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STATE OF WASHINGTON  
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON,  
  
Plaintiff,  
  
v.  
  
ASTRAZENECA  
PHARMACEUTICALS LP and  
ASTRAZENECA LP,  
  
Defendants.

NO.  
  
CONSENT DECREE AND  
JUDGMENT

JUDGMENT SUMMARY

Judgment Creditor:	State of Washington
Judgment Debtor:	AstraZeneca Pharmaceuticals LP and AstraZeneca LP
Principal Judgment Amount:	All compliance provisions as detailed in the Section entitled Compliance Provisions beginning on page 8 of this Consent Decree and Judgment plus \$68.5 million for all 37 participating states, of which the State of Washington shall received approximately \$1,612,265. Washington's share may be used for any purpose permitted under Paragraph VI. A, on pages 19-20, including costs and attorneys fees and cy pres.
Costs and Attorney's Fees:	See Paragraph VI.A
Total Judgment for Washington:	\$1,612,265

1 Post-judgment Interest Rate: None if paid in accordance with the time  
2 Provisions in Paragraph VI. A; otherwise  
the maximum rates allowed by law.  
3 Attorney for Judgment Creditor: Robert M. McKenna, Attorney General  
4 of Washington and Robert Lipson, Senior  
Counsel  
5 Attorney for Judgment Debtor: [Name of local counsel needed]  
6

7 Plaintiff, STATE OF WASHINGTON, by ROBERT McKENNA, Attorney General of  
8 Washington and ROBERT LIPSON, Senior Counsel, have filed a Complaint for a permanent  
9 injunction and other relief in this matter pursuant to the Washington Consumer Protection Act,  
10 RCW 19.86, *et seq.*, alleging that AstraZeneca Pharmaceuticals LP and AstraZeneca LP  
11 committed violations of the aforementioned Act.

12 Plaintiff, by its counsel, and AstraZeneca Pharmaceuticals LP and AstraZeneca LP, by  
13 its counsel, have agreed to the entry of this Consent Decree and Judgment (“Judgment”) by the  
14 Court without trial or adjudication of any issue of fact or law or finding of wrongdoing or  
15 liability of any kind.

16 **PARTIES**

17 1. The State of Washington (hereinafter “the State”), through its Attorney General,  
18 is the plaintiff in this case. The Washington Attorney General is charged with, among other  
19 things, the responsibility of enforcing the Consumer Protection Act.

20 2. AstraZeneca Pharmaceuticals LP and AstraZeneca LP (hereinafter  
21 “AstraZeneca”) are the Defendants in this case. AstraZeneca’s Corporate Headquarters is  
22 located at, 1800 Concord Pike, Wilmington, DE 19850-5437. As used herein, any reference to  
23 “AstraZeneca” shall mean AstraZeneca Pharmaceuticals LP and AstraZeneca LP.  
24  
25  
26

1 TRADE AND COMMERCE

2 AstraZeneca, at all times relevant hereto, engaged in trade and commerce affecting  
3 consumers, within the meaning of the Consumer Protection Act, in the State of Washington,  
4 including, but not limited to, King County.

5 PREAMBLE

6 A. The Attorneys General of thirty seven<sup>1</sup> states and the District of Columbia  
7 (collectively, the “Attorneys General,” and the “AGs”)<sup>2</sup>, conducted an investigation regarding  
8 certain AstraZeneca practices concerning Seroquel.

9 B. The Parties have agreed to resolve the claims raised by the Covered Conduct, as  
10 set forth in Section VII, by entering into this Judgment. This Judgment is entered into pursuant  
11 to and subject to the State consumer protection laws<sup>3</sup> cited in footnote 3.

12 \_\_\_\_\_  
13 <sup>1</sup> Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland,  
14 Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota,  
Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and  
Wisconsin.

15 <sup>2</sup> Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General’s  
16 Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii.  
For simplicity, the entire group will be referred to as the “Attorneys General,” and such designation, as it includes Hawaii, refers to the  
Executive Director of the State of Hawaii Office of Consumer Protection.”

17 <sup>3</sup> ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et*  
18 *seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT – *Connecticut Unfair Trade*  
19 *Practices Act*, Conn. Gen. Stat. §§ 42-110a *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527;  
DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida*  
20 *Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et seq.*; HAWAII – *Uniform Deceptive Trade*  
21 *Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*;  
ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA – *Iowa Consumer Fraud Act*, Iowa Code  
22 Section 714.16; KANSAS – *Kansas Consumer Protection Act*, K.S.A. 50-623 *et seq.*; LOUISIANA – *Unfair Trade-Practices and Consumer*  
23 *Protection Law*, LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND – *Maryland*  
24 *Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq.*; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4;  
MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MINNESOTA – *Minnesota Deceptive Trade Practices Act*, Minn.  
25 Stat. §§ 325D.43-48; *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-70;  
26 *Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – *Missouri*  
*Merchandising Practices Act*, Mo. Rev. Stat. §§ 407 *et seq.*; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*;  
NEVADA – *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE – *New Hampshire Consumer*  
*Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NEW YORK – *General Business Law*  
Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*,  
N.C.G.S. 75-1.1, *et seq.*; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio*  
*Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OKLAHOMA – *Oklahoma Consumer Protection Act* 15 O.S. §§ 751 *et seq.*; OREGON  
– *Oregon Unlawful Trade Practices Act*, ORS 646.605 *et seq.*; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer*  
*Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND – *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-  
1, *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE –  
*Tennessee Consumer Protection Act*, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection*  
*Act*, Tex. Bus. And Com. Code 17.47, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair*

