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28 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
COUNTY OF LOS ANGELES - CENTRAL CIVIL WEST

**Coordination Proceeding
 Special Title (Rule 3.550)**

BYETTA® CASES

JCCP No. 4574

**DEFENDANTS' RESPONSE TO
 REQUEST FOR ADDITIONAL
 BRIEFING ON THE ISSUE OF
 PREEMPTION**

Judge: Hon. William F. Highberger
 Dept.: 322

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1 Pursuant to the Court’s September 15, 2015 Request for Further Briefing, Defendants
2 submit this response in support of their Motion for Summary Judgment Based on Preemption.

3 1. ***The determination whether the principle of conflict preemption under Wyeth v.***
4 ***Levine applies to this case and bars Plaintiffs’ failure-to-warn claims is a question of law for***
5 ***the Court. In the Wyeth case itself, the trial court did not submit the issue of preemption to the***
6 ***jury, but decided it as a matter of law.*** The Vermont Supreme Court then reviewed the trial
7 court’s decision de novo, noting that “preemption is a question of law.”¹ The Supreme Court, in
8 turn, decided as a matter of law, based on the undisputed regulatory history of dealings between
9 Wyeth and FDA, that there was not “clear evidence” that the agency would have disapproved the
10 stronger warning proposed by the plaintiffs. *Wyeth v. Levine*, 555 U.S. 555 (2009).

11 ***No*** court since *Wyeth v. Levine* has submitted the “clear evidence” preemption test to a
12 jury to be decided as a question of fact.² ***Every*** post-*Wyeth* court has determined itself—as a
13 matter of law—whether FDA’s statements and actions add up to “clear evidence” that FDA
14 would have disapproved the plaintiff’s proposed, stronger warning.³ Sometimes the courts have
15 done so on cross-motions for summary judgment;⁴ sometimes on the defendant’s motion for
16 summary judgment;⁵ and sometimes on the defendant’s motion for judgment as a matter of law

17 ¹ *Levine v. Wyeth*, 944 A.2d 179, 184 (Vt. 2006), *aff’d*, 555 U.S. 555 (2009).

18 ² No court of which we are aware has so acted, and Plaintiffs in five briefs and two oral
arguments in the course of this controversy over preemption have cited none.

19 ³ Here, notably, Plaintiffs have avoided stating precisely what warning they propose,
20 although their regulatory expert, Dr. Fleming, testified that there should an addition to the
Adverse Reactions section of the labeling. 9/11/2015 Motion Hearing Tr. at 14, 25.

21 ⁴ *Rheinfrank v. Abbott Labs., Inc.*, 2015 U.S. Dist. LEXIS 104564 (S.D. Ohio 2015).

22 ⁵ *Gaeta v. Perrigo Pharm. Co.*, 603 F.3d 1225 (9th Cir. 2011), *vacated on other grounds*,
132 S. Ct. 497 (2011); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010);
23 *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142 (C.D. Cal. 2010); *Muzichuck v. Forest Labs Inc.*,
2015 U.S. Dist. LEXIS 5440 (N.D. W. Va. 2015); *Cross v. Forest Labs, Inc.*, 2015 U.S. Dist.
24 LEXIS 44677 (N.D. Miss. 2015); *Koho v. Forest Labs*, 17 F. Supp. 3d 1109 (W.D. Wash. 2014);
25 *Glynn v. Merck Sharp & Dohme (In re Fosamax Prods. Liab. Litig.)*, 951 F. Supp. 2d. 695
(D.N.J. 2013); *Wells ex Rel. J.W. v. Allergan*, 2013 U.S. Dist. LEXIS 13191 (W.D. Okla. 2013);
26 *Newman v. McNeil Consumer Healthcare*, 2012 U.S. Dist. LEXIS 2153 (N.D. Ill. 2012); *Dobbs v.*
Wyeth Pharm., 797 F. Supp. 1264 (W.D. Okla. 2011); *Baumgardner v. Wyeth Pharm.*, 2010 U.S.
27 Dist. LEXIS 90263 (E.D. Pa. 2010); *Aaron v. Wyeth*, 2010 U.S. Dist. LEXIS 14581 (W.D. Pa.
2010); *Hayes v. Smith Kline Beecham Corp.*, 2009 U.S. Dist. LEXIS 116081 (N.D. Okla. 2009);
28 *Forst v. SmithKline Beecham Corp.*, 639 F. Supp. 2d 948 (E.D. Wis. 2009).

