Defendants' wrongful conduct," *id.* ¶ 124, and that "[h]ad Plaintiffs known the truth about the Generic Products, they would not have purchased it or used it," *id.* ¶ 142, simply cannot save their claims from dismissal. As the Supreme Court recently made clear, a court need not accept as true plaintiffs' "legal conclusions," "[t]hreadbare recitals of the elements of a cause of action," or "conclusory statements." *Iqbal*, 129 S. Ct. at 1949; *Twombly*, 550 U.S. at 555. Thus, the Court explained, a complaint is not sufficient if it does no more than "tender[] naked assertions devoid of further factual enhancement," and conclusory statements of causation without a factual predicate are therefore insufficient to defeat a Rule 12(b)(6) motion. *Iqbal*, 129 S. Ct. at 1949 (citation and internal quotation marks omitted). This is precisely the case here.

Third, plaintiffs' claims are further doomed by their failure to sufficiently plead the *materiality* of any of defendants' alleged fraudulent misrepresentations or omissions. "A misrepresentation of fact is material if it induced the plaintiff to alter his position to his detriment. Stated in terms of reliance, materiality means that without the misrepresentation, the plaintiff would not have acted as he did." *Caro*, 18 Cal.App.4th at 668. Plaintiffs identify no such material representation or omission—and with good reason. Precisely because FDA considered and rejected the "facts" plaintiffs claim that defendants misrepresented or omitted, such "facts" cannot be material as a matter of law. Indeed, in determining that the Generic Products and Wellbutrin XL are bioequivalent, the FDA found that they are therapeutically the same—meaning they are the same in every way that matters to doctors and patients. That is precisely why FDA deemed them "interchangeable" with Wellbutrin XL. FDA went further, assessing the "facts" asserted by plaintiffs and found that the alleged undesired effects were "far more likely to be a consequence of the natural course of treated [depression] than of the small pharmacokinetic differences between the generic and branded product." FDA Review (Ex. 2).

The FDA further found "[t]he recurrent nature of [depression] offers a scientifically reasonable explanation for the reports of lack of efficacy following a switch to a generic product." *Id*. Given FDA's findings, plaintiffs' complaint fails to "state a claim for relief that is plausible on its face.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 557). Such is precisely the case here. Having conceded FDA's bioequivalence determination, plaintiffs cannot plausibly maintain the materiality of their alleged omissions or misrepresentations. Accordingly, "[b]ecause plaintiffs here have not nudged their claims across the line form conceivable to plausible, their complaint must be dismissed." *Twombly*, 550 U.S. at 570.[24]

B. Plaintiffs Fail To Plead Allegedly Fraudulent Misrepresentations Or Omissions With The Particularity Required By Rule 9(b)

The requirement in Rule 9(b) of the Federal Rules of Civil Procedure that allegations of fraud be pleaded with particularity applies to claims which are made in federal court under the CLRA and UCL. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009); *see also Brothers v. Hewlett-Packard Co.*, No. C-06-02254 RMW 2006 WL 3093685, at *6-7 (N.D. Cal. Oct. 31, 2006). Because plaintiffs' UCL and CLRA claims depend on "allegations that Defendants made misrepresentations, failed to disclose material facts, and concealed known information," those claims are "grounded in fraud." *Tietsworth v. Sears, Roebuck & Co.*, No. 5: 09-CV-00288 JF (HRL), 2009 WL 3320486, *6 (N.D. Cal. Oct. 13, 2009). When, as here, a plaintiff alleges a unified course of fraudulent misrepresentations or omissions, the claim "as a whole must satisfy the particularity requirement of Rule 9(b)." *Vess v. Ciba-Geigy Corp., USA*,

[24] Further, plaintiffs' UCL claim fails in its entirety because defendants' conduct falls completely within the UCL's "safe harbor" provision. *See Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal.4th 163, 182 (Cal. 1999). This safe harbor encompasses both conduct that legislation specifically permits, *see Cal. Emergency Physicians Med. Group v. Pacificare of Cal.*, 111 Cal.App.4th 1127, 1133 (Ct. App. 2003), and that a law requires, *see Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal.App.4th 700, 721 (2001). Importantly, the safe harbor provision extends to conduct permitted by federal law. *See Hauk v. JP Morgan Chase Bank USA*, 552 F.3d 1114, 1122 (9th Cir. 2009). Here, as explained above, federal law permitted (indeed, required) that the Generic Products be marketed as equivalent to Wellbutrin XL—that was entirely the basis for approval. *See* 21 U.S.C. § 355(j)(2)(A)(v).

317 F.3d 1097, 1103-04 (9th Cir. 2003). This requires a plaintiff to "'state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations.'" *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986); *see also Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007); *Lum v. Bank of Am.*, 361 F.3d 217, 224-25 (3d Cir. 2004); *Genova v. Third-Order Nanotechnologies, Inc.*, No. 07-CV-03552 2008 WL 399403, at *3 (E.D. Pa. Feb. 12, 2008) (plaintiff's fraud allegations insufficient because, "although Plaintiff claims that Defendants made various misrepresentations to him, he does not specify the time, place, speaker, and content of the alleged misrepresentations").

Plaintiffs fall far short of this standard. Although plaintiffs make a large *number* of allegations about defendants' alleged fraud, their complaint never alleges when any alleged misrepresentations were made, who made them, to whom they were communicated, or where they were made. *See* Compl. ¶¶ 124, 136, 141, 143-44, 153 (alleging "misrepresentations" without identifying their content); *id.* ¶ 71(b)-(e) (alleging misrepresentations without identifying their time, place, or speaker). Plaintiffs cannot satisfy Rule 9(b) without pleading "who," "where," "when," and "why." *Frederico*, 507 F.3d at 200-203; *Lum*, 361 F.3d at 217. Indeed, the complaint never attempts to identify which defendant made any alleged misrepresentation to which plaintiff, as the Third Circuit requires. *See Lum*, 361 F. 3d at 225. Indeed, as noted above, the complaint fails to even allege that *anyone*—much less plaintiffs—ever relied on defendants' alleged fraud. Accordingly, plaintiffs' UCL and CLRA claims, premised upon alleged fraud wholly untethered to time, space, or the named plaintiffs, must be dismissed.

* * *

In sum, plaintiffs' claims should be dismissed and they should not be permitted to amend their complaint again. The Third Circuit has held that leave to amend it properly denied if it would be "futile" or if it is not required in the interests of justice. *Lake v. Arnold*, 232 F.3d 360, 373 (3d Cir. 2000). Such discretion is "even broader" when, as here, a plaintiff has already had the "opportunity to amend its complaint." *Id.* at 374. Plaintiffs have had the opportunity to plead, re-plead, and further re-plead their actions. This MDL originated with ten separate state

complaints, and plaintiffs' lead counsel was on *every single complaint*. The allegations in those complaints evolved over time, articulating new and different nuances on the same core theory, and have evolved yet again in their latest live complaint. In essence, plaintiffs' counsel had eleven chances. Plaintiffs knew the legal standards and made the best possible allegations they could make. There is nothing they can do to "cure" their complaints to make them state a claim. *See, e.g.*, *St. Clair v. Citizens Fin. Group*, 340 Fed.App'x 62, 67 (3d Cir. 2009).

CONCLUSION

For the foregoing reasons the Court should grant Defendants' Motion to Dismiss.

March 26, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Joseph Wolfson, Esquire, hereby certify that, on this date, I caused to be served a true and correct copy of the foregoing **BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS** was filed electronically and made available for viewing via the Court's ECF system.

Date: March 26, 2010

s/ Joseph Wolfson JW383
Joseph Wolfson, Esq.