1 C. AstraZeneca is entering into this Judgment solely for the purpose of settlement  
2 and nothing contained herein may be taken as or construed to be an admission or concession of  
3 any violation of law or regulation, or of any other matter of fact or law, or of any liability or  
4 wrongdoing (including allegations of the Complaint), all of which AstraZeneca expressly  
5 denies. AstraZeneca does not admit any violation of law, and does not admit any wrongdoing  
6 that was or could have been alleged by any Attorney General before the date of the Judgment.  
7 No part of this Judgment, including its statements and commitments, shall constitute evidence  
8 of any liability, fault, or wrongdoing by AstraZeneca. This Judgment is made without trial or  
9 adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is  
10 the intent of the Parties that this Judgment shall not be binding or admissible in any other  
11 matter, including, but not limited to, any investigation or litigation, other than in connection  
12 with the enforcement of this Judgment. No part of this Judgment shall create a private cause of  
13 action or confer any right to any third party for violation of any federal or state statute except  
14 that a State may file an action to enforce the terms of this Judgment. To the extent that any  
15 provision of this Judgment obligates AstraZeneca to change any policy(ies) or procedure(s)  
16 and to the extent not already accomplished, AstraZeneca shall implement the policy(ies) or  
17 procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective  
18 Date of this Judgment. Nothing contained herein prevents or prohibits the use of this Judgment  
19 for purposes of enforcement by the AGs.

20 D. This Judgment does not create a waiver or limit AstraZeneca's legal rights,  
21 remedies, or defenses in any other action by the Signatory Attorney General, and does not  
22 waive or limit AstraZeneca's right to defend itself from, or make argument in, any other  
23 matter, claim, or suit, including, but not limited to any investigation or litigation relating to the

24 \_\_\_\_\_  
25 *Business Practices/Consumer Protection Act, RCW §§ 19.86 et seq.; WEST VIRGINIA – West Virginia Consumer Credit and Protection Act,*  
26 *W. Va. Code § 46A-1101 et seq.; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).*

1 existence, subject matter, or terms of this Judgment. Nothing in this Judgment shall waive,  
2 release, or otherwise affect any claims, defense, or positions AstraZeneca may have in  
3 connection with any investigations, claims, or other matters the State is not releasing  
4 hereunder.

5 E. The AGs have reviewed the terms of the Judgment and find that its entry serves  
6 the public interest.

7 **IT IS HEREBY ORDERED that:**

8 **DEFINITIONS**

9 The following definitions shall be used in construing this Judgment:

10 1. "AstraZeneca" shall mean "AstraZeneca Pharmaceuticals LP" and  
11 "AstraZeneca LP," including all of their subsidiaries, divisions, successors, and assigns doing  
12 business in the United States.

13 2. "AstraZeneca's Legal Department" shall mean personnel of the AstraZeneca  
14 Legal Department or its designee providing legal advice to AstraZeneca.

15 3. "AstraZeneca Marketing" shall mean AstraZeneca commercial personnel  
16 assigned to the U.S. Seroquel brand team.

17 4. "AstraZeneca Medical Education Grants Office" and "MEGO" shall mean the  
18 U.S.-based organization within AstraZeneca responsible for oversight of medical education  
19 grants and the acceptance, review, and payment of all medical education grant requests.

20 5. "AstraZeneca Non-SciP" shall mean AstraZeneca personnel other than  
21 AstraZeneca Scientifically Trained Personnel or SciP.

22 6. "AstraZeneca Sales" shall mean the AstraZeneca pharmaceutical sales  
23 specialists, or other AstraZeneca personnel, responsible for U.S. Seroquel sales.

24 7. "AstraZeneca Scientifically Trained Personnel" or "SciP" shall mean  
25 AstraZeneca personnel who are highly trained experts with specialized scientific and medical  
26

1 knowledge whose roles involve the provision of specialized medical or scientific information,  
2 but excludes anyone performing sales, marketing, ride alongs, or other commercial roles.

3 8. "Clinically Relevant Information" shall mean information that reasonably  
4 prudent clinicians would consider relevant when making prescribing decisions regarding  
5 Seroquel.

6 9. "Consultant" shall mean a non-AstraZeneca Health Care Professional engaged  
7 to advise regarding marketing or promotion of Seroquel.

8 10. "Covered Conduct" shall mean AstraZeneca's Promotional and marketing  
9 practices, sampling practices, dissemination of information (including clinical research results),  
10 and remuneration to Health Care Professionals, in connection with Seroquel through the  
11 Effective Date of the Judgment.

12 11. "Effective Date" shall mean the date on which a copy of this Judgment, duly  
13 executed by AstraZeneca and by the Signatory Attorney General, is approved by, and becomes  
14 a Judgment of the Court.

15 12. "FDA Guidances for Industry" shall mean draft or final documents published by  
16 the United States Department of Health and Human Services, Food and Drug Administration  
17 ("FDA") that represent the FDA's current thinking on a topic.

18 13. "Health Care Professional" or "HCP" shall mean any physician or other health  
19 care practitioner who is licensed to provide health care services or to prescribe pharmaceutical  
20 products in the United States.

