UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA ORLANDO DIVISION

In re: Seroquel Products Liability Litigation

Case No. 6-06-md-1769

This Document relates to ALL CASES

ASTRAZENECA'S MOTION AND MEMORANDUM SEEKING A "LONE PINE" ORDER REQUIRING EACH PLAINTIFF TO PRODUCE A CASE-SPECIFIC EXPERT REPORT ON INJURY AND CAUSATION

Approximately 5,670 cases have been filed in or removed to federal court, brought by plaintiffs who allege that they suffered "injuries," "diseases," and "damages" caused by Seroquel. Plaintiffs' counsel have apparently not investigated most of these claims. *See infra*, Part I. Nevertheless, plaintiffs now seek to shut down the critical discovery into these cases and instead force settlement talks. *See* Plaintiffs' Memorandum regarding Scheduling and Scope of Future Discovery (Doc. 603) ("Pls' Mem.").

This Court should not be in the business of encouraging settlement of uninvestigated claims. Rather, the time has come to sort those plaintiffs who seriously intend to litigate their cases from those who merely hope that they can hide among the many pending cases long enough to secure settlement monies in cases they have no intention of actually litigating. Weeding out such "free-riders" will conserve the resources of the judicial system and the parties by reducing the volume of cases in which case-specific discovery will be required and that ultimately will be subject to remand for trial.

Accordingly, AstraZeneca moves the Court to enter a "Lone Pine" order 1 – requiring each plaintiff to produce a Rule 26 case-specific report on injury and causation. Requiring plaintiffs to produce such reports now will place no undue burden on plaintiffs because they cannot prove injury and causation – parts of their prima facie cases – without expert evidence. As in other MDLs, a Lone Pine order here would simply require plaintiffs to do what they should have done before filing suit: investigate their claims, as required by Rule 11. See Acuna v. Brown & Root, Inc., 200 F.3d 335, 340 (5th Cir.), cert. denied, 530 U.S. 1229 (2000).

I. A "LONE PINE" ORDER WILL ALLOW THIS COURT TO STREAMLINE THE LITIGATION BY CULLING OUT UNINVESTIGATED CLAIMS.

A plaintiff's lawyer who files a complaint in an MDL has no less duty than a lawyer who files a single automobile accident case to investigate the claim and satisfy him/herself that the claim is factually well founded. However, the history of this litigation shows that many – perhaps most – lawsuits in this MDL were filed without any reasonable degree of investigation. To wit:

• This Court already has dismissed the claims of 1,201 plaintiffs for failure to provide defendants with written discovery. See, e.g., October 22, 2007 Order (Doc. 595)

A Lone Pine order is a tested pretrial case-management device in mass tort litigation, named after the seminal Lore v. Lone Pine Corp., 1986 WL 637507, at *2 (N.J. Super. November 18, 1986). In that case, the court ordered plaintiffs to submit expert reports sufficient to establishing that particularly identified injuries were caused by exposure to the toxic substances at issue, as well as supporting information. The purpose of this order was to require plaintiffs to make an objective showing early in the litigation that there was a sufficient evidentiary and scientific basis to justify continued prosecution of what otherwise threatened to be lengthy, expensive and burdensome litigation. Ultimately, the court determined that the plaintiffs were unable to proffer objective evidence capable of establishing anything close to a prima facie case on injury and causation, and dismissed the litigation.

