UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

Case No. 6:06-md-1769-Orl-22DAB

FINAL PRETRIAL ORDER AND SUGGESTION OF REMAND

Seroquel, a prescription drug manufactured and sold by AstraZeneca Pharmaceuticals, was first approved for use in the United States by the Food and Drug Administration in 1997. The drug is still on the market today as one of a number of medications known as second-generation, or "atypical," antipsychotics. Although initially indicated to treat the "manifestations of psychotic disorders," including schizophrenia, Seroquel has since been approved for various uses in patients suffering from bipolar disorder.

Several years ago, people who had been prescribed Seroquel by their doctors began filing lawsuits against AstraZeneca, primarily alleging that they had developed diabetes and other related disorders as a result of their ingestion of the drug. In July 2006, the Judicial Panel on Multidistrict Litigation transferred 92 actions, filed by 112 plaintiffs, involving alleged injuries resulting from the use of Seroquel to this Court for consolidated and coordinated pretrial proceedings. *See In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376 (J.P.M.L. 2006). Since that time, this multidistrict litigation has grown to include the personal injury claims of approximately 8,500 people from across the nation.[1] Tens of thousands of additional cases are pending in state courts in Delaware, New Jersey

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[1] At present, approximately 6,300 plaintiffs' cases remain pending.

and elsewhere.[2]

Pursuant to Rule 7.6 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, and upon review of the files in the cases now pending in MDL 1769, the Court suggests to the Judicial Panel on Multidistrict Litigation that all cases listed in Exhibits A and B[3] are ready for remand to their appropriate transferor jurisdictions. The Court finds that these cases will no longer benefit from centralized proceedings; all common discovery and other coordinated pretrial proceedings are complete, and the remaining case-specific issues are best left to the transferor courts to decide. In addition, the Court enters this Final Pretrial Order to chronicle the coordinated proceedings and to provide guidance to transferor courts after remand.[4] A copy of this Order and an index of key orders entered in this MDL will be available via a link on the main website of the U.S. District Court for the Middle District of Florida at http://www.flmd.uscourts.gov.

GENERAL MATTERS

Representative Counsel

The plaintiffs have been collectively represented by two court-approved co-lead counsel: Paul Pennock, Weitz & Luxenberg, P.C., New York, NY, and Camp Bailey, Bailey Perrin Bailey LLP,

[2] According to the Mediator's latest report (Doc. 1617), state courts are entertaining the cases of approximately 3.5 times as many plaintiffs as are currently involved in this federal MDL.

[3] The cases to be remanded to the District of Massachusetts are listed in Exhibit B. Cases to be remanded to all other districts are listed in Exhibit A.

[4] As the Manual for Complex Litigation dictates, "[a]lthough the transferor judge has the power to vacate or modify rulings made by the transferee judge [after remand], subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." Manual for Complex Litigation (Fourth) § 20.133 (2004).

Houston, TX (Doc. 122). The defendants are represented by court-approved lead counsel Fred Magaziner, Dechert LLP, Philadelphia, PA (Doc. 122). In addition, each side has been represented by a court-appointed liaison counsel: Larry Roth, Law Offices of Larry Roth, P.A., Orlando, FL, for the plaintiffs and Marjorie Shiekman, Dechert LLP, Philadelphia, PA, for the defendants (Doc. 122). The duties and responsibilities of lead and liaison counsel are delineated in Case Management Order No. 1 (Doc. 130).

Referral of Discovery Matters to Magistrate Judge

As is customary in the Middle District of Florida, the magistrate judge assigned to the litigation was entrusted with managing the pace and course of discovery. Accordingly, most motions involving discovery disputes were referred to Judge Baker for his consideration and resolution.

Conferences

The initial pretrial conference in this litigation was held in September 2006 before both the undersigned and the magistrate judge. At the initial conference, deadlines were set for the filing of a master complaint, a notice of class action status, and stipulated Plaintiff Fact Sheet and medical records authorization forms. (Doc. 30). The first discovery conference was convened by the magistrate judge in November 2006. Thereafter, status conferences were conducted by the magistrate judge approximately every six weeks to ensure that the parties were on task and to address routine discovery issues and disputes. Preparation for the status conferences was governed by Case Management Order No. 1 (Doc. 130), as amended by the Court's order of April 11, 2008 (Doc. 943).

In addition to periodic status conferences, the magistrate judge conducted in-person or telephonic hearings to address time-sensitive issues. The rules for telephonic hearings were outlined in Case Management Order No. 1. (Doc. 130). As well, the undersigned held hearings on dispositive

motions and general case management issues.

Severance

The vast majority of the plaintiffs whose cases were transferred in the first few months of the litigation were joined in only a few complaints filed in a handful of federal districts. It was immediately clear that these plaintiffs were neither similarly-situated nor grouped according to some common link, e.g., applicable state law, statute of limitations period, or medical history. To facilitate the individual treatment these and future plaintiffs required, all MDL plaintiffs' claims (except consortium claims) were automatically severed upon their arrival in the Middle District of Florida. (Doc. 129). Thus, each plaintiff proceeded with his or her own case file throughout the course of the litigation. Upon severance, each severed plaintiff was required to file a short-form amended complaint incorporating by reference the original complaint. (Doc. 172). Likewise, the defendants were to file a responsive short-form answer in the severed cases. (*Id.*) Short-form complaints were due to be filed fifteen days after service of a Plaintiff Fact Sheet or ten days after severance, whichever was later (Doc. 180), and short-form answers were due to be filed twenty days following the filing of the short-form complaint (Doc. 172).