21 14. "Labeling" shall mean all FDA-approved labels, which are a display of written,  
22 printed, or graphic matter upon the immediate container of any article, and other written,  
23 printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b)  
24 accompanying such article.

1           15.   “Multistate Executive Committee” shall mean the Attorneys General and their  
2       staffs representing Arizona, Delaware, District of Columbia, Florida, Illinois, Kansas,  
3       Maryland, Massachusetts, North Carolina, Ohio, Pennsylvania, and Vermont.

4           16.   “Multistate Working Group” shall mean the Attorneys General and their staff  
5       representing Arizona, California, Colorado, Connecticut, Delaware, District of Columbia,  
6       Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts,  
7       Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York,  
8       North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South  
9       Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

10          17.   “Off-Label” shall mean a use not consistent with the indications section of the  
11       Seroquel Labeling approved by the FDA at the time information regarding such use was  
12       communicated.

13          18.   “Parties” shall mean AstraZeneca and the Signatory Attorney General.

14          19.   “Professional Information Request Response” or “PIR Response” shall mean a  
15       non-promotional, scientific or reference communication to address Unsolicited Requests for  
16       medical information from HCPs.

17          20.   “Promotional,” “Promoting” or “Promote” shall mean representations made to  
18       HCPs, patients, consumers, payers and other customers and other practices intended to increase  
19       sales or that attempt to influence prescribing practices of HCPs.

20          21.   “Promotional Slide Deck” shall mean Promotional materials in any medium  
21       regarding Seroquel for use in speaker programs in the United States.

22          22.   “Promotional Speaker” shall mean a HCP speaker engaged to Promote Seroquel  
23       in the United States.

24          23.   “Reprints Containing Off-Label Information” shall mean articles or reprints  
25       from a Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference Publication,  
26       as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of Seroquel.



- 1 (i) AstraZeneca shall state clearly and conspicuously the  
2 FDA-approved indication(s) on the same slide in which  
3 selected symptoms are first presented;
- 4 (ii) AstraZeneca shall include a short-hand reference to the  
5 statement described in Section I.D.1.a.(i) on the same  
6 slide as each subsequent reference to selected symptoms  
7 (*e.g.*, “Seroquel is not approved for X selected symptom  
8 referenced in this slide. See list of FDA-approved  
9 indications at p. Y”); and,
- 10 (iii) AstraZeneca shall require any presenter of AstraZeneca’s  
11 Promotional Slide Decks to present the statement  
12 required in Section I.D.1.a.(i), as part of the mandatory  
13 slides.

14 2. Promotional materials have a reference indicating that the full  
15 constellation of symptoms and the relevant diagnostic criteria should be consulted and are  
16 available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current  
17 version), where applicable.

18 E. AstraZeneca shall ensure that all Promotional Speakers’ Promotional materials  
19 for Seroquel comply with AstraZeneca’s obligations in the above Sections I.A–D.

20 F. AstraZeneca’s systems and controls shall 1) be designed to ensure that financial  
21 incentives do not motivate AstraZeneca Marketing and/or Sales personnel to engage in  
22 improper promotion, sales, and marketing of Seroquel; and 2) include mechanisms to exclude  
23 from incentive compensation sales that may indicate Off-Label promotion of Seroquel.

24 G. AstraZeneca’s systems and controls shall be designed to prevent AstraZeneca  
25 Sales from detailing Seroquel to HCPs who are unlikely to prescribe Seroquel for a use  
26 consistent with its FDA-approved label. This shall be effected through systems and controls

1 requiring that AstraZeneca review the call plans for Seroquel and the bases upon, and  
2 circumstances under which HCPs belonging to specified medical specialties or types of clinical  
3 practice are included in, or excluded from, the call plans. The systems and controls shall  
4 require that AstraZeneca modify the call plans as necessary to ensure that AstraZeneca is  
5 Promoting Seroquel in a manner that complies with applicable Federal health care program and  
6 FDA requirements.

7 H. AstraZeneca's detailing systems and its controls shall prevent the delivery of  
8 samples of Seroquel to HCPs that AstraZeneca has identified as belonging to a specialty group  
9 that is unlikely to prescribe Seroquel for a use consistent with its FDA-approved label.

## 10 **II. Dissemination and Exchange of Medical Information**

### 11 A. General Terms

12 1. The content of AstraZeneca's communications concerning Off-Label  
13 uses of Seroquel shall not be false, misleading or deceptive.

### 14 B. Professional Information Request Responses

15 1. AstraZeneca Scientifically Trained Personnel shall have ultimate  
16 responsibility for developing and approving the medical content for all PIR Responses  
17 regarding Seroquel; including any that may describe Off-Label information. AstraZeneca shall  
18 not distribute any such materials unless:

- 19 a. Clinically Relevant Information is included in these materials to  
20 provide scientific balance;
- 21 b. Data in these materials are presented in an unbiased, non-  
22 Promotional manner; and
- 23 c. These materials are distinguishable from sales aids and other  
24 Promotional materials.

25 2. AstraZeneca Sales and AstraZeneca Marketing personnel shall not  
26 develop the medical content of PIR Responses regarding Seroquel.

1           3.     AstraZeneca Sales representatives shall not distribute PIR Responses  
2 regarding Seroquel unless specifically authorized to do so pursuant to II.C.6.