1 after trial.⁶ *None* of these decisions denying judgment to the defendant on the ground of
2 preemption has done so because the underlying facts were disputed. Where the courts have
3 denied judgment, they have done so because they concluded as a matter of law that the underlying
4 facts did not constitute “clear evidence” that FDA would have disapproved the proposed, stronger
5 warning. This line of consistent post-*Wyeth* authority carries forward what has long been the
6 general rule concerning preemption in the California state courts and the Ninth Circuit. The
7 California Supreme Court has said that “federal preemption presents a pure question of law.” *In*
8 *re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1089 n.10 (2008).⁷ And so, too, has the Ninth
9 Circuit.⁸

10 The Ninth Circuit’s decision in *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225 (9th Cir.
11 2011) exemplifies the courts’ consistent treatment of the “clear evidence” test as a question of
12 law. The district court in *Gaeta* granted Perrigo’s summary judgment motion and denied the
13 plaintiff’s post-*Wyeth* motion for reconsideration. On appeal, the Ninth Circuit did not remand
14 for a jury trial as to whether there was “clear evidence” that FDA would have disapproved a
15 stronger warning; rather, the Ninth Circuit itself considered whether “there is evidence in this case
16 less compelling than there was in *Levine*, that the FDA would not have approved the applicable
17 label[ing] change;” if so, the court said, “there is no preemption.” *Id.* at 1235-36.

18 Perrigo’s evidence that FDA would not have approved a warning about acute liver injury
19 from the concomitant use of ibuprofen and other drugs known to be hepatotoxic were safety

21 ⁶ *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010); *In re Actos*,
22 2014 U.S. Dist. LEXIS 121648 (W.D. La. 2014); *In re Fosamax*, 951 F. Supp. 2d. 695; *Schedin v.*
Ortho-McNeil-Janssen, 808 F. Supp. 2d 1125 (D. Minn. 2011); *Reckis v. Johnson & Johnson*, 28
23 N.E.3d 445 (Mass. 2015).

24 ⁷ *See also Spielholz v. Super. Ct.*, 86 Cal. App. 4th 1366, 1371 (2d Dist. 2001)
25 (“[p]reemption is a legal issue.”).

26 ⁸ *See Arizona v. City of Austin (In re Cement & Concrete Antitrust Litig.)*, 817 F.2d 1435,
27 1444 (9th Cir. 1987) (“The question whether federal law preempts state law is an issue of law
28 which we review de novo”), *rev’d on other grounds sub nom. California v. ARC Am. Corp.*, 490
U.S. 93 (1989); *Am. Trucking Assoc., Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir.
2009); *Niehaus v. Greyhound Lines, Inc.*, 173 F.3d 1207, 1211 (9th Cir. 1999); *Hotel Emps. &*
Rest. Emps. Int’l Union v. Nev. Gaming Comm’n, 984 F.2d 1507, 1513 (9th Cir. 1993); *Chase v.*
Trs. of W. Conference of Teamsters Pension Tr. Fund, 753 F.2d 744, 746 (9th Cir. 1985).

1 reviews of the scientific data undertaken by FDA in 2002 and 2006. It was undisputed that FDA
2 had undertaken these reviews and that, as a result, it had proposed certain additional warnings and
3 not proposed other warnings. The Court of Appeals held that “[t]he above two reviews do not
4 amount to ‘clear evidence’ that the FDA would not have approved the warnings suggested by the
5 Gaetas,” because there was no evidence that the agency had focused on the safety issue in
6 question—concomitant use of ibuprofen and other drugs known to be hepatotoxic—and
7 considered the current scientific data about that question. *Id.* at 1237. In short, the Court of
8 Appeals evaluated the undisputed regulatory history of FDA’s statements and actions regarding
9 the labeling of ibuprofen and determined as a matter of law whether that evidence “amount[ed] to
10 ‘clear evidence’ that the FDA would not have approved the [proposed] warnings.” *Id.*

