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June 11, 2007

**Via E-mail and First Class Mail:**

Stephen McConnell, Esq.  
 Dechert, LLP  
 2929 Arch Street  
 Philadelphia, PA 19104

**In Re Seroquel Litigation MDL 1769**


Enclosed, pursuant to our discussion is our Amended Request for Production of Documents to the previously served Plaintiffs' Request for Production of Documents dated May 25, 2007.

As per the discussions between the parties, several requests have been reworded, modified or withdrawn. However, as discussed, the withdrawal of such requests does not indicate that Plaintiffs have agreed not to make the same or similar Requests for Production in the future. Further, as was discussed and agreed to, Defendants will respond to the Amended Request for Production of Documents within 30 days after the service of Plaintiffs' previous Request for Production of Documents, dated May 25, 2007, which service took place on May 25, 2007. Please provide the requested documents or information in a CD format or in a Hard Drive.

The parties also discussed the possibility that Defendants may contend that some document requests have already been provided in previously served Custodial Files and other document productions. Plaintiffs requested and it was agreed that Defendants could respond to such requests by identifying the location of the documents by specific Bates Numbers for said documents.

Thank you for your cooperation, we look forward to your responses.

Sincerely,

  
 Michael Pederson, Esq.

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF FLORIDA

ORLANDO DIVISION

In Re: Seroquel Products Liability Litigation

MDL Docket No. 1769

DOCUMENT RELATES TO ALL CASES

Case No. 6:06-md-01769-ACC-DAB

**PLAINTIFFS' AMENDED REQUEST  
FOR PRODUCTION OF DOCUMENTS**

Pursuant to F.R.C.P. 34, plaintiffs request that defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca PLC, AstraZeneca AB, AstraZeneca UK Limited and any other responding entities both foreign or domestic, within 30 days after the service of Plaintiffs' Request for Production of Documents, dated on May 25, 2007, which service took place on May 25, 2007, serve written responses to the following Plaintiffs' Amended Request for Production of Documents and produce the documents and things herein described at the law offices of Weitz & Luxenberg, 180 Maiden Lane, New York, NY 10038.

INSTRUCTIONS

1. In responding to this Request, you are required to produce all documents known or reasonably available to you, regardless of whether such documents are in your possession, custody, or control or in the possession, custody, or control of your agents,

consignees, representatives or investigators, or your attorneys or their agents, employees, representatives, or investigators.

2. If any of the documents or information requested cannot be produced in full, please specify, to the extent possible, the reasons for your inability to produce the remainder, and the approximate date when you expect to produce such documents, if at all. In the event that responsive documents or information requested herein have already been produced, identify the location of such documents by specific Bates Number and identify the previous Custodial Files or other document productions where said documents or information can be found.

3. With respect to any document that has been lost, destroyed, or otherwise disposed of since its preparation or receipt, please provide the following information separately as to each such document:

- (a) A general description of the subject matter, author, recipient(s), date;
- (b) The identity of each person who has received a copy or had an opportunity to receive a copy;
- (c) The last custodian of the document or copies thereof;
- (d) The full particulars or circumstances whereby the document was disposed of, destroyed, or otherwise lost;
- (e) Copies of any document destruction instructions or directives; and
- (f) Copies of any document destruction acknowledgement forms or receipts for the destruction of documents.

4. With respect to any documents that have been deemed privileged or otherwise protected information or materials, you must provide the following information in a written response, designating and identifying those documents or information withheld from production on grounds of privilege:

- (a) The reason for withholding the document or information;
- (b) A statement of the legal basis for the claim of privilege, work product or other ground for non-disclosure;
- (c) A brief description of the document, including:
  - a. The date of the document;
  - b. The number of pages, attachments and appendices; and
  - c. The name(s) of its author(s) or preparer(s) and identification by employment and title of each such person.
- (d) The name of each person who sent, received, was copied on, or had custody of the document, together with an identification of each such person;
- (e) The present custodian; and,
- (f) The subject matter of the document, and in the case of any document relating or referring to a meeting or conversation, identification of such meeting or conversation, in sufficient detail to enable the Court to determine the propriety of any claim of privilege.