3           4.     AstraZeneca shall not knowingly disseminate any PIR Response  
4 describing any Off-Label use of Seroquel that makes any false, misleading or deceptive  
5 representation regarding Seroquel or any false or misleading or deceptive statement concerning  
6 a competing product.

7           C.     Responses to Unsolicited Requests for Off-Label information

8           1.     In responding to an Unsolicited Request for Off-Label information  
9 regarding Seroquel, including any request for a specific article related to Off-Label uses,  
10 AstraZeneca shall advise the requestor that the request concerns an Off-Label use and inform  
11 the requestor of the drug's FDA-approved indication(s), dosage and other relevant Labeling  
12 information.

13           2.     If AstraZeneca elects to respond to an Unsolicited Request for Off-Label  
14 information from a HCP regarding Seroquel, AstraZeneca Scientifically Trained Personnel  
15 shall provide accurate, objective, and scientifically balanced responses. Any such response  
16 shall not Promote Seroquel for an Off-Label use.

17           3.     Any written response to an Unsolicited Request for Off-Label  
18 information made to AstraZeneca Sales or AstraZeneca Marketing regarding Seroquel shall  
19 include:

- 20           a.     an existing PIR Response prepared in accordance with Section  
21                   II.B;
- 22           b.     a PIR Response prepared in response to the request in  
23                   accordance with Section II.B; or
- 24           c.     a report containing the results of a reasonable literature search  
25                   using terms from the request.
- 26

1           4.     Only AstraZeneca Scientifically Trained Personnel may respond in  
2 writing to an Unsolicited Request for Off-Label information regarding Seroquel unless  
3 AstraZeneca Non-SciP are specifically authorized to do so pursuant to II.C.6.

4           5.     AstraZeneca Non-SciP may respond orally to an Unsolicited Request for  
5 Off-Label information regarding Seroquel from a HCP only by offering to request on behalf of  
6 the HCP that a PIR Response or other information set forth above in II.C.3 be sent to the HCP  
7 in follow up or by offering to put the HCP in touch with the Virtual Scientific Exchange Center  
8 (“VSEC”). AstraZeneca Non-SciP shall not characterize, describe, identify, name, or offer any  
9 opinions about or summarize any Off-Label information.

10          6.     PIR Responses regarding Seroquel may be disseminated only by  
11 AstraZeneca Scientifically Trained Personnel to HCPs, and AstraZeneca Non-SciP shall not  
12 disseminate these materials to HCPs except in circumstances implicating public health and  
13 safety issues. In such circumstances, AstraZeneca Non-SciP may disseminate a PIR Response  
14 directly to HCPs, when expressly authorized by the U.S. Compliance Officer, the U.S. General  
15 Counsel, and the Vice President of Medical Affairs.

16           D.     Reprints

17           1.     AstraZeneca shall not disseminate information or written materials  
18 describing Off-Label or unapproved uses of Seroquel unless such information and materials  
19 comply with applicable FDA regulations and FDA Guidance for Industry;

20           2.     Reprints Containing Off-Label Information

21           a.     AstraZeneca Scientifically Trained Personnel shall be  
22 responsible for the identification, selection, approval and  
23 dissemination of Reprints Containing Off-Label Information  
24 regarding Seroquel.

25           b.     Requests to proactively disseminate a Reprint Containing Off-  
26 Label Information shall be submitted to the appropriate director

1 of Medical Affairs, who will convene a cross-functional team,  
2 including a representative from Clinical, Medical Affairs,  
3 AstraZeneca's U.S. Compliance Department, AstraZeneca's  
4 Legal Department, and Promotional Regulatory Affairs, to  
5 examine the facts and justification for the request to distribute a  
6 Reprint Containing Off-Label Information on a case-by-case  
7 basis.

8 c. Reprints Containing Off-Label Information shall:

9 (i) be accompanied by the full prescribing information for  
10 the product, or a clearly and conspicuously described  
11 hyperlink that will provide the reader with such  
12 information, and contain a disclosure in a prominent  
13 location, which would include the first page or as a  
14 cover page where practicable, indicating that the article  
15 may discuss Off-Label information; and

16 (ii) not be referred to or used in a Promotional manner.

17 d. Reprints Containing Off-Label Information regarding Seroquel  
18 may be disseminated only by AstraZeneca Scientifically Trained  
19 Personnel to HCPs. AstraZeneca Non-SciP shall not disseminate  
20 these materials to HCPs.

21 3. Nothing in this Judgment shall preclude AstraZeneca from  
22 disseminating Reprints which have an incidental reference to Off-Label information. If  
23 Reprints have an incidental reference to Off-Label information, such reprints shall contain the  
24 disclosure required by section II.D.2.c.(i) in a prominent location, as defined above, and such  
25 incidental reference to Off-Label information shall not be referred to or used in a Promotional  
26 manner as prohibited by Section II.D.2.c.(ii).

1 **III. Grants**

2 A. AstraZeneca shall disclose information about medical education grants,  
3 including CME grants, regarding Seroquel consistent with the current disclosures of MEGO  
4 with a link to the disclosures available through AstraZeneca's website and as required by  
5 applicable law.

6 1. AstraZeneca shall maintain this information on the website, once posted,  
7 for at least two years, or longer if applicable law so requires, and shall maintain the  
8 information in a readily accessible format for review by the States upon written request for a  
9 period of five years.