11 Also illustrative of the principle that preemption is a question of law is the very recent
12 decision in *Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015). In that case, the trial
13 court denied the defendant’s motion for summary judgment based on preemption, not because
14 there were disputed facts, but because it determined the regulatory history did not add up to clear
15 evidence that FDA would have disapproved a stronger warning.⁹ The court did not submit the
16 issue to the jury, which only addressed special issues of negligence, failure to warn, and breach of
17 warranty. 28 N.E.3d at 454–55 & nn.19-20. On appeal, the Massachusetts Supreme Judicial
18 Court did not remand for a jury to make fact findings as to whether there was “clear evidence”
19 that FDA would have disapproved the additional warnings advanced by the plaintiffs; it held as a
20 matter of law that “the defendants are correct that the FDA’s explicit rejection of the 2005 citizen
21 petition’s proposed inclusion of a specific mention of SJS or TEN by name on OTC ibuprofen
22 drug labels . . . provides the necessary ‘clear evidence’ that the FDA would have rejected the
23 addition of a warning on OTC ibuprofen’s labeling that mentioned SJS or TEN by name.” *Id.* at
24 286-87 (citing *Robinson*, 615 F.3d at 873; *In re Fosamax*, 951 F. Supp. 2d at 703; *Dobbs*, 797 F.

25 ⁹ The Supreme Judicial Court’s summary of the procedural history does not specifically
26 note the basis for the trial court’s denial of summary judgment, but does report that the court also
27 denied a companion motion in limine, based on preemption, to exclude evidence that the labeling
28 should have included a stronger warning. 28 N.E.3d at 453-54. That the trial court denied both
motions indicates that the basis of its ruling was substantive (i.e., that the defendant’s evidence
did not constitute “clear evidence”), not procedural.

1 Supp. at 1276-77). As to whether FDA would have approved a warning that did not mention SJS
2 or TEN by name, but stated only that “redness, rash, and blisters may lead to a life-threatening
3 disease,” the Court could not glean “clear evidence” from FDA’s response to the same citizen
4 petition how the agency would have responded. *Id.* at 290.

5 In sum, preemption is a question of law, and courts applying the *Wyeth v. Levine* “clear
6 evidence” test have determined as a matter of law whether the typically undisputed facts
7 regarding the regulatory history of the drug at issue add up to “clear evidence.”

8 2. ***The material facts are not disputed.*** As is true regarding motions for summary
9 judgment generally, the Court decides the question of law, if it can, based on the material
10 undisputed facts. And, in these cases, where the issue of preemption arises in the context of FDA
11 regulation of prescription-drug labeling, the material facts are almost always undisputed—as they
12 are here. That is true for all of the more than twenty cases cited and discussed above that have
13 applied the “clear evidence” test. And it is true because the regulatory history regarding the
14 drug’s labeling—namely, what FDA has said and done in the way of evaluating (i) the scientific
15 data bearing on the alleged risk and (ii) the adequacy of the labeling—defines what is relevant,
16 *see Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) (“Since *Levine* is our
17 intellectual anchor . . . we must look at the long and fairly extensive administrative history of
18 Phenergan and compare it to the administrative history of Paxil.”), and that
19 regulatory/administrative history can be readily ascertained.

20 Defendants point to seven events in the regulatory history of the incretin-based
21 medications that, taken together, add up to “clear evidence.” All seven are indisputably
22 statements made and actions taken by FDA: (1) FDA’s evaluation of the risk of pancreatic cancer,
23 as described in *The New England Journal of Medicine*, leading to its statements that “assertions
24 concerning a causal association between incretin-based drugs and . . . pancreatic cancer . . . are
25 inconsistent with the current data” and that “the current knowledge is adequately reflected in the
26 product information or labeling;” (2) FDA’s rejection of the Citizen Petition regarding Victoza
27 and FDA’s statements, among others, that it “found no new evidence regarding the risk of
28 pancreatic carcinoma in association with the use of Victoza that would support any changes to the

1 current approved labeling” and “any suspicion of causal association between exposure to Victoza
2 and pancreatic cancer is indeterminate at this time;” (3) FDA’s preparation of the Briefing Book
3 for the Advisory Committee considering approval of Saxenda and FDA’s statements that “animal,
4 observational, and clinical trial data reviewed by FDA to date have not supported a causal
5 association” and that “[p]ancreatic cancer has been hypothesized, although not proven, as a
6 potential incretin mimetic-related adverse event in the literature; plus FDA’s approval in this time
7 frame of additional medications in the incretin class without a pancreatic-cancer warning,
8 including (4) Bydureon, (5) Trulicity, (6) Tanzeum, and (7) Saxenda. All seven events took place
9 in close proximity to one another, within the space of one year.¹⁰