- (dismissing with prejudice the claims of hundreds of plaintiffs); October 2, 2007 Order (Doc. 523) (same).
- Many additional plaintiffs have filed fact sheets that convey no real information in support of their claims. See e.g., Davee Lostetter-Warsame v. AstraZeneca, 07-CV-12179, AstraZeneca's Motion to Compel Full and Complete Answers to Plaintiff Fact Sheet (Doc. 11).
- Despite plaintiffs' discovery obligations, plaintiffs' counsel have produced no medical records in most cases, suggesting that counsel failed to investigate plaintiffs' complicated medical histories before filing suit. See August 22 MDL Status Conference Tr. at 102:6-105:10, 107:23-109:8
- Approximately twenty percent of the plaintiffs selected by the Court and AstraZeneca for case-specific discovery have failed even to present for depositions to give evidence in support of their own claims. The following plaintiffs selected for case-specific discovery in August, September and October have not appeared for their depositions, or elected not to proceed: John Tucholski, Tracy Flye, Sheryl Salmons, Lisa Ellerbee, Malcolm Williams, Anthony Tomlin, Vikey Davis, Samantha Lambert, Bruce Monson, Maureen Sanchez, Robert Schuenemeyer and Shirley Green.
- Many plaintiffs who have appeared for deposition testified that they continue to take Seroquel to this day. See, e.g., Vounzetta Edgeston Dep. Tr. at 9: 6-12, 106: 9-14, 107: 12-108:4 (Ex. A) (plaintiff testified that she continues to take Seroquel because she needs it to function, even though she is aware of the potential side effects); George Fetters Dep. Tr. at 10:17-24 (Ex. B); Debra Scott Dep. Tr. at 13:25-14:1 (Ex. C).
- Many prescribers have testified that they chose to put their seriously mentally ill patients on Seroquel, despite recognized risks of weight gain and diabetes, because their patients needed the medicine. *See, e.g.,* Dr. Nora Fairley (prescriber for Timothy Ell) Dep. Tr. at 57:6-23 (Ex. D); Dr. Richard Moskovitz (prescriber for Kimberly McDaniel) Dep. Tr. at 24:10-14, 26:18-21, 118:1-6 (Ex. E); Dr. Jagdish Shah (prescriber for Lisa Grant) Dep. Tr. at 97:3-9, 101:9-102:3 (Ex. F).
- Many physicians have testified that they have placed or left diabetic patients on Seroquel because those patients need the medicine. See e.g., Dr. Daniel Koppersmith (prescriber for Elizabeth Haynie-Whynot) Dep. Tr. at 67:7-68:8; 71:2-6 (Ex. G) (testified that he continues to have many patients on Seroquel because "it's an effective medication, and the risk of diabetes is very minimal, and . . . the benefits outweigh the risks"); Dr. Luis Giuffra (prescriber for Althea Turner) Dep. Tr. at 72:10-15; 110:15-23 (Ex. H).

• When this Court initially expressed interest in trying the cases filed in Florida, plaintiffs promptly dismissed all of those cases. *Chafin v. AstraZeneca*, 06-CV-1414; *Rivera v. AstraZeneca*, 06-CV-1415, *Green v. AstraZeneca*, 06-CV-1416. And plaintiffs now seek to insulate from trial in this Court most of the cases filed by Florida residents. Pls. Mem. at 12-13.

Plaintiffs should not be allowed to insulate spurious cases from discovery and then attempt to use the volume of cases pending in this MDL in an attempt to extort a settlement from AstraZeneca. Entry of a *Lone Pine* order will require each plaintiff and his or her counsel carefully to examine the facts of a case and determine whether that plaintiff can actually muster the requisite scientific evidence and medical opinion necessary to make a prima facie showing on the essential elements of injury and causation.

In proposing a *Lone Pine* order, AstraZeneca is not urging this Court to adopt an untested case management device. Numerous other courts faced with uninvestigated volume filings have entered "*Lone Pine*" orders to cull cases that never should have been filed in the first place and to advance discovery in the remaining cases.²

² See, e.g., In re: Orthopedic Bone Screw Prod. Liab. Litig., MDL 1014, 1997 WL 303239, at *1 (E.D. Pa. February 13, 1997) (requiring that "each plaintiff identify and provide [case-specific] expert discovery with respect to at least one duly-qualified, medical expert on the issues of injury and causation"); Turner v. Firestone Tire & Rubber, No. 5-95V-152 (E.D. Tex. May 31, 1996) (requiring 106 plaintiffs to produce case-specific reports from a medical expert opining that each plaintiff's alleged injuries were caused by defendants' conduct); Atwood v. Electric Brake & Clutch Co., Inc., 605 N.E.2d 1032, 1036 (Ill. App. 1992) (affirming trial court's decision to bar personal injury claims where plaintiffs failed to comply with case management order requiring them to certify, inter alia, that "each plaintiff has identified all of his or her medical, or personal injury, claims causally related to this case by way of the expert reports"), appeal denied, 612 N.E.2d 510 (Ill. 1993); In re: Love Canal Actions, 547 N.Y.S.2d 174, 178-79 (Sup. Ct. 1989) (requiring plaintiffs to produce "reports of treating physicians and medical or other experts, supporting each individual plaintiff's claim of injury and causation" or face dismissal), aff'd, 555 N.Y.S.2d 519 (App. Dept. 1990); Lore v. Lone Pine Corp., 1986 WL 637507, at *2 (N.J. Super. November 18,1986) (dismissing with prejudice the claims of plaintiffs