Master File

For the first year of the litigation, there were no specific rules about whether case-specific motions and other documents should be filed in the Master file (6:06-md-1769-Orl-22DAB) or in particular plaintiffs' individual files. Confusion about where to file these types of motions came to a head when the defendants began filing scores of case-specific motions to dismiss based on Plaintiff Fact Sheet and medical records authorization deficiencies. Filing the same or similar motion in hundreds of individual cases proved to be burdensome on the parties and the Court. To remedy the

situation, the Court instructed the parties to file any motions or other documents raising the same or substantially similar issue with respect to more than four cases in the Master file. (Doc. 237). All other motions were to be filed in the individual files of the plaintiffs to which they pertained. (*Id.*). Orders were entered in the same manner in which the motions were filed. For court orders pertaining to more than four cases, and, thus, filed in the Master file, the Clerks Office staff was instructed either to make a notation or file a copy of the order in the individual dockets of the plaintiffs to which the order pertained. Therefore, individual docket entries may occasionally merely cross-reference relevant events occurring in the Master file, such as case dismissal for failure to serve a Plaintiff Fact Sheet. **Master Complaint**

To streamline the parties' process of drafting and evaluating thousands of separate complaints, the plaintiffs filed a master complaint presenting facts and claims common to all cases in the MDL. The master complaint was not automatically deemed filed in individual cases; it merely served as a template for complaints filed in incoming MDL member cases. At a subsequent status conference, both parties indicated a desire to withdraw the master complaint, but no official withdrawal ever occurred on the record. Even so, transferor courts will find that most individual complaints closely track the language of the master complaint. Due to the implicit withdrawal of the master complaint, no master answer was ever filed.

Service of Process

The defendants agreed to waive service of process for Seroquel-related cases alleging personal injury filed in federal court and alleging injuries consistent with the stated purpose of this MDL, subject to Fed. R. Civ. P. 4(d). (Doc. 130). Plaintiffs have 30 days from the date their cases are filed in, removed to, or transferred to the MDL to provide notice to AstraZeneca. (*Id.*).

Dismissal of Certain Defendants

By stipulation (Doc. 366), the parties agreed to dismiss the following seven entities named as defendants in specified MDL cases:

- Astra USA Holdings Corporation
- AstraZeneca Research & Development
- AstraZeneca R&D Wilmington
- AstraZeneca R&D Boston
- Astra USA, Inc.
- Astra U.S. Holdings Corporation
- KBI Sub, Inc.

The stipulation was eventually extended to all cases transferred as part of the MDL. (Doc. 643). To effectuate the stipulation, a "robot" was set up by the Clerks Office to automatically terminate these parties if they were named as defendants in any incoming MDL member case.

Case Management Orders

At the outset of the case, the Court entered a Scheduling Order governing various facets of practice and procedure and ordering all discovery proceedings and deadlines for responding to a complaint or motion stayed until after the initial pretrial conference. (Doc. 4). In addition, five Case Management Orders, which will be explained in more detail, govern practice and procedure and set discovery and motion practice deadlines. (Doc. 130, 129, 193, 263 & 792).

Preservation of Evidence

Case Management Order No. 2 (Doc. 129) outlines the parties' duties and responsibilities with respect to preservation of evidence and sets forth the procedures for seeking relief for alleged spoliation. In early 2008, it came to the Court's attention that certain Seroquel-related "intermediate data," i.e., non-final document drafts, contained within AstraZeneca's Global Electronic Library (GEL) database had been "non-retained" by the company during the pendency of the Seroquel

litigation. Based on briefing from the parties and argument heard at a hearing on the matter, it was evident that AstraZeneca had a duty to preserve the intermediate data beginning in 2003 when the first federal complaint was filed in the Middle District of Florida. (Doc. 1029). Because there was yet no final assessment of whether such data had been permanently destroyed, the Court reserved ruling on the appropriate remedy for failure to preserve evidence. (*Id.*). The parties were invited to bring the matter of an appropriate remedy back before the Court at a later date; however, the issue did not reappear for the Court's consideration.

Alternative Dispute Resolution

After several inquiries regarding the parties' willingness to engage in alternative dispute resolution, the Court appointed a special master to spur serious discussions. (Doc. 1244). Professor Stephen Saltzburg (SM-ADR) mediated a Court-ordered settlement conference in January 2010 which, although a first step toward settlement, did not resolve any of the cases. (Doc. 1607). Even so, Professor Saltzburg continues to facilitate settlement negotiations between the parties involved in both the MDL and the state court cases. Due to his extensive work with the parties to date, the Court recommends that transferor courts permit him to continue to provide ADR services after remand.

DISCOVERY

General Fact Discovery

By Defendants

The defendants were entitled to discovery in every severed MDL case via service of a Plaintiff Fact Sheet and medical records authorization forms. Case Management Order No. 2 (Doc. 129) sets

forth the protocol for service of these discovery documents and dictates a remedy for failure to timely establish service. In short, each plaintiff is required to serve a Plaintiff Fact Sheet and medical records authorization within 45 days after his or her complaint is docketed. Should a plaintiff fail to meet this deadline, the defendants are entitled to seek dismissal of the case. At the outset, cases with deficient discovery were dismissed without prejudice, at which time the plaintiff had 60 days to move to vacate the dismissal order if the discovery was thereafter served on the defendants. If the 60 days elapsed with no properly supported motion to vacate, the case was dismissed with prejudice upon the defendants' motion. This procedure eventually proved too burdensome on the Court and Clerk's office personnel (who were constantly closing and reopening cases) and the Court revised the procedure to omit the dismissal-without-prejudice step. That revision allowed the defendants to file a motion for dismissal with prejudice, which remained pending for 80 days. If the plaintiff did not remedy his or her discovery deficiency within that 80 day window, the case was automatically dismissed with prejudice and closed. (Doc. 285). Since that time, the revised procedure, or some closely-related version of it, has been regularly employed. Though ordinarily dismissal with prejudice is a sanction reserved for instances of purposeful delay or willful contempt, the Court believes it is an appropriate and just sanction in the context of this MDL, especially because plaintiffs' counsel should have gathered basic information about their clients' cases prior to filing suit. (Doc. 463).

