UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

MDL DOCKET NO. 1769

This Document Relates to ALL CASES

DEFENDANT ASTRAZENECA'S STATEMENT OF ISSUES FOR CONSIDERATION DURING DECEMBER 11, 2006 STATUS CONFERENCE

In addition to those issues the Court has requested the parties to be prepared to address, AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca") propose the following issues for discussion during the Court's December 11, 2006 Status Conference:

1. **Status Report:** Counsel will be prepared to report to the Court on the inventory of cases in this MDL and, for informational purposes, on the Seroquel cases in state courts.

2. **Proposed Case Management Order:** Attached as Exhibit A is a proposed comprehensive Case Management Order addressing a number of organizational and logistical issues.

3. **Clarification of Order Establishing PFS Deadlines:** AstraZeneca seeks clarification as to how the Court will identify which of the 500-plus plaintiffs will be subject to a specific PFS deadline in a situation in which more than 500 plaintiffs are transferred to the MDL at the same time.

4. **Dismissal of Cases:** Counsel will be prepared to discuss various mechanisms that the Court might consider to winnow out groups of cases.

5. **Pilot Program:** Almost 7,000 plaintiffs have or soon will have Seroquel® claims pending in this MDL. Given this number of plaintiffs and the generality of the allegations, the parties agree that it would be beneficial to conduct full discovery and engage in pretrial motion practice with regard to a subset of plaintiffs (sometimes referred to as "bellwether" or "pilot" plaintiffs). This type of docket-management device, or "Pilot Program," has been used in other MDL litigation to manage dockets efficiently. *See, e.g., In re Baycol Prods. Litig.*, MDL-1431, Pretrial Order No. 89 (Exhibit B).

A Pilot Program would likely have two main benefits here. First, a Pilot Program would provide a mechanism for the parties to advance the pretrial discovery and motion practice that needs to be done before any of the cases are remanded to the transferor courts. By allowing the parties to focus trial preparation on a subset of cases, issues that are likely to affect all or many of the remaining cases can be identified. Important pre-trial motions could then be decided earlier than if case specific-discovery is delayed. The rulings in the Pilot Program cases would provide useful guidance for the transferor courts in all the remaining cases. For example, defendants expect there to be numerous issues related to substantive claims and admissibility of evidence. Orders that this Court issues in the Pilot Plaintiff cases will generate precedent on central issues such as the reliability of expert opinions and the admissibility of other evidence.

Likewise, any rulings on dispositive motions would also be instructive to the transferor courts upon remand. *See, e.g., Cali v. Danek Medical, Inc.* 24 F. Supp. 2d 941, 949 (W.D. Wis. 1998) (after remand, transferor court concluded that plaintiff was bound by MDL court's dismissal of one cause of action where plaintiff had advanced no motion to reconsider the prior dismissal). These important pretrial matters are best decided in the context of a fully prepared case or set of cases rather than in the abstract.

Second, the Pilot Program would allow the parties and the Court to learn more about the types of cases in the MDL and to test the merit of plaintiffs' claims without having to conduct full discovery regarding almost 7,000 plaintiffs — a task that would be nearly impossible to complete in the time frame the Court has set as its goal for completion of the MDL proceedings. Having complete information as to a representative sample of cases is especially important here given that over 6,670 of the 7,000 plaintiffs filed boilerplate complaints with generalized allegations. This would allow the parties and the Court to reach conclusions about the global composition of cases in this MDL.