A striking use of such an order occurred in *Acuna v. Brown & Root, Inc.*, 200 F.3d 335 (5th Cir.), *cert. denied*, 530 U.S. 1229 (2000), in which a district court required each of 1,600 plaintiffs to produce, *prior to discovery*, a case-specific expert report supporting their claims of injury and causation allegedly stemming from exposure to defendants' uranium mining and processing activities. *Id.* at 338. Plaintiffs complained that pre-discovery orders imposed too high a burden for that stage in the litigation. In the alternative, they contended that they had complied with the district court's order by submitting form affidavits from a single expert. *Id.* at 338, 340. The district court dismissed plaintiffs' cases, and the Fifth Circuit affirmed. *Id.* at 340-41. The Court of Appeals held that the district court acted within its discretion to manage the litigation and observed that the orders "essentially required that information which plaintiffs should have had *before* filling their claims pursuant to Fed. R. Civ. P. 11(b)(3)." *Id.* at 340 (emphasis added). Accordingly, the Fifth Circuit concluded that the district court acted within its discretion in dismissing the cases for violating the discovery order. *Id.* at 341.

More recently, in the *Baycol* MDL, the Court ordered each plaintiff to produce a case-specific expert report on injury and causation. *See In re Baycol Products Litig.*, MDL No. 1431, PTOs 114, 131, 149. The impact on the Court's docket was remarkable. More than 22,500 plaintiffs had cases pending in the *Baycol* MDL. About 3,500 were dismissed for failure to comply with written discovery requirements. More than 6,200 were dismissed with prejudice (by stipulation or court order) after the Court ordered plaintiffs to produce

who failed to comply with a case management order requiring them to produce, *inter alia*, "[r]eports of treating physicians and medical or other experts, supporting each plaintiff's claim of injury and causation").

case-specific expert reports in support of their claims. Several thousand more plaintiffs voluntarily dismissed with prejudice outside the expert report enforcement process, although that requirement likely played a role in the decision to dismiss. Thus, about 2,275 cases (roughly ten percent of the plaintiffs who ever had a case in the MDL) proceeded to case-specific discovery, during which many more plaintiffs dismissed their cases. Today, only about 300 Baycol claimants still have cases pending in federal court, and the Court has yet to rule on several contested summary judgment motions. Thus, implementation of a "Lone Pine" order in Baycol greatly aided the Court in efficiently managing the litigation, by winnowing out cases in which plaintiffs could not or would not produce evidence in support of their claims.

Here, as in *Acuna*, *Baycol*, and other mass tort cases, a *Lone Pine* order will streamline the litigation. Most of the cases in this MDL were filed many months ago; PFSs already have been produced (albeit, many in grossly deficient form); medical records by now certainly should have been in the hands of plaintiffs' counsel for many months. A *Lone Pine* order simply will require plaintiffs' counsel to examine the facts of the cases that they have filed (something counsel should have done in the first place), to consult with medical experts, and to determine whether they can produce the evidence on injury and causation that would be necessary to litigate their cases.

II. BECAUSE EACH PLAINTIFF MUST PROVE INJURY AND CAUSATION THROUGH EXPERT TESTIMONY IN HIS OR HER CASE-IN-CHIEF, A "LONE PINE" ORDER IMPOSES NO NEW BURDEN ON PLAINTIFFS.

The chief objection typically raised in opposition to a proposed "Lone Pine" order is that such orders impose an undue burden upon plaintiffs. But that is not so.

Proof of both "injury" and "causation" are essential elements that plaintiffs bear the burden of proving in their cases-in-chief. In medically complex litigation, including pharmaceutical litigation such as this one, the courts have emphasized that these essential elements must be established through expert testimony. See In re Baycol Prods. Liab. Litig., 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004) ("personal injury cases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person"); see also Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (granting summary judgment on negligence and strict liability claims in medical device case where plaintiff presented no expert testimony on defect or causation, given that "[u]nder either theory, Plaintiff would be required to provide expert testimony that the product was defective and evidence that the product caused the injury of which she complains"); Haggerty v. Upjohn Co., 950 F. Supp. 1160, 1167 (S.D. Fla. 1996) (after determining that expert opinion was inadmissible based on Daubert in product liability case involving prescription drug Halcion, court concluded that "[w]ithout this [expert] testimony, Plaintiff cannot establish a genuine issue of material fact as to causation and [defendant] is entitled to summary judgment on this claim"), aff'd, 158 F.3d 588 (11th Cir. 1998). In fact, AstraZeneca is aware of no jurisdiction in which a plaintiff asserting a pharmaceutical product liability claim may get to a jury without

supporting expert testimony on injury and causation. See In re Baycol Prods. Liab. Litig., 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004) (collecting cases).³

Alabama, see McClain v. Metabolife Int'l, Inc., 193 F. Supp. 2d 1252, 1258 (N.D. Ala. 2002) ("an expert is required to prove causation in this case, as the interplay between ephedrine, caffeine, and the other ingredients in Metabolife 356, the varying states of pre-existing ill-health of Plaintiffs, and their various ultimate injuries is 'complex and technical in nature'").