By Plaintiffs

At the outset of the litigation, the defendants identified eighty company employees or officers ("custodians") who the defendants believed were in possession of the documents most relevant to the case. These custodial files, along with regulatory documents and organizational charts, were the main focus of early production efforts by the defendants. Case Management Order No. 2 (Doc. 129) sets

forth detailed requirements with respect to the format and timetable for production of the custodial files, as well as documents contained in company databases, company organizational charts and privilege logs. Case Management Order No. 3 (Doc. 193) outlines the practice and procedure regarding notice, attendance, conduct and use of Rule 30(b)(6) depositions of the defendants' employees and certain third parties who performed relevant work with respect to Seroquel.

It became clear early on that the defendants were struggling to adhere to the document production timetable established in Case Management Order No. 2. Plaintiffs had regularly complained at status conferences that documents were not being produced on time or in any readable or searchable form. Plaintiffs' frustration over these production deficiencies came to a head in July 2007, when they filed a motion for sanctions related to the defendants' delayed or otherwise inadequate production of electronically stored custodial files, databases, organizational charts and regulatory documents. After a day-long evidentiary hearing on the motion, it was evident that the defendants' failure to timely and systematically produce electronically stored information in any manageable, searchable form was sanctionable. (Doc. 393). A ruling on the sanction to be imposed was deferred pending the plaintiffs' showing of specific prejudice or added costs due to the defendants' "purposeful sluggishness" in production. (*Id.*).

To assist the defendants with identifying and resolving the problems they had encountered with production of electronically-stored information (ESI), and to assess appropriate sanctions, Craig Ball, Esq., was appointed as a Special Master (SM-ESI). (Doc. 511). The duties of the SM-ESI, and the allocation of his fees, were set forth by Court order. *See* Doc. 546 (setting forth duties); Doc. 688 (allocating fees as follows: plaintiffs pay 10% and defendants pay 90%). The SM-ESI kept the Court informed of developments in the production process through periodic status reports. (Docs. 613, 663,

747, 812, 939).

With the assistance of the SM-ESI, the defendants were largely able to get production of electronically-stored documents back on track. *See* Doc. 901 (certifying substantial completion of production). Meanwhile, the Court set a hearing to determine the type and amount of sanctions due to the plaintiffs for earlier production lapses; however, after presenting various pre-hearing discovery disputes to the Court for resolution and two postponements, the parties notified the Court that they had reached a confidential settlement agreement as to the nature and amount of sanctions. (Doc. 854). As a result of the settlement, the Court agreed to modify the SM-ESI's duties to define the extent to which prior production issues could be considered in assessing the pace of the defendants' future production. (Doc. 868 (approving stipulation at Doc. 855)).

From time to time, the Court was called upon to resolve disputes regarding the plaintiffs' entitlement to documents in the defendants' possession. The following is a summary of the discovery the defendants were compelled to produce:

- unredacted documents related to alleged improper relationships of former AstraZeneca employee, Dr. Wayne MacFadden (Doc. 485, affirmed by Judge Conway at 601).
- documents reviewed by AstraZeneca's corporate witnesses in preparation for depositions, except individual documents deemed privileged (Doc. 820, affirmed by Judge Conway at 880).
- internal and external communications, including emails, regarding protocols for clinical study 125 (Doc. 869)
- communications between members of the Benefit/Risk Team for Seroquel (Doc. 869)
- notes regarding contacts with any foreign regulatory authority in the UK, Australia,

Canada, Japan, Sweden and the Netherlands relating to Seroquel to the extent the information is located in the United States and kept in electronic form (Doc. 869)

- UK Marketing Authorization Applications relating to Seroquel to the extent the information is located in the United States and kept in electronic form (Doc. 869)
- Principles of Prescription Drug Promotion (Doc. 869)
- written question and oral depositions of "key opinion leaders," i.e., company-retained professors and clinicians who write and speak on the virtues of Seroquel (Doc. 884).
- metadata associated with redactions of previously produced documents (Doc. 1032)
- all documents related to submissions to the FDA regarding Seroquel, including associated correspondence, up to October 31, 2008 (Doc. 1142).

Case-Specific Discovery

The Court authorized and supervised a limited case-specific discovery program beginning in August 2007. The program focused on 30 cases per month (10 chosen by the plaintiffs, 10 chosen by defendants and 10 chosen by the Court), and the defendants were permitted to take up to three depositions in each case (plaintiff, treating physician, and prescribing physician). (Doc. 225). The cases were chosen from a jointly compiled list of plaintiffs who had served substantially complete Plaintiff Fact Sheets and medical records authorizations. In accordance with Case Management Order No. 4 (Doc. 263), the defendants were required to provide to the plaintiffs relevant documentation regarding sales representative contact with a designated plaintiff's prescribing physician. Such documentation included call notes, accounts payable records, and IMS and PIR database information regarding the prescribing physician, and was to be produced in a readily accessible format. (Doc. 348). Upon receipt of this information, designated plaintiffs were permitted to depose one sales

representative per prescribing physician. (Doc. 263).

Initially, the parties were responsible for arranging all dates and locations for depositions, subject to the guidelines set forth in Case Management Order No. 4 (Doc. 263); however, upon agreement of the parties, BrownGreer PLC was appointed as a Project Management Office (SM-PMO) to assist them with gathering medical records and scheduling depositions. (Doc. 348). The SM-PMO issued monthly reports to the Court regarding the progress of the case-specific discovery program, and occasionally resolved disputes between the parties regarding the exchange of discovery documents. At the SM-PMO's request, the Court entered four Administrative Orders to assist the PMO and the parties with particular problems encountered within the initial case-specific discovery program. *See* CS Administrative Order No. 1, Doc. 483 (authorizing PMO contact with physicians; governing payment of physician and medical record fees; authorizing PMO to issue subpoenas to physicians to compel attendance at depositions); CS Administrative Order No. 2, Doc. 484 (setting limits on fees for physician time and patient record production); CS Administrative Order No. 3, Doc. 547 (modifying time for designation of cases for case–specific discovery); and CS Administrative Order No. 4, Doc. 1000 (governing physicians' duty to accept court-approved medical records form). Though relatively successful, the program was terminated at the end of 2007 to allow more time and resources to be directed toward preparing the Florida Trial Group[5] cases for trial. (Doc. 792). Thus, most transferor courts will find that no case-specific discovery has been conducted in remanded cases.