5. All documents produced in response to this request shall be either:

- (a) Organized and labeled to correspond with the number of the specific demand to which the documents are responsive, or
- (b) Produced in the order and in the manner that they are kept in the usual course of business.

6. All documents requested shall include all documents and information that relate in whole or in part to the relevant time period, or to events or circumstances during such relevant time period, even though dated, prepared, generated or received prior to the relevant time period.

7. All documents should be produced in accordance to CMO2 and the agreed upon changes made between the parties on May 30, 2007 .

8. This Notice and Request imposes a continuing obligation upon you. If, after producing documents or information responsive to this request, additional information or documents become available to you, you are required to produce such additional documents or information.

## DEFINITIONS

As used herein, the following terms have the following meanings:

1. "Documents" includes documents within the meaning of F.R.C.P. 34 as amended effective December 1, 2006, and particularly includes "electronically stored information."

2. "Related to" and "relating to" means constituting, pertaining to, in connection with, reflecting, respecting, regarding, concerning, referring to, based upon, stating, showing, evidencing, establishing, supporting, negating, contradicting, describing,

recording, noting, embodying, memorializing, containing, mentioning, studying, analyzing, discussing, specifying, identifying or in any manner logically, factually, indirectly or directly, or in any other way connecting to the matter addressed in the request, in part or whole.

3. “Communications” means any manner or method in which information is passed from one human being or entity to another including (but not limited to) any written, oral or electronic contact, and/or discussion or exchange of information.

4. “Person” shall include an individual or entity, other than attorneys.

5. “Identify” or “identity” with respect to persons, means to give, to the extent known, the person’s full name, present or last known address and phone number, and when referring to a natural person, additionally, the present or last known place of employment.

6. “Seroquel” means the antipsychotic drug quetiapine fumarate, in any form, including (but not limited to) the medication marketed in the U.S and any foreign country by any AstraZeneca entity and sold under the brand names Seroquel, and any predecessor or non-final derivation of the drug.

7. “Antipsychotics” means any of the class of drugs or neuroleptics used for the treatment of the symptoms of psychoses including schizophrenia, bipolar mania or disorder, and other similar mental ailments and conditions.

8. “Atypical antipsychotics” means any of the class of drugs approved for the treatment of schizophrenia and Bipolar I that are primarily active on dopamine 2 receptors and ratio of serotonin (5-HT) receptor binding. Included, in this definition are the drugs

Seroquel, Abilify (aripiprazole), Clozaril (clozapine), Risperdal (risperidone), Zyprexa (Olanzapine), and Geodon (ziprasidone).

9. “Or” and “and” will be used interchangeably.

10. Unless otherwise indicated, the “relevant period” for the information sought is 1986 to the present.

11. “You,” “your,” or “Astrazeneca” refers to Defendants Astrazeneca Pharmaceuticals LP, Astrazeneca LP, AstraZeneca PLC, AstraZeneca AB and AstraZeneca UK Limited as well as all partners, directors, officers, employees, servants, agents, attorneys, joint ventures, or other representatives, including all corporations and entities affiliated with, Astrazeneca Pharmaceuticals LP, Astrazeneca LP, AstraZeneca PLC, AstraZeneca AB, and AstraZeneca UK Limited and any other named Defendants in this lawsuit foreign and domestic. The terms “you” or “your” shall also include all predecessor business entities, as well as any predecessor’s partners, directors, officers, employees, servants, agents, joint ventures or other representatives. The terms “you” or “your” shall also include all foreign subsidiaries or foreign parent companies, as well as any foreign subsidiaries’ or parent companies’ partners, directors, officers, employees, servants, agents, joint ventures or other representatives.

