IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

JAMES I ADAMS, WILLIAM M ADKINS, CECIL R ALLRED, JANET L ATKINSON, BERNADETTE M BAEMMERT, KAREN S BAILEY, DENISE BAKER, TIMOTHY BAKER, AMY L BALLENGEE, REBECCA BARROW, FOREST E BEANE, REBECCA W BEJARANO, LARRY BETHEA, WILLA F BIAS, WILLIE M BILLINGSLEY, GERALDINE BONNER, DEZZIE D BOYKIN, SHAMIKA S BROCK, DANIEL BROOKS, JENNIFER E BROOKS, EMOGENE BROWN, DORIS J BROWN, MICHAEL BROWN, DEIRDRA J BROWN, LARRY D BRUMFIELD, ANNE BUKOWSKI, JERROLD D BULLA, CASSANDRA A BURNETT, NANCY A BYINGTON, CHARLES S CADLE, MARTHA A CALL, ANGELA J CAMP, JAMES CANTRELL, LANCE C CANTRELL, GINA A CASTRO, JOANNE L CLAY, LINDA K CLEMENTS, DEBORAH A CODY, SANDRA COLLIER, BESSIE CONNOR, DUANE CRAWFORD, GLENN L CULBERT, EDITH CUMMINGS, JAMES DANIEL, SANDRA DAPHNEY, LLOYD D DAVIS, LINDA V DE LA CUEVA, ANNETTE DEAN, PHILIP C DILLON, JAVIER F DOMINGUEZ, SHARON DOTSON, BOBBY G DUVALL,CHRISTINE R EADY, KIM M EDGE, SHAWNA R EDWARDS, JULIE E EVERARD, EVELYN M FERGUSON, DAVE D FERREL, SONYA N FERST, THOMAS L FIELDS, MAX D FRANK, DAMON L FRENCH, HERMAN D FRYER, JEANIE J GARTMAN, YVONNE E GATES, NANCY E GEE, KEMMON M	Civil Action No. 06-10724-NG-JLA JURY TRIAL DEMANDED

GEE, JAMES A GENTRY, IRENE M)
GILBERT, REGINA GILCREST,)
CURTIS A GILLIAM, MICHAEL R)
GLASS, KENNETH A GOLDIE,)
CAROLYN S GOODE, TRACEY I)
GOODSON, LUTRICIA B GORDON,)
DORIS E GORDON, NANCY GREEN,)
SHIRLEY GREEN, ALICE D)
GRIFFIN, JOSEPH D HAMILTON,)
RODNEY D HAMILTON, FRANCES)
A. HAMMOND, TOWANDA)
HAMPTON, JAMES T HARMON,)
ROSE A HARPER, JACKIE D)
HARRIS, REALLOR HARRIS,)
VIRGINIA HARRIS, CAROLYN R)
HARRIS, WERNETTA O HARRIS,)
PAULA D HENDERSON, ANDREIA M)
HENNINGS, DOROTHY A HENRY,)
BABY M HERNANDEZ, SANDRA R)
HILL, JOSEPH E HODGES,)
RUDOLFO C HOLGUIN, JIMMY W)
HOPPER, PATRICIA A JARRARD,)
ROGER JOHNSON, JAMES G)
JOHNSON, JENNIFER JOHNSON,)
LA'NEQUA JOHNSON, BARBARA)
JONES, GAIL H JONES, RICHARD B)
JONES, RICKY L JONES, VERNELLE)
E KEY, CONNIE M KLEIN,)
GABRIELLA LADANYI, STEVIE J)
LAWHORN, GWENDOLYN)
LAWSON, LINDSAY LEE, JOHN D)
LEMAR, MIRIAM C LEWIS,)
ROBERTA LIAS, LAVERN)
LOCKHART, JOE LOETHER,)
HECTOR E LONGORIA, MICHAEL J)
LOPEZ, SARAH R LOVIN,)
JAQUELYN MANNERS, LESA A)
MANNS, RONALD V MARTIN,)
CYNTHIA M MCCASLIN, GARRY S)
MCCUTCHEON, HARRY L)
MCDANIEL, WILLIAM M)
MCDERMOTT, NANCY L)
MCKEEVER, JANICE M MCKINNEY,)
CYNTHIA MCREAKEN, CAROL A)
MEADOWS-ONEAL, DONNA F)
MICHL, VANESSA MOODY, JAMES)