10 Plaintiffs dispute the legal significance of these statements and actions, and they argue that
11 other facts are equally or more important,¹¹ but they cannot dispute that FDA made the
12 statements, drew the conclusions, and took the actions it did. Plaintiffs also argue, of course, that
13 FDA is a “black box” and that one cannot know “how [it] looked at the data, what methods [it]
14 used, and how [it] resolved inconsistencies or conflicts.”¹² But that argument is indistinguishable
15 from the claim that FDA came to the wrong conclusion about the risk of pancreatic cancer. The
16 “clear evidence” test does not authorize second-guessing FDA, however; it asks only whether
17 FDA focused on the safety issue and reached a conclusion that the labeling was adequate in light
18 of an up-to-date evaluation of the scientific data. For the same reason, Plaintiffs’ “data points”¹³
19 are not material facts; they are Plaintiffs’ evidence that the drugs supposedly cause pancreatic
20 cancer, and, thus, evidence that FDA reached the wrong conclusion. As for Plaintiffs’ claim that
21 Defendants failed to disclose safety data to FDA, Defendants certainly dispute it, but the dispute
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23 ¹⁰ Defendants contend that the first event alone—the evaluation and conclusions set forth in
24 the FDA/EMA Assessment—satisfies the “clear evidence” test and that the additional events only
25 bolster that evidence. Thus, even if one of the seven events were disputed, that circumstance
26 would not warrant denial of Defendants’ motion for summary judgment; the Court still would be
27 required to decide whether one or more of the other six events add up to “clear evidence.”

28 ¹¹ See Defendants’ Reply in Support of Separate Stmt. Of Undisputed Material Facts at 2-15
(in particular, Nos. 2, 5-11).

¹² Motion Hearing Tr. at 125:13-17.

¹³ Motion Hearing Tr. at 110-13.

1 is not material both because *Buckman v. Pls.’ Legal Comm.*, 531 U.S. 341 (2001) precludes
2 consideration of the evidence and because there is no record evidence that the allegedly
3 undisclosed data would have affected FDA’s conclusions about the risk of pancreatic cancer and
4 the adequacy of the labeling.¹⁴ Thus, this Court (and the MDL court), like the courts cited in
5 footnotes 1 through 4, are in a position to decide as a matter of law, and to decide now, whether
6 some or all of these statements and actions by FDA constitute “clear evidence.”

7 The undisputed character of the facts is even clearer here than in the many cases cited
8 above, because Plaintiffs’ regulatory expert, Dr. Alexander Fleming, admitted the critical
9 components of Defendants’ clear evidence—namely that FDA (1) conducted a robust evaluation
10 of the scientific data relevant to the risk of pancreatic cancer;¹⁵ (2) did so, in part, in order to
11 determine the adequacy of the labeling;¹⁶ (3) concluded that the labeling adequately reflects the
12 current knowledge about the risk of pancreatic cancer;¹⁷ and (4) also concluded that the scientific
13 data do not meet the regulatory threshold for including an additional warning in the Warnings or
14 Adverse Reactions sections of the labeling.¹⁸ He admits, too, that these conclusions represent
15 FDA’s official position¹⁹ and that in view of FDA’s lengthy and robust evaluation, as well as its
16 conclusions, it would be “absurd” to think FDA would have approved a CBE containing a
17 pancreatic-cancer warning.²⁰

18 ¹⁴ See *id.* at 88-91 (explaining absence of record evidence).

19 ¹⁵ Fleming Dep. at 92:13-16; 108:3-5; 127:18-19.

20 ¹⁶ *Id.* at 82:24-83:6.

21 ¹⁷ *Id.* at 107:2-6.

22 ¹⁸ *Id.* at 153:11-19; 153:20-154:3.

23 ¹⁹ *Id.* at 84:22-25.

24 ²⁰ *Id.* at 201:21-202:1. Contrary to Plaintiffs’ counsel’s claim, Dr. Fleming’s answer was not
25 in response to a “hypothetical,” but punctuated a series of questions about FDA’s evaluation of
26 the scientific data, and conclusions about the data, as described in the NEJM. Motion Hearing Tr.
27 at 69:3-4; see Fleming Dep. at 200:14-201:11; 201:18-202:1. Even apart from this sequence of
28 questions and answers, however, Dr. Fleming testified, “Well, of course, we’ve already
established that this was, perhaps, an unprecedented exercise as culminated in the Egan report. . . .
I’m not aware of a CBE being accepted under a similar circumstance.” Fleming Dep. at 146:22-
147:2 (emphasis added).