12. “Injuries” shall refer to the development and/or exacerbation of endocrine or metabolic conditions or disorders, including pancreatitis, hyperprolactinemia, weight gain, and any and all diabetes-related symptoms or injuries including (without limitation) diabetes, diabetes mellitus, insulin dependent diabetes mellitus (IDDM), non-insulin dependent diabetes mellitus (NIDDM), type I diabetes, type II diabetes, hyperglycemia, glucose dysregulation, ketoacidosis, diabetic coma, and death.

13. "Warning" shall mean a statement advising plaintiffs and their treating physicians of an association between the use of SEROQUEL and the incidence of injuries.

#### REQUESTS FOR PRODUCTION OF DOCUMENTS

1. All corporate organizational charts that show the legal and business relationship between AstraZeneca PLC and ICI American Holdings and any corporate entities that are related to and/or affiliated with the previously identified companies.

2. All corporate organizational charts for the non-U.S. business entities that were involved in the research and development, regulatory, marketing, production, and sales of Seroquel.

3. A list of all current and past employees who held senior leadership positions from Vice President on up for the non-U.S. business entities who were involved in the research and development, clinical studies, drug safety, regulatory, risk management, marketing, production, and sales of Seroquel from its initial development to the present.

4. A list of all current and previous Senior Executive Team (SET) members from the date of the merger between Astra AB and Zeneca Group PLC to the present.

5. All SET meeting minutes and/or agenda including video conference recordings and all documents prepared for the participants for such meetings regarding Seroquel, from the date of the merger between Astra AB and Zeneca Group PLC to the present.



6. All documents, materials and agendas prepared for discussion prior to or during the SET members meetings related to Seroquel from the date of the merger between Astra AB and Zeneca Group PLC to the present.

7. All documents and communications between SET members related to Seroquel from the date of the merger between Astra AB and Zeneca Group PLC to the present.

8. A list of all current and previous United States Leadership Team (USLT) members from the team's inception to the present.

9. All USLT meeting minutes and/or agenda including video conference recordings and all documents prepared for the participants for such meetings regarding Seroquel, from the team's inception to the present.

10. All documents, materials and agendas prepared for discussion prior to or during the USLT members meetings related to Seroquel.

11. The patent application for Seroquel and any amendments thereto.

12. All patient information sheets intended for dissemination in Japan, the United Kingdom, Australia, Canada, Sweden, and any other foreign country regarding Seroquel and any English translations that exist.

13. All Dear Doctor/Healthcare Provider Letters intended for dissemination in Japan, the United Kingdom, Australia, Canada, Sweden and any other foreign country regarding Seroquel and any English translations that exist.

14. All draft package inserts, patient information sheets, and Dear Doctor/Healthcare Provider letters pertaining to Seroquel that were prepared for any foreign country and any English translations that exist.

15. All documents produced by you during the course of all United States Attorney investigations related to Seroquel.
16. All documents in your possession related to any research or clinical trials in which Dr. Richard Borison had any involvement.
17. All documents in your possession related to any research or clinical trials in which Bruce Diamond had any involvement.
18. All documents in your possession related to any research or clinical trials in which Eric Poehlman had any involvement.
19. All documents in your possession related to any research or clinical trials in which Walter DeNino had any involvement.
20. All blood test results, charts, graphs and databases relating to Defendant's use of QUICKI in their studies.
21. All draft protocols, protocols, and amendments to protocols related to Study 125.
22. All documents, drafts and any amendments to the Statistical Analysis Plan for Study 125.
23. All e-mails, and both internal and external communications regarding protocols to Study 125.
24. All drafts and amendments to the clinical study report of Study 125.
25. All underlying documents and communications for Study 125.
26. All case report forms relating to the adverse events as referenced in Defendants Discussion Document (AZ/SER 4302750) on Seroquel.
27. All records for the 117 weight gain reports referenced to Seroquel in

discussion document (AZ/SER 2258529).

