

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

STATE OF COLORADO

by Attorney General John W. Suthers  
1525 Sherman Street, Fifth Floor  
Denver, Colorado 80203

COMMONWEALTH OF VIRGINIA

by Attorney General Robert F. McDonnell  
900 East Main Street  
Richmond, Virginia 23219

STATE OF MARYLAND

by Attorney General Douglas F. Gansler  
200 St. Paul Street  
Baltimore, Maryland 21202

STATE OF ALASKA

by Attorney General Talis J. Colberg  
1031 W. 4th Avenue #200  
Anchorage, Alaska 99501

STATE OF ARIZONA

by Attorney General Terry Goddard  
1275 West Washington  
Phoenix, Arizona 85007-2926

STATE OF ARKANSAS

by Attorney General Dustin McDaniel  
323 Center Street, Suite 200  
Little Rock, Arkansas 72201

STATE OF CALIFORNIA

by Attorney General Edmund G. Brown, Jr.  
1515 Clay St.  
Oakland, California 94612

STATE OF DELAWARE

by Attorney General Joseph R. Biden III  
Carvel State Office Building  
820 N. French Street  
Wilmington, Delaware 19801

Civil Action No. 1:05-cv-02182-CKK-AK

DISTRICT OF COLUMBIA  
by Attorney General Linda Singer  
441 Fourth Street, NW, Suite 450N  
Washington, District of Columbia 20001

STATE OF FLORIDA  
by Attorney General Bill McCollum  
PL-01 The Capitol  
Tallahassee, Florida 32399

STATE OF IDAHO  
by Attorney General Lawrence Wasden  
650 W. State Street, Lower Level  
Boise, Idaho 83720-0010

STATE OF ILLINOIS  
by Attorney General Lisa Madigan  
100 West Randolph Street  
Chicago, Illinois 60601

STATE OF IOWA  
by Attorney General Thomas J. Miller  
2nd Floor, Hoover Office Building  
East 13th and Walnut  
Des Moines, Iowa 50319

STATE OF KANSAS  
by Attorney General Stephen N. Six  
120 SW 10th Street, 2nd Floor  
Topeka, Kansas 66612

COMMONWEALTH OF KENTUCKY  
by Attorney General Jack Conway  
1024 Capital Center Drive  
Frankfort, Kentucky 40601

STATE OF LOUISIANA  
by Attorney General James D. "Buddy" Caldwell  
1885 N. 3rd Street, 4th Floor  
Baton Rouge, Louisiana 70802

STATE OF MAINE  
by Attorney General G. Steven Rowe  
6 State House Station  
Augusta, Maine 04333-0006

COMMONWEALTH OF MASSACHUSETTS

by Attorney General Martha Coakley  
One Ashburton Place  
Boston, Massachusetts 02108

STATE OF MICHIGAN

by Attorney General Michael A. Cox  
G. Mennen Williams Building, 6th Floor  
525 W. Ottawa Street  
Lansing, Michigan 48913

STATE OF MINNESOTA

by Attorney General Lori Swanson  
102 State Capitol  
St. Paul, Minnesota 55155-1609

STATE OF MISSISSIPPI

by Attorney General Jim Hood  
Post Office Box 22947  
Jackson, Mississippi 39225

STATE OF MISSOURI

by Attorney General Jeremiah (Jay) W. Nixon  
P.O. Box 899  
Jefferson City, MO 65102

STATE OF NEVADA

By Attorney General Catherine Cortez Masto  
555 East Washington Avenue, Suite 3900  
Las Vegas, Nevada 89101

STATE OF NEW YORK

by Attorney General Andrew M. Cuomo  
120 Broadway, Suite 26C  
New York, New York 10271-0332

STATE OF NORTH CAROLINA

by Attorney General Roy Cooper  
9001 Mail Service Center  
Raleigh, NC 27699-9001

STATE OF NORTH DAKOTA

by Attorney General Wayne Stenehjem  
P.O. Box 1054  
Bismarck, North Dakota 58502-1054

STATE OF OHIO

by Attorney General Marc Dann  
150 East Gay Street, 20th Floor  
Columbus, Ohio 43215