10 B. MEGO shall manage all requests to AstraZeneca for funding related to medical  
11 education grants regarding Seroquel. Approval decisions shall be made by MEGO alone, and  
12 shall be kept separate from the AstraZeneca Sales and AstraZeneca Marketing organizations.

13 C. AstraZeneca shall not use medical education grants or any other type of grant to  
14 Promote Seroquel. This provision includes, but is not limited to, the following prohibitions:

15 1. AstraZeneca Sales and AstraZeneca Marketing personnel shall not  
16 initiate, coordinate or implement grant applications on behalf of any customer or HCP;

17 2. AstraZeneca Sales and AstraZeneca Marketing personnel shall not be  
18 involved in selecting grantees or medical education speakers; and

19 3. AstraZeneca shall not measure or attempt to track in any way the impact  
20 of grants or speaking fees on the participating HCPs' subsequent prescribing habits, practices  
21 or patterns.

22 D. AstraZeneca shall not condition funding of a medical education program grant  
23 request relating to Seroquel upon the requestor's selection or rejection of particular speakers.

24 E. AstraZeneca shall not suggest, control, or attempt to influence selection of the  
25 specific topic, title, content, speakers or audience for CMEs relating to Seroquel, consistent  
26 with Accreditation Council for Continuing Medical Education Guidelines.

1 F. AstraZeneca Sales and AstraZeneca Marketing personnel shall not approve  
2 grant requests relating to Seroquel, nor attempt to influence the awarding of grants to any  
3 customers or HCPs for their prescribing habits, practices or patterns.

4 G. AstraZeneca shall contractually require the medical education provider to  
5 clearly and conspicuously disclose to medical education program attendees AstraZeneca's  
6 financial support of the medical education program and any financial relationship with faculty  
7 and speakers at such medical education program.

8 H. After the initial delivery of a medical education program, AstraZeneca shall not  
9 knowingly fund the same program, nor shall it provide additional funding for re-distribution of  
10 the same program, if the program's speakers are Promoting Seroquel for Off-Label uses in that  
11 program.

#### 12 **IV. Payments to Consultants and Speakers**

13 A. This Section shall be effective for five (5) years from the Effective Date of this  
14 Judgment and shall apply to U.S. based Consultants and Promotional Speakers performing  
15 Promotional activities for AstraZeneca.

##### 16 B. Phase I Reporting.

17 1. AstraZeneca shall continue to post in a prominent position on its website  
18 an easily accessible and readily searchable listing of all U.S.-based physicians and Related  
19 Entities (as defined below in Section IV.D.5) who or which received Phase I Payments (as  
20 defined below in Section IV.D.2) directly or indirectly from AstraZeneca during the first six  
21 months of 2010 and the aggregate value of such Phase I Payments.

22 2. On or before February 28, 2011, AstraZeneca shall also post on its  
23 website a listing of updated information about all Phase I Payments provided during the last six  
24 months of 2010. On or before May 31, 2011, AstraZeneca shall also post on its website a  
25 listing of updated information about all Phase I Payments provided during the first quarter of  
26 2011. On or before June 30, 2011, AstraZeneca shall also post on its website a report of the

1 cumulative value of the Phase I Payments provided to each physician, and/or Related Entity  
2 during 2010. The quarterly, six-month, and annual reports shall be easily accessible and  
3 readily searchable.

4 3. Each listing made pursuant to this Section IV. B shall include a  
5 complete list of all individual physicians and Related Entities to whom or to which  
6 AstraZeneca directly or indirectly made Payments in the preceding six-month period, quarter,  
7 or year (as applicable). Each listing shall be arranged alphabetically according to the  
8 physicians' last name or the name of the Related Entity. For each physician, the applicable  
9 listing shall include the following information: i) physician's full name; ii) name of any  
10 Related Entities (if applicable); iii) city and state that the physician or Related Entity has  
11 provided to AstraZeneca for contact purposes; and (iv) the aggregate value of the payment(s)  
12 in the preceding quarter, six-month period, or year (as applicable). If payments for multiple  
13 physicians have been made to one Related Entity, the aggregate value of all payments to the  
14 Related Entity will be the reported amount.

15 C. Phase II Reporting

16 1. On or before August 31, 2011, AstraZeneca shall post in a prominent  
17 position on its website an easily accessible and readily searchable listing of all U.S.-based  
18 physicians and Related Entities who or which received Phase II Payments (as defined below in  
19 Section IV.D.3) directly or indirectly from AstraZeneca during the second quarter of 2011 and  
20 the aggregate value of such Phase II Payments.

21 2. After the August 31, 2011 posting, 30 days after the end of each  
22 subsequent calendar quarter, AstraZeneca shall post on its website a listing of updated  
23 information about all Phase II Payments provided from the first reporting quarter of the year  
24 through the close of the most recent quarter of the year. Beginning in 2012, on or before May  
25 1 of each year, AstraZeneca shall also post on its website a report of the cumulative value of  
26 the Phase II Payments provided to each physician, and/or Related Entity during each preceding

1 calendar year. The quarterly and annual reports shall be easily accessible and readily  
2 searchable.