D MOORE, MILDRED L MOREMAN,)
DECKRICE L MORRISSEY, LOUISE)
W MOSS, BRENDA A MULLINS,)
JAMES NEWSOME, LARRY E)
PALEN, SUSAN B PATEL, LASHAWN)
N PATRICK, PAULA R PAUL,)
JANICE S PEARSON, TANITA W.)
PERDUE, TERRI PEREZ, YOLANDA)
PEREZ, JAMES L PIERCE, PALIUS D)
PITTS, JANET L POOLE, NICHELLE)
D POWELL, MICHAEL A PRATER,)
CHARLES H. PRICE, KENNY)
PUCKETT, DIANA G)
QUESENBERRY, PATRICK B QUINN,)
RICHARD A RADDATZ, GERARD)
RAMIREZ, SHERI REYES, OCELIA)
D RICHARDSON, MARY RIVERS,)
PATRICIA RIVERS, JESSICA D)
ROBBINS, DORIS B ROBERTS, JACK)
D ROBINETTE, SHARON A ROBLES,)
ISABELLA S ROGERS, ELAINE)
ROLAND, SARA G ROMERO,)
VERESSA C ROSSER, RON L)
RUTLEDGE, MARY F SALINAS,)
PAUL G SALYER, LUANNA)
SATTERWHITE, TERRY P SAULS,)
PATTIE S SAXTON, REBECCA)
SCHERER, MARTHA M SCHILL,)
JERRY SCOTT, MARIANE D SCUTT,)
KAREN F. SELFRIDGE, RAYMOND T)
SEPULVEDA, ALBERT B SHEALY,)
BIFF L SHEPPARD, MELANIE C)
SHEPPARD, DOROTHY J)
SHINHOLSTER, DESIRE'E J SIKES,)
VIRGINIA L SIMPSON, KIMBERLY J)
SIZEMORE, GARY P SKIDMORE,)
ELIZABETH J SMITH, CHERRYL L)
SMITH, RUTH SMITH, ALBERTA G)
SOOD, LETHA M SPRINGER,)
THOMAS E STEELE, ROBERT C)
STILLS, LARRY J STINSON, JESSE J)
STORY, SAMANTHA A STUMPF,)
RITA L STURGUES, LINDA S)
TERRELL, LINDA K THOMAS, AMY)
THOMAS, THERESA THOMPSON,)
KATHLEEN J TILLEY, FRANK L)

TILLMAN, DORIS F TODD, EDWARD E TOLBERT, LOUISE C TUCKER, LARRY N UPCHURCH, ROBERT P VAN HOOSE, LISA VANCE, KELLY L WADE, TERESA R WALLACE, MARIAN WASHINGTON, RULETTA WATSON, DEBRA WEAVER, REGINA WELCH, ROBERT W WELLS, CARL WEST, FRANK WESTBROOK, PAUL U WHIDBY, RODNEY P WHITEHEAD, MARY S WILLARD, WILLIAM E WILLIAMS, ROBERT L WILLIAMS, KATRINA WILLIAMS, CYNTHIA C WILLIAMS, ANN M WILMOTH, ROBERT A WINGARD, HEATHER A WOLFE, EDNA M WOLFORD, BUFUS WOODS, BRIAN A WOODS, ANGELA BACON, *INDIVIDUALLY AND AS REPRESENTATIVE OF THE ESTATE OF THOMAS E WRIGHT (DEC.),* REGINALD R WRIGHT, DORALEE D WYMAN, PEGGY S YELEY Plaintiffs, vs. ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, KBI SUB INC., ASTRAZENECA AB, ASTRA USA, INC., ASTRAZENECA R&D BOSTON, ASTRAZENECA R&D WILMINGTON, and ASTRAZENECA PLC, Defendants.	)

ANSWER OF ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP

Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca") answer Plaintiffs' Original Complaint as follows:

This Answer is filed on behalf of AstraZeneca LP and AstraZeneca Pharmaceuticals LP only, and AstraZeneca makes no response on behalf of other entities. More specifically, AstraZeneca makes no response to the allegations of Plaintiffs' complaint on behalf of Astra USA, Inc., AstraZeneca AB, AstraZeneca PLC, and KBI Sub Inc. AstraZeneca states that, to its knowledge, there are no separate entities named AstraZeneca R&D Boston and AstraZeneca R&D Wilmington.