A Pilot Program is likely to work best if the plaintiffs in it are representative and the selection process operates without bias from either side; otherwise, neither side will have confidence in the information gained from the process. *See* Manual for Complex Litigation 4th § 22.315 (2004). AstraZeneca therefore proposes that plaintiffs be selected randomly. As experience has shown, random selection is often the most accurate method of obtaining a truly

representative range of plaintiffs. *Id.* ("To obtain the most representative cases from the available pool, a judge should direct the parties to select the cases randomly . . . ."); *see also In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997) (noting that to achieve the best representation, "the sample must be a randomly selected one"). Random selection is also the most unbiased plaintiff selection method, because it is by its very nature neutral — not only as between AstraZeneca and the plaintiffs, but also as between the many plaintiffs' firms who have a stake in this litigation. In addition, at this early stage, it is the only fair method for plaintiff selection given that AstraZeneca currently has no information about plaintiffs, whereas plaintiffs' counsel presumably have access to more information about their clients' claims.

The sample size must also be large enough to make sure that the plaintiffs are representative of the variations in the group and to account for inevitable drop outs. Based on the current numbers of cases and principles of sample selection, AstraZeneca proposes selection of a random sample of 300 plaintiffs. Selection of 300 plaintiffs – a little less than five percent of the total number of plaintiffs – should be enough to provide meaningful information about the range of plaintiffs who have pending claims in this MDL.

AstraZeneca proposes that the plaintiffs be selected using the following procedure: all plaintiffs who have cases pending in the MDL as of January 1, 2007, would be arranged in alphabetical order. Each plaintiff would then be assigned a consecutive number, starting with 1 and so on. Using the research tool

known as Research Randomizer (www.randomizer.org), 300 of the numbers would then be generated, yielding the initial list of Pilot Program plaintiffs.

There would be one opportunity for a plaintiff to drop out of the Pilot Program and to be replaced by another randomly selected plaintiff. If a randomly-selected plaintiff chooses to dismiss his or her claims by January 18, 2007, that plaintiff could be replaced with another one also selected randomly. After January 18, no replacement plaintiffs would be permitted. Instead, if a plaintiff chooses to dismiss his or her claims, the Pilot Pool would simply reduce in size.[1]

Plaintiff-specific discovery for the Pilot Program cases would then proceed apace. Each plaintiff in the Pilot Program would be required to submit a Plaintiff Fact Sheet, executed HIPAA releases, and other responsive documents by January 18, 2007, thereby allowing AstraZeneca to commence record collection immediately. If any plaintiff fails to timely meet these requirements, his or her claims would be subject to dismissal with prejudice on AstraZeneca's motion and, in any event, that plaintiff would be eliminated from the Pilot Pool. After receiving the requisite records, AstraZeneca would commence fact witness depositions as to each pilot plaintiff, with the expectation that all such depositions would be complete by August 31, 2007. Once factual discovery is complete, the

---

[1] A continual replacement of dismissed plaintiffs is not viable because it would become impossible for AstraZeneca to take discovery of all the plaintiffs in the program, and there would be no end point at which the Court and the parties could examine the list of surviving cases to reach conclusion about the overall quality and composition of cases in this MDL.

parties would then have approximately six months to conduct discovery of their respective plaintiff-specific experts. Expert depositions would conclude no later than February 22, 2008. Upon completion of plaintiff-specific discovery, the parties would be required to file all *Daubert* and other dispositive motions by March 21, 2008. Opposition briefs would be due by April 22, 2008, and reply briefs by May 12, 2008.

AstraZeneca does not propose the Pilot Program as an alternative to plaintiff-specific discovery in all the remaining cases. Written discovery as to all plaintiffs would proceed with all non-pilot plaintiffs continuing to submit completed Plaintiff Fact Sheets, HIPAA releases, and other responsive documents within the deadlines established by the Court's November 21, 2006 Order. AstraZeneca would collect all relevant records and review the information disclosed by the non-pilot plaintiffs in an effort to expedite the overall litigation. No additional plaintiff-specific discovery would proceed as to non-pilot plaintiffs while the Pilot Program is progressing. The parties would meet and confer after completion of the Pilot Program to discuss the future course of this MDL as to all non-pilot plaintiffs.