28. A complete inventory listing the Case Report Forms that the Defendants, Iron Mountain or any other entity under the control of Defendants has stored / archived with respect to all Seroquel related clinical trials sponsored by the Defendants.

29. A complete inventory listing the Case Report Forms that the Defendants, Iron Mountain or any other entity under the control of Defendants has stored / archived with respect to all Seroquel related clinical trials conducted under the Investigator Sponsored Study (ISS) program.

30. All “Keep Under Review” lists for Seroquel from the time Seroquel was introduced to the market to the present.

31. All Patient Risk Management Plans (PRMP) for Seroquel, or similar documents, from the time Seroquel was introduced to the market to the present.

32. All minutes from the Safety Evaluation and Review Meetings (SERM) and Pre-SERM meetings for Seroquel from the time Seroquel was introduced to the market to the present.

33. All discussion documents and agendas prepared for the Safety Evaluation and Review Meetings (SERM) and Pre-SERM meetings for Seroquel as described in the Patient Risk Management Plan (PRMP) (AZ/SER 3783050 – AZ/SER 3783104) and Overview of Drug Safety (AZ/SER 0491060 – AZ/SER 0491069) from the time Seroquel was introduced to the market to the present.

34. All Justification Documents concerning Seroquel label changes prepared from the time Seroquel was introduced to the market to the present.

35. All Justification Documents concerning changes to the Seroquel Core Data Sheets (CDS) prepared from the time Seroquel was introduced to the market to the present.

36. All Position Papers concerning any safety or efficacy topic related to Seroquel prepared from the time Seroquel was introduced to the market to the present.

37. All Standard Operating Procedures (SOP) concerning pharmacovigilance and safety surveillance utilized by you from the time Seroquel was introduced to the market to the present.

38. All “Working Instructions” related to pharmacovigilance and safety surveillance utilized by you from the time Seroquel was introduced to the market to the present.

39. All reports concerning whether Standard Operating Procedures (SOP) related to pharmacovigilance and safety surveillance were complied with by you from the time Seroquel was introduced to the market to the present.

40. All Periodic Safety Update Reports (PSUR) for Seroquel from the time Seroquel was introduced to the market to the present.

41. All regulatory authority queries and any responses to regulatory authority queries as referenced in Overview of Drug Safety (AZ/SER 0491068 - AZ/SER 0491069) regarding Seroquel from the time Seroquel was introduced to the market to the present.

42. All marketing company queries and responses to marketing company queries as referenced in Overview of Drug Safety (AZ/SER 0491068 - AZ/SER 0491069) regarding Seroquel from the time Seroquel was introduced to the market to the present.

43. All reports of adverse events (AE), serious adverse events (SEA), adverse drug reactions (ADR), or Serious Unexpected Suspected Adverse Reactions (SUSAR) received by you concerning Seroquel.

44. All reports provided by you to the FDA, concerned member state authorities, or concerned ethics committees regarding adverse events (AE), serious adverse events (SEA), adverse drug reactions (ADR), or Serious Unexpected Suspected Adverse Reactions (SUSAR) for Seroquel from the time Seroquel was introduced to the market to the present. This request includes, but is not limited to, weekly listings of SUSAR as referenced in the Patient Risk Management Plan (PRMP) for Seroquel (AZ/SER 3783076).

45. All laboratory abnormalities reflecting hyperglycemia and glycemic dysregulation reported to or by you in connection with Seroquel from the time Seroquel was introduced to the market to the present.

46. All Annual Safety Reports for Seroquel from the time Seroquel was introduced to the market to the present.

47. All Line Listings (LL), including Quarterly Line Listings (QLL), for Seroquel from the time Seroquel was introduced to the market to the present.

48. All quarterly reports prepared by Drug Safety Compliance, Support & Systems for Seroquel from the time Seroquel was introduced to the market to the present.

49. All documents describing the MedRa coding system, including the MedRa dictionary, from the time Seroquel was introduced to the market to the present.