I. INTRODUCTION

1. AstraZeneca admits that, pursuant to approval by the Food and Drug Administration ("FDA"), it manufactures, markets, distributes, and sells SEROQUEL® (quetiapine fumarate) for prescription by licensed physicians in the United States. AstraZeneca denies that it sold SEROQUEL® to Plaintiffs, and states that SEROQUEL® is dispensed by pharmacies pursuant to prescriptions written by licensed physicians. AstraZeneca denies any remaining or inconsistent allegations of paragraph 1.

II. PARTIES

A. PLAINTIFFS

2. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies same.

B. DEFENDANTS

3. AstraZeneca admits that AstraZeneca LP is a Delaware limited partnership, but denies that its principal place of business is located at 50 Otis Street, Westborough, MA 01581-4500. AstraZeneca admits that AstraZeneca LP's principal place of business is located in Delaware. AstraZeneca admits that AstraZeneca LP advertises, markets, promotes, distributes, and sells SEROQUEL®, a prescription medication, in the State of Massachusetts. AstraZeneca admits that AstraZeneca LP's registered agent for service of process in Massachusetts is CT

Corporation System, 101 Federal Street, Boston, MA 02110. AstraZeneca denies any remaining or inconsistent allegations of paragraph 3.

4. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is the general partner of AstraZeneca LP. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is a Delaware limited partnership with its principal place of business in Delaware. AstraZeneca further admits that AstraZeneca Pharmaceuticals LP advertises, markets, promotes, distributes, and sells SEROQUEL®, a prescription medication, in the State of Massachusetts. AstraZeneca admits that AstraZeneca Pharmaceuticals LP's registered agent for service of process in Massachusetts is CT Corporation System, 101 Federal Street, Boston, MA 02110. AstraZeneca denies any remaining or inconsistent allegations of paragraph 4.

5. AstraZeneca admits that KBI Sub Inc. is a Delaware corporation with its principal place of business in New Jersey. AstraZeneca further admits that KBI Sub Inc. is the limited partner of AstraZeneca LP. AstraZeneca denies that KBI Sub Inc. is a proper defendant in this action. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 5, and therefore denies same.

6. AstraZeneca admits that AstraZeneca AB is a Swedish corporation with its principal place of business in Sweden. AstraZeneca further admits that AstraZeneca AB is the general partner of AstraZeneca Pharmaceuticals LP. AstraZeneca denies that AstraZeneca AB is a proper defendant in this action. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6, and therefore denies same.

7. AstraZeneca admits that Astra USA, Inc. is a New York corporation, but denies that its principal place of business is located at 128 Sidney Street, Cambridge, MA 02139. AstraZeneca admits that the principal place of business of Astra USA, Inc. is located in

Delaware. AstraZeneca further admits that Astra USA, Inc. is a limited partner of AstraZeneca Pharmaceuticals LP. AstraZeneca denies that Astra USA, Inc. is a proper defendant in this action. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 7, and therefore denies same.

8. AstraZeneca denies that AstraZeneca R&D Boston is a Delaware company with its principal place of business in Massachusetts. By way of further response, AstraZeneca states that AstraZeneca R&D Boston is not an independent legal entity. AstraZeneca denies that AstraZeneca R&D Boston is a proper defendant in this action. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 8, and therefore denies same.

9. AstraZeneca denies the allegations of paragraph 9. By way of further response, AstraZeneca states that no legal entity named AstraZeneca R&D Wilmington exists. AstraZeneca denies that AstraZeneca R&D Wilmington is a proper defendant in this action.

10. AstraZeneca admits that AstraZeneca PLC is a corporation organized under the laws of the United Kingdom but denies that its principal place of business in the United States is located at 35 Gatehouse Drive, Waltham, MA 02451. AstraZeneca admits that AstraZeneca PLC is the ultimate parent company of AstraZeneca LP and AstraZeneca Pharmaceuticals LP. AstraZeneca denies that AstraZeneca PLC is a proper defendant in this action. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10, and therefore denies same.