6. **Record Collection**: The parties have acknowledged in open court the necessity of expeditiously collecting plaintiffs' records in order that these cases may be properly assessed. Toward that end, on November 17, 2006, counsel for AstraZeneca forwarded plaintiffs' counsel a proposed pretrial order that set forth

the protocol by which plaintiffs' records would be collected. Plaintiffs have recently forwarded comments that AstraZeneca has taken under consideration.

7. **State/Federal Coordination:** All parties will benefit if Seroquel litigation in state courts is coordinated with this MDL. Counsel will be prepared to discuss how such coordination might be achieved.

8. **Preservation of Documents:** Plaintiffs have requested extensive information about AstraZeneca's document preservation efforts. AstraZeneca is gathering the appropriate information, and has had several discussions with plaintiffs' counsel. AstraZeneca suggests that the parties continue to meet and confer regarding preservation issues.

9. **AstraZeneca's Production of Common-Issue Documents:** As Plaintiffs counsel acknowledged, the most efficient and expeditious way to produce documents to plaintiffs is to identify the employees at AstraZeneca with Seroquel responsibilities and to produce documents by custodian. This approach obviates the need for requests for production and the burden to the Court and parties of discovery motions regarding documents. Plaintiffs' "preemption" discovery to AstraZeneca demonstrates the propriety of this approach, as that discovery seeks virtually every document in AstraZeneca's possession related to Seroquel. *See, e.g.*, Plaintiffs' Requests for Production (attached as Exhibit C). AstraZeneca has endeavored to identify relevant individuals and collect all documents from those individuals that relate to Seroquel. AstraZeneca proposes

that it provide plaintiffs with a list of the identified document custodians and that the parties meet and confer to prioritize the custodians for production.

10. **Preemption:** AstraZeneca has refined its thoughts on preemption and will be prepared to discuss the issue with the Court.

11. **Defendant's Fact Sheet:** Plaintiffs have proposed that AstraZeneca be required to provide a Defendant's Fact Sheet ("DFS") for each and every physician who prescribed Seroquel to any one of the thousands of plaintiffs.

Plaintiffs' DFS proposal is unreasonable. Plaintiffs would have AstraZeneca expend extraordinary effort unearthing information about plaintiffs and their doctors in thousands of cases that might be dismissed, abandoned, or disposed of via summary judgment, a preemption motion, or some other mechanism. If DFSs are ever warranted at all, they will be warranted in those cases that are shown after the winnowing process still to have some vitality. AstraZeneca should not have to provide DFSs in cases that will be dismissed early on for failure to fill out the required Plaintiffs' Fact Sheets or medical authorizations, or in which plaintiffs have not taken Seroquel or have no injury.

Further, certain requests in the proposed DFS are improper not just because they are premature and inefficient, but also because they are designed to harass AstraZeneca, rather than gather information relevant to a plaintiff's case. A few examples include:

- all of the requests are unlimited as to time
- many of the requests are not even limited to Seroquel

- plaintiffs request information about every Seroquel sample ever provided to every physician
- plaintiffs request information about tracking physician's prescribing practices.

As described above, AstraZeneca is proposing a "Pilot Program" to allow the Court and the parties to develop a better understanding of the variety of cases in the MDL and the issues that those cases present. It is inevitable that as the Pilot Program progresses, many of the cases will be dismissed – voluntarily or by Order of the Court – and that the Pilot Program will reveal other cases that are ripe for summary judgment motions or the like. As to the cases that remain, the Pilot Program will educate all involved – the Court and the parties – on how the litigation should proceed. If plaintiffs believe at some point down the road, after much more is known about the cases, that the DFS process would be useful, plaintiffs can raise it again with the Court, and AstraZeneca will be prepared to discuss it – a discussion that will be much more useful to the Court because it will be informed by the Court's and the parties' understanding of the cases.

WHEREFORE, AstraZeneca respectfully requests that the above-referenced issues be placed on the agenda for this Court's December 11, 2006 Status Conference.