50. All Investigative Brochures and Investigator Brochure updates for Seroquel from the time Seroquel was introduced to the market to the present.

51. All Core Data Sheets and Core Data Sheet updates for Seroquel from the time Seroquel was introduced to the market to the present.

52. All Good Clinical Practices utilized by you for Seroquel as referenced in the Patient Risk Management Plan (PRMP) for Seroquel (AZ/SER 3783077) from the time Seroquel was introduced to the market to the present.

53. All informed consent forms used in clinical trials involving Seroquel.

54. All materials prepared by or for Barry Arnold for all seminars, conferences and presentations on the subject of pharmacovigilance and safety surveillance from the time Seroquel was introduced to the market to the present.

55. All company clinical comments generated by you in connection with any Global Drug Safety Physician's (GDSP) review of reports for Seroquel with a fatal outcome, reports assessed as life threatening, and reports of topics that are classified as "Keep Under Review Topics," from the time Seroquel was introduced to the market to the present.

56. All minutes of meetings of Benefit/Risk Team for Seroquel from the time Seroquel was introduced to the market to the present.

57. All materials and agendas prepared for discussion prior to or during the meetings of Benefit/Risk Team for Seroquel from the time Seroquel was introduced to the market to the present.

58. All communications between members of the Benefit/Risk Team for Seroquel related to team issues from the time Seroquel was introduced to the market to the present.

59. All communications between attendees of the Safety Evaluation and Review Meetings (SERM) and Pre-SERM meetings related to safety issues concerning Seroquel from the time Seroquel was introduced to the market to the present

60. All Pharmacovigilance Plans for Seroquel.

61. All minutes or notes of meetings of the Regulatory Core Team for Seroquel.

62. All minutes or notes of meetings of the Regulatory Project Team for Seroquel.

63. All minutes or notes of meetings of the Defense Team for Seroquel.

64. All minutes or notes of meetings of the Labeling Team for Seroquel.

65. All minutes or notes of meetings of the Executive Approved Team for Seroquel.

66. All Agency Contacts (FDA) for Seroquel, not yet provided in the IND or NDA.

67. All notes regarding contacts with any foreign regulatory authority about Seroquel.

68. All Risk Opportunity Logs for Seroquel.

69. All Regulatory Risk Assessments for Seroquel.

70. All warning letters from DDMAC, all responses to such letters and all follow-up responses from the FDA, not yet provided in the IND or NDA.

71. All documents related to "Seroquel Stride."

72. All documents related to "CNS Newsflash."

73. All documents related to "Seroquel Highlights."

74. All documents related to "Manager's Briefs."

75. All UK Marketing Authorization Applications for Seroquel.

76. All drafts and amendments to Seroquel Product Strategic Plans from 1996

to the present.



Plaintiffs reserve the right to make additional request for production of documents upon further review of the documents provided and upon completion of depositions of defendants.

Dated: New York, New York  
June 11, 2007.

PLAINTIFFS' STEERING COMMITTEE

By: /s/ Paul J. Pennock

Paul J. Pennock

***Plaintiffs' Co-Lead Counsel***

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Orlando, Florida 32804

CERTIFICATION OF SERVICE

I HEREBY CERTIFY that on this 11<sup>th</sup> day of June, 2007, that I e-mailed the foregoing request for production of documents to the Defendants, along with a copy by e-mail to all participants in the CM/ECF system, and that I mailed the foregoing document by First Class Mail to the non-CM/ECF participants listed on the attached service list.

PLAINTIFFS' STEERING COMMITTEE

By: /s/ Paul J. Pennock

Paul J. Pennock

***Plaintiffs' Co-Lead Counsel***

WEITZ & LUXENBERG, P.C.

180 Maiden Lane

New York, NY 10038

**SERVICE LIST**

**In Re: Seroquel Products Liability Litigation  
MDL Docket No. 1769 - Orl - 22DAB**

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