STATE OF OKLAHOMA

by Attorney General W.A. Drew Edmonson  
313 NE 21st Street  
Oklahoma City, Oklahoma 73105

STATE OF OREGON

by Attorney General Hardy Myers  
1162 Court Street NE  
Salem, Oregon 97301

STATE OF RHODE ISLAND

by Attorney General Patrick C. Lynch  
150 South Main Street  
Providence, Rhode Island 02903

STATE OF SOUTH CAROLINA

by Attorney General Henry D. McMaster  
Rembert C. Dennis Building  
1000 Assembly Street, Room 519  
Columbia, South Carolina 29201

STATE OF TENNESSEE

by Attorney General Robert E. Cooper, Jr.  
P.O. Box 20207  
Nashville, Tennessee 37202-0207

STATE OF TEXAS

by Attorney General Greg Abbott  
P.O. Box 12548  
Austin, Texas 78711

STATE OF UTAH

by Attorney General Mark L. Shurtleff  
160 East 300 South, Fifth Floor  
Salt Lake City, Utah 84111

and

STATE OF VERMONT  
by Attorney General William H. Sorrell  
109 State Street  
Montpelier, Vermont 05609-1001

PLAINTIFFS,

v.

BARR PHARMACEUTICALS, INC.  
2 Quaker Road  
Box 2900  
Pomona, New York 10970

DEFENDANT.

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JOINT MOTION FOR ENTRY OF FINAL ORDER AND  
STIPULATED PERMANENT INJUNCTION

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The states of Colorado, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Vermont, the Commonwealths of Kentucky, Massachusetts and Virginia, and the District of Columbia, by their Attorneys General (“Plaintiff States” or “States”) and Defendant Barr Pharmaceuticals, Inc. (“Barr”), by its attorneys, respectfully move this Court to enter the accompanying proposed Final Order and Stipulated Permanent Injunction (“Final Order”). Entry of the Final Order will end the litigation between the Plaintiff States and Barr. A copy of the Final Order is attached as Exhibit A. As grounds for this request, the parties state as follows:

1. On October 3, 2006, the Plaintiff States filed their Second Amended Complaint against Barr pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and state antitrust, consumer protection

and/or unfair competition statutes and related state laws, seeking civil penalties, injunctive and other equitable relief (the “State Action”). The Plaintiff States’ Second Amended Complaint alleges that Barr and Warner Chilcott violated such laws by entering into an agreement that eliminated competition from Barr’s generic version of regular Ovcon 35, a branded oral contraceptive product sold by Warner Chilcott.

2. In their Second Amended Complaint, the Plaintiff States seek a permanent injunction to invalidate the exclusivity provision that prevented Barr from introducing a generic version of Ovcon, and such other equitable relief as the Court finds necessary to redress and prevent recurrence of defendants’ violation.

3. Barr launched a generic version of regular Ovcon in October 2006, shortly after Warner Chilcott irrevocably waived the exclusivity provision in its agreement with Barr.

4. Barr has reached a settlement with the Plaintiff States. In so doing, it does not admit any issues of fact or law, other than the Court’s jurisdiction to enter and enforce the Final Order. The proposed Final Order embodying the settlement terms is entered for settlement purposes only and does not constitute any evidence against, or an admission of liability, wrongdoing, or any issue of fact or law, by Barr.

5. The proposed Final Order contains three principal elements: a monetary payment to the Plaintiff States; a general conduct prohibition that prevents Barr from entering into certain agreements, including agreements similar to the one challenged here; and a provision requiring Barr in the future to give notice to the Plaintiff States of a broader group of agreements.

6. Barr and the Plaintiff States have agreed to accept the Final Order. Accordingly, Barr and the Plaintiff States jointly request that the Court enter the attached Final Order and

place it on the public record, thereby bringing the litigation between the Plaintiff States and Barr to an end.

Respectfully submitted,

JOHN W. SUTHERS  
Colorado Attorney General

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Devin M. Laiho

Assistant Attorney General  
Consumer Protection Section  
1525 Sherman Street, Seventh Floor  
Denver, Colorado 80203  
303-866-5079  
Devin.Laiho@state.co.us

For the Plaintiff States

Dated: **[DATE]**, 2008

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Karen N. Walker (D.C. Bar # 412137)  
Mark L. Kovner (D.C. Bar # 430431)  
Patrick M. Bryan (D.C. Bar # 490177)  
KIRKLAND & ELLIS LLP  
655 Fifteenth Street, N.W., Suite 1200  
Washington, D.C. 20005  
Tel. (202) 879-5000  
Fax (202) 879-5200

For Barr Pharmaceuticals, Inc.