See In re Fosamax, 951 F. Supp. 2d at 703 (specifically taking into account for purposes
of the “clear evidence” analysis that plaintiff’s regulatory expert admitted “that the FDA
‘rejected’ Defendant’s PAS.”).

1 The record is therefore ripe for decision. This Court and the MDL court allowed Plaintiffs
2 one year to pursue discovery relevant to preemption. At the end of that period, Plaintiffs did not
3 ask for more time or more discovery. Indeed, in the MDL proceeding, Plaintiffs themselves
4 moved affirmatively for summary judgment, asserting that the court could and should decide
5 preemption as a matter of law.²¹

6 3. ***Even if there were disputed facts material to the regulatory history of the***
7 ***incretin-based drugs, the Court has authority, by analogy, to resolve them.*** It may do so, just as
8 it resolves antecedent factual disputes in connection with issues of personal and subject matter
9 jurisdiction. *See Snowney v. Harrah's Entm't, Inc.*, 35 Cal. 4th 1054, 1062 (2005) (holding that
10 where “no conflict in the evidence exists . . . the question of jurisdiction is purely one of law”)
11 (alternation in original) (internal quotation omitted);²² *see also Brown v. Desert Christian Ctr.*,
12 193 Cal. App. 4th 733, 741-42 (5th Dist. 2011) (“Once the issue of workers’ compensation
13 exclusivity was specifically raised by the pleadings and had to be judicially decided, the trial
14 court continued to have jurisdiction . . . to determine its own jurisdiction, until it resolved the
15 disputed jurisdictional facts in defendant’s favor and entered the dismissal.”); *Burdick v. Superior*
16 *Court*, 233 Cal. App. 4th 8, 17 (4th Dist. 2015) (“When evidence of jurisdiction is in dispute, we
17 accept the trial court’s resolution of factual issues, draw all reasonable inferences in support of the
18 trial court’s order, and review the trial court’s determination of factual issues for substantial
19 evidence.”).²³ The trial court is free to weigh the evidence bearing on its jurisdiction, because at

20 ²¹ *See* Depew Decl., Ex. 44. Plaintiffs’ counsel remarked at the hearing, “I certainly don’t
21 intend to spend a lot of time on the affirmative motion because I think it’s the same question.”
22 Motion Hearing Tr. at 64:2-4.

23 ²² In *Snowney*, the parties submitted declarations in support of, and in opposition to, the
24 motion to quash for lack of personal jurisdiction. As here, each party’s declarations did not so
25 much dispute common facts as highlight different facts. The court held that California could
26 exercise specific jurisdiction over the defendants based on facts largely unmentioned in
27 defendants’ declaration. *See* 35 Cal. 4th at 1060, 1063-64.

28 ²³ The same rule applies in federal court. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006)
29 (“[I]f subject-matter jurisdiction turns on contested facts, the trial judge may be authorized to
30 review the evidence and resolve the dispute on her own.”); *Land v. Dollar*, 330 U.S. 731, 735 n.4
31 (1947) (“But when a question of the District Court’s jurisdiction is raised, . . . the court may
32 inquire by affidavits or otherwise, into the facts as they exist.”), *overruled by implication on other*
33 *grounds, Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949); *Mortensen v.*

1 issue is “its very power to hear the case.” *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d
2 884, 891 (3d Cir. 1977). A similar rationale applies where preemption is at issue, for there are
3 reasons of logic and judicial efficiency to decide as a threshold question whether state-based
4 claims should even proceed. And where preemption is concerned, as with jurisdiction, the
5 antecedent facts are largely distinct from the facts that go to the merits.²⁴ The facts material to the
6 “clear evidence” test focus on what FDA has said and done about the labeling, as it concerns the
7 safety issue at hand, because the test asks whether FDA would have disapproved the plaintiff’s
8 proposed warning. On the merits, however, the material facts concern the Defendants and
9 whether they provided an adequate warning, based on what was known about the risk of
10 pancreatic cancer.²⁵

11 4. ***The cases cited by Plaintiffs are not to the point.*** As the Court notes, *City of*
12 *Auburn v. Qwest Corp.*, 260 F.3d 1160, 1172 (9th Cir. 2001), is a discussion of ripeness, not a
13 determination that there was a triable issue of material fact. Notably, in reversing the district
14 court and finding the defense of preemption ripe for decision, the Ninth Circuit held that the
15 defendant’s “counterclaim presents a pure question of law: Are the . . . ordinances [at issue]
16 preempted by state or federal law?” *Id.* at 1172.