Expert Discovery

[5] As will be explained in more detail later in this Order, this bellwether trial group, involving cases filed directly in the Middle District of Florida and cases in which the parties consented to venue in this district, was formed to give the parties the opportunity to move some cases more quickly toward trial during the pendency of the MDL.

The parties entered into a stipulation regarding the use of expert discovery in multiple MDL cases. (Doc. 1138).

Privileged Materials

Case Management Order No. 2 (Doc. 129) required the defendants to provide a privilege log to the plaintiffs in compliance with the Federal Rules of Civil Procedure. The plaintiffs eventually mounted a challenge to the defendants' privilege designations, requiring the Court to conduct an *in camera* inspection of a representative group of documents, along with privilege log entries. Upon inspection, it appeared that the bulk of these documents were not privileged, but the Court agreed to conduct a more in-depth review with the assistance of a designated AstraZeneca representative at a future date and time. (Doc. 980). At that ex parte conference, the Court issued guidelines to assist AstraZeneca with remedying the apparent over-designation. The plaintiffs' reassertion of their challenge almost a year later was rejected as untimely. (Doc. 1546).

Protective Order/Confidentiality

For the first year of the litigation, document confidentiality was maintained via a stipulation between the parties. At the parties' urging, however, a protective order governing the designation, handling, use and disclosure of confidential discovery materials was entered in September 2007. (Doc. 478). The Court later approved the parties' proposal for a third party endorsement of the protective order (Doc. 541), with minor modifications (Doc. 587). Witness refusal to endorse the protective order was remedied by an amendment allowing the use of confidential documents at depositions but otherwise prohibiting their release via attachment to exhibits or transcripts stemming from the deposition. (Doc. 1032, approving stipulated amendment at Doc. 1027).

The plaintiffs' request for a protective order barring AstraZeneca sales representatives from

contact with treating and prescribing physicians in the cases slated for case-specific discovery was denied due to lack of record evidence that such contacts constituted a pattern of untoward behavior. (Doc. 639).

The protective order played a prominent role in documents filed with respect to *Daubert* and summary judgment motions in the Florida Trial Group cases. At that time, with guidance from the Court at a hearing, the parties were permitted to file portions of their motions and responses under seal if they contained confidential patient medical information or other presumptively confidential company information. This permission was granted provided the parties subsequently filed redacted versions in the public docket so that the public interest in viewing them could be realized.

Before the parties were able to agree on appropriate redactions for these documents, however, Bloomberg L.P. requested to intervene in the case to assert the right of the press to access documents filed under seal. Bloomberg was permitted to intervene for the limited purpose of being heard at a scheduled hearing on the matter. At that hearing, however, the parties announced that they had reached an agreement in which AstraZeneca was to de-designate all but a few documents, contained within six defined document categories, previously filed under seal. Within a few days of the hearing, public versions of AstraZeneca's *Daubert* and summary judgment motions, as well as the plaintiffs' responses to these motions, were filed.

A few months later, the parties informed the Court that they had agreed both upon de-designation of documents contained in three of the remaining categories (2008 FDA correspondence, unpublished clinical study reports, and documents related to Dr. MacFadden) and retention of confidential status for the remaining three categories (post-January 2004 sales representative call notes, IMS data, and foreign regulatory documents). Believing that all documents should be de-

designated, Bloomberg filed a motion to unseal the remainder of the documents retained as confidential. The motion was granted in part and denied in part as follows: (1) post-January 1, 2004 sales representative call notes were removed from coverage under the protective order, with specified redactions; (2) IMS Health, Inc. data reflecting the prescribing histories of doctors used by AstraZeneca for marketing Seroquel was removed from coverage under the protective order, with specified redactions; and (3) Dutch and French regulatory documents did not require unsealing because they were irrelevant and inadmissible at trial. (Doc. 1497, affirmed by Judge Conway at 1556).

***Zyprexa* Documents**

It came to the Court's attention early on in the litigation that a handful of plaintiffs in this MDL may also have advanced similar claims in the Zyprexa MDL. The defendants were permitted to seek discovery of certain litigation-related documents in the possession of the manufacturer of Zyprexa, Eli Lilly & Co. (Doc. 586), as well as the plaintiffs involved in both litigations (Doc. 1024).

Non-Party Documents

In late 2007, the plaintiffs sought to compel discovery of documents in possession of a number of third party vendors who had provided marketing, training and publishing services to AstraZeneca in relation to Seroquel. Some of these vendors, Parexel MMS, Simpson Healthcare Executives, Saatchi & Saatchi Healthcare, Harris Interactive, Inc., and Edelman, Inc., opposed this discovery request on the ground that it was overbroad and unduly burdensome. The disputes were originally filed in the District of Connecticut and the Southern District of New York, but the presiding judges opted to transfer them to the Middle District of Florida to be collectively handled by Judge Baker in the context of the MDL.

The disputes involving Simpson Healthcare Executives and Saatchi & Saatchi Healthcare were resolved among the parties with the Court's guidance over the course of three hearings. Edelman, Inc. was compelled to make a rolling production of the non-privileged documents requested by the plaintiffs (Doc. 723), but the remainder of the dispute was resolved among the parties with the Court's guidance. Finally, after further conference with plaintiffs' counsel at the Court's direction, Harris Interactive, Inc. agreed to produce a narrowed list of documents requested by the plaintiffs and was ordered by the Court to bear its own costs of such production (Doc. 733).