Arizona, see Cloud v. Pfizer Inc., 198 F. Supp. 2d 1118, 1138-39 (D. Ariz. 2001) (dismissing plaintiff's claim that the prescription drug Zoloft caused her husband to commit suicide after striking proposed expert's testimony; "in the absence of [the expert's] testimony, Plaintiff cannot prove causation").

<u>California</u>, see Sanderson v. International Flavors & Fragrances, Inc., 950 F. Supp. 981, 985, 1004 (C.D. Cal. 1996) (in product liability action involving exposure to aldehydes contained in perfumes, summary judgment in favor of defendant where plaintiff's expert testimony on causation was inadmissible; "to hold a defendant liable, plaintiff must prove 'a reasonable medical probability based upon competent expert testimony that the defendant's conduct contributed to plaintiff's injury') (citation omitted).

Georgia, see Lawson v. Smith & Nephew Richards, Inc., 1999 WL 1129677, *2 (N.D. Ga. September 30, 1999) (in medical device case, "[e]xpert medical testimony is required to carry a plaintiff's burden of proving causation" because, without "expert medical testimony as to causation, no genuine issue of material fact exists, and the Court must grant summary judgment for Defendant.").

<u>Illinois</u>, see Wintz By and Through Wintz v. Northrop Corp., 110 F.3d 508, 515 (7th Cir. 1997) (in product liability action involving alleged bromide exposure, court indicated that "[u]nder Illinois law, to serve as the sole basis for a conclusion that an act was the proximate cause of the plaintiff's injury, an expert must be able to testify with a reasonable degree of medical certainty that proximate cause existed").

Kentucky, see Love v. Danek Medical, Inc., 1998 WL 1048241, *2 (W.D. Ky. November 25, 1998) (where testimony of plaintiff's expert on causation was unreliable and without sufficient factual support in medical device case, summary judgment granted defendant on strict liability, negligence and breach of warranty claims).

Indeed, courts in jurisdictions across the land have emphasized precisely this point. See also:

Louisiana, see In re Propulsid Prods. Liab. Litig., 261 F. Supp. 2d 603, 618 (E.D. La. 2003) (summary judgment granted to defendants in product liability case involving the prescription drug Propulsid after court excluded plaintiff's experts on medical causation; "[w]ith the exclusion of the plaintiff's experts on causation, the plaintiff lacks an essential element of proof").

Mississippi, see Coleman v. Danek Medical, Inc., 43 F. Supp. 2d 637, 648-51 (S.D. Miss. 1999) (granting summary judgment to defendants on plaintiffs' product liability and negligence per se claims involving prescription medical device where plaintiffs could not set forth evidence of causation after court granted defendants' motion to strike the report and testimony of plaintiff's expert).

Ohio, see Graham v. American Cyanamid Co., 350 F.3d 496, 513 (6th Cir. 2003), cert. denied, Lundy v. American Cyanamid Co., 541 U.S. 990 (2004) (in product liability case involving polio vaccine, "[t]o establish strict liability under Ohio law, plaintiffs must produce expert testimony that the defect at issue 'proximately caused the [ir] claimed injuries'") (citation omitted).

<u>Pennsylvania</u>, see Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003) ("In a [product liability] case such as this one" concerning prescription drug Palodel, which "involv[es] complex issues of causation not readily apparent to the finder of fact, plaintiff must present admissible expert testimony to carry her burden.").

Tennessee, see Jastrebski v. Smith & Nephew Richards, Inc., 1999 WL 144935, *6 (Tenn. Ct. App. Mar. 18, 1999) (in product liability action involving prescription medical device, court held: "Plaintiff's testimony cannot substitute for the expert testimony required to establish a causal connection between an alleged defect in the product and a specific injury. The product in dispute is a technically complex prescription medical device, and expert testimony is required to establish the causal connection between the alleged defect in the device and Plaintiff's claimed injuries.").

