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9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA
11 SAN FRANCISCO DIVISION

12 IN RE: BEXTRA AND CELEBREX
13 MARKETING SALES PRACTICES AND
14 PRODUCT LIABILITY LITIGATION

CASE NO. 05-CV-01699 CRB
MDL No. 1699

15 This Document Relates To:
16 ALL CASES.

**PFIZER DEFENDANTS' MOTION FOR
ENTRY OF *LONE PINE* CASE
MANAGEMENT ORDER; MEMORANDUM
OF POINTS AND AUTHORITIES IN
SUPPORT THEREOF**

*[Declaration of Loren H. Brown in Support of
Motion filed separately]*

Date: August 1, 2008
Time: 10:00 a.m.
Judge: Hon. Charles R. Breyer, Courtroom 8

1 **SUMMARY OF ARGUMENT**

2 *Lone Pine* orders¹ are designed to assist courts in managing mass tort dockets that
 3 frequently consist of thousands of cases, some of which may have merit, and many others of
 4 which may have no merit at all. It is neither practical nor productive to go through protracted
 5 discovery in thousands of cases just to see whether each one has some threshold evidence of
 6 medical causation. Similarly, a so-called “bellwether” trial has significant limitations because it
 7 often addresses only one unique set of facts in just one case, which may provide meaningful
 8 information for only a fraction of other cases on the docket, if it provides meaningful information
 9 for any other cases at all. The *Lone Pine* procedure promotes judicial efficiency by weeding out
 10 cases that lack a bare minimum of medical proof, thus allowing the Court to organize the
 11 remaining cases for appropriate disposition by motion, trial, or resolution.

12 A *Lone Pine* order is the next logical step in a process that will help the Court resolve its
 13 entire docket of Celebrex and Bextra cases. Specifically, Pfizer seeks an order that compels each
 14 claimant to produce the following: (1) a Rule 26(a)(2) case-specific expert report on the issue of
 15 medical causation; (2) medical records that confirm an injury; (3) prescription records that
 16 document the medication history and dosages prescribed; and (4) proof of when a plaintiff took a
 17 particular dosage of a medication in relation to a confirmed injury.²

18 Production of such basic and threshold evidence is not overly burdensome, as its
 19 compilation would be part of any good faith investigation that preceded the filing of a lawsuit.
 20 Moreover, the benefits to the Court of requiring plaintiffs to supply this information far outweigh
 21 any minimal burden occasioned by a *Lone Pine* order. First, for those plaintiffs who do not
 22 possess this *prima facie* evidence, the *Lone Pine* procedure efficiently will dispose of those cases
 23 without protracted discovery on other issues, additional motion practice, or further delay. It also

24 _____
 25 ¹ The term “*Lone Pine* orders” refers to case management orders requiring plaintiffs to present
 26 certain case-specific evidence relating to specific causation before the case may proceed further in
 27 discovery. The term “*Lone Pine* reports” refers to the expert reports typically submitted in
 response to a *Lone Pine* order. Both terms are derived from *Lore v. Lone Pine Corp.*, No. L-
 33606-85, 1986 WL 637507 (N.J. Super. Ct. Nov. 18, 1986), *appeal dismissed*, No. A-2502-
 86TB (N.J. Super. Ct. App. Div. March 20, 1987).

28 ² Pfizer has filed with these moving papers a proposed *Lone Pine* order. See [Proposed] Pretrial
 Order No. 29: Provision of Case-Specific Expert Reports Regarding Specific Causation.

1 will put the burden of weeding out legally deficient claims where the law places it in the first
2 instance – on the plaintiffs.

3 Second, a *Lone Pine* procedure provides an efficient, one-step process for the Court to
4 dismiss all cases covered by its prior rulings under *Daubert v. Merrell Dow Pharmaceuticals*, 509
5 U.S. 579 (1993). Those rulings preclude claims by plaintiffs taking 200 mg per day or less of
6 Celebrex, as well as those who did not suffer an injury within three days of taking any dose of
7 that medication. Cases where a plaintiff cannot produce reliable evidence and an expert report
8 proving that his or her case falls outside the scope of the Court’s *Daubert* rulings can be disposed
9 of without additional motion practice or further discovery.