3 D. Definitions and Miscellaneous Provisions

4 1. AstraZeneca shall continue to make each annual listing and the most  
5 recent six-month or quarterly listing of Payments available on its website. AstraZeneca shall  
6 retain and make available to each Signatory Attorney General, upon request, relevant business  
7 records sufficient to demonstrate the purpose of the Payment and (where applicable) the  
8 performance of a service by the HCP related to all applicable Payments and to the annual, six-  
9 month, and/or quarterly listings of Payments. Nothing in this Section IV affects the  
10 responsibility of AstraZeneca to comply with (or liability for noncompliance with) all  
11 applicable state laws as they relate to all applicable Payments made to physicians or Related  
12 Entities.

13 2. For purposes of Section IV.B, the term "Phase I Payments" is defined as  
14 all fees paid in connection with U.S.-based physicians serving as Promotional Speakers in the  
15 United States or participating in prerequisite speaker training for such Promotional Speaker  
16 engagements.

17 3. For purposes of Section IV.C, the term "Phase II Payments" is defined  
18 to include all Phase I Payments and all other "payments or transfers of value" as that term is  
19 defined in § 1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care  
20 Act ("PPACA") and any regulations promulgated thereunder. The term Phase II Payments  
21 includes, by way of example, the types of payments or transfers of value enumerated in §  
22 1128G(a)(1)(A)(vi) of PPACA. The term includes all payments or transfers of value made to  
23 Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a  
24 physician for whom AstraZeneca would otherwise report a Payment if made directly to the  
25 physician. The term "Phase II Payments" also includes any payments or transfers of value  
26

1 made, directly by AstraZeneca or by a vendor retained by AstraZeneca to a physician or  
2 Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

3 4. The term "Payments" as used in the definition of Phase I Payments and  
4 Phase II Payments does not include transfers of value or other items that are not included or are  
5 excluded from the definition of "payment" as set forth in § 1128G(e)(10) under Section 6002  
6 of PPACA and any regulations promulgated thereunder.

7 5. For purposes of this Section IV, the term "Related Entity" is defined to  
8 be any entity by or in which any physician receiving Payments is employed, has tenure, or has  
9 an ownership interest.

10 E. Once the Federal Physician Payments Sunshine Act becomes effective,  
11 AstraZeneca shall comply with the Federal Physician Payments Sunshine Act, Section 6002 of  
12 the PPACA and it is agreed that AstraZeneca's compliance with the Physician Payment  
13 Sunshine Provision of PPACA will constitute compliance with Section IV of this Final  
14 Judgment and Consent Decree.

15 **V. Clinical Research Results**

16 A. AstraZeneca shall report clinical research regarding Seroquel in an accurate,  
17 objective and balanced manner as follows and as required by applicable law:

18 1. To the extent permitted by the National Library of Medicine and as  
19 required by the FDA Amendments Act of 2007 (Public Law No. 110-85), AstraZeneca shall  
20 register clinical trials and submit clinical trial results to the registry and results data bank  
21 regarding Seroquel as required by the FDA Amendments Act and any accompanying  
22 regulations that may be promulgated pursuant to that Act. With respect to Seroquel,  
23 AstraZeneca registers on a publicly accessible NIH website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) the  
24 initiation of all AstraZeneca-sponsored clinical studies involving individuals and posts a  
25 summary of the results of all AstraZeneca-sponsored clinical studies in patients or volunteers  
26

1 for marketed and investigative products on the above-referenced NIH website and on a  
2 company website ([www.astrazenecaclinicaltrials.com](http://www.astrazenecaclinicaltrials.com)).

3 B. When presenting information about a clinical study regarding Seroquel,  
4 AstraZeneca shall not do any of the following in a manner that causes the Promotional  
5 materials to be false, misleading or deceptive:

6 1. present favorable information or conclusions from a study that is  
7 inadequate in design, scope, or conduct to furnish significant support for such information or  
8 conclusions;

9 2. use the concept of statistical significance to support a claim without  
10 providing the appropriate clinical context, or which fails to reveal the range of variations  
11 around the quoted average results;

12 3. use statistical analyses and techniques on a retrospective basis to  
13 discover and cite findings not soundly supported by the study, or to suggest scientific validity  
14 and rigor for data from studies the design or protocol of which are not amenable to formal  
15 statistical evaluations;

16 4. present the information in a way that implies that the study represents  
17 larger or more general experience with the drug than it actually does; or

18 5. use statistics on numbers of patients, or counts of favorable results or  
19 side effects, derived from pooling data, unless such pooling has been done in a statistically  
20 rigorous manner, pursuant to a protocol, and that the method of pooling has been disclosed.

## 21 PAYMENT AND RELEASE PROVISIONS

### 22 VI. Terms Relating to Payment

23 A. No later than 30 days after the Effective Date of this Judgment, AstraZeneca  
24 shall pay \$68.5 million to be divided and paid by AstraZeneca directly to each Signatory  
25 Attorney General of the Multistate Working Group in an amount to be designated by and in the  
26 sole discretion of the Multistate Executive Committee. Washington's share is anticipated to be

1 approximately \$1,612,265. The Parties acknowledge that the payment described herein is not a  
2 fine or penalty, or payment in lieu thereof. The payment received by plaintiff State of  
3 Washington shall be used by the Attorney General's Office for attorneys' fees and other costs  
4 of investigation and litigation, enforcement of the terms of this Judgment, future consumer  
5 protection purposes, consumer education, and/or as cy pres to facilitate programs directed at  
6 mental health, and/or to facilitate programs directed at the proper use of prescription drugs by  
7 the medical community and consumers.