11. AstraZeneca admits that Plaintiffs purport to refer to all named Defendants collectively as "Defendants," but denies that AstraZeneca caused Plaintiffs' damages. AstraZeneca denies that the defendants in this action may be properly referred to collectively and

states that this Answer is filed on behalf of AstraZeneca LP and AstraZeneca Pharmaceuticals LP only. AstraZeneca denies any remaining or inconsistent allegations of paragraph 11.

III. JURISDICTION & VENUE

12. AstraZeneca states that paragraph 12 states legal conclusions to which no response is required. To the extent that the allegations regarding jurisdiction over AstraZeneca are construed as factual allegations, AstraZeneca admits that it transacts business in Massachusetts, but denies that it engaged in tortious acts in Massachusetts. AstraZeneca further denies that any defendant in this action is a Massachusetts resident. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 regarding the citizenship of Plaintiffs, and therefore denies same. To the extent that any remaining allegations of paragraph 12 are construed as factual allegations, they are denied. AstraZeneca admits that this Court has subject matter jurisdiction over this action.

IV. FACTS

13. AstraZeneca admits that, pursuant to FDA approval, it designed, tests, monitors, manufactures, labels, advertises, markets, promotes, sells, and distributes SEROQUEL® for prescription by licensed physicians in the United States. AstraZeneca denies that it sells prescription medications directly to the "mainstream public." AstraZeneca denies any remaining or inconsistent allegations of paragraph 13.

14. AstraZeneca admits that SEROQUEL® is an "anti-psychotic" medication and belongs to a class of drugs referred to as "atypical anti-psychotics." AstraZeneca states that SEROQUEL® was approved by the FDA on September 26, 1997. AstraZeneca denies any remaining or inconsistent allegations of paragraph 14.

15. AstraZeneca states that SEROQUEL® was approved by the FDA on September 26, 1997, and is indicated for the treatment of schizophrenia in adults. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15, and therefore denies same.

16. AstraZeneca states that on January 12, 2004, the FDA approved SEROQUEL® for use in the treatment of acute manic episodes associated with Bipolar I disorder. AstraZeneca denies that such approval was directed to any other defendant in this action.

17. AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore denies same.

18. AstraZeneca admits that worldwide sales of SEROQUEL® in 1998 were approximately $66 million. AstraZeneca further admits that worldwide sales of SEROQUEL® in 2005 were approximately $2.76 billion. AstraZeneca admits that worldwide sales of NEXIUM® in 2005 were approximately $4.63 billion. AstraZeneca states that the remaining allegations are conclusory, vague, and ambiguous, and therefore AstraZeneca lacks knowledge or information sufficient to form a belief as to the truth of those allegations and denies same.

19. AstraZeneca denies the allegations of paragraph 19.

20. AstraZeneca admits that there have been reports of weight gain and hyperglycemia in people who were prescribed SEROQUEL®, but denies that SEROQUEL® causes diabetes. AstraZeneca denies any remaining or inconsistent allegations of paragraph 20.

21. AstraZeneca admits that, following the FDA's 1997 approval of SEROQUEL® and its subsequent release into the market, adverse event reports involving weight gain and hyperglycemia were filed with the FDA's MedWatch database. AstraZeneca further admits that those adverse event reports are publicly available on the FDA's Medwatch database.

AstraZeneca denies that paragraph 21 accurately characterizes the type or number of adverse event reports filed with the MedWatch database. To the extent the allegations of paragraph 21 are inconsistent with the information contained on that database, they are denied.

22. AstraZeneca admits that it received a letter from the FDA dated September 11, 2003, directed to all manufacturers of atypical antipsychotics, which provided class labeling that included warnings related to glucose dysregulation. AstraZeneca denies that SEROQUEL® causes diabetes. AstraZeneca denies that paragraph 22 accurately quotes the class labeling or accurately characterizes the FDA's letter of September 11, 2003. AstraZeneca denies all remaining or inconsistent allegations of paragraph 22.

23. AstraZeneca admits that it submitted a proposed Dear Health Care Provider Letter to the FDA for review in the Fall of 2003, which, following approval by the FDA, was issued on January 30, 2004. AstraZeneca further admits that on April 22, 2004, it issued a second Dear Health Care Provider letter, which included information inadvertently omitted from the January 30, 2004, letter. AstraZeneca denies Plaintiffs' characterization of the 2004 Dear Health Care Provider letters and specifically denies that AstraZeneca was "forced" to issue a letter in April 2004 because "the first one was misleading." AstraZeneca denies all remaining or inconsistent allegations of paragraph 23.