10 Third, to the extent that plaintiffs comply with the *Lone Pine* order, the Court will be left
11 with a group of Celebrex cases that fall outside the *Daubert* rulings and a group of Bextra cases
12 that were not subjected to similar *Daubert* challenges. At that point, the Court can group cases
13 that share common issues or facts, allowing for motion practice in cases that have other legal
14 deficiencies and for other forms of disposition. For example, requiring case-specific expert
15 reports with supporting medical documentation will help weed out both time-barred claims and
16 claims that accrued after a boxed cardiovascular warning was added to the labels of Celebrex and
17 all other anti-inflammatory medications. This may be a significant number of cases, as it has
18 been more than three years since the FDA recommended label changes, yet Pfizer continues to be
19 served with new Celebrex lawsuits. A plaintiff’s actual date of injury can be proven with
20 minimal burden on the plaintiffs, and it would be very inefficient to require full discovery in all
21 such cases that turn on this single, straightforward fact.

22 Finally, additional *Daubert* procedures related to Bextra could resolve significant groups
23 of additional cases, and at the same time leave intact those Bextra cases that may be appropriate
24 for other forms of resolution. In sum, a *Lone Pine* order will conserve judicial resources, help
25 eliminate legally deficient claims, and allow for a more expeditious resolution of this MDL
26 Court’s remaining product liability docket. Accordingly, the Court should GRANT Pfizer’s
27 motion and issue its proposed Pretrial Order No. 29.

28 /////

1 **I. A LONE PINE CASE MANAGEMENT ORDER WILL PROMOTE JUDICIAL**
 2 **ECONOMY AND HELP THE COURT MANAGE ITS DOCKET.**

3 Like many courts before it, this Court should enter a *Lone Pine* order to facilitate the
 4 efficient management of its large docket. The Court has the authority to enter such an order.
 5 Federal Rule of Civil Procedure 16(c)(2) provides that a court “may consider and take appropriate
 6 action” on: (1) “formulating and simplifying the issues, and eliminating frivolous claims or
 7 defenses;” (2) “controlling and scheduling discovery, including orders affecting disclosures and
 8 discovery under Rule 26”; (3) “adopting special procedures for managing potentially difficult or
 9 protracted actions that may involve complex issues, multiple parties, difficult legal questions, or
 10 unusual proof problems;” and (4) “facilitating in other ways the just, speedy, and inexpensive
 11 disposition of the action.” Fed. R. Civ. P. 16(c)(2)(A), (F), (L), (P); Fed. R. Civ. P. 16 advis.
 12 comm. note, 1983 amendment (encouraging special pretrial procedures in complex cases).

13 *Lone Pine* orders, which “are designed to handle the complex issues and potential burdens
 14 on defendants and the court in mass tort litigation,” are appropriately issued in federal court
 15 “under the wide discretion afforded district judges over the management of discovery under Fed.
 16 R. Civ. P. 16.” *Acuna v. Brown & Root Inc.*, 200 F.3d 335, 340 (5th Cir. 2000), *cert. denied*, 530
 17 U.S. 1229 (2000). Trial courts also enjoy broad discretion in determining the admissibility of
 18 scientific evidence supporting causation. Fed. R. Evid. 104(a) (“Preliminary questions
 19 concerning . . . the admissibility of evidence shall be determined by the court.”); *Kumho Tire Co.,*
 20 *Ltd. v. Carmichael*, 526 U.S. 137, 152-53 (1999) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136,
 21 143 (1997), and noting that trial courts have “considerable leeway” and “broad latitude” in
 22 deciding how to assess admissibility and whether expert testimony is sufficiently reliable).

23 In addition to their specific discretion under Federal Rule of Civil Procedure 16 and
 24 Federal Rule of Evidence 104, trial courts also have inherent and wide-ranging power to “control
 25 the preparation, processing, and presentation of civil cases.” *Planned Parenthood of Cent. N. J.*
 26 *v. Verniero*, 22 F. Supp. 2d 331, 339 (D.N.J. 1998) (citing *United States v. R.J. Reynolds Tobacco*
 27 *Co.*, 416 F. Supp. 316, 322 (D.N.J. 1976)) (internal quotations omitted); Fed. R. Civ. P. 1
 28 (providing that the Rules “should be construed and administered to secure the just, speedy, and

1 inexpensive determination of every action”). Many courts have cited their inherent power to
 2 achieve the orderly and just disposition of their dockets as grounds for issuing case management
 3 orders like the one requested here. “Managerial power is . . . a critical necessity We face the
 4 hard necessity that, within proper limits, judges must be permitted to bring management power to
 5 bear upon massive and complex litigation to prevent it from monopolizing the services of the
 6 court to the exclusion of other litigants.” *Asbestos Claims Facility v. Berry & Berry*, 219 Cal.
 7 App. 3d 9, 19-21 (1990), *disapproved on other grounds in Kowis v. Howard*, 3 Cal. 4th 888, 896
 8 (1992); *see also In re Air Crash Disaster at Fla. Everglades on December 29, 1972*, 549 F.2d
 9 1006, 1012 (5th Cir. 1977); *Cottle v. Superior Court*, 3 Cal. App. 4th 1367, 1377-78 (1992); *In re*
 10 *Love Canal Actions*, 547 N.Y.S.2d 174, 177-79 (N.Y. Sup. Ct. 1989).