<u>Texas</u>, see Taylor v. TMJ Implants, Inc., 1999 WL 351673, *5 (Tex. Ct. App. June 3, 1999) ("Expert testimony is required on the issue of causation where the determination of that issue 'is not one that lay people would ordinarily be competent to make.' In this case we determine that expert testimony was necessary to establish a causal nexus between the alleged defective design and marketing of TMJ's product and Plaintiff's injuries, if any.") (citations omitted).

<u>Virginia</u>, see Hartwell v. Danek Medical, Inc., 47 F. Supp. 2d 703, 707 (W.D. Va. 1999) (granting summary judgment to defendants on product liability claims

Consequently, requiring each plaintiff to come forward with a Rule 26 expert report on injury and causation will not impose any new duty upon that plaintiff. While entry of a "Lone Pine" order may require that the report be produced earlier in the litigation than otherwise, such a minor modification in discovery sequence is well within this Court's authority to manage complex, multidistrict litigation efficiently. See Fed. R. Civ. P. 16(c)(12) (authorizing adoption of "special procedures for managing potentially difficult or protracted actions that may involve complex legal issues, multiple parties, difficult legal questions or unusual proof problems"); see also Fed. R. Civ. P. 16, advisory committee notes (noting that Rule 16 "provides explicit authorization" for a district court to adopt special pretrial procedures designed to expedite the adjudication of large, complex or particularly difficult cases). Indeed, as the Fifth Circuit emphasized in Acuna, "Lone Pine orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation," and are properly "issued under the wide discretion afforded district judges over the management of discovery under Fed. R. Civ. P. 16." 200 F.3d at 339.

involving medical device where plaintiff's expert testimony was inadmissible; "[p]roof of legal causation in a medical device case must be by expert testimony and the expert's opinion must be stated in terms of reasonable probability").

West Virginia, see Rohrbough by Rohrbough v. Wyeth Lab., Inc., 719 F. Supp. 470, 473 (N.D.W. Va. 1989) (expert testimony was required to prove that vaccine caused plaintiff's injuries because of the "high degree of scientific complexity" inherent in the case), aff'd, 916 F.2d 970 (4th Cir. 1990).

III. THIS COURT SHOULD ORDER EACH PLAINTIFF TO PRODUCE A CASE-SPECIFIC EXPERT REPORT.

Accordingly, AstraZeneca proposes that the Court enter a pretrial order that will require each plaintiff to produce a case-specific expert report by the following deadlines:

All cases already designated for case-specific discovery and all cases involving Florida-resident plaintiffs: **January 30, 2007**

All remaining cases: April 30, 2007

At a minimum, the report should be required to include: a precise identification of the nature of the plaintiff's alleged *injuries*, along with the details of any medical exams, testing, diagnosis or treatment relied upon to support any claimed injuries; a sworn statement by a competent medical expert that the expert believes to the appropriate degree of medical certainty that plaintiff's use of Seroquel *caused* plaintiff's alleged injuries, along with a detailed description of all facts, medical and scientific literature or other authorities relied upon by the expert to support such opinion; and a complete set of medical records relied upon in forming the expert's opinion. In short, *the report should comply with Rule 26*. Plaintiffs who fail to comply with this order – like plaintiffs who failed to produce fact sheets – should be dismissed with prejudice. *See Baycol* PTO 113, 131, 149.

CONCLUSION

It would streamline this litigation for the Court to enter a *Lone Pine* order that requires plaintiffs at this stage to come forward with concrete expert evidence on injury and causation. The proposed case management order would require plaintiffs' counsel to investigate the cases they have filed and would lead to dismissal of the many plaintiffs who

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have no evidentiary basis for their claims; submission of expert reports in the remaining cases would be a useful, indeed necessary, step in pretrial discovery. For the foregoing reasons, AstraZeneca moves the Court to enter an order requiring each plaintiff to produce a case-specific expert report on injury and causation pursuant to the schedule proposed above.

Respectfully submitted on this the 29th day of October, 2007,

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CERTIFICATE OF CONFERENCE

I hereby certify that counsel for AstraZeneca contacted Lead Counsel for plaintiffs in a good faith effort to obtain plaintiffs' consent to this motion. Plaintiffs oppose this motion.

/s/ A. Elizabeth Balakhani

CERTIFICATE OF SERVICE

I hereby certify that, on the 29th of October, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that the foregoing document and the notice of electronic filing was served on Plaintiffs' Liaison Counsel in accordance with CMO No. 1.

/s/ A. Elizabeth Balakhani

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