Parexel was ordered to produce a corporate representative with knowledge of the Seroquel-related documents in Parexel's possession for a 30(b)(6) deposition (Doc. 723), and, after further meetings with plaintiffs' counsel, the company agreed to produce a narrowed group of documents without the need for Court intervention. A few months later, the Court was called upon to intervene in a dispute over the timeliness of Parexel's production of these documents, and ultimately ordered the company to make production on a revised timetable. (Doc. 897).

GLOBAL ISSUES

Preemption

Early in the litigation, AstraZeneca sought judgment on the pleadings with respect to the plaintiffs' failure to warn claims, arguing that they were preempted by federal law. At that time, the Court determined that the motion was too narrowly framed (encompassing only a portion of the failure to warn claim) and denied the motion without prejudice to refiling at a later stage of the litigation. (Doc. 644).

Renewed briefing on the issue was solicited by the Court shortly after the United States

Supreme Court issued its opinion in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), a prescription drug preemption case presenting substantially the same issues previously raised by AstraZeneca. Ultimately, the Court has decided that the issue turns on disputed facts and is not amenable to resolution without trial. The Court expects to rule on preemption, if raised, in conjunction with the next case scheduled for trial.[6]

Admissibility of Expert Testimony

The defendants sought to exclude the testimony of three of the plaintiffs' general causation experts, Drs. Laura Plunkett, Donna Arnett and William Wirshing.[7] The general causation testimony of all three of these experts was found to be admissible under *Daubert*. *See* Doc. 1271 (Dr. Wirshing); Doc. 1465 (Dr. Arnett); Doc. 1467 (Dr. Plunkett). As well, certain challenged non-causation testimony of these experts was found to be admissible. (Doc. 1480).

Trial Preparation

The Court assisted the parties with preservation of the generic fact witness testimony of Dr. Lisa Rarick (AstraZeneca's FDA regulatory expert) and Dr. John Patterson (former AstraZeneca officer), as well as the general causation expert testimony of Dr. Paul Woolf (AstraZeneca's expert). An additional AstraZeneca fact witness, Mark Scott, was withdrawn from live testimony. The Court ordered the defendants to submit his deposition in lieu of live testimony by September 30, 2009.

[6] Five Florida cases are presently scheduled for trial beginning in July 2010. As well, the first wave of Eleventh Circuit Trial Cases is set for trial beginning in January 2011.

[7] Though these motions were filed in the context of the Florida Trial Group cases, the Court was guided by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93 (1993) and its progeny, thus rendering these rulings applicable in federal courts as well as state courts operating under *Daubert*.

(Doc. 1478). Mr. Scott's deposition has never been filed. Therefore, the Court recommends that transferor courts prohibit AstraZeneca from calling Mark Scott as a witness in any future Seroquel trial.

Each witness' testimony was videotaped for use at multiple Seroquel trials. To facilitate near-seamless incorporation of pre-recorded testimony into future trials, the parties compiled a joint master trial exhibit list that is intended to be used in all future Seroquel trials. *See* Doc 1525. The Court attempted to issue rulings on objections to other generic fact witness testimony submitted by deposition but ultimately found that evaluation of the testimony outside the context of trial was unduly burdensome. Thus, this task will fall to the transferor courts to handle on a case-by-case basis.

CASE-SPECIFIC ISSUES REMAINING TO BE DECIDED BY TRANSFEROR COURTS

The following is an outline of the significant case-specific issues transferor courts should be prepared to entertain once case-specific discovery is complete.

Choice of Law

Resolution of the state law to be applied to a particular case is a necessary precursor to any informed consideration of the merits of state law claims. As the Court will explain later, transfer of cases to venues in which the plaintiffs reside should, in most cases, ease the difficulty of making the choice of law determination. As well, the parties may be willing to stipulate to the applicable state law, as they did in the Florida cases.

Merits of Substantive Claims

Transferor courts should be prepared to address the elements and burdens of proof for all state law claims, including strict liability failure to warn and design defect, negligence, fraud/intentional

misrepresentation, negligent misrepresentation, breach of warranty, conspiracy, and consumer protection act claims. Medical causation, both general and specific, is likely to be a particularly contentious issue. Causation standards vary among states and, as this Court saw in the first two Florida Trial Group Cases, they are often difficult to pin down and apply. *See, e.g.*, *Guinn v. AstraZeneca Pharms. LP, et al.*, 598 F. Supp. 2d 1239, 1244-46 (M.D. Fla. 2009).

Daubert

Transferor courts should expect *Daubert* challenges to case-specific medical and damages experts. This Court's *Daubert* rulings in two of the Florida Trial Group cases may be helpful in this regard. *See Guinn v. AstraZeneca Pharms. LP, et al.*, 598 F. Supp. 2d 1239 (M.D. Fla. 2009), *aff'd*, No. 09-11104, 2010 WL 1286947 (11th Cir. April 6, 2010); *Haller v. AstraZeneca Pharms. LP, et al.*, 598 F. Supp. 2d 1271 (M.D. Fla. 2009).

Statutes of Limitations

The defendants have not submitted any statutes of limitations issues for this Court to resolve. Therefore, the Court anticipates that transferor courts will be required to evaluate whether the plaintiffs have timely filed their claims on a case-by-case basis.

Learned Intermediary Doctrine

The affirmative defense likely to command the most attention will be the learned intermediary doctrine, a defense that is variably accepted and applied among the states. Transfer of cases to their "home" districts would help alleviate the need for application of foreign state law.

Damages Caps and Other Limitations on Recovery

Transferor courts should be prepared to sort out whether each plaintiff's recovery of damages is barred or limited by state statute or any of AstraZeneca's affirmative defenses, e.g., failure to

mitigate or contributory/comparative fault. Also, as previously indicated, some plaintiffs in this litigation may have also filed their cases in the *Zyprexa* litigation. Therefore, transferor courts should expect to encounter motions seeking dismissal based on a plaintiffs' prior recovery of damages in *Zyprexa*.