# EXHIBIT A

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

STATE OF COLORADO

by Attorney General John W. Suthers  
1525 Sherman Street, Fifth Floor  
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900 East Main Street  
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650 W. State Street, Lower Level  
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Augusta, Maine 04333-0006

COMMONWEALTH OF MASSACHUSETTS

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One Ashburton Place  
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by Attorney General Michael A. Cox  
G. Mennen Williams Building, 6th Floor  
525 W. Ottawa Street  
Lansing, Michigan 48913

STATE OF MINNESOTA

by Attorney General Lori Swanson  
102 State Capitol  
St. Paul, Minnesota 55155-1609

STATE OF MISSISSIPPI

by Attorney General Jim Hood  
Post Office Box 22947  
Jackson, Mississippi 39225

STATE OF MISSOURI

by Attorney General Jeremiah (Jay) W. Nixon  
P.O. Box 899  
Jefferson City, MO 65102

STATE OF NEVADA

By Attorney General Catherine Cortez Masto  
555 East Washington Avenue, Suite 3900  
Las Vegas, Nevada 89101

STATE OF NEW YORK

by Attorney General Andrew M. Cuomo  
120 Broadway, Suite 26C  
New York, New York 10271-0332

STATE OF NORTH CAROLINA

by Attorney General Roy Cooper  
9001 Mail Service Center  
Raleigh, NC 27699-9001

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by Attorney General Wayne Stenehjem  
P.O. Box 1054  
Bismarck, North Dakota 58502-1054

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1162 Court Street NE  
Salem, Oregon 97301

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by Attorney General Patrick C. Lynch  
150 South Main Street  
Providence, Rhode Island 02903

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by Attorney General Henry D. McMaster  
Rembert C. Dennis Building  
1000 Assembly Street, Room 519  
Columbia, South Carolina 29201

STATE OF TENNESSEE

by Attorney General Robert E. Cooper, Jr.  
P.O. Box 20207  
Nashville, Tennessee 37202-0207

STATE OF TEXAS

by Attorney General Greg Abbott  
P.O. Box 12548  
Austin, Texas 78711

STATE OF UTAH

by Attorney General Mark L. Shurtleff  
160 East 300 South, Fifth Floor  
Salt Lake City, Utah 84111

and

STATE OF VERMONT  
by Attorney General William H. Sorrell  
109 State Street  
Montpelier, Vermont 05609-1001

PLAINTIFFS,

v.

BARR PHARMACEUTICALS, INC.  
2 Quaker Road  
Box 2900  
Pomona, New York 10970

DEFENDANT.

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**FINAL ORDER AND STIPULATED PERMANENT INJUNCTION**

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**WHEREAS** Plaintiffs, the states of Colorado, Alaska, Arizona, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Vermont, the commonwealths of Kentucky, Massachusetts and Virginia, and the District of Columbia, by their Attorneys General, (“Plaintiff States” or “States”), filed their Second Amended Complaint, on October 3, 2006, pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1337, and state antitrust, consumer protection and/or unfair competition statutes and related state laws, seeking civil penalties; injunctive and other equitable relief;

**AND WHEREAS**, in conjunction with the filing of this Final Order and Stipulated Permanent Injunction (“Final Order”), Plaintiff States and Barr Pharmaceuticals, Inc. (“Barr”), by their

respective attorneys, have stipulated and agreed to entry by the Court of this Final Order without trial or adjudication of any issue of fact or law;

**AND WHEREAS**, this Final Order is entered for settlement purposes only and does not constitute any evidence against, or an admission of liability, wrongdoing, or of any issue of fact or law, by Defendant Barr;

**AND WHEREAS**, the parties agree to be bound by the provisions of this Final Order pending its approval by the Court;

**AND WHEREAS**, Defendant Barr has launched the generic product at issue in the Complaint and this Final Order, as described herein, requires Defendant Barr to refrain from entering into certain identified types of agreements in the future;