24. AstraZeneca admits that in January of 2006 it received notice of an investigation by the U.S. Attorney's Office in Los Angeles into field promotional activities in the area served by AstraZeneca's Los Angeles regional business center. AstraZeneca denies any remaining or inconsistent allegations of paragraph 24.

25. AstraZeneca denies the allegations of paragraph 25.

V. DISCOVERY RULE & FRAUDULENT CONCEALMENT

26. AstraZeneca states that the allegations contained in paragraph 26 of the Complaint are legal conclusions to which no response is required. To the extent that the allegations are construed as factual allegations, AstraZeneca denies same.

27. AstraZeneca states that the allegations contained in paragraph 27 of the Complaint are legal conclusions to which no response is required. To the extent that the allegations are construed as factual allegations, AstraZeneca denies same.

28. AstraZeneca denies the allegations of paragraph 28.

VI. CAUSES OF ACTION

A. STRICT PRODUCTS LIABILITY

29. AstraZeneca states that the allegations of paragraph 29 are legal conclusions to which no response is required. To the extent that the allegations of paragraph 29 are construed as factual allegations, they are denied.

1. DESIGN DEFECT

30. AstraZeneca denies the allegations of paragraph 30.

31. AstraZeneca admits that, pursuant to FDA approval, it distributes, supplies, and sells SEROQUEL® for prescription by licensed physicians in the State of Massachusetts and elsewhere in the United States. AstraZeneca lacks knowledge or information sufficient to admit or deny whether Plaintiffs were prescribed SEROQUEL® by Plaintiffs' physicians or whether Plaintiffs used SEROQUEL® in a manner reasonably foreseeable by AstraZeneca, and therefore denies same. AstraZeneca denies any remaining or inconsistent allegations of paragraph 31.

32. AstraZeneca lacks knowledge or information sufficient to admit or deny the allegation that the SEROQUEL® allegedly ingested by Plaintiffs reached Plaintiffs without

substantial change in its condition. AstraZeneca denies the remaining allegations of paragraph 32.

2. MARKETING DEFECT-INADEQUATE AND IMPROPER WARNINGS

33. AstraZeneca admits that, pursuant to FDA approval, it manufactures, labels, advertises, markets, distributes, supplies, and sells SEROQUEL® for prescription by licensed physicians in the State of Massachusetts and elsewhere in the United States. AstraZeneca denies the remaining allegations of paragraph 33.

34. AstraZeneca lacks knowledge or information sufficient to admit or deny whether Plaintiffs were prescribed SEROQUEL® by their physicians or whether any such physicians used SEROQUEL® in a manner reasonably foreseeable by AstraZeneca. AstraZeneca further lacks knowledge or information sufficient to admit or deny whether any SEROQUEL® reached Plaintiffs without substantial change in its condition. AstraZeneca denies that SEROQUEL® is unreasonably dangerous in nature. AstraZeneca denies the remaining allegations of paragraph 34.

35. AstraZeneca denies the allegations of paragraph 35.

B. NEGLIGENCE

36. AstraZeneca states that the allegations of paragraph 36, including all its subparts, are legal conclusions to which no response is required. To the extent that the allegations of paragraph 36 are construed as factual allegations, AstraZeneca denies that paragraph 36 fully and accurately states AstraZeneca's duties under the applicable law. AstraZeneca admits that, pursuant to FDA approval, it manufactures, distributes, supplies, and sells SEROQUEL® for prescription by licensed physicians in the United States. AstraZeneca denies the remaining allegations of paragraph 36, including all its subparts.

37. AstraZeneca denies the allegations of paragraph 37.

C. INTENTIONAL MISREPRESENTATION

38. AstraZeneca denies the allegations of paragraph 38.

39. AstraZeneca denies the allegations of paragraph 39, including all its subparts.

40. AstraZeneca denies the allegations of paragraph 40.

41. AstraZeneca denies the allegations of paragraph 41.

D. NEGLIGENT MISREPRESENTATION

42. AstraZeneca denies the allegations of paragraph 42. By way of further response, AstraZeneca states that the FDA has concluded that SEROQUEL® is safe and effective when prescribed and used in accordance with the FDA-approved labeling.