17 Almost wholly inapposite is *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1108 (1996)—
18 decided thirteen years ***before*** *Wyeth v. Levine*—which concerned whether “a plaintiff alleging
19 injury from ingesting a prescription drug can state a claim against the manufacturer for strict
20 liability and breach of warranty for failure to warn about the known or reasonably scientifically

21 *First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 n.16 (3d Cir. 1977) (“That the district court is
22 free to determine facts relevant to its jurisdiction has long been clear.”).

23 ²⁴ *Cf. Augustine v. United States*, 704 F.2d 1074, 1077 (9th Cir. 1983) (Courts should refrain
24 from resolving factual issues “where the jurisdictional issue and substantive issues are so
intertwined that the question of jurisdiction is dependent on the resolution of factual issues going
to the merits.”) (internal quotations omitted).

25 ²⁵ The inquiry as to whether FDA would have disapproved the plaintiff’s proposed warning
26 can also be compared to the determination whether an activity is “abnormally dangerous,” giving
rise to strict liability. The Restatement identifies several relevant factors and states that “[w]hether
27 the activity is an abnormally dangerous one is to be determined *by the court.*” Restatement (2d) of
Torts, § 520, cmt. 1 (emphasis added). As is true of preemption, the antecedent facts to be
28 resolved by the court are different from the facts relevant to the merits.

1 knowable dangerous propensities of its product.”²⁶ The California Supreme Court rejected the
2 defendant’s argument that a strict liability standard was “inconsistent with federal regulatory
3 policy” as a general matter, but recognized the applicability of conflict-preemption principles,
4 saying, “a pharmaceutical manufacturer may not be held liable for failing to give a warning it has
5 been *expressly precluded* by the FDA from giving.” *Id.* at 1113, 1115 n.4 (emphasis in original).
6 The decision says nothing about whether preemption is a question of law or fact.

7 Wholly irrelevant is *Johnson & Johnson v. Superior Court*, 192 Cal. App. 4th 757 (2d
8 Dist. 2011), which did not address preemption, but concerned whether the defendant was entitled
9 to summary adjudication of the plaintiff’s claim for punitive damages. Unlike the defense of
10 preemption, “[i]n the usual case, the question of whether the defendant’s conduct will support an
11 award of punitive damages is for the trier of fact.” *Id.* at 762 (internal quotation marks omitted).
12 The court’s decision does nothing more than opine that there was an issue of fact regarding the
13 defendant’s alleged malice. *See id.* at 765-66.

14 5. ***Plaintiffs’ apparent current contention that preemption should be decided by a***
15 ***jury is inconsistent both with the essential nature of preemption and with public policy.*** If
16 preemption is a triable issue, it will not be decided once and for all in this consolidated
17 proceeding, but will have to be decided over and over, jury by jury. Some juries could decide that
18 a pancreatic-cancer warning is preempted, while others could decide it is not, and the collateral
19 estoppel doctrine would not prevent such inconsistent results.²⁷ Such results would be at odds
20 with the principle that “federal preemption presents a pure question of law,” *In re Farm Raised*
21 *Salmon Cases*, 42 Cal. 4th at 1089 n.10, for a question of law has one right answer.

22
23 ²⁶ Motion Hearing Tr. at 127:3-22 (“You asked about whether we have a question of law or
24 fact. . . . I ran back to the books and I addressed it at pages 11 and 12 of our brief.”) (citing
Carlin, 13 Cal. 45th 1104; *Johnson & Johnson*, 192 Cal. App. 4th 757).