**AND WHEREAS**, Barr agrees to make a monetary payment to the Plaintiff States in the amount of \$5.9 million, subject to the terms and conditions provided herein;

**AND WHEREAS**, Defendant Barr has represented to the Plaintiff States that the relief required below can and will be made and that Defendant Barr will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the terms of the relief contained below;

**AND WHEREAS**, Barr retains the right to seek to modify this Final Order, either unilaterally or jointly with the Plaintiff States (at the Plaintiff States' discretion), pursuant to Fed. R. Civ. P. 60(b)(6);

**AND WHEREAS**, Defendant Barr, without admitting that it has violated any provision of federal or state law, agrees to the entry of this Final Order;

**NOW THEREFORE**, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is

**ORDERED, ADJUDGED AND DECREED THAT:**

**I. Jurisdiction and Venue**

- A. Solely for purposes of entry of this Final Order and enforcement thereof, this Court has jurisdiction over the parties and the subject matter of this action.
- B. Solely for purposes of entry of this Final Order and enforcement thereof, venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).
- C. The parties waive all rights to appeal or otherwise challenge or contest the validity of this Final Order.
- D. Entry of this order is in the public interest.

## II. Definitions

As used in this Final Order:

- A. “Agreement” means anything that would constitute a contract, combination, or conspiracy within the meaning of Section 1 of the Sherman Act, 15 U.S.C. § 1, regardless of whether such contract, combination, or conspiracy is in restraint of trade.
- B. “ANDA” means an Abbreviated New Drug Application filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j).
- C. “ANDA Filer” means the party to a Branded/Generic Supply Agreement or a Branded/Generic Agreement who controls an ANDA for the Subject Drug Product or has the exclusive right to distribute the Generic Product.
- D. “Barr” means Barr Pharmaceuticals, Inc., and its officers, directors, employees, agents and representatives, successors, and assigns; United States subsidiaries, divisions, groups, and affiliates controlled by Barr; and the officers, directors, employees, agents and representatives, successors, and assigns of each.
- E. “Branded/Generic Agreement” means any Agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product.
- F. “Branded/Generic Supply Agreement” means any supply agreement in or affecting Commerce in the United States in which a party is the NDA Holder and another party is the ANDA Filer for the same Subject Drug Product, and the ANDA Filer agrees to supply Generic Product to the NDA Holder.
- G. “Commerce” has the same definition as it has in the Clayton Act, 15 U.S.C. § 12.

- H. “Drug Product” means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- I. “Enter Into” and “Entering Into” means join, participate in, implement, adhere to, maintain, organize, enforce, or facilitate.
- J. “FDA” means the United States Food and Drug Administration.
- K. “Generic Product” means a Drug Product manufactured under an ANDA.
- L. “Plaintiff States’ Liaison Counsel” or “Liaison Counsel” means counsel for the States of Colorado and New York, unless the Plaintiff States appoint other counsel to serve as Liaison Counsel and so advise Barr in writing; in no event shall there be more than two Liaison Counsel at a time.
- M. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), et seq.
- N. “NDA Holder” means the party to a Branded/Generic Agreement or a Branded/Generic Supply Agreement that controls the NDA for the Subject Drug Product, or has the exclusive right to distribute branded Subject Drug Product.
- O. “Patent Infringement Claim” means any written allegation of patent infringement, whether or not included in a complaint filed with a court of law, including, but not limited to, where the alleged infringer challenges only patent validity.
- P. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- Q. “Qualifying Pharmaceutical Company” means a pharmaceutical company, other than the NDA Holder or Barr, that (i) has annual gross sales of generic pharmaceutical products in

the United States of at least \$250 million; and (ii) neither controls an ANDA for a Subject Generic Equivalent nor has the exclusive right to distribute a Subject Generic Equivalent.

R. “Subject Drug Product” means a Drug Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.

S. “Subject Generic Equivalent” means a Generic Product that is bioequivalent to the branded Subject Drug Product.

T. “Subject Generic Product” means a Generic Product that is the subject of the Branded/Generic Agreement or the Branded/Generic Supply Agreement.