11 In light of these docket management considerations, and in recognition that case-specific
 12 questions of exposure and the relationship of exposure to injury are threshold issues in plaintiffs’
 13 cases, numerous federal³ and state⁴ courts have ordered plaintiffs to make a *prima facie* showing

14 ³ *See Acuna*, 200 F.3d at 340 (requiring approximately 600 plaintiffs to produce expert affidavits
 15 opining that their injuries more likely than not were caused by exposure to the substance at issue
 16 and staying other discovery); *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 500-01, 503 (9th Cir.
 17 1994) (affirming order requiring plaintiffs to submit affidavits from physicians listing the
 18 scientific basis for the physician’s opinion that the injuries were caused by exposure to the
 19 chemical and granting summary judgment where plaintiffs failed to provide reliable affidavits);
 20 *Burns v. Universal Crop Prot. Alliance*, 4:07CV00535, 2007 WL 2811533, at *3 (E.D. Ark. Sept.
 21 25, 2007) (granting *Lone Pine* order requiring 82 plaintiff farmers to provide expert proof that
 22 herbicide manufacturers caused crop damage); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d
 23 567, 575 (S.D.N.Y. 2006) (“*Rezulin IV*”) (granting summary judgment where *Lone Pine* reports
 24 provided insufficient evidence of exposure and dose levels to support causation); *In re Rezulin*
 25 *Prods. Liab. Litig.*, MDL No. 1348, No. 00 Civ. 2843 (LAK), 2005 WL 1105067, *passim*
 26 (S.D.N.Y. May 9, 2005) (“*Rezulin II*”) (initial *Lone Pine* order); *In re Baycol Prods. Liab. Litig.*,
 27 MDL No. 1431 (MJD/JGL) 2004 WL 2578976, at *3-4 (D. Minn. Nov. 1, 2004) (Pretrial Order
 28 No. 131) (“*Baycol II*”) (amending initial *Lone Pine* order); *In re Baycol Prods. Liab. Litig.*, No.
 MDL 1431 (MJD/JGL) 2004 WL 626866, at *1 (D. Minn. Mar. 18, 2004) (Pretrial Order No.
 114) (“*Baycol I*”) (initial *Lone Pine* order); *Diamond v. Immunex Corp.*, No. 2:03 CV 564, Order
 at 1 (W.D. La. Aug. 15, 2003) (ordering, *sua sponte*, plaintiff to submit evidence of causation
 because the “burden is on plaintiffs to present competent summary judgment evidence showing a
 causal relationship”) (Brown Decl., Ex. 1); *In re 2000 ExxonMobil Release Litig.*, Master Docket
 No. 00-MD-1-C, C.A. Nos. 01-1047, 01-1048, 01-1074, 01-1090, 01-1112, Order at 6 (M.D. La.
 March 3, 2003) (ordering plaintiffs to produce an affidavit of a qualified treating or other
 physician identifying the substance to which exposure is claimed, the diagnosis of the plaintiff’s
 alleged injury, and stating to a reasonable medical probability that the injury was caused by
 exposure to the substance) (Brown Decl., Ex. 2); *Grant v. E.I. Du Pont De Nemours*, No. 91-55-
 Civ-4H, 1993 WL 146634, at *4-5 (E.D.N.C. Feb. 17, 1993) (entering order requiring plaintiffs to
 provide case-specific expert affidavits and noting that failure to comply could result in dismissal
 of action); *Eggar v. Burlington N. RR. Co.*, No. CV89-159-BLG-JFB, 1991 WL 315487, at *5
 (D. Mont. Dec. 18, 1991) (requiring a physician affidavit on issues of injury and causation and