FURTHER PROCEEDINGS NEEDED IN REMAND COURTS

As an initial matter, the Court recommends that, after considering and facilitating any recommended re-transfers as detailed in the next section, transferor courts stay remanded cases until the next wave of Florida Trial Group cases achieve final disposition in this Court, whether by jury verdict or summary judgment. The first of these cases is scheduled for trial in July 2010.

Transfer to "Home" Districts

As previously mentioned, early in the litigation the Court recognized that the bulk of the cases transferred as MDL member cases were originally filed in the District of Massachusetts. As it turned out, only a handful of these cases were filed by plaintiffs who actually resided in Massachusetts. Plaintiffs' counsel never clearly articulated the reason for these mass filings in Massachusetts and the Court has been unable to discern a reason on its own. In the Court's view, the most efficient way to handle these and other cases on remand is to transfer them to the district in which they should have been filed. Doing so would not only ease the District of Massachusetts' burden of handling thousands of cases after remand, but would, in most cases, allow transferor courts to avoid interpreting and applying the law of states other than those in which they sit. Thus, at the Court's request, the parties filed a list of all cases pending in the MDL identifying each plaintiff's name, case number, states of residence and citizenship and the district in which the case was originally filed. (Doc. 1385). The

Court has used this data, along with the amended short-form complaints filed in each case, to provide recommendations to transferor courts regarding potential districts in which these cases should have been filed. These recommendations are set forth for each remanded case in Exhibits A and B. Transferor courts must decide whether it is prudent to transfer non-resident cases to the district in which they should have been filed in accordance with this Court's recommendations. Similarly, courts should be prepared to receive new cases from other districts who have decided that transfer to the plaintiffs' home districts is preferable.

Case Assignment/Management

Upon receipt of remand cases (including any that are re-transferred to their "home" districts), transferor courts will have a few initial case management decisions to make, e.g., how cases should be assigned within the district, how many judges should be involved, and whether a single magistrate judge should be assigned for remaining non-dispositive pretrial matters. In districts receiving a large number of remanded cases, transferor courts may wish to designate lead and liaison counsel to coordinate any remaining discovery and pretrial efforts. Case Management Order No. 1 (Doc. 130) may be helpful in this regard.

General Discovery

All general fact and expert discovery in these cases has been completed before remand. Therefore, transferor courts need not be concerned with facilitating general expert, corporate and third party discovery unless the plaintiffs make a compelling request based on new developments in the case. Should transferor courts deem it appropriate to reopen general fact discovery, they are urged to implement the rules and procedures for Rule 30(b)(6) depositions set forth in Case Management Order No. 3 (Doc. 193), if applicable.

Case-Specific Discovery and Trial Preparation

Except in a handful of cases that participated in the limited case-specific discovery program, all case-specific discovery has been reserved for the transferor courts. (Docs. 1419, 1593). In some cases, discovery documents provided to the defendants by the plaintiffs, e.g., Plaintiff Fact Sheets, accompanying responsive documents, and medical records authorizations, are over three years old. Therefore, at the outset, and after consultation with the parties regarding the need for fact sheet updates, courts should set a due date for service of materially complete updated Plaintiff Fact Sheets and accompanying responsive documents. Courts are encouraged to implement a remedy for untimely, incomplete or absent fact sheets similar to the one used by this Court in Case Management Order No. 2 (Doc. 129), as amended (Doc. 285).

In districts receiving a substantial number of remand cases, transferor courts may find it useful to conduct their own bellwether trial program rather than moving all cases toward trial at once. In these instances, the Court recommends a case selection and discovery plan similar to that implemented in this Court in the Florida Trial Group cases. What follows is a brief overview.

Case Management Order No. 5 (Doc. 792), as later amended (Doc. 957), outlines the procedure for selection of cases for trial. In short, seventy-five cases were selected for limited case-specific discovery, and then thirty of those cases were eventually selected for full case-specific discovery. The Court highly recommends urging the parties to employ the services of a Project Management Office to coordinate the retrieval of medical records from physicians as well as the dates and locations of depositions. Transferor courts may also want to give the Project Management Office limited authority to arbitrate disputes pertaining to case-specific discovery. *See* Doc. 943 (outlining procedures for seeking relief from SM-PMO and Court). In addition, CS Administrative Orders 1,

2 and 4 (Docs. 483, 484, 1000) may prove useful tools for transferor courts dealing with complaints about physicians who are reluctant or unwilling to hand over medical records or give depositions.

Limited Case-Specific Discovery

Limited case-specific discovery in seventy-five cases should require three to four months to complete. This so-called "Discovery Pool" should be composed of twenty-five cases chosen by the plaintiffs, twenty-five cases chosen by the defendants and twenty-five cases chosen by the Court.

By the time cases are chosen for limited case-specific discovery, the defendants should already be in possession of substantially complete and updated Plaintiff Fact Sheets and medical records authorizations for all plaintiffs whose cases have been remanded. In addition, transferor courts should require the defendants to provide documentation regarding any AstraZeneca sales representative contact with prescribing physicians in cases designated for limited discovery, preferably within two weeks of designation. (Doc. 792).

The defendants should be permitted to designate and take a maximum of three depositions per case (the plaintiff or his or her personal representative, treating physician, and prescribing physician). (Doc. 225). In addition, within one week of receiving sales representative documentation, the plaintiffs should be permitted to designate for deposition one sales representative associated with each prescribing physician to be deposed by the defendants. (Doc. 792).

Depositions should generally not exceed seven hours of actual deposition time, absent agreement or court order. (Doc. 263). Physician depositions should be limited to fours hours—two hours for the defendants and two hours for the plaintiffs. (Doc. 792). Sales representative depositions should also be limited to four hours. (Doc. 263). Counsel may be permitted to increase

the time for physician and sales representative depositions to a maximum of seven hours by agreement. (*Id.*). ***Full Case-Specific Discovery***

Of the cases remaining in the discovery pool following the close of limited discovery, at least 30 cases should be selected for full discovery (15 chosen by the plaintiffs, 15 chosen by defendants). Full discovery in these "Initial Trial Pool" cases should take no longer than three or four months to complete and should generally be conducted in accordance with the Federal Rules of Civil Procedure.