### **III. Prohibited Agreements**

Until the expiration of this Final Order as provided in Paragraph VII, Barr is enjoined from Entering Into, or attempting to Enter Into, directly or indirectly, or through any corporate or other device:

A. Any Branded/Generic Supply Agreement where:

- 1) Barr is the ANDA Filer; and
- 2) Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution or sale of the Subject Generic Product.

B. Any Branded/Generic Agreement where:

- 1) Barr is the ANDA Filer;
- 2) Barr receives monetary or other valuable consideration;
- 3) Barr agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution, or sale of the Subject Generic Product; and

4) Such Branded/Generic Agreement unreasonably restrains competition.

*Provided, however,* that nothing in Paragraph III.A. shall prohibit Barr from entering into such Branded/Generic Supply Agreement, if, prior to or contemporaneously with entering into such Branded/Generic Supply Agreement,

- 1) Barr has, in good faith, assigned, transferred, or otherwise given, to a Qualifying Pharmaceutical Company, the rights as Barr may possess them necessary to manufacture, market, distribute, and sell the Subject Generic Product (“Transfer Agreement”);
- 2) the Qualifying Pharmaceutical Company has agreed, in good faith and as part of the Transfer Agreement, to use commercially reasonable efforts to exploit such rights as soon as practicable;
- 3) Barr has agreed in good faith to supply (which includes, if applicable, acting in good faith to obtain the regulatory and other approvals necessary to supply) the Subject Generic Product to such Qualifying Pharmaceutical Company on such terms and conditions that will allow the Qualifying Pharmaceutical Company to compete effectively for sales of the Subject Generic Equivalent until such time as the Qualifying Pharmaceutical Company can manufacture commercial quantities of the Subject Generic Product on its own or obtain commercial quantities of the Subject Generic Equivalent from another source;
- 4) Barr has provided a copy of this Final Order and Stipulated Permanent Injunction to the persons responsible for assisting with the Transfer Agreement, of the Qualifying Pharmaceutical Company;

- 5) the Qualifying Pharmaceutical Company has agreed to cooperate with any inquiry made by a Plaintiff State relating to the activities covered by the provision; and
- 6) Barr has provided notice to the Plaintiff States of any such Transfer Agreement with a Qualifying Pharmaceutical Company, in the form specified in Paragraph IV.C.

*Provided, further,* that nothing in this Paragraph III shall prohibit Barr from entering into a Branded/Generic Agreement, including a Branded/Generic Supply Agreement, that resolves a Patent Infringement Claim involving the Subject Drug Product, where such Branded/Generic Agreement does not unreasonably restrain competition.

#### **IV. Agreements Subject to Notification**

- A. Commencing with the date of entry of this Final Order and for a period of ten years, Barr shall provide notice to the Plaintiff States' Liaison Counsel of:
  - 1) any Branded/Generic Supply Agreement entered into after the date of entry of this Final Order, and
  - 2) any Branded/Generic Agreement entered into after the date of entry of this Final Order in which Barr is the ANDA Filer and agrees to refrain from or limit for any period of time the research, development, manufacturing, marketing, distribution, or sale of the Subject Drug Product, except those that resolve a Patent Infringement Claim (except as otherwise provided by this Final Order).  
("Agreements Subject to Notification").
- B. The notification required by Paragraph IV.A. shall be made within the later of:
  - 1) Thirty days after the entry of this Final Order, or
  - 2) within ten business days after the Agreement Subject to Notification is executed.

- C. The notification required by Paragraph IV.A. of this Final Order shall be in the form of a letter (“Notification Letter”) submitted to the Plaintiff States’ Liaison Counsel containing the following information:
- 1) A statement that the purpose of the Notification Letter is to give the Plaintiff States notification of an Agreement Subject to Notification as required by Paragraph IV of this Final Order;
  - 2) Identification of all Persons involved in the Agreement Subject to Notification; and
  - 3) A copy of the Agreement Subject to Notification, and in the event that any Agreement Subject to Notification has not been reduced to text, written descriptions of such Agreement Subject to Notification that are sufficient to disclose all the terms and conditions of the Agreement Subject to Notification.
- D. In addition to the Notification required by Paragraphs A-C. above, and until the expiration of this Final Order, Barr shall provide to the Plaintiff States’ Liaison Counsel copies of all materials required to be submitted to the Federal Trade Commission pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (including any subsequent modifications of the notification provisions created by such Act) (“MMA Materials”). The MMA Materials shall be provided to the Liaison Counsel within the time frame and in the form applicable to submissions to the Federal Trade Commission under the Medicare Prescription Drug Improvement and Modernization Act of 2003.
- E. All Notification Letters and MMA Materials shall be submitted to the Plaintiff States’ Liaison Counsel at the addresses listed in Paragraph V.D.