43. AstraZeneca denies the allegations of paragraph 43, including all its subparts.

44. AstraZeneca denies the allegations of paragraph 44.

E. EXPRESS WARRANTY

45. AstraZeneca admits that, pursuant to FDA approval, it sells SEROQUEL® for prescription by licensed physicians in the United States. AstraZeneca denies the remaining allegations of paragraph 45.

46. AstraZeneca denies the allegations of paragraph 46.

F. IMPLIED WARRANTY

1. WARRANTY OF MERCHANTABILITY

47. AstraZeneca admits that, pursuant to FDA approval, it sells SEROQUEL® for prescription by licensed physicians in the United States. AstraZeneca denies the remaining allegations of paragraph 47.

2. WARRANTY OF FITNESS

48. AstraZeneca denies the allegations of paragraph 48.

49. AstraZeneca denies the allegations of paragraph 49.

50. AstraZeneca denies the allegations of paragraph 50.

G. CIVIL CONSPIRACY

51. AstraZeneca denies the allegations of paragraph 51.

52. AstraZeneca denies the allegations of paragraph 52, including all its subparts.

53. AstraZeneca denies the allegations of paragraph 53.

54. AstraZeneca states that the allegations of paragraph 54 are legal conclusions to which no response is required. To the extent that the allegations of paragraph 54 are construed as factual allegations, they are denied.

55. AstraZeneca denies the allegations of paragraph 55.

VII. DAMAGES

56. To the extent paragraph 56 states legal conclusions, no response is required. To the extent that the allegations of paragraph 56, including all it subparts, are construed as factual allegations, they are denied.

VIII. WRONGFUL DEATH & SURVIVAL DAMAGES

57. AstraZeneca denies the allegations of paragraph 57, including all its subparts.

VIII. PUNITIVE DAMAGES

58. AstraZeneca denies the allegations of paragraph 58.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries were proximately caused by circumstances, events, or persons over whom AstraZeneca had no authority or control and for which AstraZeneca is not answerable in damages to Plaintiffs.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs and their agents, including Plaintiffs' Physicians, assumed the risks, if any, inherent in the use of SEROQUEL®.

THIRD AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims were caused by the actions, omissions or products of persons or entities, over whom AstraZeneca has no dominion, authority or control, AstraZeneca is entitled to have its liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to applicable law.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' recovery is barred and/or should be reduced under applicable law because of Plaintiffs' contributory negligence or fault and/or comparative negligence or fault.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries, if related to Plaintiffs' use of SEROQUEL®, were caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse of the product after it left the control of AstraZeneca.

SIXTH AFFIRMATIVE DEFENSE

The New Drug Application for SEROQUEL® was approved by the United States Food and Drug Administration under the applicable statute, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder. Compliance with such statutes and regulations by AstraZeneca

demonstrates that SEROQUEL® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiffs' claims against AstraZeneca. Compliance with such regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

EIGHTH AFFIRMATIVE DEFENSE

All labeling for SEROQUEL® has been approved by the United States Food and Drug Administration under the applicable statute, 21 U.S.C. § 201 *et seq*., and regulations promulgated thereunder. As the agency charged with implementing the Food, Drug, and Cosmetic Act, the FDA affirmatively has stated that "under existing preemption principles, FDA approval of labeling . . . preempts conflicting or contrary State law." 71 *Fed. Reg.* at 3,934. Moreover, the FDA has stated, "Given the comprehensiveness of FDA regulation of . . . labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representations of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug." *Id*. at 3,935. Plaintiffs' claims based on the labeling for SEROQUEL® are therefore preempted by federal law pursuant to the Supremacy Clause of the United States Constitution.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against AstraZeneca are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k, in that the benefits of SEROQUEL® outweigh any risks that may be associated with its use, and that the SEROQUEL® allegedly ingested by Plaintiffs was properly prepared and marketed, was accompanied by appropriate labeling, and contained no design or manufacturing defects.