1 of medical causation early in the litigation. Such orders are especially warranted in complex
 2 personal injury cases where: (1) there are numerous plaintiffs; (2) further discovery would be
 3 costly; and/or (3) plaintiffs' claims appear suspect or lack evidentiary support. *See, e.g., Lore*,
 4 1986 WL 637507 at *1-4; *see also Burns*, 2007 WL 2811533 at *2-3 (noting that requiring each
 5 plaintiff to produce information providing minimal evidentiary support for his or her claims of
 6 medical causation serves to ensure cases lacking factual support for a critical element of liability
 7 will not consume the resources of the Court and unduly burden defendants). As a result, *Lone*
 8 *Pine* orders are particularly common in pharmaceutical product liability cases and were used
 9 successfully by federal and state courts in the *Baycol* and *Rezulin* litigations. *Rezulin IV*, 441 F.
 10 Supp. 2d at 575; *Rezulin II*, 2005 WL 1105067; *Baycol II*, 2004 WL 2578976, at *3-4; *Baycol I*,
 11 2004 WL 626866, at *1; *In re: N.Y. Rezulin Prods. Liab. Litig.*, Master Index No. 752,000/00,
 12 Order (N.Y. Sup. Ct. N.Y. Co. July 7, 2004) (Brown Decl., Ex. 3); *In re Baycol Litig.*, November
 13 Term, 2001, No. 0001, Order (Ct. Com. Pl. Phila. Co. Dec. 12, 2003) (Brown Decl., Ex. 4).

14 A *Lone Pine* order is particularly appropriate here given the plaintiffs' history of
 15 dismissing their claims rather than complying with basic discovery obligations. On February 13,
 16 2006, the Court issued Pretrial Order No. 6, which requires plaintiffs to submit Plaintiff Fact
 17 Sheets and other discovery relating to their claims. Since the date of that order, 2,096 plaintiffs
 18 either have agreed to dismiss their claims or have had their claims dismissed with prejudice by
 19 this Court for failing to comply with that order. (Brown Decl. ¶ 6.) The plaintiffs' unwillingness
 20 to provide essential information necessary to evaluate their claims further justifies the use of *Lone*
 21 *Pine* reports to manage this Court's docket. Importantly, many courts that issue *Lone Pine* orders
 22 requiring plaintiffs to specify the specific chemicals believed to have caused the alleged injury),
 23 *aff'd*, 29 F.3d 499 (9th Cir. 1994).

24 ⁴ *Bell v. Exxonmobil Corp.*, No. 01-04-00171-CV, 2005 WL 497295, at *4 (Tex. App. March 3,
 25 2005) (affirming dismissal of plaintiffs' claims for failure to comply with *Lone Pine* order); *In re:*
 26 *New York Rezulin Prods. Liab. Litig.*, Master Index No. 752,000/00, Order, *passim* (N.Y. Sup. Ct.
 27 N.Y. County July 7, 2004) (ordering plaintiffs to serve case-specific expert reports before case-
 28 specific depositions commenced) (Brown Decl., Ex. 3); *In re Baycol Litig.*, November Term,
 2001, No. 0001, Order, *passim* (Ct. Com. Pl. Phila. Co. Dec. 12, 2003) (same) (Brown Decl., Ex.
 4); *Martinez v. City of San Antonio*, 40 S.W.3d 587, 591 n.1 (Tex. App. 2001) (quoting *Acuna* in
 a matter involving approximately 600 plaintiffs and affirming summary judgment after failure to
 comply with *Lone Pine* order); *In re Mohawk Rubber Co.*, 982 S.W.2d 494, 498-99 (Tex. App.
 1998) (reversing trial court and directing *Lone Pine* order in toxic exposure case).

1 include notice of possible sanctions for failure to timely serve the requisite case-specific expert
2 reports, including, for example, dismissal with prejudice.⁵

3 **II. LONE PINE REPORTS MERELY REQUIRE PLAINTIFFS TO PROVIDE PRIMA**
4 **FACIE EVIDENCE THEY SHOULD HAVE HAD BEFORE FILING SUIT.**

5 Under *Daubert*, each plaintiff must proffer expert testimony to prove general and specific
6 causation as part of his or her *prima facie* case. See *Rezulin IV*, 441 F. Supp. 2d at 575. Such
7 testimony must be: (1) based on scientific knowledge that will assist the trier of fact; (2) offered
8 by a witness qualified as an expert; (3) based upon sufficient facts or data; (4) the product of
9 sufficiently reliable principles and methods; and (5) applied reliably to the facts of the case. Fed.
10 R. Evid. 702; *Daubert*, 509 U.S. at 592-94; *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531,
11 539 (S.D.N.Y. 2004) (“*Rezulin I*”). In product liability cases like those before this Court, *Lone*
12 *Pine* orders are particularly important because “[s]cientific knowledge of the harmful level of
13 exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are
14 minimal facts necessary to sustain the plaintiffs’ burden” *Allen v. Pa. Eng’g Corp.*, 102 F.3d
15 194, 199 (5th Cir. 1996).