## 8 VII. Release

9 A. By its execution of this Judgment, the State of Washington releases and forever  
10 discharges AstraZeneca, and all of its past and present subsidiaries, divisions, affiliates, co-  
11 promoters, controlled joint ventures, predecessors, successors, and assigns and each and all of  
12 their current and former officers, directors, shareholders, employees, agents, contractors, and  
13 attorneys (collectively, the "Released Parties") of and from the following: all civil claims,  
14 causes of action, *parens patriae* claims, damages, restitution, fines, costs, attorneys fees,  
15 remedies and/or penalties that the Washington Attorney General has asserted or could have  
16 asserted against the Released Parties under the Washington Consumer Protection Act or any  
17 amendment thereto, or common law claims concerning unfair, deceptive, or fraudulent trade  
18 practices resulting from the Covered Conduct up to and including the Effective Date  
19 (collectively, the "Released Claims").

20 B. Notwithstanding any term of this Judgment, specifically reserved and excluded  
21 from the Released Claims as to any entity or person, including Released Parties, are any and all  
22 of the following:

23 1. Any criminal liability that any person or entity, including Released  
24 Parties, has or may have to the State of Washington;

25 2. Any civil or administrative liability that any person or entity, including  
26 Released Parties, has or may have to the State of Washington not expressly covered by the

1 release in Section VII.A above, including, but not limited to, any and all of the following  
2 claims:

- 3 a. State or federal antitrust violations;
- 4 b. Claims involving “best price,” “average wholesale price” or  
5 “wholesale acquisition cost;”
- 6 c. Medicaid violations, including but not limited to federal  
7 Medicaid drug rebate statute violations, Medicaid fraud or abuse,  
8 and/or kickback violations related to any state’s Medicaid  
9 program; and
- 10 d. State false claims violations.

11 3. Actions of state program payors of the State of Washington arising from  
12 the purchase of Seroquel, except for the release of civil penalties under the state consumer  
13 protection laws cited in footnote 3.

14 4. Any claims individual consumers have or may have under the State of  
15 Washington’s above cited consumer protection laws against any person or entity, including  
16 Released Parties.

17 **PROVISIONS RELATED TO OTHER LAWS AND DISPUTE RESOLUTION**

18 **VIII. Conflicts with Other Laws**

19 A. This Judgment (or any portion thereof) shall in no way be construed to prohibit  
20 AstraZeneca from making representations with respect to Seroquel that are permitted under  
21 Federal law or in Labeling for the drug under the most current draft or final standard  
22 promulgated by the FDA or the most current draft or final FDA Guidances for Industry, or  
23 permitted or required under any Investigational New Drug Application, New Drug  
24 Application, Supplemental New Drug Application, or Abbreviated New Drug Application  
25 approved by FDA, unless facts are or become known to AstraZeneca that such representation,  
26 taken in its entirety, is false, misleading or deceptive. Nothing in this paragraph should be

1 interpreted to excuse AstraZeneca from implementing any of the affirmative obligations  
2 described in the Compliance Provisions of this Judgment. If, subsequent to the Effective Date  
3 of this Judgment, the laws or regulations of the United States are changed so as to expressly  
4 authorize conduct that is expressly prohibited by this Judgment, then such conduct shall not  
5 constitute a violation of this judgment. Provided however, if AstraZeneca intends to engage in  
6 the expressly authorized conduct, AstraZeneca shall notify the Attorneys General (or the  
7 Attorney General of the affected state) within 30 business days prior to engaging in the  
8 expressly authorized conduct.

9           B.       If, subsequent to the Effective Date of this Judgment, the federal government  
10 or any state, or any federal or state agency, enacts or promulgates legislation, regulations, or  
11 guidances with respect to matters governed by this Judgment that creates a conflict with any of  
12 the Compliance Provisions of the Judgment and AstraZeneca intends to comply with the newly  
13 enacted legislation, regulation, or guidance, AstraZeneca shall notify the Attorneys General (or  
14 the Attorney General of the affected State) of the same. If the Attorney General agrees, he/she  
15 shall consent to a modification of such provision of the Judgment to the extent necessary to  
16 eliminate such conflict. If any Attorney General disagrees and the Parties are not able to  
17 resolve the disagreement, AstraZeneca shall seek a modification from an appropriate court of  
18 any provision of this Judgment that presents a conflict with any such federal or state law,  
19 regulation, or guidance. The disagreement of an Attorney General shall in no way impact  
20 AstraZeneca's ability to take action in any state and/or territory not represented by that  
21 Attorney General. Changes in federal or state laws, regulations, or guidances with respect to  
22 the matters governed by this Judgment shall not be deemed to create a conflict with a provision  
23 of this Judgment unless AstraZeneca cannot reasonably comply with both such law, regulation,  
24 or guidance and the applicable provision of this Judgment.