TENTH AFFIRMATIVE DEFENSE

Persons other than AstraZeneca stood in the position of learned intermediary between Plaintiffs and AstraZeneca which therefore owed and breached no duty to warn Plaintiffs directly, and the SEROQUEL® Plaintiffs allegedly used was therefore neither unreasonably dangerous nor defective by virtue of any alleged absence of adequate warnings or instructions.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted against AstraZeneca in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription drug SEROQUEL®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint against AstraZeneca fails to state a claim upon which relief may be granted.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against AstraZeneca are barred, in whole or in part, by laches, waiver and/or estoppel.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate alleged damages.

SIXTEENTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of AstraZeneca was not the proximate and/or competent producing cause of such alleged injuries and damages.

SEVENTEENTH AFFIRMATIVE DEFENSE

The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including AstraZeneca.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted for several or joint and several liability.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the commercial speech relating to SEROQUEL® was not false or misleading and is protected under the First Amendment to the United States Constitution and the applicable state constitution.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

TWENTY-FIRST AFFIRMATIVE DEFENSE

This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning SEROQUEL®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction which AstraZeneca could not reasonably foresee.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs, or Plaintiffs' physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of SEROQUEL® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings provided by AstraZeneca and others generally available in the medical and scientific

literature. Therefore, Defendant AstraZeneca had no duty to warn of any alleged danger or defect.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the Plaintiffs without substantially impairing the usefulness or intended purpose of the product.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

AstraZeneca did not sell or distribute the prescription drug SEROQUEL® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims for breach of warranty are therefore barred by lack of privity between Plaintiffs and AstraZeneca.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable provisions of the applicable state's Uniform Commercial Code.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that they purport to impose liability upon AstraZeneca for any conduct in which it engaged in the exercise of its rights under federal law, including, without limitation, the Constitution of the United States and the First Amendment thereto.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim for which relief can be granted for fraud, misrepresentation, omission, or concealment insofar as Plaintiffs have failed to plead such claims with sufficient particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim for which relief can be granted for fraud, misrepresentation, omission, or concealment.

THIRTY-THIRD AFFIRMATIVE DEFENSE

This Court is not the proper forum and is not a convenient forum for the adjudication of Plaintiffs' claims.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

This Court is not the proper venue.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

The joinder of multiple plaintiffs in this action is improper under Fed. R. Civ. P. 20 and 21.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim against AstraZeneca upon which relief can be granted for punitive damages.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claim for punitive damages is barred under the applicable state and federal law, including *State Farm Mut. Auto. Ins. Co. v. Campbell et al.*, 538 U.S. 408 (2003). Permitting recovery of punitive damages in this action would contravene AstraZeneca's rights as reserved

by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitutions.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Unless AstraZeneca's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate AstraZeneca's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claim for punitive damages against AstraZeneca cannot be maintained, because an award of punitive damages would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitutions, and the applicable state common law and public policies.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claim for punitive damages against AstraZeneca cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of

sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of AstraZeneca; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards. Any such verdict would violate AstraZeneca's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

FORTY-FIRST AFFIRMATIVE DEFENSE

To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of AstraZeneca and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the applicable state constitutions.

FORTY-SECOND AFFIRMATIVE DEFENSE

With respect to Plaintiffs' demand for punitive damages, AstraZeneca specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive damages awards under federal law and the applicable state law.

FORTY-THIRD AFFIRMATIVE DEFENSE

No act or omission of AstraZeneca was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiffs or with conscious disregard and indifference to the rights, safety and welfare of Plaintiffs, and therefore Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive damages.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint seeks damages in excess of those permitted by law. AstraZeneca asserts any statutory or judicial protection from punitive damages which is available under the applicable law, and any award of punitive damages is barred.

FORTY-FIFTH AFFIRMATIVE DEFENSE

AstraZeneca has not knowingly or intentionally waived any affirmative defenses and asserts all defenses available under applicable law. AstraZeneca reserves the right to modify, clarify, amend, or supplement these separate or affirmative defenses as discovery proceeds in this case.

JURY DEMAND

AstraZeneca hereby demands a trial by jury.

PRAYER

WHEREFORE, AstraZeneca prays that this Court enter judgment on its behalf and against Plaintiffs, that Plaintiffs take nothing thereby, and that the Court grant AstraZeneca such other and further relief as allowed by law.

June 27, 2006

Respectfully submitted,

ASTRAZENECA LP and
ASTRAZENECA PHARMACEUTICALS LP

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