## V. Notice and Reporting Requirements

- A. Barr shall file a verified, written report with the Plaintiff States' Liaison Counsel setting forth in detail the manner and form in which it has complied and is complying with this Final Order:
- 1) within ninety days from the date this Final Order is entered;
  - 2) annually thereafter for three years on the anniversary of the date this Final Order is entered; and
  - 3) at any such other times as the Plaintiff States' Liaison Counsel may request by written notice.
- B. For a period of three years from the date this Final Order is entered, Barr shall maintain and make available to Plaintiff States for inspection and copying upon reasonable notice, records sufficient to describe in detail any action taken in connection with the activities covered by this Final Order.
- C. Until expiration of this Final Order, as provided in Paragraph VII, Barr shall notify the Plaintiff States' Liaison Counsel at least thirty days prior to any
- 1) proposed dissolution of Barr
  - 2) acquisition, merger or consolidation of Barr, or
  - 3) any other change in Barr that may affect compliance obligations arising out of this Final Order.
- D. Barr shall address each notice and report required by Paragraph IV of the Final Order to Plaintiff States' Liaison Counsel at the below addresses unless otherwise directed in writing by such Liaison Counsel:

Office of the Colorado Attorney General  
Antitrust Enforcement  
1525 Sherman Street, Seventh Floor  
Denver, Colorado 80203

Office of the New York Attorney General  
Chief, Antitrust Bureau  
120 Broadway, 26<sup>th</sup> Floor  
New York, New York 10271

## **VI. Monetary Relief**

Not later than ten business days after receiving the Payment Information (defined below),

Barr shall pay the sum of \$5.9 million to the Plaintiff States (the “Payment”) under the following terms and conditions:

A. The Payment must be made by wire transfer or ACH transfer made payable and delivered as directed by the Plaintiff States. The Plaintiff States shall advise undersigned counsel for Barr in writing of the information necessary for Barr to effectuate the wire transfer or ACH transfer within five business days after entry of this Final Order (“Payment Information”). Barr shall have no dominion, control or title to the Payment. The Payment shall be used by the Attorney General of each Plaintiff State at his/her sole discretion according to the terms of this Final Order. The Attorney General of each Plaintiff State shall use these funds consistently with his/her state laws for any of the following purposes:

- 1) payment of attorneys’ fees and costs;
- 2) antitrust or consumer protection law enforcement;
- 3) deposit into a state antitrust or consumer protection revolving fund; or
- 4) as otherwise provided by state law.<sup>1</sup>

All funds paid to the Plaintiff States pursuant to this Final Order shall be deposited into accounts administered by the Plaintiff States or their agent(s).

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<sup>1</sup> With respect to the State of Colorado, its apportionment shall be used first for reimbursement of Colorado’s actual costs and attorneys fees and second, to be held along with any interest thereon, in trust

B. Barr shall have no right to challenge the Plaintiff States' distribution of the Payment. Barr shall have no right to contest the manner in which the funds are utilized.

**VII. Termination of Final Order**

This Final Order shall take effect on, and expire ten years from, the date this Final Order is entered.

**VIII. Retention of Jurisdiction**

The Court retains jurisdiction of this matter for purposes of construction, modification and enforcement of this Final Order.

**X. Dismissal and Costs**

This action shall be dismissed with prejudice. Unless specifically set forth in this agreement, each party shall bear its own costs of this action.

Entered this \_\_\_\_ day of \_\_\_\_\_, 2008.

\_\_\_\_\_  
Colleen Kollar-Kotelly  
U.S. District Judge

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by the Attorney General for future consumer education, consumer fraud or antitrust enforcement efforts.