Specifically, each party should be permitted to depose a maximum of ten witnesses in each case. (Doc. 1006). Witness designations should be served no later than twenty days following the selection of the Initial Trial Pool cases. (*Id.*). Further guidance regarding the procedures used to designate witnesses and to count designations against each party's ten deposition limit can be found in CS Administrative Order No. 5 (Doc. 1006).

All depositions except sales representative depositions should be subject to the seven-hour time limit contained in Fed. R. Civ. P. 30(d). Sales representative depositions should be limited to 5 hours. (Doc. 792). The parties should be permitted to re-depose witnesses who were deposed during limited case-specific discovery; however, these depositions should still count against the limit of 10 depositions per side. (*Id.*).

Trial Groups

At the close of fact discovery, transferor courts should further narrow the group of cases scheduled for trial. For example, in the Florida Trial Group cases, two groups of twelve cases were selected. (Doc. 1044). Within each group, cases were ranked, and trial was to proceed in the plaintiffs' highest ranked case first, followed by the defendants' highest ranked case, and further alternating accordingly. (*Id.*). Separate pretrial deadlines were set forth for each of the two groups,

with the first group completing pretrial preparation a few months before the second group. (*Id.*, as modified at Doc. 1059).

Expert Discovery

Closely following the close of fact discovery, the parties should be required to exchange reports for all case-specific experts expected to testify at trial, with each party permitted to depose the other party's experts within the month or so following receipt of the expert reports. (Doc. 792). All general experts should already have been designated and deposed prior to remand.

In the interest of preserving the defendants' choice of local medical experts, the defendants should be permitted to retain a local physician as an expert in a trial group case even if they have been listed as a treater or prescriber on another trial group plaintiff's fact sheet. (Doc. 912, affirmed by Judge Conway at Doc. 973). A court-approved Memorandum to Doctors stating the limitations of communications about other plaintiff-patients may be useful in this regard. (Doc. 913).

Final Preparation

Final trial preparation in the Florida Group One cases was governed by two additional Court orders. (Docs. 1181, 1187). The Court's *in limine* rulings (Docs. 1253 (affirmed at 1348), 1261 and 1471) in the Florida cases may be useful in other jurisdictions.

SUMMARY OF RECOMMENDATIONS

Case Management

1. Re-transfer appropriate cases (p. 21)

2. Anticipate transfer in of cases (p. 21)

3. Establish case management plan based on number of cases (p. 22)

4. Establish discovery, pretrial motion and trial schedules (see pp. 22-6)

5. Temporary stay while Florida Trial Group cases are tried should be considered (pp. 20-1)

Discovery

1. If not already done, each plaintiff should provide properly executed up-to-date Plaintiff Fact Sheets (pp. 22-3)

2.General discovery is completed and closed (p. 22)

3. Strong limits on case-specific discovery should be established (pp. 22-4)

4. Special Master (PMO) is available to assist the parties with scheduling depositions and obtaining medical records (p. 23)

Alternative Dispute Resolution

Special Master Stephen Saltzburg should be appointed to continue his efforts (p. 7)

Legal Issues

The following legal issues are likely to arise, and the court should consider appropriate methods for the issues to be presented for efficient disposition:

- Choice of law (p. 19)
- Federal preemption (p. 17)
- Substantive merits (especially specific causation as to each case under applicable state law) (p. 19)
- Daubert issues (primarily as to causation and damages) (p. 19-20)
- Statute of limitations (p. 20)
- Learned intermediary doctrine (p. 20)
- Damages caps (p. 20)

OTHER PROCEEDINGS IN THIS COURT

Florida-Related Consent-to-Venue Cases

Early efforts to form a Florida trial group were thwarted by the lack of cases filed directly in the Middle District of Florida. To remedy the situation, the parties mutually consented to re-lay venue in this district in approximately 180 Florida-related cases originally filed in the District of Massachusetts and elsewhere. *See* Docs. 726, 727. It was generally agreed among the parties that this was the only way the cases could be tried in Florida without offending the principles set forth in *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach, et al.*, 523 U.S. 26 (1998). Therefore, these cases, although originally filed elsewhere, will remain in the Middle District of Florida for ultimate disposition. A list of these cases is attached as Exhibit C.

Status of Florida Trial Group

The first case up for trial (the plaintiffs' highest-ranked case) was *Linda Guinn v. AstraZeneca Pharms. LP, et al.*, No. 6:07-cv-10291-Orl-22DAB. Shortly before trial was to begin in the *Guinn* case, however, the defendants were awarded summary judgment on all claims both for Guinn's failure to secure a specific causation witness whose testimony was able to meet *Daubert*, and failure to uphold her burden of demonstrating that Seroquel was the specific cause of her diabetes. *See Guinn v. AstraZeneca Pharms. LP, et al.*, 598 F. Supp. 2d 1239 (M.D. Fla. 2009), *aff'd*, No. 09-11104, 2010 WL 1286947 (11th Cir. April 6, 2010). The defendants' highest-ranked case, the next case in line to be tried, met the same fate.[8] *See Haller v. AstraZeneca Pharms. LP, et al.*, 598 F. Supp. 2d 1271

[8] In addition, the Court is aware of at least three other recent state court decisions granting summary judgment in favor of AstraZeneca due to the plaintiff's failure to produce admissible evidence of proximate cause. *See Scaife v. AstraZeneca LP*, No. 06C-04-218 SER, 2009 WL 1610575 (Del. Super. Ct. June 9, 2009); *Hopkins v. AstraZeneca Pharms. LP and AstraZeneca LP*, No. 06C-01-325 SER, 2010 WL 1267219 (Del. Super. Ct. March 31, 2010); *Jones v. AstraZeneca LP, et al.*, No. 07C-01-420-SER, 2010 WL 1267114 (Del. Super. Ct. March 31, 2010).

(M.D. Fla. 2009).