Respectfully submitted,

/s/ Michael W. Davis
Michael W. Davis
James W. Mizgala
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, IL 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

E-mail: mdavis@sidley.com
jmizgala@sidley.com

Counsel for AstraZeneca Pharmaceuticals LP and AstraZeneca LP

Dated: December 6, 2006

CERTIFICATE OF SERVICE

I hereby certify that, on the 6th of December, 2006, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to the non-CM/ECF participants listed on the attached Service List.

/s/ Michael W. Davis

SERVICE LIST
(As of November 9, 2006)

In Re: Seroquel Products Liability Litigation
MDL Docket No. 1769

Paul J. Pennock, Esq. Michael E. Pederson, Esq. Weitz & Luxenberg, P.C. 180 Maiden Lane - 17th Floor New York, NY 10038 Telephone: (212) 558-5500 Ppennock@weitzlux.com MPederson@weitzlux.com	Camp Bailey, Esq. Michael W. Perrin, Esq. Fletcher Trammell, Esq. Bailey Perrin Bailey, LLP The Lyric Centre 440 Louisiana, Suite 2100 Houston, TX 77002 Telephone: (713) 425-7240 cbailey@bpblaw.com mperrin@bpblaw.com
Larry Roth, Esq. Law Offices of Larry M. Roth, P.A. Post Office Box 547637 Orlando, FL 32854-7637 Telephone: (407) 872-2239 LROTH@roth-law.com	Tommy Fibich, Esq. Fibich, Hampton & Leebron, L.L.P. 1401 McKinney, Suite 1800 Five Houston Center Houston, TX 77010 Telephone: (713) 751-0025 tfibich@fhl-law.com
Matthew F. Pawa, Esq. Law Offices of Matthew F. Pawa, P.C. 1280 Centre St., Suite 230 Newton Centre, MA 02459 Telephone: (617) 641-9550 Mp@pawalaw.com	John Driscoll, Esq. Brown & Crouppen, PC 720 Olive St. St. Louis, MO 63101 Telephone: (314) 421-0216 Jdriscoll@brownandcrouppen.com
Keith M. Jensen, Esq. Jensen, Belew & Gonzalez, PLLC 1024 North Main Fort Worth, TX 76106 Telephone: (817) 334-0762 kj@kjensenlaw.com	Scott Allen, Esq. Cruse, Scott, Henderson & Allen, L.L.P. 2777 Allen Parkway, 7th Floor Houston, Texas 77019 Telephone: (713) 650-6600 sallen@crusescott.com

Matthew E. Lundy, Esq. Lundy & Davis, LLP 333 North Sam Houston Parkway East Suite 375 Houston, TX 77060 Telephone: (281) 272-0797 mlundy@lundydavis.com	Todd Harvey, Esq. Whatley Drake, LLC 2323 2nd Avenue North Birmingham, AL 35203 Telephone: (205) 328-9576 THARVEY@whatleydrake.com
Lawrence J. Gornick, Esq. William A. Levin, Esq. Dennis J. Canty, Esq. Levin Simes Kaiser & Gornick LLP 44 Montgomery Street, 36th Floor San Francisco, CA 94104 Telephone: (415) 646-7160 lgornick@lskg-law.com dcanty@lskg-law.com	Gregory P. Forney, Esq. Shaffer Lombardo Shurin 911 Main Street, Suite 2000 Kansas City, MO 64105 Telephone: (816) 931-0500 gforney@sls-law.com
Robert L. Salim, Esq. Robert L. Salim Attorney at Law PO Box 2069 Natchitoches, LA 71457-2069 Telephone: (318) 352-5999 robertsalim@cp-tel.net	Eric B. Milliken, Esq. 3 Sir Barton Ct. Newark, DE 19702 ***Pro Se***
Justin Witkin, Esq. Aylstock, Witkin & Sasser, PLC 4400 Bayou Boulevard Suite 58 Pensacola, FL 32503 Telephone: (850) 916-7450 Jwitkin@AWS-LAW.com	Louisiana Wholesale Drug Co. Inc. C/O Gayle R. White Registered Agent Highway 167N Sunset, LA 70584 ***Pro Se***
Aaron C. Johnson, Esq. Summers & Johnson 717 Thomas Weston, MO 64098 Telephone: (816) 640-9940 firm@summersandjohnson.com	Catherine Solomon 3100 N.E. 83 Gladstone, MO 64119 ***Pro Se***