16 Notably, a plaintiff should possess sufficient scientific support for the theory that his or
17 her injury was caused by exposure to the defendant’s drug prior to filing an action. “Each
18 plaintiff should have had at least some information regarding the nature of his injuries, the
19 circumstances under which he could have been exposed to harmful substances, and the basis for
20 believing that the named defendants were responsible for his injuries.” *Acuna*, 200 F.3d at 340
21 (noting that Fed. R. Civ. Proc. 11(b)(3) and similar state rules require such supporting evidence
22 before filing a lawsuit); *id.* (citing *Beanal v. Freeport-McMoran, Inc.*, 197 F.3d 161, 165 (5th Cir.
23 1999)). As another court observed: “[P]rior to the institution of such a cause of action, attorneys
24 for plaintiffs must be prepared to substantiate, to a reasonable degree, the allegations of personal
25 injury . . . and proximate cause This court is not willing to continue the instant action with

26 ⁵ *Rezulin II*, 2005 WL 1105067, at *2 (pretrial *Lone Pine* order); see also *Schwan v. CNH Am.*
27 *LLC*, No. 4:04CV3384, 2007 WL 1345193 (D. Neb. Apr. 11, 2007) (granting defendants’ motion
28 for partial summary judgment against 135 plaintiffs who failed to make evidentiary disclosures as
required by the court’s prior *Lone Pine* order); *In re Rezulin Prods. Liab. Litig.*, MDL No. 1348,
No. 00 Civ. 2843 (LAK), 2006 WL 1274751, at *1 (S.D.N.Y. May 10, 2006) (“*Rezulin III*”)
(order regarding failure to provide expert reports required by prior *Lone Pine* order).

1 the hope that the defendants eventually will capitulate and give a sum of money to satisfy
2 plaintiffs and their attorney without having been put to the test of proving their cause of action.”
3 *In re Love Canal Actions*, 547 N.Y.S.2d at 177-78 (quoting *Lore*, 1986 WL 637507, at *4),
4 *modified by* 555 N.Y.S.2d 519 (N.Y. App. Div. 1990). Thus, an order requiring plaintiffs to
5 provide *Lone Pine* reports merely would hold plaintiffs to their initial burden of proof and force
6 them to provide evidence now—nearly three years after these multi-district proceedings
7 commenced—that they should have had before filing suit.

8 Where plaintiffs are unable to provide such evidence, the Court will have a variety of
9 simple and efficient mechanisms for dismissing their claims. For example, the Court may dismiss
10 plaintiffs who fail to comply with its case management order. *See, e.g., In re*
11 *Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1232 (9th Cir. 2006) (“Case
12 management orders are the engine that drives disposition on the merits.”). Where plaintiffs
13 nominally comply with the *Lone Pine* order but cannot provide reliable evidence of causation
14 (*e.g.*, because the Court has ruled that the evidence does not satisfy *Daubert*), the plaintiffs’
15 complaints will be subject to motions for summary judgment. Fed. R. Civ. P. 56(b); *see also*
16 *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1195 (5th Cir. 1986); *Sanderson v. Int’l Flavors &*
17 *Fragrances, Inc.*, 950 F. Supp. 981, 984 (C.D. Cal. 1996); *Martinez*, 40 S.W.3d at 591.

18 To the extent that plaintiffs comply with the *Lone Pine* order, the Court will be able to
19 group the remaining cases that share common issues or facts, allowing for motion practice in
20 cases that have other legal deficiencies and for other forms of disposition in the remaining cases.
21 For example, some cases may be time-barred, and others may involve injuries that occurred after
22 the boxed cardiovascular warning was added to the labels of Celebrex and all other anti-
23 inflammatory medications, thereby fatally undermining a claim based on a purported failure to
24 warn. The Court also may wish to consider additional *Daubert* procedures related to Bextra.
25 Thus, a *Lone Pine* order will conserve judicial resources, eliminate deficient claims, and allow for
26 expeditious resolution of this Court’s remaining product liability docket.

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