After consulting the parties regarding their desire to continue preparing Florida cases for trial, and noting that Guinn planned to appeal, the Court administratively closed the remainder of the Group One cases (Doc. 1331), denied without prejudice case-specific *Daubert* motions (Docs. 1483, 1484 & 1485) and opted to put the Florida cases on hold pending the outcome of the *Guinn* appeal. The Eleventh Circuit Court of Appeals' opinion was issued on April 6, 2010, and affirmed the Court's exclusion of Guinn's specific causation expert on *Daubert* grounds. *See Guinn v. AstraZeneca Pharms. LP, et al.*, No. 09-11104, 2010 WL 1286947 (11th Cir. April 6, 2010). The Court has scheduled a final pretrial conference in the remaining five Group One cases for June 2010, with the first of these trials to commence in July 2010.

Third-Party Payor Cases

Three cases instituted by health and welfare benefit plans were transferred by the Panel in December 2007. *See Ironworkers Local Union No. 68 & Participating Employers Health & Welfare Funds, et al. v. AstraZeneca Pharms. LP, et al.*, No. 6:07-cv-5000-Orl-22DAB; *International Brotherhood of Electrical Workers Local 98 v. AstraZeneca Pharms. LP, et al.*, No. 6:07-cv-5001-Orl-22DAB; *Teamsters Joint Council Local No. 53 Retiree Health & Welfare Fund v. AstraZeneca Pharms. LP*, No. 6:07-cv-5002-Orl-22DAB. The three cases were consolidated under Case No. 6:07-cv-5000-Orl-22DAB, and the plaintiffs were ordered to file an amended consolidated complaint. (Doc. 848). In a nutshell, the complaint alleged that the defendants engaged in an illegal scheme to market Seroquel for off-label uses, in violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO), various state consumer protection statutes and the common law. As a result of the defendants' illegal conduct, the plaintiffs claimed that they were duped into paying

hundreds of millions of dollars for Seroquel both to treat conditions for which the drug was not approved and where less expensive, and equally safe and effective, alternative treatments existed. The defendants' motion to dismiss the complaint was granted for the plaintiffs' failure to sufficiently demonstrate that the defendants' actions caused the plaintiffs to suffer the damages they claimed. *See* Doc. 49, *Ironworkers Local Union 68 and Participating Employers Health and Welfare Funds, et al. v. AstraZeneca Pharms. LP, et al.*, No. 6:07-cv-5000-Orl-22DAB. The plaintiffs appealed the ruling, and the case was argued in the Eleventh Circuit Court of Appeals in February 2010.[9]

Another third party payor case transferred by the Panel in February 2009 was dismissed on similar grounds. *See* Doc. 17, *Pennsylvania Employees Benefit Trust Fund v. AstraZeneca Pharms. LP, et al.*, No. 6:09-cv-5003-Orl-22DAB.

NMS Cases

In April 2008, the Panel transferred two actions involving plaintiffs who alleged they developed Neuroleptic Malignant Syndrome as a result of their use of Seroquel. *See Hensley v. AstraZeneca Pharms. LP, et al.*, No. 6:08-cv-6000-Orl-22DAB; *Garza v. AstraZeneca Pharms. LP, et al.*, No. 6:08-cv-6001-Orl-22DAB. These cases were promptly integrated into the MDL and proceeded under the scheduling and case management orders governing the diabetes cases. *See, e.g.*, Doc. 9, *Hensley v. AstraZeneca Pharms. LP, et al.*, No. 6:08-cv-6000-Orl-22DAB. At that time, the Court learned that there were six other cases pending in the MDL in which the plaintiffs had alleged only NMS as their injury and 39 cases in which the plaintiffs had alleged NMS as among several

[9] On a related note, AstraZeneca recently finalized a settlement with the U.S. Justice Department regarding alleged illegal marketing and sales practices. *See, e.g.*, Brent Kendall, *UPDATE: Justice Dept Confirms Settlement In Seroquel Probe*, The Wall Street Journal, Apr. 27, 2010, http://online.wsj.com/article/BT-CO-20100427-717519.html.

injuries. An April 2009 update showed two additional cases in which the plaintiffs named NMS among their alleged injuries. The parties have not sought discovery specific to these cases in this Court, and, to the extent NMS-specific discovery is incomplete, the Court reserves coordination of this discovery for the appropriate transferor courts.

Eleventh Circuit Trial Group

In an effort to move a group of cases toward trial while the Florida cases were on hold pending the outcome of the *Guinn* appeal, a new trial group consisting of cases filed in the Eleventh Circuit by non-Florida-resident plaintiffs was recently formed. *See* Doc. 1586. Though some of the cases in the trial group were originally filed in other districts within the Eleventh Circuit, they will be eligible for trial in the Middle District of Florida via intra-circuit assignment. These cases, contained in Exhibit D,[10] therefore, do not require remand to their respective transferor jurisdictions.

Shortly after the cases within the new trial group were announced, nineteen trial group plaintiffs represented by the same law firm voluntarily dismissed their cases. These cases were refiled in the District of Minnesota within days, and were eventually transferred back to this MDL via the Panel. Though these cases are no longer cases that can be tried in the Middle District of Florida, the plaintiffs have been ordered to rejoin the trial group for pretrial and discovery purposes. *See* Doc. 1606. Thus, it is contemplated that these cases, contained in Exhibit E, will proceed along with the second wave of Eleventh Circuit trial group cases up until trial, at which time this Court will suggest that they be remanded to the District of Minnesota. Should the Panel wish to remand these cases at the same time as all other cases, the transferor court is urged to maintain the pretrial schedule

[10] Exhibit D also contains intra-circuit assignment cases that are not part of the trial group.

set forth in this Court's amended scheduling orders.

DONE and **ORDERED** in Chambers, in Orlando, Florida on May 13, 2010.

Copies furnished to:

Counsel of Record
Unrepresented Party

ANNE C. CONWAY
United States District Judge