Todd S. Hageman, Esq. Simon and Passanante, PC 701 Market St., Suite 1450 St. Louis, MO 63101 Telephone: (314) 241-2929 thageman@spstl-law.com	Randy Niemeyer 15863 Pike 43 Bowling Green, MO 63334 ***Pro Se***
Thomas Campion, Esq. Andrew C. White, Esq. Drinker Biddle & Reath, LLP 500 Campus Drive Florham Park, New Jersey 07932-1047 Telephone: (973) 360-1100 tcampion@dbr.com andrew.white@dbr.com	Matthew J. Hamilton, Esq. Pepper Hamilton 3000 Two Logan Square 18th & Arch Street Philadelphia, PA 19103 Telephone: (215) 981-4000 hamiltonm@pepperlaw.com
Elizabeth Raines, Esq. Baker, Sterchi, Cowden & Rice, LLC 2400 Pershing Road, Suite 500 Kansas City, MO 64108 Telephone: (816) 471-2121 raines@bscr-law.com	Timothy Reese Balducci, Esq. The Langston Law Firm, PA P.O. Box 787 100 South Main Street Booneville, MS 38829-0787 Telephone: (662) 728-3138 tbalducci@langstonlaw.com
Kenneth W. Bean, Esq. Sandberg, Phoenix & von Gontard One City Centre 15th Floor St. Louis, MO 63101-1880 Telephone: (314) 231-3332 kbean@spvg.com	Robert L. Ciotti, Esq. Carlton Fields, P.A. 4221 W. Boy Scout Boulevard Suite 1000 Tampa, FL 33607-5736 Telephone: (813) 223-7000 rciotti@carltonfields.com
Aaron K. Dickey, Esq. Goldenberg and Heller, PC P.O. Box 959 2227 S. State Road 157 Edwardsville, IL 62025 Telephone: (618) 650-7107 aaron@ghalaw.com	Jona R. Hefner, Esq. 3441 W. Memorial, Suite 4 Oklahoma City, OK 73134-7000 Telephone: (405) 286-3000 attorneyokc@hotmail.com

Mark P. Robinson, Jr., Esq. Robinson, Calcagnie & Robinson 620 Newport Center Drive, 7th Floor Newport Beach, CA 92660 Telephone: (949) 720-1288 mrobinson@robinson-pilaw.com	David P. Matthews, Esq. Abraham, Watkins, Nichols, Sorrels, Matthews & Friend 800 Commerce Street Houston, TX 77002-1776 Telephone: (713) 222-7211 dmatthews@abrahamwatkins.com
Robert A. Schwartz, Esq. Bailey & Galyen 18333 Egret Bay Blvd., Suite 120 Houston, TX 77058 Telephone: (281) 335-7744 bschwartz@galyen.com	Robert G. Smith, Jr., Esq. Lorance & Thompson, PC 2900 N. Loop W, Suite 500 Houston, TX 77092 Telephone: (713) 868-5560 rgs@lorancethompson.com
Mary B. Cotton John D. Giddens, P.A. P.O. Box 22546 Jackson, MS 39225-2546	Salvatore M. Machi Ted Machi & Associates PC 18333 Egret Bay Blvd., Suite 120 Houston, TX 77058 Telephone: (281) 335-7744
Howard Nations Howard L. Nations Attorney At Law 4515 Yoakum Blvd. Houston, TX 77006-5895 Telephone: (713) 807-8400	