25 ²⁷ If Defendants, or any of them, were to prevail on preemption with one jury, the hundreds
26 of plaintiffs who were not parties to that trial could not be precluded from relitigating the issue.
27 *See, e.g., Pac. Lumber Co. v. State Water Res. Control Bd.*, 37 Cal. 4th 921, 943 (2006) (“[T]he
28 party against whom preclusion is sought must be the same as, or in privity with, the party to the
former proceeding”) (quoting *Lucido v. Super. Ct.*, 51 Cal. 3d 335, 341 (1990)). Nor would an
adverse finding on preemption as to one Defendant bind any other Defendant, or even necessarily
the Defendant who lost. *Id.*

1 That is especially true here, where FDA went to unprecedented lengths to study these
2 drugs and to convey a consistent message about its conclusions to the medical community.
3 *Dowhal v. SmithKline Beecham Consumer Healthcare* is pertinent in this regard, because in
4 failure-to-warn cases involving FDA-regulated drugs, there is more at stake than the interests of
5 the plaintiff and the defendant-manufacturer. 32 Cal. 4th 910 (2004). FDA balances the benefits
6 of a proposed warning against “the dangers of overwarning” and may, for example, choose to
7 prohibit a truthful warning if the warning would be “misleading or fail to communicate the facts
8 necessary for the protection of users.” *Id.* at 931-32. Juries are not equipped or empowered to
9 second-guess this balancing or to consider the interests of unrepresented parties. *Cf. Riegel v.*
10 *Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (noting, in a medical device case, “[a] jury . . . sees
11 only the cost of a more dangerous design, and is not concerned with its benefits; the patients who
12 reaped those benefits are not represented in court.”).²⁸

13 6. ***In conclusion, Plaintiffs cannot be right that, if there is a dispute “about what***
14 ***the FDA would have done, then . . . [Defendants] lose their preemption defense completely.”***²⁹
15 The plaintiff and defendant always dispute what FDA would have done, because the plaintiff
16 always contends that FDA would have acted differently if the defendant had proposed a different
17 warning at a different time. If a dispute about whether the evidence adds up to “clear evidence”
18 precluded summary judgment, then summary judgment would be an impossibility. But the post-
19 *Wyeth* cases are unanimous that the determination of whether the undisputed facts about the
20 regulatory history add up to “clear evidence” is a legal issue, to be resolved by the court as a
21 matter of law. And every one of those cases, either pro or con, decide preemption on a motion for
22 summary judgment or motion for judgment as a matter of law.

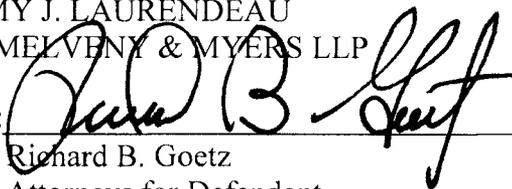
23 ²⁸ Defendants also cite *Dowhal* for the point that Plaintiffs’ claims are barred on general
24 obstacle-preemption grounds, apart from impossibility-preemption grounds, *see* Motion Hearing
25 Tr. at 36:12-38:11, and to explain the policy rationale for requiring courts, rather than juries, to
26 decide preemption. *See id.* at 35:7-36:11. Although the California Supreme Court in *Dowhal* did
27 not expressly address whether preemption is a purely legal issue, it treated it as one: There, the
28 trial court granted defendant’s summary judgment motion based on preemption, the Court of
Appeal reversed, and the Supreme Court reversed the judgment of the Court of Appeal, finding
plaintiff’s claim preempted as a matter of law. 32 Cal. 4th at 922, 935.

²⁹ Motion Hearing Tr. at 66:3-4.

1 Dated: September 28, 2015

Respectfully submitted,

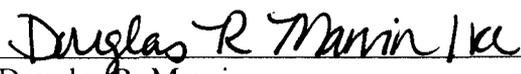
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PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is O'MELVENY & MYERS LLP, 400 South Hope Street, Los Angeles, California 90071-2899. On September 28, 2015, I served the following document(s) by the method indicated below:

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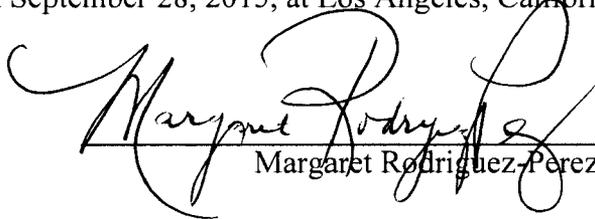
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I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on September 28, 2015, at Los Angeles, California.


Margaret Rodriguez-Perez

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