1 **IX. Dispute Resolution**

2 A. For the purposes of resolving disputes with respect to compliance with this  
3 Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe  
4 that AstraZeneca has engaged in a practice that violates a provision of this Judgment  
5 subsequent to the Effective Date of this Judgment, then such Attorney General shall notify  
6 AstraZeneca in writing of the specific objection, identify with particularity the provisions of  
7 this Judgment that the practice appears to violate, and give AstraZeneca thirty (30) days to  
8 respond to the notification; provided, however, that a Signatory Attorney General may take any  
9 action if the Signatory Attorney General concludes that, because of the specific practice, a  
10 threat to the health or safety of the public requires immediate action. Upon receipt of written  
11 notice, AstraZeneca shall provide a good-faith written response to the Attorney General  
12 notification, containing either a statement explaining why AstraZeneca believes it is in  
13 compliance with the Judgment, or a detailed explanation of how the alleged violation occurred  
14 and statement explaining how and when AstraZeneca intends to remedy the alleged violation.  
15 Nothing in this paragraph shall be interpreted to limit the State's Civil Investigative Demand  
16 ("CID") or investigative subpoena authority, to the extent such authority exists under  
17 applicable state law, and AstraZeneca reserves all of its rights with respect to a CID or  
18 investigative subpoena issued pursuant to such authority.

19 B. Upon giving AstraZeneca thirty (30) days to respond to the notification  
20 described above, the Signatory Attorney General shall also be permitted reasonable access to  
21 inspect and copy relevant, non-privileged, non-work product records and documents in the  
22 possession, custody or control of AstraZeneca that relate to AstraZeneca's compliance with  
23 each provision of this Judgment as to which cause that is legally sufficient in the State has been  
24 shown.

25 C. If the Signatory Attorney General makes or requests copies of any documents  
26 during the course of that inspection, the Signatory Attorney General will provide a list of those

1 documents to AstraZeneca. Any and all documents and information (including, but not limited  
2 to, electronic information) provided in response to a request by the State shall be protected to  
3 the extent provided by the requesting State's Freedom of Information Act or other state law.  
4 Such documents or information shall not be disclosed by the State to any other party or entity  
5 (pursuant to a FOIA request, subpoena, or otherwise) without first providing notice to  
6 AstraZeneca, to the extent allowed by law, so that AstraZeneca may take necessary steps to  
7 protect its confidential documents or information prior to disclosure.

8 D. The State of Washington may assert any claim that AstraZeneca has violated  
9 this Judgment in that State in a separate civil action to enforce compliance with this Judgment,  
10 or may seek any other relief afforded by law, but only after providing AstraZeneca an  
11 opportunity to respond to the notification described in Paragraph IX.A. above, provided,  
12 however, that a Signatory Attorney General may take any action if the Signatory Attorney  
13 General concludes that, because of the specific practice, a threat to the health or safety of the  
14 public of that State requires immediate action.

15 **X. Timely Written Requests for Extensions**

16 Nothing will prevent the State from agreeing in writing to provide AstraZeneca with  
17 additional time to perform any act or to file any notification required by the Judgment. The  
18 Attorney General shall not unreasonably withhold his/her agreement to the request for  
19 additional time.

20 **XI. General Provisions**

21 A. AstraZeneca shall not cause or encourage third parties, nor knowingly permit  
22 third parties acting on its behalf, to engage in practices from which AstraZeneca is prohibited  
23 by this Judgment.

24 B. This Judgment represents the full and complete terms of the settlement entered  
25 into by the Parties hereto. In any action undertaken by the Parties, neither prior versions of this  
26

1 Judgment, nor prior versions of any of its terms, that were not entered by the Court in this  
2 Judgment, may be introduced for any purpose whatsoever.

3 C. This Court retains jurisdiction of this Judgment and the Parties hereto for the  
4 purpose of enforcing and modifying this Judgment and for the purpose of granting such  
5 additional relief as may be necessary and appropriate.

6 D. This Judgment may be executed in counterparts, and a facsimile or .pdf  
7 signature shall be deemed to be, and shall have the same force and effect as, an original  
8 signature.

9 E. All Notices under this Judgment shall be provided to John C. Dodds and the  
10 U.S. Compliance Officer of AstraZeneca Pharmaceuticals LP by Overnight Mail at:

11 John C. Dodds  
12 Morgan, Lewis & Bockius LLP  
13 1701 Market St.  
14 Philadelphia, PA 19103

15 Marie L. Martino  
16 U.S. Compliance Officer  
17 AstraZeneca Pharmaceuticals LP  
18 1800 Concord Pike  
19 PO Box 15437  
20 Wilmington, DE 19850-5437

21 DATED this \_\_\_\_ day of \_\_\_\_\_, 2011.

22 \_\_\_\_\_  
23 JUDGE/COURT COMMISSIONER

24 Presented by:

25 ROBERT M. MCKENNA  
26 Attorney General

27  3/2/11  
28 \_\_\_\_\_  
29 ROBERT LIPSON, WSBA #11889  
30 Assistant Attorney General  
31 Attorneys for State of Washington

1 Approved by and Notice of Presentation  
Waived:

2 SCHWABE WILLIAMSON & WYATT,  
3 P.C.

4 

5 NANCY ERFLE, WSBA #20644  
MARY JO NEWHOUSE, WSBA #16396  
Attorneys for AstraZeneca Pharmaceuticals  
6 LP and AstraZeneca LP

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1 Approved by:

2 MORGAN, LEWIS & BOCKIUS.LLP

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5 JOHN C. DODDS  
6 Attorney for AstraZeneca Pharmaceuticals LP  
and AstraZeneca LP

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ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP

By: Marie L. Martino

Date: 3/10/11

Marie L. Martino  
U.S. Compliance Officer  
AstraZeneca  
1800 Concord Pike  
PO Box 15437  
Wilmington, DE 19850-5437